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Nutrición Hospitalaria

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La calidad de los macronutrientes y el riesgo de enfermar

The quality of macronutrients and the risk of illness

Está bien establecido que tanto la cantidad como la calidad de los nutrientes y de los alimentos se asocian con el riesgo de enfermar en las poblaciones. De hecho, la adherencia a una dieta más saludable se asocia con un mayor número de años sin enfermedad cardiovascular o diabetes independientemente del índice de masa corporal (IMC), la actividad física o el tabaquismo (1). Sin embargo, debido a la extrema complejidad de la alimentación humana, aún queda mucho por investigar acerca de los factores nutricionales asociados a enfermar. En este contexto, algo tan básico como la calidad de los macronutrientes que forman parte de la dieta habitual, no han recibido la suficiente atención.

El estudio de Santiago y cols. realizado en la cohorte SUN, que se publica en este número de la revista *Nutrición Hospitalaria* (2) viene a llenar este vacío de información. Es un estudio con un gran tamaño muestral, largo seguimiento, reevaluaciones nutricionales periódicas realizadas con herramientas validadas y muy utilizadas en investigación epidemiológica y que han tenido en cuenta un gran número de covariables. En esta investigación han podido llegar a la conclusión de que tan importante como la cantidad de macronutrientes de la dieta es la calidad de éstos a la hora de explicar la aparición de obesidad y sobrepeso en una población.

La cohorte SUN se inició hace 25 años en Navarra, cuenta con más de 20.000 participantes y ha aportado infinidad de información acerca de hábitos de vida y riesgo cardiometabólico de gran utilidad para la salud pública y para entender cuáles son las causas y cómo se desarrollan las enfermedades metabólicas prevalentes (3). Su detallado estudio nutricional ha aportado una muy valiosa información en estos aspectos y ha contribuido a afianzar la idea de que las principales estrategias de prevención y tratamiento de las enfermedades metabólicas prevalentes (obesidad, diabetes, síndrome metabólico) pasan por la modificación de la dieta.

En este trabajo han utilizado una interesante herramienta, el "Macronutrient Quality Index" (MQI) que sintetiza en una única variable la calidad de los macronutrientes de la dieta. El MQI es la suma de 3 subíndices que cuantifican la calidad de los carbohidratos, la grasa y las proteínas de la dieta en base a la información obtenida de una encuesta de frecuencia de consumo de alimentos.

En el estudio PREDIMED las mejoras del índice de calidad de los carbohidratos, que forma parte del cálculo del MQI, se asociaron con cambios favorables en diversos factores de riesgo cardiovascular, incluyendo el peso corporal (4), independientemente de otras variables de gran influencia como la ingesta energética o la actividad física. Resultados similares se han encontrado también en la propia cohorte SUN (5) donde el MQI se asocia inversamente con la incidencia de eventos cardiovasculares. Sin embargo, solo el índice de calidad de los carbohidratos se ha asociado a la mortalidad en la cohorte SUN (6). El MQI también se asocia al deterioro metabólico en personas obesas, aunque no en personas normopeso, en una pequeña cohorte de personas metabólicamente sanas (7).

Aunque el estudio de los nutrientes y alimentos aislados aporta una información valiosa a la patofisiología de las enfermedades metabólicas, los patrones alimentarios son más importantes para entender el porqué unas poblaciones presentan mayores tasas de prevalencia e incidencia de determinadas enfermedades.

editorial

Los índices nutricionales, como el utilizado en el trabajo de Santiago y cols. (2), ayudan a sintetizar y capturar la compleja información de la dieta, caracterizándola de una manera amplia (8) y generando evidencia científica que apoya las directrices nutricionales que hay que transmitir a la población para mejorar la salud de todos.

Conflicto de intereses: los autores declaran no tener conflicto de interés.

Inteligencia artificial: los autores declaran no haber usado inteligencia artificial (IA) ni ninguna herramienta que use IA para la redacción del artículo.

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ARÁN

Nutrición Hospitalaria

Trabajo Original

Pediatría

Comparación de los niveles séricos de ácido úrico y enzimas hepáticas entre adolescentes con obesidad y con síndrome metabólico

Comparison of serum uric acid and liver enzyme levels in adolescents with obesity and with metabolic syndrome

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Resumen

Introducción: se ha observado una relación entre los niveles elevados de enzimas hepáticas y ácido úrico, y la presencia del síndrome metabólico (SM) en la población pediátrica.

Objetivo: comparar los niveles séricos de enzimas hepáticas y ácido úrico entre adolescentes con y sin SM.

Métodos: se realizó un estudio transversal en adolescentes con obesidad de entre 10 y 18 años. Se analizaron: datos somatométricos, insulina sérica, perfil lipídico, niveles de ácido úrico y enzimas hepáticas (aspartato-aminotransferasa [AST], alanina-aminotransferasa [ALT] y gamma-glutamil-transferasa [GGT]). Análisis estadístico: se utilizó la t de Student o la prueba del chi cuadrado para evaluar las diferencias entre los grupos.

Resultados: se incluyeron en total 1095 adolescentes con obesidad (444 con SM y 651 sin SM). El grupo con SM tuvo un IMC mayor (con SM 2,3 *vs.* sin SM 2,1; $p < 0,001$), sin diferencias en la grasa corporal (42,9 % *vs.* 42,9 %, $p = 0,978$). El grupo con SM tuvo niveles de AST (34,4 *vs.* 29,5, $p = 0,013$), ALT (42,2 *vs.* 34,6, $p = 0,003$) y ácido úrico (6,17 *vs.* 5,74, $p = 0,002$) significativamente más altos en comparación con el grupo sin SM. La proporción de ALT (40,5 % *vs.* 29,5 %, $p = 0,029$) y ácido úrico alterado (58,1 % *vs.* 45,6 %, $p = 0,019$) fue mayor en el grupo con SM.

Conclusiones: los niveles séricos de ALT, AST y ácido úrico de los adolescentes con obesidad y SM fueron mayores en comparación a los adolescentes sin SM. La ALT alterada y la hiperuricemia fueron condiciones que aumentan la probabilidad de presentar SM.

Palabras clave:

Obesidad. Enzimas hepáticas. Síndrome metabólico. Adolescente.

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Abstract

Introduction: a relationship has been observed between elevated levels of liver enzymes and uric acid with the presence of metabolic syndrome (MS) in the pediatric population.

Objective: to compare serum liver enzyme and uric acid levels between adolescents with and without MS.

Methods: a cross-sectional study was carried out in adolescents with obesity between 10 and 18 years old. Somatometric data, serum insulin, lipid profile, uric acid levels and liver enzymes (aspartate aminotransferase [AST], alanine aminotransferase [ALT] and gamma-glutamyl transferase [GGT]) were analyzed. Statistical analysis: Student's t test or the Chi-square test was used to evaluate differences between groups.

Results: a total of 1095 adolescents with obesity were included (444 with MS and 651 without MS). The group with MS had a higher BMI (with MS 2.28 *vs* without MS 2.11 $p < 0.001$), with no difference in body fat (42.9 % *vs* 42.9 %, $p = 0.978$). The MS group had significantly higher levels of AST (34.4 *vs.* 29.5, $p = 0.013$), ALT (42.2 *vs.* 34.6, $p = 0.003$), and uric acid (6.17 *vs.* 5.74, $p = 0.002$). comparison to the group without MS. The proportion of ALT (40.5 % *vs* 29.5 %, $p = 0.029$) and altered uric acid (58.1 % *vs.* 45.6 %, $p = 0.019$) was higher in the MS group.

Conclusions: serum levels of ALT, AST and uric acid in adolescents with obesity and MS were higher compared to those without MS. Altered ALT was a risk factor for SM.

Keywords:

Obesity. Liver enzymes. Uric acid. Metabolic syndrome. Adolescent.

ANTECEDENTES

La obesidad infantil se ha convertido en un importante problema de salud pública mundial. Según la Organización Mundial de la Salud (OMS), la obesidad infantil es uno de los principales desafíos contemporáneos debido al papel de la obesidad como principal factor de riesgo de eventos cardiometabólicos. Además, la resistencia a la insulina (RI) y el ambiente proinflamatorio se han implicado en la fisiopatología de la obesidad y, por consecuencia, en la presencia del síndrome metabólico (SM) (1-5).

Por otro lado, los estudios han sugerido una relación entre el aumento de los niveles de enzimas hepáticas, especialmente la alanina-aminotransferasa (ALT), y el SM, que están asociados con factores de riesgo cardiometabólico. Por ejemplo, los individuos con dislipidemia mostraron niveles séricos de ALT significativamente más altos en comparación con los individuos con perfil lipídico normal (6-8).

La obesidad y otras enfermedades metabólicas provocan daño hepático y aumento de los niveles de enzimas hepáticas (8). La disfunción hepática induce un estado de RI y el desarrollo de diabetes *mellitus* de tipo 2 (DM2) a largo plazo. Basado en esto, varios estudios han informado niveles elevados de ALT en pacientes con DM2 independientemente del peso corporal, lo que sugiere que el nivel de ALT puede predecir el SM (9-11). La gamma-glutamil-transferasa (GGT) está relacionada con el estrés oxidativo y la inflamación crónica, los cuales desempeñan un papel importante en la patogénesis de la DM2 (12).

En otro contexto, el ácido úrico induce un estado de estrés oxidativo y altera la expresión del factor de crecimiento similar a la insulina–I (IGF-I), produciendo una disminución del IGF hepático y a su vez del flujo plasmático renal y la filtración glomerular de ácido úrico, de manera que altera el metabolismo de la insulina, creando resistencia (13,14). Existen estudios en pacientes adolescentes que han encontrado relación de los niveles de ácido úrico elevados en la etapa de la adolescencia en pacientes con obesidad, asociado a niveles séricos elevados de lípidos, glucosa e insulina, así como elevación de la presión arterial, como parte de un efecto de estrés oxidativo, pero aun sin considerarse como escrutinio en el SM (14).

Se ha observado una relación entre los niveles elevados de enzimas hepáticas y ácido úrico y el SM en la población pediátrica con y sin obesidad. Sin embargo, el patrón de los niveles de enzimas hepáticas y ácido úrico en adolescentes con obesidad, según la presencia o ausencia de SM, no está bien caracterizado.

El objetivo de este estudio fue comparar las concentraciones séricas de ácido úrico y enzimas hepáticas en pacientes pediátrico con obesidad, con y sin SM.

MATERIAL Y MÉTODOS

DISEÑO DEL ESTUDIO

Se realizó un estudio transversal entre enero de 2018 y mayo de 2022 en cuatro centros pediátricos de tercer nivel de atención en México. Se incluyeron pacientes de 10 a 18 años con diagnóstico de obesidad (IMC > percentil 95 según las tablas de crecimiento de la CDC de 2000). Los criterios de exclusión fueron: 1) presencia de alguna condición asociada o uso de medicamentos que potencialmente influyan en el peso o el apetito (síndromes genéticos, uso de esteroides, fluoxetina, sensibilizadores de insulina, anorexigénicos o inhibidores de la absorción de grasas intestinales); 2) uso de medicación hepatotóxica; 3) enfermedad hepática crónica; 4) que no acepten participar. Se recabaron datos pertenecientes de las siguientes variables: datos antropométricos, concentraciones plasmáticas en ayunas de colesterol de alta densidad (cHDL), colesterol de baja densidad (cLDL), triglicéridos (TGL), glucosa, insulina, enzimas hepáticas (aspartato aminotransferasa [AST], ALT y GGT).

La madurez sexual fue evaluada por un endocrinólogo pediatra mediante la escala de Tanner.

ANTROPOMETRÍA

Un nutricionista certificado registró los indicadores antropométricos de cada sujeto. La estatura se midió utilizando el estadiómetro SECA modelo 769. La medición del peso se

realizó mediante el método de bioimpedancia (Tanita BC-568 Segmental Body Composition Monitor, Tokio, Japón) con el paciente descalzo y usando solo ropa interior, como se describe en otro lugar.

MEDICIÓN DEL PERFIL CARDIOMETABÓLICO Y ENZIMAS HEPÁTICAS

Después de un mínimo de 12 horas de ayuno, se obtuvieron muestras de sangre del antebrazo a través de la vena antecubital entre las 7:00 y las 8:00 horas. Las muestras de suero se congelaron a -20 °C hasta su análisis. Los niveles de glucosa, TGL, HDLc, ácido úrico y enzimas hepáticas se determinaron mediante métodos enzimáticos colorimétricos (Bayer Diagnostics, Puteaux, Francia). La insulina se midió mediante quimioluminiscencia (Roche-Hitachi Modular P y D). Se consideraron aceptables coeficientes de variación intra e interensayo < 7 %. También se generó una curva estándar para cada ensayo.

DEFINICIONES

El índice de resistencia a la insulina (HOMA-IR) se calculó según la siguiente fórmula: HOMA-IR = glucosa en ayunas (mg/dL) × insulina en ayunas (μU/mL) / 405. El punto de corte del HOMA-IR para el diagnóstico de RI fue 2,5 (15). La hipertrigliceridemia se evaluó de la siguiente manera: TGL ≥ 150 mg/dL (6,16). Además, se consideró el cHDL reducido cuando las concentraciones séricas de cHDL < 40 mg/dL en hombres y < 50 mg/dL en mujeres, según lo recomendado por la Federación Internacional de Diabetes (IDF) (6,16). Los umbrales utilizados para los niveles altos de ALT y AST fueron > 40 U/L y > 30 U/L, respectivamente (17). Se consideró que el ácido úrico estaba alterado cuando las concentraciones séricas fueron ≥ 6,0 mg/dL (18). El desarrollo puberal se clasificó de la siguiente manera: estadio 1 de Tanner, prepuberal; Estadio de Tanner 2 a 4, puberal; y Tanner etapa 5, pospuberal.

ANÁLISIS ESTADÍSTICO

La prueba de Kolmogórov-Smirnov reveló una distribución no paramétrica de las variables continuas. Por lo tanto, se realizó una transformación logarítmica de las variables continuas para normalizar su distribución. Las variables continuas se presentan como media y error estándar, y las diferencias entre grupos se evalúan mediante la prueba t de Student. Las variables categóricas se presentan como frecuencias y porcentajes, y las diferencias entre grupos se evalúan mediante la prueba del chi cuadrado.

Los valores de $p < 0,05$ se consideraron indicativos de significación estadística.

Se utilizó el programa STATA v.12.0 para los análisis estadísticos.

CONSIDERACIÓN ÉTICA

El protocolo del estudio cumplió con los principios de la Declaración de Helsinki y fue aprobado por el Comité Nacional de Ética en Investigación y Salud del Instituto Mexicano del Seguro Social (IMSS) (número de registro R-2014-785-024). Los padres/cuidadores dieron su consentimiento informado por escrito y cada niño dio su consentimiento.

RESULTADOS

Se identificaron un total de 1350 adolescentes potenciales, de los cuales se excluyeron cuatro pacientes con datos de laboratorio incompletos, 12 pacientes < 10 años, 147 pacientes con sobrepeso y 84 que se negaron a participar.

Finalmente, se incluyeron en el estudio 1095 adolescentes con obesidad. La edad promedio fue de 12,6 años, con ligero predominio del sexo masculino (58,6 %). El promedio de la puntuación z del IMC fue de 2,2. Según la evaluación de la etapa de la pubertad, se encontró que el 93,7 % de los sujetos ($n = 1026$) eran púberes (Tanner 2-5) (Tabla I).

El promedio de las concentraciones séricas de los triglicéridos en nuestra cohorte fue ligeramente mayor de 150 mg/dL, mientras que el promedio del cHDL fue menor de 40 mg/dL (Tabla I). Los promedios de las concentraciones séricas de AST, ALT y GGT fueron de 31,5 mg/dL, 37,7 mg/dL y 31,8 mg/dL, respectivamente, y el del ácido úrico fue de 5,9 mg/dL. Hasta el 63,3 % de los pacientes incluidos en el estudio presentaban resistencia a la insulina.

COMPARACIÓN ENTRE SUJETOS CON Y SIN SÍNDROME METABÓLICO

Al comparar las características generales entre los adolescentes con y sin SM, la edad, y el puntaje z del IMC en el grupo de SM fueron significativamente mayores que los del grupo sin SM; sin diferencia en el porcentaje de grasa corporal (42,9 % *vs.* 42,9 %, $p = 0,978$) (Tabla I).

Aquellos con SM tuvieron niveles séricos más altos de enzimas hepáticas y de ácido úrico en comparación con aquellos sin SM (AST: 34,4 U/L *vs.* 29,1 U/L, $p = 0,013$; ALT: 42,2 UI/L *vs.* 34,6 UI/L, $p = 0,003$; GGT: 34,4 UI/L *vs.* 30,0 UI/L, $p = 0,057$; ácido úrico: 6,2 mg/dL *vs.* 5,7 mg/dL, $p = 0,002$) (Tabla I).

Con respecto al puntaje de HOMA-IR, los pacientes con SM fue mayor el puntaje en comparación a los que no presentaban SM (6,0 *vs.* 3,8, $p = 0,005$); sin embargo, la proporción de pacientes con resistencia a la insulina entre los grupos no fue diferente (65,3 % *vs.* 61,9 %, $p = 0,504$) (Tabla I).

Al comparar la proporción de sujetos con hiperuricemia y enzimas hepáticas alteradas, el grupo con SM tuvo una proporción significativamente mayor de sujetos ALT alterado (40,5 % *vs.* 29,5 %, $p = 0,029$) e hiperuricemia (58,1 % *vs.* 45,6 %, $p = 0,019$) entre los adolescentes con SM en comparación con aquellos sin SM (Tabla I).

Tabla I. Comparación de características generales y niveles de ácido úrico y enzimas hepáticas entre adolescentes con obesidad con y sin síndrome metabólico

	Todos	Síndrome metabólico		*p*
	(*n* = 1095)	Con (*n* = 444)	Sin (*n* = 651)	
	Media (error estándar)			
Edad (años)	12,6 ± 0,1	12,9 ± 0,1	12,4 ± 0,1	0,030
Sexo masculino*	642 (58,6)	231 (52,0)	354 (54,4)	0,658
Score Z del IMC	2,2 ± 0,01	2,3 ± 0,02	2,1 ± 0,02	*< 0,001*
Grasa corporal, %	42,9 ± 0,3	42,9 ± 0,6	42,9 ±0,4	0,978
*Pubertad**				*0,024*
Prepuberal	69 (6,3)	12 (2,7)	57 (8,8)	
Puberal	912 (83,3)	372 (83,8)	540 (82,9)	
Pospuberal	114 (10,4)	60 (13,5)	54 (8,3)	
Colesterol total (mg/dL)	162,3 ± 1,7	167,7 ± 2,9	158,5 ± 1,9	0,003
Triglicéridos (mg/dL)	151,0 ± 3,8	194,1 ± 6,4	121,4 ± 3,3	< 0,001
Colesterol HDL (mg/dL)	37,4 ± 0,4	34,9 ± 0,6	39,1 ± 0,6	< 0,001
AST (U/L)	31,5 ± 1,1	34,4 ± 2,4	29,5 ± 0,7	*0,013*
ALT (U/L)	37,7 ± 1,4	42,2 ± 2,5	34,6 ± 1,5	*0,003*
GGT (U/L)	31,8 ± 1,4	34,4 ± 1,8	30,0 ± 1,9	0,057
Ácido úrico (mg/dL)	5,9 ± 0,1	6,2 ± 0,1	5,7 ± 0,1	*0,002*
HOMA-IR	4,7 ± 0,3	6,0 ± 0,8	3,8 ± 0,2	*0,005*
AST alterada*	462 (42,2)	207 (46,6)	255 (39,2)	0,157
ALT alterada*	372 (34,0)	180 (40,5)	192 (29,5)	*0,029*
Ácido úrico alterado*	555 (50,7)	258 (58,1)	297 (45,6)	*0,019*
HOMA-IR alterado*	687 (63,3)	288 (65,3)	399 (61,9)	0,504

**Frecuencia (%). AST: aspartato-aminotransferasa; ALT: alanina-aminotransferasa; GGT: gamma-glutamil-transferasa (GGT).*

DISCUSIÓN

En los hallazgos de nuestro estudio se pudo identificar que los adolescentes con obesidad y SM el *score* Z del IMC fue mayor, así como los niveles de AST, ALT, ácido úrico y HOMA-IR fueron mayores en comparación a los adolescentes sin SM. No hubo diferencia en el porcentaje de grasa corporal, en los niveles séricos de GGT, ni en la proporción de la AST alterada ni en la RI entre los grupos.

Con respecto a las enzimas hepáticas, los estudios de adolescentes coreanos han demostrado una fuerte asociación entre el síndrome metabólico y los niveles elevados de ALT (19). Otro estudio de 4200 estudiantes de 7 a 18 años identificó el nivel de ALT como un factor de riesgo del síndrome metabólico (OR: 1,013; IC 95 % 1,001-1,025, $p = 0,033$) y dislipidemia (OR 1,051; IC 95 % 1,034-1,068, $p < 0,001$) (6). Además, en un estudio de adolescentes en Europa (de 12,5 a 19,5 años), los niveles de ALT se asociaron con el número de factores de riesgo cardiometabólico (16). También otro estudio de 236 niños de entre 6 y 12 años encontró niveles más altos de ALT en aquellos que tenían síndrome metabólico (42,1 UI/L; IC 95 %: 33,4-50,7 *vs.* 23,9 UI/L; IC 95 %: 21,0-26,8; $p < 0,001$) (20). Finalmente, un estudio realizado en población pediátrica con obesidad identificó una correlación de los niveles de ALT con la IR (21). Nuestros resultados son consistentes con los de estudios previos en los que los niveles de ALT se asociaron con el SM.

Según algunos estudios, la enfermedad del hígado graso no alcohólico (NAFLD) se considera el componente hepático del SM. Se demostró que los sujetos con sobrepeso y obesidad con RI tenían un mayor riesgo de desarrollar NAFLD (22,23). Por lo

tanto, se considera que la RI desempeña un papel crucial en la fisiopatología de la NAFLD. Esta asociación con la obesidad conduce a la supresión de la lipólisis del tejido adiposo, lo que lleva a un aumento del flujo de ácidos grasos libres hacia el hígado (24-26). El exceso de tejido adiposo se asocia con la síntesis de adipocinas y citocinas proinflamatorias como el factor de necrosis tumoral, la interleucina 6 (IL-6) y la interleucina 8 (IL-8). Este entorno proinflamatorio conduce a la esteatosis hepática y a la progresión del daño hepatocelular (27). En la NAFLD, la disminución de la actividad de la proteína-quinasa activada por AMP (AMPK) condiciona la acumulación de lípidos, agrava la lipotoxicidad y en forma independiente promueve la presencia de ateroesclerosis (28).

La ALT es una enzima hepática limitada al componente citoplasmático de las células hepáticas. Debido a su localización en las células hepáticas, se considera uno de los indicadores de la salud hepatocelular. Se ha sugerido que el nivel elevado de ALT refleja esteatosis hepática y cambios fisiológicos que predicen el desarrollo de DM2 (11).

La AST es menos específica del hígado porque también se libera debido al daño del corazón, el músculo esquelético, los riñones, el cerebro, el páncreas y los glóbulos rojos (29). Por otro lado, la GGT es una enzima heterodimérica de naturaleza glicoproteica localizada en múltiples tejidos y células, incluyendo epidídimo, fibroblastos, linfocitos, pulmón y páncreas; muestra una actividad particularmente alta en el riñón (30). Por lo tanto, la actividad de la GGT hepática es mucho más débil porque se expresa en una variedad de tipos de células además de los hepatocitos, incluidos los linfocitos T, y esto explicaría por qué no se vio alterada en este grupo de pacientes (31).

Con respecto al ácido úrico, Saed Safiri y cols. incluyeron 367 adolescentes que dividieron en terciles de acuerdo con los niveles séricos de ácido úrico (3.er tercil con ácido úrico > 6,04 mg/dL) y encontraron que los pacientes del último tercil tenian mayor frecuencia de SM ($p < 0,001$) (32). Se han encontrado estudios que de forma aislada evalúan los niveles de ácido úrico con cada uno de los componentes del síndrome metabólico, la mayoría de ellos en pacientes con obesidad, con resultados similares a los de nuestro estudio, donde los adolescentes con obesidad que tienen niveles de ácido úrico en el cuarto percentil (≥ 6,81 mg/dl) tuvieron mayor proporción de hiperglucemia, hipertrigliceridemia y síndrome metabólico. Se ha descrito que la obesidad crea un estado inflamatorio con la subsecuente elevación de la concentración de ácido úrico, creando estrés oxidativo y, por ende, un mayor riesgo de presentar alteraciones metabólicas. Aún existe controversia en cuanto al desarrollo cronológico de la génesis de los niveles séricos elevados de ácido úrico en asociación con la obesidad (33-35).

Los mecanismos biológicos por los cuales el ácido úrico incrementa el riesgo de desarrollar síndrome metabólico siguen teniendo escasa claridad. Recientemente, algunos investigadores han reportado que la ingesta alta de alimentos ricos en purinas y fructosa puede aumentar los niveles séricos de ácido úrico y desempeñar un papel fundamental como generadora de obesidad y en el desarrollo del síndrome metabólico (36).

Cabe mencionar que la grasa corporal fue semejante entre los pacientes con y sin SM. Esto se debe a la homogeneidad del grupo, ya que todos presentaban obesidad. Por otro lado, el puntaje de HOMA-IR fue mayor en el grupo con SM, lo mismo que los niveles de ALT y AST, lo cual sugiere que, a mayor puntaje de HOMA, mayor riesgo existe de daño hepático.

Nuestros resultados sugieren que la ALT y el ácido úrico elevado son marcadores indirectos de la presencia de SM y, específicamente, la ALT alterada, ya que la proporción de esta alteración fue mayor entre los pacientes con y sin SM (40,5 % *vs.* 29,5 %). Por lo tanto, puede usarse como estudio de tamizaje cuando no se cuente con el perfil de lípidos completos en un paciente pediátrico con obesidad.

Si bien la medición de los niveles de enzimas hepáticas es un estudio que se puede realizar de forma rutinaria en la práctica clínica, no forma parte de los componentes del SM o los factores de riesgo cardiometabólico en la población pediátrica. Por tanto, este estudio aconseja continuar las investigaciones e identificar que la ALT alterada, en el contexto de pacientes pediátricos con obesidad, podría funcionar como otro factor de riesgo independiente del HOMA para la enfermedad cardiovascular.

CONCLUSIÓN

Los niveles séricos de ALT, AST y ácido úrico son mayores en los adolescentes con obesidad y SM en comparación a los que no presentaban SM. La proporción de ALT alterado es mayor en los adolescentes con SM y obesidad. Las enzimas hepáticas y ácido úrico elevado se podrían utilizar como factores de riesgo cardiometabólico independiente en pacientes pediátricos con obesidad.

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ARÁN

Nutrición Hospitalaria

Trabajo Original

Pediatría

Riesgo de desnutrición e inseguridad alimentaria en pacientes pediátricos con cáncer. Estudio NutriCare

Risk of malnutrition and food insecurity in pediatric cancer patients. The NutriCare Study

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Resumen

Introducción: el cáncer y sus tratamientos se asocian a un estado nutricional deficiente en los niños, niñas y adolescentes.

Objetivo: establecer el riesgo nutricional de los pacientes pediátricos y el grado la inseguridad alimentaria y nutricional en los hogares de los niños, niñas y adolescentes con cáncer que han estado hospitalizados en un centro oncológico pediátrico de alta complejidad.

Métodos: estudio observacional prospectivo realizado en la Fundación Hospital Pediátrico la Misericordia – HOMI. Se incluyeron 41 niños, niñas y adolescentes de 0 a 17 años y 11 meses con diagnóstico de cáncer infantil durante el período de estudio. A los pacientes incluidos durante la hospitalización se les aplicó la herramienta de tamización nutricional para el cáncer infantil SCAN, versión en español, validada en HOMI por este mismo grupo de investigacion, y la Escala Latinoamericana y Caribeña de Seguridad Alimentaria y Nutricional – ELCSA, adaptadas y validadas en Colombia.

Resultados: el 76 % ($n = 31$) de los pacientes se clasificaron como "En riesgo de desnutrición" mediante la herramienta de tamización nutricional SCAN-SP. Se observó que el 56 % del conjunto de hogares tenían inseguridad alimentaria, siendo la clasificación de la inseguridad alimentaria leve en el 29 %, moderada en el 20 % y severa en el 7 % de los hogares con menores de 18 años.

Conclusión: en el proceso de cuidado integral en oncología pediátrica, el marco nutricional es de vital importancia; por esto, tener en cuenta factores que incluyan no solo la evaluación del riesgo y la valoración nutricional completa sino también la medición objetiva de la seguridad alimentaria siempre deben incluirse.

Palabras clave:

Desnutrición. Cáncer infantil. Cribado nutricional. Seguridad alimentaria.

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Abstract

Introduction: cancer and its treatments have been associated with poor nutritional status in children and adolescents.

Objective: to establish the nutritional risk of pediatric patients and the degree of food and nutritional insecurity in the homes of children and adolescents with cancer who have been hospitalized in a high complexity pediatric oncology center.

Methods: a prospective observational study conducted at the Fundación Hospital Pediátrico la Misericordia - HOMI. It included a sample of 41 children and adolescents aged 0 to 17 years and 11 months with a diagnosis of childhood cancer during the study period. The participants recruited during hospitalization had the application of the SCAN nutritional screening tool for childhood cancer, Spanish version, validated in HOMI and the Latin American and Caribbean Scale of Food and Nutritional Security — ELCSA, adapted and validated in Colombia.

Results: 76 % ($n = 31$) of the patients were classified as "At risk of malnutrition" using the SCAN-SP nutritional screening tool. It was observed that 56 % of all households had a proportion of food insecurity, of which the classification of food insecurity was mild in 29 %, moderate in 20 % and severe in 7 % of households with children under 18 years of age.

Conclusion: in the framework of the nutritional care process, it is important to take into account factors that include a complete nutritional risk assessment and evaluation that includes the measurement of food security.

Keywords:

Malnutrition. Childhood cancer. Nutritional screening. Food security.

INTRODUCCIÓN

Anualmente, el cáncer infantil afecta a numerosos niños y adolescentes alrededor del mundo. Cada año se diagnostica el cáncer infantil a 360.114 niños y adolescentes de entre 0 y 15 años a nivel mundial (1). Específicamente en América Latina y el Caribe, los datos estimados por el Modelo de Referencia del Banco Mundial y GLOBOCAN 2018 indican que el número de casos en niños menores de 15 años es de 29.002 (8,1 %) y 23.110 (11,6 %), respectivamente, según las regiones y categorías del Índice de Desarrollo Humano de la Organización de las Naciones Unidas (1).

Además de las cifras reportadas, es evidente que la carga global del cáncer infantil está subestimada, constituyendo un problema de salud pública significativo. Es más probable que se pasen por alto casos de cáncer en los países con niveles más bajos de desarrollo humano, especialmente aquellos tipos de cáncer que presentan síntomas inespecíficos, como las leucemias y los tumores cerebrales (1,2).

A medida que mejoran las tasas de curación de los niños con cáncer, es crucial analizar estas mejoras considerando el contexto socioeconómico, incluyendo la seguridad alimentaria. Es esencial adoptar un enfoque integral que contemple la pobreza tanto a nivel comunitario como familiar, junto con factores individuales, para entender cómo la pobreza afecta a los resultados del tratamiento del cáncer en esta población (3).

A pesar de los avances en el tratamiento y la supervivencia de los niños con cáncer, estos resultados pueden verse influenciados por factores no clínicos como los determinantes sociales de la salud. Estos incluyen la estabilidad económica, el acceso y la calidad de la educación y atención médica, el entorno construido y el contexto social y comunitario. Dentro de estos dominios existen factores cuantificables como la seguridad alimentaria, que es el foco central de esta investigación (4).

Otro aspecto relevante es la identificación de la desnutrición, frecuentemente subestimada, la cual es crucial pues afecta a la supervivencia debido a su influencia sobre la función inmunitaria y el metabolismo de medicamentos (2). Actualmente, la desnutrición relacionada con la enfermedad (DRM) es un problema frecuente en los pacientes pediátricos, originada por factores como la reducción de la ingesta de alimentos, la alteración de la utilización de nutrientes, la malabsorción y los cambios metabólicos vinculados a las enfermedades subyacentes, como el cáncer. Por esta razón, Sidiartha I. Gusti Lanang (5), recomienda implementar un proceso de tamización para la desnutrición lo antes posible. Alimentar precozmente a los pacientes puede ser beneficioso, permitiendo, tras la detección y evaluación, establecer un soporte nutricional con un enfoque multidisciplinario para optimizar los resultados de los niños afectados por la DRM.

En los niños con cáncer, la desnutrición es un problema común, por lo cual es importante comprender los factores de riesgo, los efectos sobre el resultado y las intervenciones factibles en el manejo de los pacientes, aún más teniendo en cuenta que la desnutrición se produce debido al desequilibrio del gasto energético y es el resultado de interacciones multifactoriales, incluidos el tipo de tumor y la terapia, conllevando a un mal resultado clínico y una disminución directamente proporcional de la calidad de vida (6).

De acuerdo con la Organización de las Naciones Unidas para la Alimentación y la Agricultura (FAO), la seguridad alimentaria existe cuando todas *"las personas tienen, en todo momento, acceso físico, social y económico a alimentos suficientes, inocuos y nutritivos que satisfacen sus necesidades energéticas diarias y preferencias alimentarias para llevar una vida activa y sana"* (7), concepto establecido en la Cumbre Mundial sobre la Alimentación de 1996.

La prevalencia de la inseguridad alimentaria, definida como la incapacidad de adquirir suficientes alimentos debido a insuficiencia de dinero u otros recursos, es notablemente mayor entre los supervivientes de cáncer que entre la población general (8). Es importante hacer referencia a cómo la pobreza incide en los resultados terapéuticos durante el tratamiento del cáncer, según la percepción de los pacientes y los cuidadores. Esta variable podría representar un factor predictivo significativo de las disparidades observadas en los resultados de los tratamientos para el cáncer pediátrico (9).

Actualmente disponemos de la Escala Latinoamericana y del Caribe sobre Seguridad Alimentaria, una herramienta de medición objetiva, eficaz y validada que se basa en las experiencias directas de los hogares con la inseguridad alimentaria (10). Esta escala permite evaluar y entender el fenómeno de la inseguri-

dad alimentaria, analizando las experiencias vivenciales de los miembros del hogar frente a las manifestaciones extremas de la pobreza, como el hambre (11).

La inseguridad alimentaria de los hogares de los pacientes con cáncer es una preocupación del sistema de salud, pese a que, cada vez más, la utilización de regímenes adaptados para el tratamiento de las neoplasias pediátricas ha mejorado los resultados clínicos de los niños que reciben tratamiento en los países de ingresos bajos y medios. Es importante destacar que el deterioro nutricional está vinculado a peores resultados en el tratamiento del cáncer, incluyendo un mayor abandono de la terapia oncológica; esto se debe, probablemente, al incremento del riesgo de toxicidad asociada al tratamiento (12).

El presente artículo es el resultado de una investigación posdoctoral que tuvo como objetivo establecer el riesgo nutricional de los pacientes pediátricos y el grado de inseguridad alimentaria y nutricional en los hogares de niños, niñas y adolescentes con cáncer que han estado hospitalizados durante el tiempo del estudio en la Fundación Hospital Pediátrico la Misericordia — HOMI.

MATERIAL Y MÉTODOS

Siguiendo el marco conceptual expuesto, se realizó un estudio observacional prospectivo. El levantamiento de la información tuvo lugar en la Fundación Hospital Pediátrico la Misericordia – HOMI, institución líder en diagnóstico y tratamiento de cáncer infantil en Colombia, en la cual se diagnostica y atiende el mayor número de niños con cáncer en el país, además de tener un equipo de 12 oncohematólogos pediatras (el 15 % del total de oncohematólogos pediatras de Colombia), siendo el equipo más grande del país. Se realizó un muestreo por conveniencia en el que se incluyeron todos los niños de 0 a 17 años y 11 meses que se encontraban hospitalizados durante el período del estudio y que cumplían los siguientes criterios de inclusión: un nuevo diagnóstico de cáncer infantil. Como criterios de exclusión se plantearon: pacientes con síndrome de Down y pacientes que presentasen algún grado de incapacidad motora de origen cerebral (IMOC). Fue obligatorio durante el desarrollo de la investigación que los pacientes se encontraran en compañía de padres y cuidadores con sus respectivos consentimientos informados y asentimientos debidamente diligenciados.

El reclutamiento fue realizado por un investigador asesor acompañante de la doctora responsable de la investigación posdoctoral responsable del estudio en la institución.

La clasificación nutricional de los pacientes pediátricos se evaluó utilizando la herramienta de tamización nutricional para el cáncer infantil llamada SCAN, versión en español, que fue validada en la institución HOMI (13). Este instrumento permitió identificar a los pacientes en riesgo de desnutrición al medir diversos factores como la reducción en la ingesta de alimentos, la pérdida de peso, y síntomas relacionados al tracto gastrointestinal, entre otros. Además, se utilizó la Escala Latinoamericana y Caribeña de Seguridad Alimentaria y Nutricional (ELCSA), adaptada y validada en Colombia, para evaluar la seguridad alimentaria y nutricional en los hogares de los pacientes (14,15), proporcionando una perspectiva más amplia del entorno nutricional y socioeconómico que rodea al paciente.

Los participantes reclutados durante la hospitalización contaron con la aplicación de las herramientas SCAN (13) y ELCSA (14,15). Las herramientas se presentan en las figuras 1 y 2, respectivamente.

Pregunta	Puntaje
¿Tiene el paciente un cáncer de alto riesgo?	1
¿Está actualmente el paciente bajo tratamiento intensivo?	1
¿Presenta el paciente algunos síntomas relacionados al tracto gastrointestinal?	2
¿Ha presentado el paciente pobre ingesta la última semana?	2
¿Ha tenido el paciente pérdida de peso en el último mes?	2
¿Muestra el paciente signos de desnutrición?	2
	Total

Un puntaje igual o mayor a 3 indica que el niño está en riesgo de desnutrición y debe ser referido a un nutricionista para una extensiva valoración.

Figura 1.

Herramienta de tamización nutricional para el cáncer infantil. Versión en español (SCAN-SP). Modificado de: Macana Muñoz SD, et al. (16)

Estadísticamente, es de precisar que la validación de la herramienta SCAN establece como punto de corte para el riesgo nutricional un puntaje de 3 (mayor o igual a 3: riesgo nutricional alto; menor a 3, riesgo nutricional bajo).

Complementariamente, la ELCSA está constituida por 15 ítems; los 9 primeros se refieren a situaciones relacionadas con los adultos y los restantes a las de los niños; la respuesta a cada ítem es dicotómica, asignándose un puntaje de uno [1] , a la respuesta "Sí", y a la respuesta "No" un puntaje de cero [0]. Los puntos de corte utilizados para clasificar el grado de inseguridad alimentaria (ISA) en el hogar fueron aquellos para hogares integrados por personas adultas y menores de 18 años.

ANÁLISIS ESTADÍSTICO

El análisis se realizó a partir de la base de datos anonimizada en un archivo *XLSX* con 44 columnas y 41 filas (cada columna

Seguridad alimentaria		
1	En el último mes, por falta de dinero u otros recursos, ¿alguna vez usted se preocupó porque los alimentos se acabarán en su hogar?	SÍ ❑ NO ❑
2	En el último mes, por falta de dinero u otros recursos, ¿alguna vez en su hogar se quedaron sin alimentos?	SÍ ❑ NO ❑
3	En el último mes, por falta de dinero u otros recursos, ¿alguna vez en su hogar dejaron de tener una alimentación saludable*?	SÍ ❑ NO ❑
4	En el último mes, por falta de dinero u otros recursos, ¿alguna vez usted o algún adulto en su hogar tuvo una alimentación basada en poca variedad de alimentos?	SÍ ❑ NO ❑
5	En el último mes, por falta de dinero u otros recursos, ¿alguna vez usted o algún adulto en su hogar dejo de desayunar, almorzar o cenar?	SÍ ❑ NO ❑
6	En el último mes, por falta de dinero u otros recursos, ¿alguna vez usted o algún adulto en su hogar comió menos de lo que debía comer?	SÍ ❑ NO ❑
7	En el último mes, por falta de dinero u otros recursos, ¿alguna vez usted o algún adulto en su hogar sintió hambre pero no comió?	SÍ ❑ NO ❑
8	En el último mes, por falta de dinero u otros recursos, ¿alguna vez usted o algún adulto en su hogar sólo comió una vez al día o dejó de comer durante todo un día?	SÍ ❑ NO ❑
A partir de aquí las preguntas estarán relacionadas con menores de 18 años que pertenezcan al hogar		
9	En el último mes, por falta de dinero u otros recursos, ¿alguna vez algún menor de 18 años en su hogar dejó de tener una alimentación saludable*?	SÍ ❑ NO ❑
10	En el último mes, por falta de dinero u otros recursos, ¿alguna vez algún menor de 18 años en su hogar tuvo una alimentación basada en poca variedad de alimentos?	SÍ ❑ NO ❑
11	En el último mes, por falta de dinero u otros recursos, ¿alguna vez algún menor de 18 años en su hogar dejo de desayunar, almorzar o cenar?	SÍ ❑ NO ❑
12	En el último mes, por falta de dinero u otros recursos, ¿alguna vez algún menor de 18 años en su hogar comió menos de lo que debía?	SÍ ❑ NO ❑
13	En el último mes, por falta de dinero u otros recursos, ¿alguna vez tuvieron que disminuir la cantidad servida en las comidas a algún menor de 18 años en su hogar?	SÍ ❑ NO ❑
14	En el último mes, por falta de dinero u otros recursos, ¿alguna vez algún menor de 18 años en su hogar sintió hambre pero no comió?	SÍ ❑ NO ❑
15	En el último mes, por falta de dinero u otros recursos, ¿alguna vez algún menor de 18 años sólo comió una vez al día o dejó de comer durante todo un día?	SÍ ❑ NO ❑

Figura 2.

Escala Latinoamericana y Caribeña de Seguridad Alimentaria (ELCSA) (Fuente: FAO [10]. Disponible en: https://www.fao.org/3/i3065s/i3065s.pdf).

correspondió a una variable y cada fila a un paciente de la muestra). Se realizo inicialmente un análisis descriptivo presentando las variables a través de porcentajes y tablas de frecuencias, diagramas de cajas y bigotes. Se evaluó la posible asociación entre variables, mediante el uso de tablas de contingencia, diagramas de dispersión con líneas de regresión y mapas. Así mismo se realizó un *análisis* de correspondencias *múltiples (ACM)* para explorar la asociación de cada una de las preguntas con el indicador final, tanto en la encuesta SCAN como en la ELCSA.

Para ello, se usó el primer plano factorial generado por los interrogantes y se incluyó la representación de los niveles de respuesta sobre dicho plano, realizando un agrupamiento que permitió realizar una descripción complementaria. Se utilizo un modelo de tipo lineal generalizado multinomial con el *enlace logit,* para establecer la relación entre los niveles de riesgo nutricional y la seguridad alimentaria, basados en las demás características de los pacientes, escogiendo el modelo de mejor ajuste de los datos a través del criterio de información de Akaike (AIC), el criterio de información bayesiana (BIC), el valor *p* y el R ajustado. Se estableció el nivel de significancia con un valor de $p < 0,05$. Los análisis se realizaron a través del software estadístico R, versión libre 4.2.1.

CONSIDERACIONES ÉTICAS

La presente investigación se llevó a cabo de acuerdo con las directrices establecidas por la Asociación Médica Mundial y la Declaración de Helsinki (16,17). Así mismo se garantizó el cumplimiento de la resolución 8430 de 1993 del Ministerio de Salud y Protección Social de Colombia (18), por lo cual contó con la aprobación del Comité de Ética e Investigación de la Fundación Hospital Pediátrico La Misericordia - HOMI mediante acta No. 69-512-22R.

RESULTADOS

El total fue de 41 pacientes, predominantemente de sexo masculino (51 %). La moda se presenta con los que tienen 6 años (nacidos en 2016), con 9 pacientes. La edad máxima del grupo de estudio fue de 16 años (nacidos en 2006). Los grupos de patología se clasificaron según la 10.ª revisión de la Clasificación Internacional de Enfermedades y Problemas Relacionados con la Salud. Las características demográficas y las principales características diagnósticas de los pacientes se presentan en la tabla I. Con relación a la procedencia, se observó que el mayor número de pacientes fueron remitidos de la ciudad capital Bogotá, con un reporte de 32 pacientes, y los demás puntos presentaron 1 caso por diferentes regiones de procedencia, como se observa en la figura 3.

Tabla I. Características demográficas y diagnósticas de la población

Características	*n* (%)
Sexo	
Femenino	20 (49)
Masculino	21 (51)
Edad en años	
Menores de 5 años	10
6-11 años	18
12-16 años	13
Principales diagnósticos (CIE-10)	
C910 Leucemia linfoblástica aguda [ALL o LLA]	17 (41 %)
Otros diagnósticos (AGRUPA 23 CIE-10)	24 (59 %)
Diagnóstico nutricional	
E43X Desnutrición proteicocalórica severa, no especificada	4 (9,8 %)
E440 Desnutrición proteicocalórica moderada	4 (9,8 %)
E441 Desnutrición proteicocalórica leve	17 (41,5 %)
Eutrófico	2 (4,9 %)
F508 Otros trastornos de la ingestión de alimentos	5 (12 %)
Sobrepeso	9 (22 %)

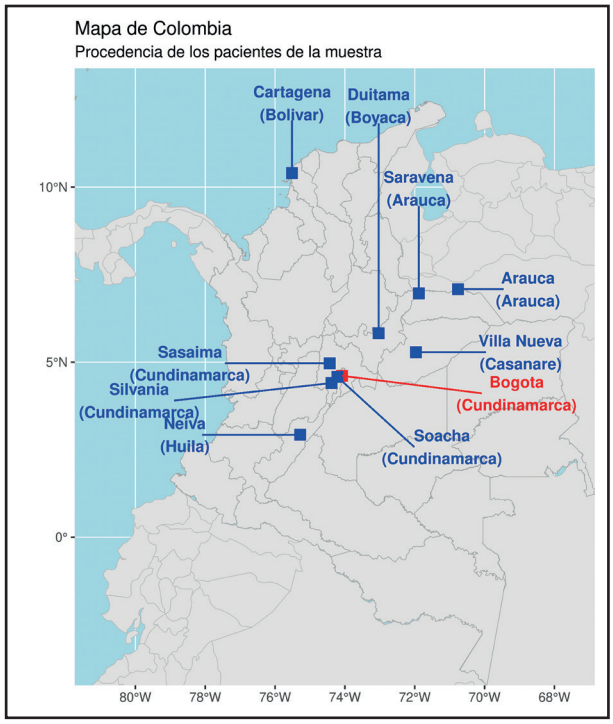

Figura 3.
Procedencia de los pacientes.

RIESGO NUTRICIONAL SCAN

En los resultados de la tamización nutricional con la herramienta SCAN-SP se puede observar que el 76 % (*n* = 31) de los pacientes se clasificaron como "En riesgo de desnutrición" (Tabla II).

Tabla II. Caracterización de la población para clasificar el grado de ISA

Grado de seguridad alimentaria / Clasificación de la (in)seguridad alimentaria	*n* (%)
Seguros - 0	18 (44 %)
ISA leve - 1 A 5	12 (29 %)
ISA moderada - 6 A 10	8 (20 %)
ISA severa - 11 A 15	3 (7 %)
Total	41 (100 %)
Riesgo nutricional scan	***n* (%)**
Riesgo nutricional alto	31 (76 %)
Riesgo nutricional bajo	10 (24 %)
Total	41 (100 %)

ISA: inseguridad alimentaria.

El puntaje promedio de la herramienta SCAN-SP fue de 5, con unos puntajes mínimo de 0 y máximo de 10. En relación con la información recolectada a través de la tamización, cabe resaltar que la pregunta que tuvo la mayor cantidad de respuestas afirmativas fue aquella que indaga si el paciente estaba bajo tratamiento intensivo, con un 75 %, seguida de las preguntas que evaluaban si el paciente tenía un cáncer de alto riesgo: 68 %. La reducción de la ingesta de alimentos se presentó en el 43 % y la pérdida de peso en un 47 %. Los síntomas relacionados con el tracto gastrointestinal se presentaron en el 23 %.

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En el presente estudio se observó que el 56 % del conjunto de hogares tuvo cierta proporción de inseguridad alimentaria. En la tabla II se presenta la caracterización de la población para clasificar el grado de ISA.

Es destacable que, al analizar las cinco preguntas en orden descendente de acuerdo con la frecuencia de respuestas afirmativas en la Encuesta de Límites de la Canasta Familiar (ELCSA), se observó que los adultos a cargo del hogar habían expresado su preocupación en el último mes debido a la escasez de recursos económicos. Manifestaron inquietud por la posibilidad de quedarse sin alimentos en el hogar y reconocieron haber dejado de mantener una dieta saludable. Además, indicaron haber dejado de realizar alguna de las comidas diarias, ya sea el desayuno, el almuerzo o la cena.

DISCUSIÓN

Los resultados de esta investigación revelaron que el 76 % de la población estudiada está en riesgo nutricional, cifra que coincide con los datos reportados en la literatura existente. Por ejemplo, un estudio realizado en un hospital terciario pediátrico en Madrid, España, que incluyó a niños recién diagnosticados de cáncer entre agosto de 2018 y mayo de 2019, aplicó el cuestionario SCAN a 49 pacientes y encontró que 22 de ellos (45 %) presentaban riesgo de desnutrición (19). Otros estudios indican variabilidad en el riesgo de desnutrición, con porcentajes que oscilan entre el 30 % y el 85 % (20-23).

Dado el papel crítico del estado nutricional en el tratamiento del cáncer infantil, existen diversas guías y recomendaciones que subrayan la necesidad de implementar un proceso de cuidado nutricional exhaustivo (24-28). En un reciente artículo de la revista “The Lancet Child & Adolescent Health” sobre nutrición durante el tratamiento del cáncer infantil, se destaca la importancia crucial de mantener un adecuado estado nutricional como parte integral de varias de las medidas de resultados de salud. El artículo señala que el 75 % de los niños y adolescentes con cáncer presentan malnutrición, ya sea desnutrición o sobrenutrición. Aunque se ha observado este problema durante las últimas dos décadas, los avances en la comprensión de los factores subyacentes de la desnutrición en esta población han sido limitados. Ante esta falta de investigación se insta a promover estudios que mejoren la evaluación e intervención nutricional para este grupo (29) objeto del presente proyecto de investigación posdoctoral.

Es esencial considerar la seguridad alimentaria y las preocupaciones financieras en el cuidado nutricional para mejorar las tasas de supervivencia del cáncer. Los bajos niveles socioeconómicos y las altas comorbilidades aumentan la inseguridad alimentaria entre los sobrevivientes, destacando la necesidad de políticas efectivas de apoyo (30,31).

Por otra parte, se observó que el 56 % del conjunto de hogares de los pacientes participantes en el estudio tenían cierta inseguridad alimentaria, siendo el resultado superior a la prevalencia de los hogares colombianos con inseguridad alimentaria, la cual es del 54,2 % según la Encuesta Nacional de la Situación Nutricional ENSIN (32). Una revisión sistemática que incluyó 15 artículos sobre inseguridad alimentaria general reportó que la prevalencia de la inseguridad oscilaba entre el 4,0 % y el 26,2 %, lo que se superpone a la prevalencia de la inseguridad alimentaria en la población general de los Estados Unidos, refiriéndose este reporte a una población adulta oncológica (33).

La evaluación de la seguridad alimentaria en entornos médicos pediátricos requiere una investigación más extensa para controlar los factores de riesgo y brindar datos objetivos sobre la morbilidad asociada a las enfermedades oncológicas. Esto puede impactar en la seguridad financiera familiar y, por consiguiente, en la calidad de vida (34).

En el cuidado nutricional de los pacientes con cáncer es crucial integrar la evaluación de la seguridad alimentaria, que está profundamente interconectada con las preocupaciones financieras, y su efecto sobre la supervivencia del cáncer. Los niveles socioeconómicos bajos y las comorbilidades significativas incrementan la inseguridad alimentaria entre los sobrevivientes, que se enfrentan a serias dificultades económicas para satisfacer necesidades básicas como la alimentación. Por ello se requieren con urgencia políticas públicas que aborden estos problemas, utilizando un enfoque integral y coordinado para mejorar la calidad de vida de los afectados y sus familias.

CONCLUSIÓN

El riesgo de desnutrición evaluado mediante la herramienta de tamización nutricional SCAN-SP se identificó en el 76 % de los pacientes; se observó adicionalmente que el 56 % del conjunto de hogares con menores de 18 años tenía cierta proporción de inseguridad alimentaria, lo cual evidencia la necesidad de un proceso de cuidado integral en la oncología pediátrica, uno que incluya no solo la evaluación del riesgo y la valoración nutricional completa sino también la medición objetiva de la seguridad alimentaria, para así establecer planes de intervención integrales que impacten en el tratamiento oncológico.

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Trabajo Original

Pediatría

Lower levels of vitamin D are associated with an increase in carotid intima-media thickness in children and adolescents with obesity

Los niveles bajos de vitamina D se asocian a un aumento del grosor íntima-media carotídeo en los niños y adolescentes con obesidad

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Abstract

Background: the relationship between vitamin D deficiency and carotid intima-media thickness (CIMT) in children and adolescents with obesity is unknown. The aim of this study was to investigate the correlation between vitamin D levels and CIMT in children and adolescents with obesity.

Methods: a total of 440 children and adolescents aged 6-16 with obesity were included in the study. Anthropometric measurements, blood pressure measurements, blood lipids, blood glucose, and vitamin D levels were measured. Bilateral carotid ultrasound was performed to assess CIMT. The relationships between vitamin D levels and CIMT were assessed using multivariate linear regression with Generalized Linear Models and restricted cubic splines. Binary logistic regression analyses were conducted to explore the association between vitamin D status and the risk of abnormal CIMT.

Results: vitamin D levels were inversely correlated with CIMT in subjects with serum 25-hydroxyvitamin D [25(OH)D] levels less than or equal to 50 nmol/L (β = -0.147, 95 % CI [-0.263, -0.030], $p = 0.013$), but this correlation was not significant in subjects with serum 25(OH)D levels above 50 nmol/L. After correcting for various confounders, the risk of abnormal CIMT was significantly higher in the vitamin D deficiency group (OR = 2.080, 95 % CI [1.112, 3.891], $p = 0.022$).

Conclusions: vitamin D deficiency is an independent risk factor for abnormal CIMT, and vitamin D deficiency may play a promoting role in the atherosclerotic process in children and adolescents with obesity.

Keywords:

Children and adolescents. Obesity. Vitamin D. Carotid intima-media thickness.

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Resumen

Antecedentes: se desconoce la relación entre la deficiencia de vitamina D y el grosor íntima-media carotídeo (GIMC) en los niños y adolescentes con obesidad. El objetivo de este estudio fue investigar la correlación entre los niveles de vitamina D y el grosor íntima-media carotídeo en niños y adolescentes con obesidad.

Métodos: se incluyeron en el estudio un total de 440 niños y adolescentes de entre 6 y 16 años con obesidad. Se midieron los parámetros antropométricos, la presión arterial, los lípidos sanguíneos, la glucosa en sangre y los niveles de vitamina D. Se realizó una ecografía carotídea bilateral para evaluar el grosor íntima-media carotídeo (GIMC). Las relaciones entre los niveles de vitamina D y el GIMC se evaluaron mediante una regresión lineal multivariante con modelos lineales generalizados y "splines" cúbicos restringidos. Se realizaron análisis de regresión logística binaria para explorar la asociación entre el estado de la vitamina D y el riesgo de un GIMC anormal.

Resultados: los niveles de vitamina D se correlacionaron inversamente con el GIMC en los sujetos con niveles séricos de 25(OH)D inferiores o iguales a 50 nmol/L (ß = -0,147; IC del 95 %, [-0,263; -0,030], $p = 0,013$), pero esta correlación no fue significativa en los sujetos con niveles séricos de 25(OH)D superiores a 50 nmol/L. Una vez corregidos varios factores de confusión, el riesgo de un GIMC anormal fue significativamente mayor en el grupo con deficiencia de vitamina D (OR = 2,080; IC del 95 %, [1,112; 3,891], $p = 0,022$).

Conclusiones: la deficiencia de vitamina D es un factor de riesgo independiente para la anomalía del GIMC, y la deficiencia de vitamina D puede desempeñar un papel promotor en el proceso aterosclerótico en niños y adolescentes con obesidad.

Palabras clave:

Niños y adolescentes. Obesidad. Vitamina D. Grosor íntima-media carotídeo.

BACKGROUND

Childhood obesity is one of the most prevalent global public health issues (1,2). According to current estimates, there are 381 million children globally who are affected by overweight or obesity (3). Obesity has become a serious health issue in China. The latest national prevalence estimates for 2015-2019 showed that 7.9 % of children and adolescents aged 6-17 and 16.4 % of adults (≥ 18 years) suffer from obesity (4). Children with risk factors such as obesity, dyslipidemia, hypertension, and diabetes *mellitus* have a higher risk of cardiovascular disease (CVD) in adulthood. Children with obesity have a higher risk of vitamin D deficiency, systemic inflammation, dyslipidemia, and cardiometabolic risk factors (5,6).

Carotid intima-media thickness (CIMT) is recognized by the American Society of Echocardiography and the European Society of Pediatric Cardiology as a surrogate biomarker of atherosclerosis, providing important information about vascular health in the pediatric population (7,8). The process of atherosclerosis starts early in children and adolescents with obesity (9). Studies have shown that children and adolescents with obesity and cardiovascular risk factors tend to have higher CIMT (10).

Vitamin D, a fat-soluble vitamin with both endocrine and autocrine functions (11), may play an important role in endothelial and smooth muscle vascular cells. Its deficiency may lead to vascular homeostasis imbalance and decreased arterial compliance, which are associated with the development of atherosclerosis and abnormal arterial wall thickness in adults (12). A general deficiency in vitamin D has been found in a large number of studies among individuals with obesity (13). It is inconclusive whether vitamin D deficiency exacerbates dyslipidemia and atherosclerosis in children and adolescents with obesity. Vitamin D deficiency may be a cardiovascular risk factor from childhood; however, only a few studies have investigated the association of serum vitamin D with cardiovascular disease risk factors during childhood. The purpose of this research was to explore the potential association between serum 25(OH)D levels and CIMT.

METHODS

PARTICIPANTS

This study was a single-center, retrospective, cross-sectional analysis. A total of 440 children and adolescents with obesity aged 6-16 years who underwent physical examination in the Endocrinology Department and Clinical Nutrition Department of the Children's Hospital of Nanjing Medical University from January 1, 2018, to December 31, 2022, were selected as research subjects. According to the WHO 2007 criteria, obesity was diagnosed in participants with a BMI z score ≥ 2 SD.

Inclusion criteria were as follows: 6-16 years of age; obesity; no major comorbidities or underlying diseases; and complete data. The exclusion criteria were as follows: younger than 6 years old; incomplete basic information and biochemical indicators; severe liver and kidney diseases; children and adolescents with type 2 diabetes; secondary obesity caused by other factors.

RESEARCH METHOD

Height and weight were measured by professionals using the OMRON (SK-L08) measuring instrument. BMI (kg/m²) = weight (kg) / height² (m²). The BMI z-score was calculated for each participant using the WHO Anthroplus software and the WHO 2007 growth reference.

Waist and hip circumference were measured in centimeters at the narrowest level at the waist between the costal margin and iliac crest and hip circumference at the largest level across the buttocks. Blood pressure was measured by the OMRON electronic blood pressure monitor (HEM-705CP). Fasting venous blood was taken and centrifuged at 3000 rpm for 10 minutes (centrifugation radius: 15 cm). The serum and plasma were separated, and fasting blood glucose (FBG), 2 h postprandial glucose (2hPG), uric acid (UA), triacylglycerol (TG), total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C), and low-density lipoprotein cholesterol (LDL-C) were detected using the Cobas® 8000 automatic biochemical analyzer. Glycated hemoglobin (HbA1c) was tested by high-performance liquid chromatography (Bio-Rad D10 Automatic Analyzer,

Hercules, CA, USA). An automatic electrochemiluminescence immunoanalyzer (Roche, Basel, Switzerland) was used to determine 25(OH)D. According to the standard (14), 25(OH)D level > 50 nmol/L was considered sufficient, 30-50 nmol/L was insufficient, and < 30 nmol/L was deficient.

Netherlandish Philips IU22 color Doppler ultrasound diagnostic instrument (Amsterdam, The Netherlands) was adopted, and the probe frequency was set at 5~37 MHz. Ultrasound scans were performed to assess CIMT of the right and left carotid arteries. The common carotid IMT was measured at its thickest part 1 cm proximal to the bifurcation. CIMT was expressed as the average of left and right CIMT ([Left CIMT + Right CIMT] / 2). Abnormal CIMT was determined if the value was ≥ 95th percentile for age, sex, and height (15). Season was defined as: winter: December-February; spring: March-May; summer: June-August; autumn: September-November.

STATISTICAL ANALYSIS

Statistical analysis was performed using with SPSS version 25.0 (SPSS Inc., Chicago, IL, USA) and the R version 4.3.1. The total number of cases (*n*) and percentage (%) are used to represent count data. Normally distributed variables are described by the mean standard deviation, while skewed variables are described by the median, 25th, and 75th percentiles. The chi-square test was used for the statistical analysis of the counting data. Pairwise comparisons of measurement data subject to normal distribution were tested by independent sample t-test while those among multiple groups were analyzed by one-way analysis of variance (ANOVA), and the LSD (least significant difference) test was used for pair comparison after one-way ANOVA. If the samples did not meet the requirements of ANOVA, such as a normal distribution or homogeneity of variance, then a non-parametric test (Kruskal-Wallis) was used, and the Bonferroni method was used for comparison. We performed a multivariate linear regression using Generalized Linear Models to explore the association between CIMT and vitamin D levels after adjustment for other variables. In the multiple linear regression analysis, all data were transformed to z scores to obtain standardized regression coefficients. Restricted cubic splines were used to evaluate linear and nonlinear associations. Binary logistic regression analyses were used to explore the association between vitamin D status and the risk of abnormal CIMT. The difference of $p < 0.05$ was statistically significant.

RESULTS

CHARACTERISTICS OF THE STUDY POPULATION

In this study we included 440 children and adolescents aged 6-16 years. Table I summarizes the demographic characteristics, anthropometric and biochemical measurements, and carotid intima-media thickness according to vitamin D status. There were 119 patients with vitamin D deficiency (79 males and 40 females; median age, 11.68 years, 27.1 % of total subjects); 228 patients with vitamin D insufficiency (155 males and 73 females; median age, 11.34 years, 51.8 % of total subjects); and 93 patients with vitamin D sufficiency (70 males and 23 females; median age, 11.35 years, 21.1 % of total subjects). There were no significant differences in sex, HAZ (height-for-age z-score), BMI z-score, WC (waist circumference), SBP (systolic blood pressure), HbA1c (hemoglobin A1c), FPG (fasting plasma glucose), 2hPG (2 h postprandial plasma glucose), UA (uric acid), TC (total cholesterol), or LDL-C (low-density lipoprotein cholesterol) among the three groups (all $p > 0.05$). However, we found significant differences in CIMT and the risk of abnormal CIMT among the three groups. A post-hoc Bonferroni analysis revealed that CIMT was significantly higher in the vitamin D deficient group than in the vitamin D insufficient and vitamin D sufficient groups. Additionally, the risk of abnormal CIMT was significantly higher in the vitamin D-deficient group compared to the vitamin D-sufficient group.

On the basis of CIMT values, the subjects were divided into normal CIMT group and abnormal CIMT group. The basic characteristics of subjects according to CIMT were shown in table II. No significant differences were observed in age, sex, HAZ, BMI z-score, WC, HC, SBP, DBP, FPG, 2hPG, UA, TG, TC, HDL-C, LDL-C, or season of blood collection (all $p > 0.05$). However, we observed that vitamin D levels were significantly lower in the CIMT abnormal group than in the CIMT normal group.

CORRELATIONS BETWEEN CIMT AND VITAMIN D LEVELS

To adjust for the effects of confounding factors, we used Generalized Linear Models for multiple linear regression analysis to assess the relationship between vitamin D levels and CIMT. Table III reports the standardized regression coefficients (ß) and 95 % CIs for the Generalized Linear Models. Vitamin D levels are categorized as: low vitamin D levels (vitamin D levels (≤ 50 mmol/L) and normal vitamin D levels (> 50 mmol/L). Our results showed a significant negative correlation between vitamin D levels and CIMT in the low vitamin D level group, even after adjusting for various confounding factors ($p < 0.05$). However, in the vitamin D normal group, vitamin D levels were not associated with CIMT ($p > 0.05$). and the interaction in all models $p > 0.05$. The significance of the multiplication interaction between vitamin D and BMI z-score was estimated by adding cross-product terms in models, in all the models the interaction term was non-significant ($p > 0.05$). Restricted cubic splines were also generated to visualize this relationship, adjusting for age, sex and BMI z-score (Fig. 1). Modeling of vitamin D levels using restricted triplicate spline revealed that vitamin D levels did not correlate with CIMT in the vicinity of a reference vitamin D concentration of 50 nmol/L, low vitamin D levels were linearly and negatively correlated with CIMT (p for nonlinear = 0.2708).

Figure 1 shows fitted restricted cubic spline and 95 % CI, indicating no evidence of non-linear association between vitamin D levels and CIMT (p for nonlinearity = 0.2708). The restricted cubic splines model adjusted for age, sex, and BMI z-score.

Table I. Characteristics of the study population according to vitamin D status

Variables	Sufficient group (*n* = 93)	Insufficient group (*n* = 228)	Deficient group (*n* = 119)	*p*
Age (years)	11.35 (9.38, 12.32)	11.34 (9.61, 12.34)	11.68 (10.07, 13.17)	*0.017*†
Sex, boys (%)	70 (75.3 %)	155 (68.0 %)	79 (66.4 %)	0.333
HAZ	1.37 (0.69, 2.15)	1.49 (0.76, 2.04)	1.59 (0.56, 2.43)	0.736
BMI z-score	3.08 (2.75, 3.57)	2.88 (2.59, 3.57)	2.96 (2.61, 3.58)	0.510
WC (cm)	93.00 (86.00, 100.00)	92.25 (86.25, 100)	95 (86.50, 104.50)	0.139
HC (cm)	97.00 (92.25, 105.00)	98.60 (91.95, 104.00)	101.00 (92.50, 110.20)	*0.044*
SBP (mmHg)	129.00 (120.00, 139.50)	126.00 (118.00, 135.00)	130.00 (119.00, 141.00)	0.113
DBP (mmHg)	73.73 ± 1.14	72.86 ± 0.64	75.76 ± 1.01	*0.047*‡
HbA1c (%)	5.40 (5.15, 5.70)	5.30 (5.18, 5.60)	5.30 (5.20, 5.60)	0.627
FPG (mmol/L)	4.65 ± 0.04	4.55 ± 0.03	4.63 ± 0.04	0.07
2hPG (mmol/L)	6.22 (5.64, 6.98)	6.50 (5.80, 7.27)	6.57 (5.87, 7.25)	0.379
UA (µmol/L)	410.00 (345.00, 463.50)	389.00 (329.50, 453.00)	408.00 (345.00, 476.00)	0.578
TG (mmol/L)	1.12 (0.82, 1.61)	1.11 (0.88, 1.51)	1.33 (0.92, 1.79)	*0.040*
TC (mmol/L)	3.96 (3.50, 4.57)	3.99 (3.36, 4.49)	3.99 (3.53, 4.53)	0.560
HDL-C (mmol/L)	1.15 (1.01, 1.32)	1.07 (0.96, 1.22)	1.08 (0.98, 1.27)	*0.045**
LDL-C (mmol/L)	2.29 (1.92, 2.69)	2.23 (1.82, 2.74)	2.19 (1.83, 2.64)	0.850
25(OH)D (nmol/L)	59.51 (54.49, 69.42)	40.16 (36.53, 44.14)	25.49 (22.44, 28.17)	*< 0.001*,†,‡*
CIMT (mm)	0.47 (0.41, 0.53)	0.48 (0.43, 0.54)	0.5 (0.47, 0.57)	*0.002†,‡*
Abnormal CIMT (%)	51 (54.8 %)	154 (67.5 %)	90 (75.6 %)	*0.006*†
Season of blood collection				
Spring	17 (18.3 %)	38 (16.7 %)	26 (21.8 %)	
Summer	50 (53.8 %)	120 (52.6 %)	41 (34.5 %)	
Autumn	17 (18.3 %)	46 (20.2 %)	22 (18.5 %)	
Winter	9 (9.7 %)	24 (10.5 %)	30 (25.2 %)	*0.002*

Italics type denotes significant ($p < 0.05$*) values; *insufficient group vs. sufficient group,* $p < 0.05$*; †deficient group* vs. *sufficient group,* $p < 0.05$*; ‡deficient group* vs. *insufficient group,* $p < 0.05$*. BMI: body mass index; HAZ: height-for-age z-score; WC: waist circumference; HC: hip circumference; SBP: systolic blood pressure; DBP: diastolic blood pressure; HbA1c: hemoglobin A1c; FPG: fasting plasma glucose; 2hPG: 2 h postprandial plasma glucose; UA: uric acid; TG: triacylglycerol; TC: total cholesterol; HDL-C: high-density lipoprotein cholesterol; LDL-C: low-density lipoprotein cholesterol; CIMT: carotid intima-media thickness.*

ODDS RATIOS (95 % CIS) OF ABNORMAL CIMT ACCORDING TO VITAMIN D STATUS

Multivariate logistic regression was applied to assess the association between vitamin D status and abnormal CIMT (Table IV). In the unadjusted model, the ORs for abnormal CIMT in the vitamin D insufficient and vitamin D deficient groups compared with the vitamin D sufficient group were 1.714 (1.046-2.808) and 2.556 (1.424-4.586), respectively. After further adjustment for various confounders, the vitamin D deficiency group remained significantly associated with an increased risk of abnormal CIMT (OR: 2.080, 95 % CI: 1.112-3.891). However, the vitamin D insufficiency group was no longer associated with a risk of abnormal CIMT. No significant interaction was found between serum 25(OH)D levels and BMI z-score (*p* for all interactions > 0.05).

Table II. Characteristics of the study population according to carotid intima-media thickness

Variables	Normal CIMT (*n* = 145)	Abnormal CIMT (*n* = 295)	*p*
Age (years)	11.27 (9.40, 12.67)	11.46 (9.80, 12.56)	0.318
Sex, boys (%)	99 (68.3 %)	205 (69.5%)	0.795
HAZ	1.51 (0.55, 2.21)	1.46 (0.75, 2.16)	0.914
BMI z-score	2.98 (2.62, 3.58)	2.96 (2.64, 3.57)	0.886
WC (cm)	92.50 (87.00, 98.50)	93.50 (86.00, 102.80)	0.161
HC (cm)	98.00 (92.00, 104.00)	99.50 (91.50, 107.00)	0.250
SBP (mmHg)	128.00 (118.00, 140.00)	127.00 (119.00, 138.00)	0.823
DBP (mmHg)	73.34 ± 9.92	74.07 ± 10.62	0.485
HbA1c (%)	5.40 (5.30, 5.60)	5.30 (5.10, 5.60)	*0.006*
FPG (mmol/L)	4.61 ± 0.42	4.58 ± 0.44	0.611
2hPG (mmol/L)	6.36 (5.64, 7.25)	6.46 (5.81, 7.17)	0.917
UA (μmol/L)	400.00 (348.00, 454.00)	392.00 (330.00, 457.00)	0.319
TG (mmol/L)	1.11 (0.83, 1.48)	1.19 (0.90, 1.70)	0.052
TC (mmol/L)	3.94 (3.44, 4.49)	3.99 (3.43, 4.53)	0.704
HDL-C (mmol/L)	1.10 (1.00, 1.26)	1.07 (0.96, 1.24)	0.116
LDL-C (mmol/L)	2.24 (1.82, 2.64)	2.24 (1.84, 2.71)	0.907
25(OH)D (nmol/L)	42.18 (32.20, 52.93)	37.9 (29.02, 46.28)	*0.002*
CIMT (mm)	0.40 (0.40, 0.43)	0.52 (0.49, 0.58)	*< 0.001*
Season of blood collection			
Spring	32 (22.1 %)	49 (16.6 %)	
Summer	60 (41.4 %)	151 (51.2 %)	
Autumn	28 (19.3 %)	57 (19.3 %)	
Winter	25 (17.2 %)	38 (12.9 %)	0.186

Italics type denotes significant ($p < 0.05$) values. BMI: body mass index; HAZ: height-for-age z-score; WC: waist circumference; HC: hip circumference; SBP: systolic blood pressure; DBP: diastolic blood pressure; HbA1c: hemoglobin A1c; FPG: fasting plasma glucose; 2hPG: 2 h postprandial plasma glucose; UA: uric acid; TG: triacylglycerol; TC: total cholesterol; HDL-C: high-density lipoprotein cholesterol; LDL-C: low-density lipoprotein cholesterol; CIMT: carotid intima-media thickness.

SUBGROUP ANALYSES OF THE ASSOCIATION BETWEEN VITAMIN D STATUS AND ABNORMAL CIMT

A subgroup analysis was subsequently performed to evaluate the effect on different age groups (6-11 and 12-16 years), sex groups and BMI z-score groups (< 3/≥ 3). The forest plot of the subgroup analysis is presented in figure 2. Subgroup analyses by age group showed that vitamin D deficiency was not significantly different from the risk of abnormal CIMT in different age groups ($p > 0.05$). Sex-stratified subgroup analysis showed that the risk of abnormal CIMT was significantly higher in girls with vitamin D deficiency than in the vitamin D-sufficient group, but no similar association was found in boys. Subgroup analysis by BMI z-score showed that the risk of CIMT abnormalities was significantly higher in the vitamin D-deficient and vitamin D-insufficient groups than in the vitamin D-sufficient group in the BMI z-score ≥ 3 group, but was not significantly different in the BMI z-score < 3 group. Subgroup analyses indicated no significant interaction in the subgroup analysis (all *p*-values for interaction were > 0.05).

DISCUSSION

There has been controversy regarding the relationship between vitamin D and CIMT. Our findings support that there is a negative correlation between vitamin D and CIMT in the range of low vitamin D levels (≤ 50 nmol/L) and that vitamin D deficiency

Table III. Association between serum 25(OH)D levels and CIMT according to serum 25(OH)D levels

Subjects	Model	ß	95 % CI	*p*
All subjects (n = 440)	Model 1	-0.142	-0.234 to -0.05	*0.003*
	Model 2	-0.100	-0.196 to -0.003	*0.043*
	Model 3	-0.108	-0.205 to -0.011	*0.029*
Normal 25(OH)D level (n = 93)	Model 1	-0.042	-0.245 to 0.161	0.686
	Model 2	-0.019	-0.202 to 0.165	0.843
	Model 3	-0.003	-0.189 to 0.001	0.972
Low 25(OH)D level (n = 347)	Model 1	-0.155	-0.259 to -0.051	*0.003*
	Model 2	-0.144	-0.260 to -0.028	*0.015*
	Model 3	-0.147	-0.263 to -0.030	*0.013*

*Italics type denotes significant (p < 0.05) values. Model 1 was unadjusted. Model 2 is adjusted for age, sex, HAZ, BMI z-score, WC, HC, SBP, DBP, HbA1c, FPG, 2hPG, UA, blood lipid profile, and season of blood collection. Model 3 is adjusted as for Model 2 + BMI z-score * 25(OH)D.*

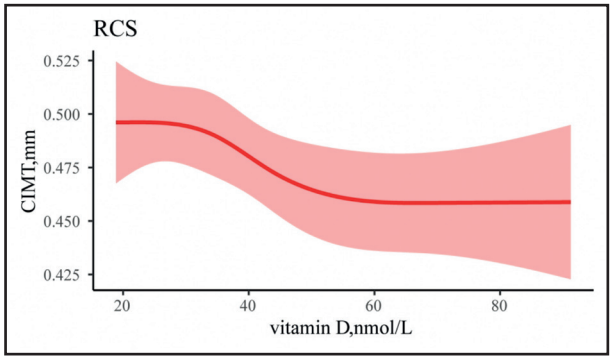

Figure 1.
Linear association between vitamin D levels and CIMT.

exacerbates the risk of CIMT abnormalities in children and adolescents with obesity.

Obesity during childhood and adolescence is significantly associated with an increased risk for cardiovascular and metabolic disease, colorectal cancer, and breast cancer in adulthood (16,17). Compared with their counterparts without obesity, children and adolescents with obesity have a higher risk of vitamin D deficiency (18,19). In our study, only 21.1 % of Chinese children and adolescents with obesity had normal vitamin D levels, and 27.1 % of children and adolescents were vitamin D deficient. Vitamin D levels are thought to be lower in people with obesity because it is sequestered in fat cells (20).

It is well known that CIMT is an accurate predictor of systemic atherosclerosis and an objective measure of early atherosclerosis, and obtaining CIMT using ultrasonography is currently a non-invasive tool for obtaining abnormal changes in blood vessels (21). Studies have linked vitamin D deficiency to atherosclerosis (22). Vitamin D deficiency may be an independent risk factor for atherosclerosis in children and adolescents with obesity. Vitamin D deficiency can lead to endothelial dysfunction, increased arterial stiffness and increased CIMT (23). A meta-analysis showed serum vitamin D levels as a preventive measure of carotid plaque (24). Many studies have reported an association between vitamin D

Table IV. Logistic regression of the association between different vitamin D status and abnormal CIMT

Vitamin D status	Model 1			Model 2		
	OR_1	95 % CI_1	p_1	OR_2	95 % CI_2	p_2
Vitamin D sufficient	1.000 (Ref.)	–	–	1.000 (Ref.)	–	–
Vitamin D insufficient	1.714	1.046-2.808	*0.032*	1.571	0.928-2.658	*0.093*
Vitamin D deficient	2.556	1.424-4.586	*0.002*	2.080	1.112-3.891	*0.022*
p for trend	0.002			0.022		

Italics type denotes significant (p < 0.05) values. Model 1 is unadjusted. Model 2 is adjusted for age, sex, HAZ, BMI z-score, WC, HC, SBP, DBP, HbA1c, FPG, 2hPG, UA, blood lipid profile, and season of blood collection.

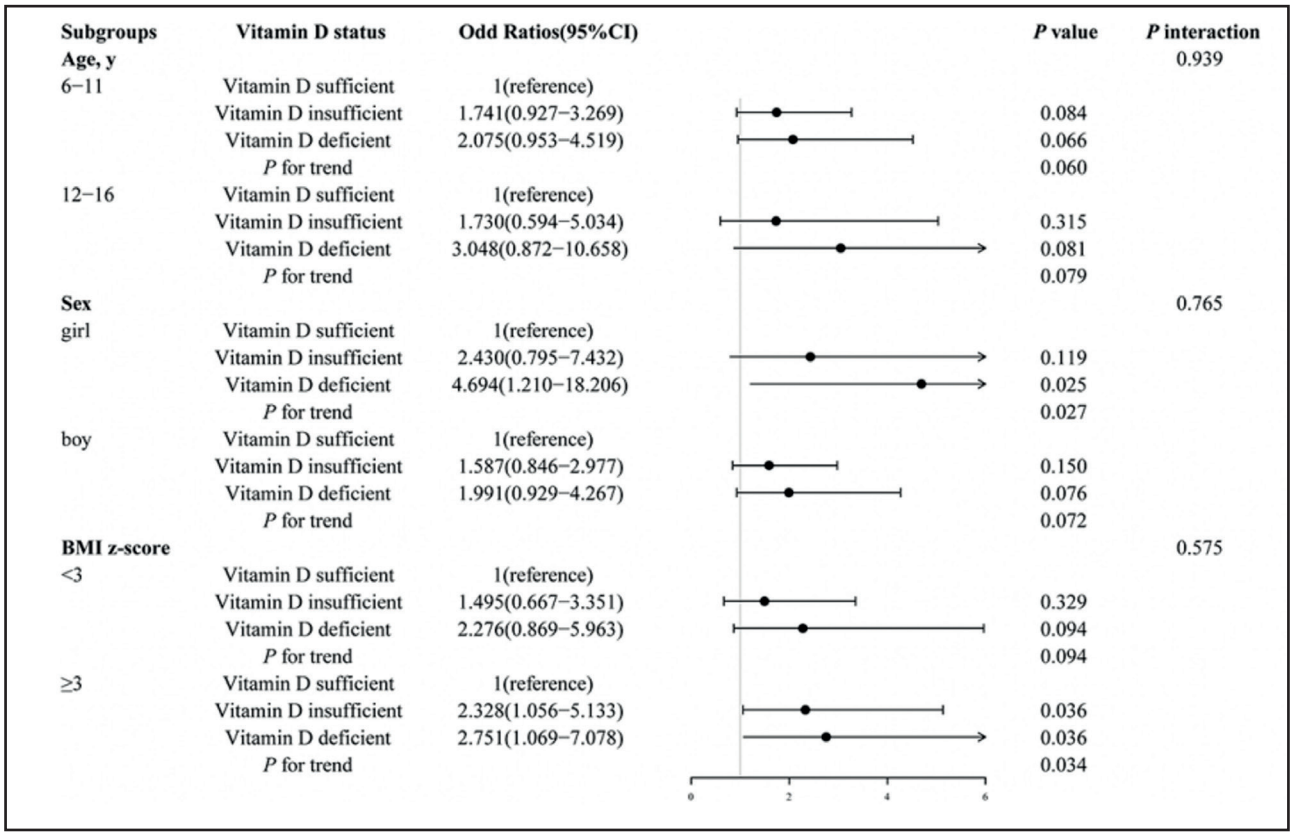

Figure 2.

Forest plot of subgroup analysis of the association between vitamin D status and abnormal CIMT. Each stratification adjusted for all the factors of model 2 in the multivariable logistic regression, except for the stratification factor itself.

status and carotid intima-media thickness; however, the available pediatric studies are very limited. According to a recent meta-analysis of 19 observational and 3 randomized studies, there is a negative correlation between serum vitamin D and CIMT. Additionally, the study found that vitamin D supplementation has a positive effect on reducing CIMT (25). In our study, we also found a negative association between vitamin D levels and CIMT, which is similar to other studies (26,27), but not consistent with previous studies (5,28). The discrepancy in findings may be due to differences in study populations, as most current studies on vitamin D and CIMT are based on the general population aged 18-75 years. A study in a cohort of children and adolescents with obesity found that CIMT was increased in vitamin D-deficient patients with obesity, and vitamin D levels were negatively correlated with CIMT, similar to our results (29). However, another study in children with obesity provided opposite results. In a cross-sectional study of children with obesity aged 15 to 17 years, no association was found between vitamin D and CIMT (12). To our knowledge, the present study is the first study to suggest a negative correlation between vitamin D and CIMT within low vitamin D levels.

The relationship between serum vitamin D and CIMT is not completely clear. However, most researchers currently believe that vitamin D plays a vital role in activating the renin-angiotensin system. Its deficiency leads to an increase in serum parathyroid hormone (PTH) and a decrease in insulin-like growth factor-1 (IGF-1). Accumulating evidence suggests that reduced IGF-1 concentrations contribute to cardiovascular disease (30). With regard to CIMT, thresholds in the pediatric population are still not standardized, but most studies suggest that obesity and the metabolic syndrome are contributing factors to an increase in CIMT, mainly due to inflammatory processes. The role of vitamin D deficiency in the development of atherosclerosis may be mediated by vascular inflammation, and these include elevated levels of inflammatory cytokines such as C-reactive protein (CRP), tumor necrosis factor-alpha (TNF-α), and interleukin 6, as well as low levels of interleukin 10 (31). It has also been shown that 25 hydroxyvitamin D interacts with vascular endothelial vitamin D receptors and reduces smooth muscle cell proliferation, thereby providing cardiovascular protection (32). Some studies have found that vitamin D deficiency can lead to endothelial damage in the early stages of atherosclerosis without progression to clinical cardiovascular disease, which would have a key role in preventing cardiovascular mortality and morbidity (33).

There is no doubt that most researchers believe that children with obesity develop vascular destruction earlier than their normal-weight peers. The additive effect of obesity, independent of age, was evident in the CIMT values. Significant difference

in CIMT between normal weight and individuals with obesity (34,35). In normal-weight children and adolescents, CIMT is not affected by sex or age (36). Some researchers have found significantly higher values of vascular biomarkers in post-pubertal children with obesity compared to pre-pubertal children with obesity (37). In our study, there is no significant difference between vitamin D deficiency and the risk of abnormal CIMT in different age groups, which may be due to the sample size of subgroups. Our study found a significantly higher risk of abnormal CIMT in vitamin D-deficient girls than in the vitamin D-sufficient group, but no similar association was found in boys. Excess androgens in girls with obesity may lead to an acceleration of the atherosclerotic process, resulting in an increase in CIMT (38). The results could inform policymakers about developing effective strategies for preventing the development of cardiovascular disease in children and adolescents with obesity.

A healthy lifestyle intervention may be able to partially reverse cardiovascular impairment in children with obesity. Adopting prompt behavioral programs in childhood with obesity is crucial for preventing and treating precocious complications (39). A study indicated that adherence to a healthy dietary pattern could prevent increased CIMT in children and adolescents with overweight and obesity (40). A healthy diet and regular exercise combined with vitamin D treatment could reduce cardiovascular disease in children and adolescents with obesity and vitamin D deficiency.

However, our study was limited. First, it was a cross-sectional observational study. We could not determine whether CIMT had a predictive value for cardiovascular outcomes in children and adolescents with obesity, which required prospective longitudinal studies. Second, this study was a small sample study that enrolled patients only from the Children's Hospital of Nanjing Medical University and did not participate in the larger multicenter study. Third, this study did not collect information on physical activity levels or vitamin D supplements, all of which can affect vitamin D concentrations.

Although the study has many limitations, our findings highlight the need for more evidence to establish these links. Particularly, more research is needed to identify potential biological pathways supporting the independent association between vitamin D deficiency and CIMT, explore whether medical interventions improve arterial remodeling, and ultimately determine the effectiveness of targeted preventive interventions.

CONCLUSIONS

In this study, it was found that vitamin D deficiency is an independent risk factor for abnormal CIMT, and vitamin D deficiency may play a promoting role in the atherosclerotic process in children and adolescents with obesity. Therefore, supplementing adequate amounts of vitamin D in children and adolescents with obesity may help prevent atherosclerosis, but this needs to be further confirmed in a large-scale international multicenter clinical trial.

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ARÁN

Nutrición Hospitalaria

Trabajo Original

Pediatría

Efecto de una intervención nutricional sobre el contenido de nutrientes de los refrigerios escolares en escuelas de educación pública de México

Effect of a nutritional intervention on nutrient content in school snacks in public schools in Mexico

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Resumen

Introducción: las intervenciones nutricionales (IN) en escolares permiten realizar acciones de promoción de la salud, actividad física y nutrición para la prevención de la malnutrición.

Objetivo: evaluar el efecto de una IN respecto el contenido de nutrientes de los refrigerios escolares (RE) en escuelas de educación pública en México.

Métodos: estudio descriptivo, longitudinal y prospectivo con una muestra de 812 niños, se clasificaron en grupo intervención (GI) y grupo control (GC). Se realizaron mediciones antropométricas (peso, estatura circunferencia cintura), para identificar el estado nutricional (EN); para evaluar los RE, se registró los alimentos y bebidas que los niños llevaron de casa para consumir durante el recreo, en una lista de cotejo; se procedió a realizar la IN en el GI, durante 12 semanas con un refuerzo de 6 semanas y se realizó la evaluación final que incluyó EN y RE en ambos grupos.

Resultados: se observó un aumento de 1,3 % de sobrepeso (SP) y obesidad (OB) en el GI, mientras que en el GC aumentó 5,4 %. En los RE, el GC mostró un mayor consumo de calorías, carbohidratos y azúcares. En el análisis intragrupo, el GI disminuyó carbohidratos, azúcares. Esta intervención mostro un efecto pequeño en la disminución de calorías, carbohidratos y ácidos poliinsaturados del GI comparado con el GC.

Conclusión: la IN presentó efecto positivo en la disminución del contenido de energía y carbohidratos de los refrigerios de los escolares y por consiguiente una tendencia más lenta en la prevalencia de SP y OB en el GI comparado con el GC.

Palabras clave:

Escolares. Refrigerio escolar. Estado nutricional. Obesidad. México.

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Abstract

Introduction: nutritional interventions (NI) in schoolchildren allow to take action in health promotion, physical activity, and nutrition actions for the prevention of malnutrition.

Objective: to evaluate the effect of an NI on the nutrient content in school snacks (SS) in public education schools in Mexico.

Methods: descriptive, longitudinal, and prospective study with a sample of 812 children were classified into intervention group (IG) and control group (CG). Anthropometric measurements (weight, height, waist circumference) were made to identify nutritional status (NS); to evaluate the SS, the food and beverages that the children took from home to consume during the break were recorded on a checklist; the NI was performed in the IG for 12 weeks with a 6-week reinforcement and the final evaluation was carried out that included NS and overweight (OW) in both groups.

Results: a 1.4 % increase in overweight (OW) and obesity (OB) was observed in the IG, while in the CG it increased 5.5 %. In the SS, the CG showed a higher consumption of calories, carbohydrates, and sugars. In the intragroup analysis, the IG decreased carbohydrates, sugars. This intervention showed a small effect on the decrease of calories, carbohydrates and polyunsaturated acids of the IG compared to the CG.

Conclusion: NI had a positive effect on the decrease in the energy and carbohydrate content of school snacks and therefore a slower trend in the prevalence of OW and OB in the IG compared to the CG.

Keywords:

School children. School snacks. Nutritional status. Obesity. Mexico.

INTRODUCCIÓN

El sobrepeso (SP) y la obesidad (OB) infantil es un problema de salud pública y durante las últimas décadas se ha cuadruplicado en el mundo, específicamente entre los niños de 5 a 19 años los cuales se sitúan en un riesgo latente de desarrollar enfermedades cardiometabólicas y/o degenerativas (1). En México, la última Encuesta Nacional de Salud y Nutrición sobre la COVID-19 mostró que el 37,4 % de los niños escolares presentaban una prevalencia combinada de SP y OB; en cuanto a la zona frontera (Chihuahua, Coahuila, Nuevo León y Tamaulipas), se identificó una prevalencia del 34,6 % (2). Entre los factores que desarrollan estas enfermedades se encuentran el consumo elevado de alimentos no recomendables, el sedentarismo y la disminución del consumo de cereales integrales y de frutas y verduras, siendo estas últimas una buena fuente de compuestos bioactivos que se relacionan con la prevención de enfermedades (3).

González y Flores (4) mencionan que en la etapa escolar se consolidan hábitos saludables para prevenir problemas de malnutrición y sugieren realizar intervenciones nutricionales que incluyan acciones de promoción de la salud, actividad física y nutrición, y que la escuela es el lugar adecuado, por el tiempo que pasan los jóvenes en ella (5). Evans y cols. (6) evaluaron el consumo de alimentos otorgados por la escuela, así como también el consumo en casa, y encontraron que los niños comían una dieta más saludable en la escuela, con menor cantidad de azúcares totales y sodio, y niveles más altos de proteínas, fibra, zinc y ácido fólico, así como mayor variedad de alimentos frescos y más agua, mientras que los niños que llevaban la comida de casa consumían mayor cantidad de bebidas azucaradas, snacks con grasa, sal y azúcar. Viggiano y cols. (7), en Italia, utilizaron un juego de mesa llamado Kaledo para realizar la promoción de estilos de vida saludables dentro de un programa de intervención nutricional en niños de diez escuelas primarias, y encontraron que, en el grupo intervenido, aumentó el consumo de alimentos saludables ($p < 0,01$) durante el tiempo que pasaban en la escuela. En Chile, Díaz y cols. (8) implementaron una intervención nutricional para mejorar la alimentación y la actividad física entre los escolares chilenos, con apoyo de talleres y materiales educativos. Encontraron que los niños disminuyeron de peso corporal, específicamente las niñas, y que la calidad alimentaria aumentaba en ambos sexos.

Antes de la pandemia de COVID-19, Sanromán-Martínez y cols. (9) realizaron una intervención educativa en escuelas primarias a tiempo completo de Cd. Mante, Tamaulipas, México. Aplicaron nueve sesiones educativas para escolares y padres de familia con el fin de modificar las conductas alimentarias y la actividad física, y reportaron que el exceso de peso había disminuido en el grupo de intervención. En cuanto a la frecuencia de consumo de alimentos, aumentaron el consumo de verduras, frutas y agua, y la actividad física ($p < 0,0001$) con respecto al grupo de control. En Reynosa, Tamaulipas, México, Alemán-Castillo y cols. (10) realizaron una intervención educativa nutricional para modificar la calidad de los refrigerios escolares que se consumen en la escuela primaria por medio de pláticas alimentarias por ocho semanas; al finalizar la intervención, el grupo intervenido había incrementado el consumo de fruta y verdura ($p = 0,024$) y disminuido el consumo de bebidas azucaradas ($p = 0,008$), en comparación con el grupo de control.

En el confinamiento, Porter y cols. (11) realizaron una prueba piloto para mejorar la alimentación por medio de educación nutricional evaluando la percepción de las madres de niños londinenses, quienes describieron que, durante el confinamiento por COVID-19, realizaron compras de comida no saludable, como galletas o productos azucarados. Al finalizar la intervención, la mayoría de las madres reportaron cambios positivos en la dieta de los niños. Oddo y cols. (12) realizaron una intervención nutricional en escolares de Indonesia. En ella otorgaron suplementos de hierro y ácido fólico, además de pláticas de orientación nutricional y actividad física, en las escuelas públicas y observaron que los estudiantes aumentaron el consumo de frutas y verduras ricas en vitamina A ($p < 0,05$) y disminuyeron el consumo de bebidas azucaradas y snacks ($p < 0,05$).

En México, Cruz y Macossay (13) aprovecharon las plataformas digitales para realizar talleres de educación nutricional a niños de ocho a doce años inscritos en escuelas públicas. Al finalizar la intervención reportaron una disminución el consumo de alimentos procesados y/o chatarra; aumentó el consumo de legumbres, productos lácteos y agua potable en el grupo de la intervención comparado con el grupo de control.

De acuerdo con los estudios presentados, se concluye que los programas o intervenciones de educación nutricional presentan efectos positivos para la salud de los escolares; sin embargo,

solo se enmarcan resultados en la selección de alimentos y la formación de hábitos alimentarios, pero no se muestran efectos sobre el consumo de nutrientes dentro del refrigerio escolar. Es por ello que el objetivo del presente estudio fue evaluar el efecto de una intervención nutricional sobre el contenido de nutrientes de los refrigerios de escolares de educación pública en México.

MATERIAL Y MÉTODOS

PARTICIPANTES

Estudio descriptivo, longitudinal y prospectivo con una muestra de 812 niños de 8 a 12 años, inscritos en escuelas públicas seleccionadas por conveniencia de la Cd. Reynosa, Tamaulipas, México. Se formaron dos grupos, uno de intervención (GI) y un grupo de control (GC). Se solicito a los padres de familia que firmaran un consentimiento informado para participar en el estudio. Los criterios de inclusión fueron: niños de ambos sexos de 7 a 12 años inscritos en las escuelas públicas participantes; los criterios de exclusión fueron: niños que consumieran algún fármaco o presentaran enfermedades que modificara el peso corporal; los criterios de eliminación fueron: niños que no completaran sus datos antropométricos y/o de la revisión del refrigerio escolar.

CONSIDERACIONES ÉTICAS

El presente estudio fue aprobado por el Comité de Ética de la Universidad Autónoma de Tamaulipas, Unidad Académica Multidisciplinaria Reynosa-Aztlán.

INSTRUMENTOS

Evaluación del estado nutricional

Para evaluar el estado nutricional se tomó la variable antropométrica del peso (kg). Para ello se solicitó que el escolar estuviera sin zapatos y con ropa ligera, tal como lo indica la NOM-047-SSA2-2015 (14); en la medición del peso se solicitó al niño que se colocase simétricamente con los pies en el centro de la báscula (Tanita BF-689 para niños) y los talones juntos, las puntas ligeramente separadas, en posición de firmes, con los hombros y los brazos relajados a los lados del cuerpo y la mirada hacia el frente. Con respecto a la medición de la talla, el niño se situó sin zapatos, sin accesorios en la cabeza o peinados altos que interfirieran con la medición; se utilizó un estadiómetro portátil (Seca 213), se colocó al escolar en el centro de la base del estadiómetro con los talones juntos y las puntas de los pies ligeramente separadas, la cabeza y los hombros relajados, los brazos colgando a los lados del cuerpo, la espalda y las piernas pegadas a la pared, y la cabeza con la mirada hacia el frente. Para evaluar la circunferencia de cintura: la medición se realizó de acuerdo, a la NOM-043-SSA2-2012 (15); para ello se utilizó una cinta métrica (Body Flex Tape). Se midió el mínimo perímetro de la cintura, identificando el punto medio entre la costilla inferior y la cresta iliaca; la medición se realizó al final de una espiración normal. Con el peso corporal (kg) y la talla (cm) del niño se calculó el puntaje Z del IMC a través del programa Anthro Plus, identificando el bajo peso como < -2 DE (desviación estándar), el peso normal como -1,99 DE a < 1 DE, el sobrepeso como > 1 DE a < 2 DE, y la obesidad como > 2 DE (16).

Identificación de los refrigerios escolares

Para realizar la evaluación de la calidad nutrimental de los refrigerios escolares se utilizó una lista de cotejo de los alimentos contenidos en la lonchera escolar (17), previamente validada. Durante cinco días consecutivos y por observación directa se registraron los alimentos y bebidas que llevaron desde casa a la escuela los niños que integraron el GI y el GC, antes y después de la intervención nutricional. El procedimiento fue el siguiente: se solicitó a los niños que colocaran todos los alimentos que fueran a consumir durante la hora destinada al recreo escolar, tanto los alimentos sólidos y los dulces como las bebidas. Después se registraron los alimentos observados dentro de la lista de cotejo. A continuación se utilizó el programa Nutrimind®, versión 15.0, a fin de determinar el contenido nutrimental de los refrigerios escolares.

INTERVENCIÓN NUTRICIONAL

La intervención nutricional se realizó durante 12 semanas consecutivas, de septiembre a noviembre del 2022, y se realizó un refuerzo durante 6 semanas de enero y febrero de 2023. Se consideraron los criterios de la NOM-043-SSA2-2012 para brindar orientación alimentaria a la población escolar. Las actividades fueron realizadas durante 20 minutos por cada grupo cada semana, considerando de segundo a sexto grado de las primarias del GI. En el GC no se realizaron acciones de orientación alimentaria. En la figura 1 se muestra el diseño del estudio.

ANÁLISIS ESTADÍSTICO

Se calculó el puntaje Z del IMC para diagnosticar el estado nutricional, utilizando el programa WHO (World Health Organization, por sus siglas en inglés) Antro Plus (versión 1.0.4). Se determinó la normalidad de las variables del estudio aplicando la prueba de Kolmogorov-Smirnov; debido a su distribución no paramétrica se aplicó la prueba de Wilcoxon para muestras relacionadas (intergrupos) y la prueba de la U de Mann-Whitney para muestras independientes (intragrupos), con significancia de $p \leq 0,05$ para el contenido nutrimental, antes y después de la intervención nutricional y comparándose entre grupos. Para reportar el estado nutricional de los escolares se utilizó la prueba estadística del chi cuadrado ($p \leq 0,05$) para comparar el estado nutricional según el GI y el GC y por sexos. Se calculó el tamaño del efecto (TE) sobre el contenido nutrimental de los refrigerios escolares intragrupos

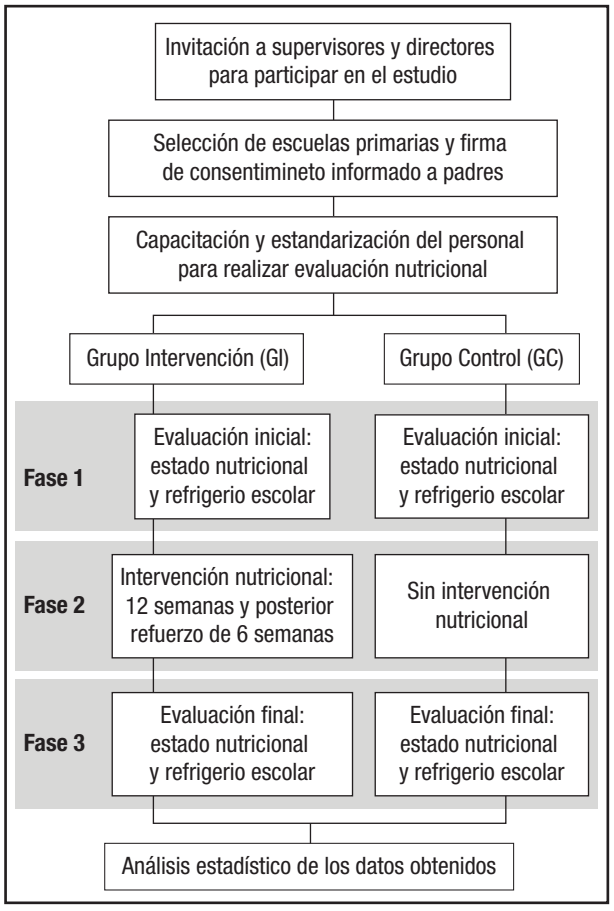

Figura 1.

Diseño del estudio. Fuente: elaboración propia.

(pre y post) utilizando el estadístico "g" de Hedges, considerando que de 0 a 0,19 no hubo efecto; de 0,20 a 0,49 el efecto fue pequeño; de 0,50 a 0,79 el efecto fue moderado; de 0,80 a 1,29 el efecto fue grande y si ≥ 1,3 el efecto fue muy grande. Los análisis estadísticos mencionados se realizaron con el programa IBM SPSS (versión 21.0) para Windows.

RESULTADOS

ESTADO NUTRICIONAL

Se evaluaron 812 niños de edad escolar, el 48,9 % fueron niñas y el 51,1 % niños. Antes de la IN los niños del GI y del GC presentaban un EN similar (p = 0,076). El 51,3 % del GI y el 45,5 % del GC presentaban exceso de peso (SP: sobrepeso y OB: obesidad). Al final de la intervención, la tendencia observada fue hacia al aumento: en el GI aumentó en 1,3 puntos porcentuales el SP y la OB, mientras que en el GC el aumento fue de 5,4 puntos porcentuales; al comparar por sexos en la postintervención se encontró que las niñas del GI presentaban un aumento del 1,0 % en el SP y la OB, y los niños un aumento del 0,3 % en el SP y la OB; en cuanto al GC, las niñas presentaron un aumento del 4,1 % en el SP y la OB, y los niños un aumento del 1,3 % en el SP y la OB (Fig. 2). Se evaluó la medición de la circunferencia de la cintura (CC) para identificar a los niños que mostraran valores elevados para su edad y sexo, se encontró que el GI mostraba una menor prevalencia del riesgo comparado con el GC (46 % *vs.* 54 %, p = 0,420), como se muestra en la figura 3. Fernández y cols. (18) han descrito que el aumento de la CC incrementa el riesgo de desarrollar hipertensión, diabetes, dislipidemias, síndrome metabólico y enfermedades cardiovasculares.

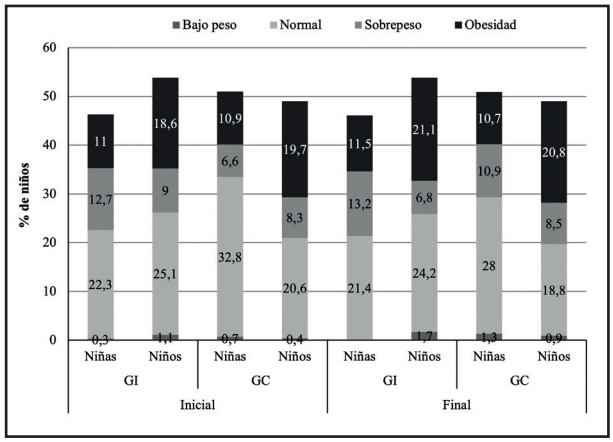

Figura 2.

Comparación del estado nutricional por sexos antes y después de la intervención. Fuente: elaboración propia.

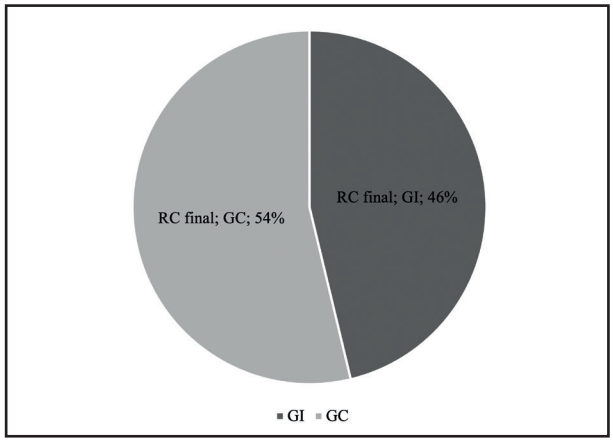

Figura 3.

Riesgo cardiovascular de escolares de Reynosa, Tamaulipas comparado por GI y GC. Fuente: elaboración propia.

INGESTA DE NUTRIENTES CONTENIDOS EN LOS REFRIGERIOS DE LOS ESCOLARES PRE Y POSTINTERVENCIÓN

En la tabla I se muestra que, antes de la IN, el contenido de nutrientes de los refrigerios escolares de ambos grupos era igual (GI y GC). Al finalizar la intervención se observó una disminución de las ca-

lorías a partir de carbohidratos y azúcares, además de una reducción de lípidos y colesterol, que era mayor en el grupo de intervención.

El resultado antes mencionado, se confirma con los resultados obtenidos intragrupo, donde se observó una disminución de las calorías al final de la intervención en el GI, con tendencia a la disminución en los carbohidratos ($p = 0,019$) y los azúcares ($p = 0,001$), mientras que en el GC se observó un aumento de las calorías (Tabla II).

Tabla I. Ingesta de nutrientes al inicio y al final de la intervención nutricional y comparada entre GI y GC

	Inicial			Final		
	GI media ± DE	**GC media ± DE**	***p***	**GI media ± DE**	**GC media ± DE**	***p***
Calorías (kcal)	375,46 ± 137,11	373,57 ± 112,61	0,815	361,54 ± 141,89	405,81 ± 204,54	0,018*
Carbohidratos (g)	52,05 ± 22,54	51,66 ± 17,68	0,828	48,81 ± 21,41	54,94 ± 26,69	0,003*
Azúcares (g)	15,43 ± 13,27	16,02 ± 12,71	0,435	13,18 ± 14,53	16,08 ± 15,53	0,039*
Fibra (g)	2,29 ± 2,36	1,94 ± 1,71	0,532	1,93 ± 2,21	1,73 ± 1,86	0,930
Proteínas (g)	13,27 ± 6,95	11,93 ± 6,22	0,103	12,49 ± 6,44	13,00 ± 7,70	0,825
Lípidos (g)	13,01 ± 7,44	13,63 ± 7,84	0,275	12,75 ± 7,10	16,36 ± 29,69	0,146
Colesterol (mg)	68,37 ± 80,63	60,87 ± 62,13	0,599	65,42 ± 67,39	54,16 ± 73,44	0,009*
AGM (g)	1,42 ± 2,57	1,33 ± 1,85	0,553	1,48 ± 2,74	1,14 ± 2,12	0,281
AGP (g)	0,49 ± 0,99	0,38 ± 0,59	0,947	0,49 ± 1,01	0,32 ± 0,62	0,314
AGS (g)	0,64 ± 1,01	0,73 ± 1,23	0,890	0,91 ± 3,04	0,60 ± 1,29	0,147

*AGM: ácidos grasos monoinsaturados; AGP: ácidos grasos poliinsaturados; AGS: ácidos grasos saturados. *Prueba U de Mann-Whitney para muestras independientes con significancia de $p \leq 0,05$. Fuente: elaboración propia.*

Tabla II. Cambios en la ingesta de nutrientes en cada uno de los grupos de escolares

	GI			GC		
	Inicial media ± DE	**Final media ± DE**	***p***	**Inicial media ± DE**	**Final media ± DE**	***p***
Calorías (kcal)	375,46 ± 137,11	361,54 ± 141,89	0,188	373,57 ± 112,61	405,81 ± 204,54	0,301
Carbohidratos (g)	52,05 ± 22,54	48,81 ± 21,41	0,019*	51,66 ± 17,68	54,94 ± 26,69	0,232
Azúcares (g)	15,43 ± 13,27	13,18 ± 14,53	0,001*	16,02 ± 12,71	16,08 ± 15,53	0,455
Fibra (g)	2,29 ± 2,36	1,93 ± 2,21	0,001*	1,94 ± 1,71	1,73 ± 1,86	0,001*
Proteínas (g)	13,27 ± 6,95	12,49 ± 6,44	0,906	11,93 ± 6,22	13,00 ± 7,70	0,779
Lípidos (g)	13,01 ± 7,44	12,75 ± 7,10	0,801	13,63 ± 7,84	16,36 ± 29,69	0,489
Colesterol (mg)	68,37 ± 80,63	65,42 ± 67,39	0,641	60,87 ± 62,13	54,16 ± 73,44	0,095
AGM (g)	1,42 ± 2,57	1,48 ± 2,74	0,411	1,33 ± 1,85	1,14 ± 2,12	0,133
AGP (g)	0,49 ± 0,99	0,49 ± 1,01	0,937	0,38 ± 0,59	0,32 ± 0,62	0,218
AGS (g)	0,64 ± 1,01	0,91 ± 3,04	0,275	0,73 ± 1,23	0,60 ± 1,29	0,083

*AGM: ácidos grasos monoinsaturados; AGP: ácidos grasos poliinsaturados; AGS: ácidos grasos saturados. *Prueba de Wilcoxon para muestras relacionadas con significancia de $p \leq 0,05$. Fuente: elaboración propia.*

TAMAÑO DEL EFECTO DE LA INTERVENCIÓN SOBRE EL CONTENIDO NUTRIMENTAL DE LOS REFRIGERIOS ESCOLARES

En la tabla III se muestra el tamaño del efecto de la intervención nutricional sobre el consumo de los nutrientes; destaca un tamaño pequeño en la ingesta final de calorías (TE = 0,251), carbohidratos (TE = 0,253) y ácidos poliinsaturados (TE = 0,203) del GC comparado con el GI, y en la evaluación intragrupo del GI y el GC no se mostró efecto alguno (Tabla IV).

DISCUSIÓN

El estado nutricional de los niños se calculó mediante el puntaje Z del IMC; se identificó que, en las condiciones iniciales, el 51,3 % del GI y el 45,5 % del GC presentaban SP y OB sin mostrar diferencias (p = 0,076). Estos resultados superan los reportados por Benítez-Guerrero y cols. (19) en una intervención nutricional prepandemia en donde los escolares del GI presentaban un 43,3 % y los del GC un 40,3 % de SP y OB. Por su parte, Sanromán-Martínez y cols. (9), en condiciones basales, reportaron un 46,4 % en el GI, que es menos de lo reportado en el presente estudio, pero se ve superado en el GC (60,9 %) de niños de Cd. Mante, Tamaulipas. Durante la pandemia de COVID-19 son pocos los estudios que han realizado alguna intervención nutricional en escolares; uno de ellos es el de Cruz y Macossay (13), en donde reportaron que, antes de una intervención nutricional en línea, el 53 % del GI y el 54 % del GC presentaban SP y OB, prevalencia que supera la del presente estudio. Por otra parte, la ENSANUT 2021 sobre la COVID-19 reportó un 37,4 % de SP y OB, y en la zona fronteriza de México se encontraron un 40,8 % de niños con exceso de peso (2,20).

En el presente estudio, al final de la intervención se encontró una tendencia hacia el aumento de la prevalencia de SP y OB (GI: 1,3 % y GC: 5,4 %); sin embargo, dicha tendencia fue menor en el GI con una diferencia de 4,1 puntos porcentuales al compararlo con el GC. Si bien el exceso de peso ya estaba presente antes de la contingencia, esta se agravó durante el confinamiento como consecuencia del ambiente obesogénico que se desarrolló en casa y el limitante de la actividad física de los niños, como lo describen Vážná y cols. (21) en niños de la República Checa, quienes mostraron un aumento significativo entre 2019 y 2021 entre los escolares de 7 y 13 años ($p \leq 0,05$). Jarnig y cols. (22), en un estudio longitudinal del estado nutricional antes y durante la pandemia de COVID-19 en niños de Austria, reportaron que del 2019 al 2021 hubo un incremento del 3,3 % en el SP y del 2,0 % en la OB ($p \leq 0,05$), mayor en los niños que en las niñas. Por su parte, Santorelli y cols. (23) reportaron en Inglaterra un incremento del exceso de peso después de la pandemia de COVID-19 del 5,4 % (p = 0,002), mayor en los niños (4,8 %) que en las niñas (2,8 %). Arévalo y cols. (24), durante la pandemia, encontraron en escolares colombianos un 36,14 % de exceso de peso (SP: 23,84 % y OB: 12,30 %). Ríos-Castillo y cols. (25) reportaron en niños de Panamá un aumentó de 1,4 kg en el GI y de 1,3 kg en el GC, mostrando los varones mayor obesidad (niños: 20 %) y las niñas mayor sobrepeso (niñas: 30 %).

En cuanto a los refrigerios, se observó que en el GI disminuyeron 13,9 calorías (p = 0,188), 3,24 g de carbohidratos (p = 0,019) y 2,25 g de azúcares (p = 0,001), y en el GC aumentó la ingesta

Tabla III. Tamaño del efecto en la ingesta de nutrientes al inicio y al final de la intervención comparada por GI y GC

	Inicial			Final		
	GI media ± DE	GC media ± DE	TE g	GI media ± DE	GC media ± DE	TE g
Calorías (kcal)	375,46 ± 137,11	373,57 ± 112,61	0,015	361,54 ± 141,89	405,81 ± 204,54	0,251*
Carbohidratos (g)	52,05 ± 22,54	51,66 ± 17,68	0,019	48,81 ± 21,41	54,94 ± 26,69	0,253*
Azúcares (mg)	15,43 ± 13,27	16,02 ± 12,71	0,045	13,18 ± 14,53	16,08 ± 15,53	0,193
Fibra (g)	2,29 ± 2,36	1,94 ± 1,71	0,170	1,93 ± 2,21	1,73 ± 1,86	0,098
Proteínas (g)	13,27 ± 6,95	11,93 ± 6,22	0,203*	12,49 ± 6,44	13,00 ± 7,70	0,072
Lípidos (g)	13,01 ± 7,44	13,63 ± 7,84	0,081	12,75 ± 7,10	16,36 ± 29,69	0,167
Colesterol (mg)	68,37 ± 80,63	60,87 ± 62,13	0,104	65,42 ± 67,39	54,16 ± 73,44	0,160
AGM (g)	1,42 ± 2,57	1,33 ± 1,85	0,040	1,48 ± 2,74	1,14 ± 2,12	0,139
AGP (g)	0,49 ± 0,99	0,38 ± 0,59	0,135	0,49 ± 1,01	0,32 ± 0,62	0,203*
AGS (g)	0,64 ± 1,01	0,73 ± 1,23	0,080	0,91 ± 3,04	0,60 ± 1,29	0,133

*AGM: ácidos grasos monoinsaturados; AGP: ácidos grasos poliinsaturados; AGS: ácidos grasos saturados. TE: tamaño del efecto. *TE pequeño. Fuente: elaboración propia.*

Tabla IV. Tamaño del efecto en la ingesta de nutrientes en cada uno de los grupos del estudio

	GI			GC		
	Inicial media ± DE	Final media ± DE	TE g	Inicial media ± DE	Final media ± DE	TE g
Calorías (kcal)	375,46 ± 137,11	361,54 ± 141,89	0,100	373,57 ± 112,61	405,81 ± 204,54	0,195
Carbohidratos (g)	52,05 ± 22,54	48,81 ± 21,41	0,147	51,66 ± 17,68	54,94 ± 26,69	0,145
Azúcares (mg)	15,43 ± 13,27	13,18 ± 14,53	0,162	16,02 ± 12,71	16,08 ± 15,53	0,004
Fibra (g)	2,29 ± 2,36	1,93 ± 2,21	0,157	1,94 ± 1,71	1,73 ± 1,86	0,117
Proteínas (g)	13,27 ± 6,95	12,49 ± 6,44	0,116	11,93 ± 6,22	13,00 ± 7,70	0,153
Lípidos (g)	13,01 ± 7,44	12,75 ± 7,10	0,036	13,63 ± 7,84	16,36 ± 29,69	0,126
Colesterol (mg)	68,37 ± 80,63	65,42 ± 67,39	0,040	60,87 ± 62,13	54,16 ± 73,44	0,099
AGM (g)	1,42 ± 2,57	1,48 ± 2,74	0,023	1,33 ± 1,85	1,14 ± 2,12	0,095
AGP (g)	0,49 ± 0,99	0,49 ± 1,01	0,000	0,38 ± 0,59	0,32 ± 0,62	0,099
AGS (g)	0,64 ± 1,01	0,91 ± 3,04	0,119	0,73 ± 1,23	0,60 ± 1,29	0,103

AGM: ácidos grasos monoinsaturados; AGP: ácidos grasos poliinsaturados; AGS: ácidos grasos saturados. TE: tamaño del efecto. Fuente: elaboración propia.

de nutrientes. Resultados similares fueron reportados por Rohde y cols. (26) después de una intervención nutricional en niños de Dinamarca; encontraron una menor ingesta de energía, carbohidratos y azúcares. De igual manera, Marcano-Olivier y cols. (27) reportaron cambios en el contenido nutricional de los refrigerios en niños de Inglaterra, con disminución de 46,51 calorías en el GI ($p < 0,001$) y aumento de 86,19 calorías ($p \leq 0,05$) en el GC; en cuanto a los lípidos, en el GI hubo disminuciones de 5 g de grasas ($p < 0,001$) y 2 g de grasas saturadas ($p \leq 0,05$), mientras que el GC mostró una tendencia al alza en la ingesta de lípidos. Sin embargo, Restrepo-Mesa y cols. (28) reportaron en Colombia que, al final de la intervención nutricional en escolares, el GI mostró un aumento del consumo de fibra (0,5 g, $p = 0,002$), de grasa total (9,8 g, $p = 0,002$) y de proteínas (12,1 g, $p = 0,001$), y en el GC disminuyeron las proteínas en 9,1 g ($p = 0,011$).

En el tamaño del efecto por medio del estadístico de la g de Hedges, se encontró que el GI mostró un efecto pequeño en la ingesta de grasas poliinsaturadas (TE = 0,203) y el GC un aumento del consumo de calorías (TE = 0,251) y carbohidratos (TE = 0,253).

Cotton y cols. (29) reportaron en su revisión que las intervenciones nutricionales presentan un efecto pequeño sobre el aumento del consumo de frutas y verduras (TE = 0,228), un efecto muy pequeño sobre la reducción de la ingesta de azúcares (TE = 0,144) y un efecto pequeño y/o mediano sobre la reducción de la energía (TE = 0,396) tal como se describe en el presente estudio, donde al final de la intervención, el GC aumentó el consumo de azúcares (TE = 0,193) y de energía (TE = 0,251) con respecto al GI, en el cual se realizaron sesiones de educación nutricional dirigidas por nutriólogas para la elaboración e integración de un refrigerio saludable, por lo que se evidenció que la participación del personal de salud, como los nutriólogos, tiene un efecto positivo en la selección de alimentos saludables. O'Brien y cols. (30) destacan la importancia de las escuelas como promotoras de la salud, donde el desarrollo de intervenciones nutricionales representa un efecto positivo en la mejora de la calidad nutricional y la implementación de estilos de vida saludables en la comunidad escolar. Con respecto a las limitaciones, el presente estudio se realizó por conveniencia de acuerdo con la aceptación de los padres de familia, los niños y las escuelas primarias. No obstante, la principal fortaleza fue que la IN se realizó en el tiempo inmediato al regreso a las clases presenciales de los escolares, por lo que se puede observar el efecto de la pandemia sobre los hábitos alimentarios y el estado nutricional de los niños.

CONCLUSIONES

La intervención nutricional mostró una tendencia más lenta hacia la elevación de la prevalencia del sobrepeso y la obesidad, con efecto en la disminución de la energía y los carbohidratos de los refrigerios escolares comparativamente con el grupo de control al final de la intervención. Por todo ello es necesario continuar el fortalecimiento de las intervenciones nutricionales sobre la población escolar con el fin de proteger la salud de la misma.

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ARÁN

Nutrición Hospitalaria

Trabajo Original

Obesidad y síndrome metabólico

Type 2 diabetes *mellitus,* obesity, cesarean section delivery, and lack of exclusive breastfeeding exposure in patients from the Guadalajara Metropolitan Area, Mexico

Diabetes mellitus *de tipo 2, obesidad, parto por cesárea y falta de exposición a la lactancia materna exclusiva en pacientes de la Zona Metropolitana de Guadalajara, México*

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Abstract

Introduction: the combination of cesarean section delivery and limited exposure to full breastfeeding (FBF) in the first six months of life may increase the risk of obesity and diabetes *mellitus*. This study aimed to establish an association between type 2 diabetes *mellitus* (T2DM) in adulthood, cesarean section delivery and incomplete full breastfeeding (FBF) in individuals from the metropolitan area of Guadalajara, Mexico.

Methodology: this analytical cross-sectional study included patients over 18 years of age with T2DM and normal weight, overweight or obesity, regardless of sex. Informed consent was obtained. Variables encompassed T2DM, type of delivery method, first-year diet, family history, demographic, socioeconomic, and educational characteristics, and anthropometric measurements. For statistical analysis, Student's t test, chi-square tests and odds ratios were employed.

Results: the study evaluated 218 patients with an average age of 57.8 years (± 12.7) and an average age at T2DM diagnosis of 46.2 years (± 12.5). FBF (65.6 %) and partial breastfeeding (PBF) (23.8 %) prevailed in the first six months. The average age at T2DM diagnosis was 46.7 years (± 12.1) for vaginally born patients and 30.7 years (± 15.5) for cesarean-born patients ($p = 0.001$). Cesarean delivery increased obesity risk by nine times in patients with T2DM [OR = 8.9 (CI, 1.05, 75.2), $p = 0.02$].

Conclusion: prioritizing the limitation of nonmedically justified cesarean section deliveries is crucial to mitigate the risk of obesity and T2DM in adulthood.

Keywords:

Diabetes *mellitus* type 2. Obesity. Birth method. Diet type.

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Resumen

Introducción: la combinación de parto por cesárea y exposición limitada a la lactancia materna completa (LMC) en los primeros seis meses de vida puede aumentar el riesgo de obesidad y diabetes *mellitus*. Este estudio tuvo como objetivo establecer una asociación entre la diabetes *mellitus* de tipo 2 (DM2) en la edad adulta, el parto por cesárea y la lactancia materna incompleta (LMI) en individuos del área metropolitana de Guadalajara.

Metodología: este estudio transversal y analítico incluyó pacientes mayores de 18 años con DM2 y normopeso, sobrepeso u obesidad, independientemente del sexo. Las variables abarcaron la DM2, el tipo de método de parto, la dieta del primer año, los antecedentes familiares, las características demográficas, socioeconómicas y educativas, y las medidas antropométricas. Se utilizaron las pruebas t de Student, chi-cuadrada y odds ratio.

Resultados: el estudio evaluó a 218 pacientes con una edad promedio de 57,8 años (± 12,7) y una edad promedio al diagnóstico de DM2 de 46,2 años (± 12,5). En los primeros seis meses prevalecieron la lactancia materna (65,6 %) y la lactancia materna parcial (23,8 %). La edad promedio al diagnóstico de DM2 fue de 46,7 años (± 12,1) para los pacientes nacidos por vía vaginal y de 30,7 años (± 15,5) para los pacientes nacidos por cesárea ($p = 0,001$). El parto por cesárea aumentó nueve veces el riesgo de obesidad en pacientes con DM2 [OR = 8,9 (IC: 1,05, 75,2), $p = 0,02$].

Conclusión: es crucial priorizar la limitación de los partos por cesárea no justificados por razones médicas para mitigar el riesgo de obesidad y DM2 en la edad adulta.

Palabras clave:

Diabetes *mellitus* de tipo 2. Obesidad. Método de nacimiento. Tipo de dieta.

INTRODUCTION

Approximately 80 % of the population living with type 2 diabetes *mellitus* (T2DM) resides in low- or middle-income countries, and Mexico ranks among the top 10 countries with the highest prevalence of this pathology (1). In 2022, the National Health and Nutrition Survey reported an increase in the frequency of T2DM to 12.6 % (2). T2DM is a complex disorder involving the interaction of genetic and environmental factors (3). These factors produce heritable changes in gene function without modifying the DNA sequence. For instance, environmental factors include diet and exercise (4). Epigenetic studies on T2DM and obesity have revealed an association between DNA methylation and certain metabolic traits. In obesity, this DNA methylation can lead to increased production of fat cells, along with mutations in genes related to insulin resistance (4,5).

Likewise, a global increase in the incidence of cesarean sections has been documented, and there is speculation that the combination of a higher incidence of cesarean sections and lower exposure of infants to exclusive breastfeeding (EBF) during the first six months of life may increase the risk of obesity and T2DM (6). Currently, only a limited number of conclusive studies associate breastfeeding with a lower risk of obesity in adults (7) or the potential risk of overweight and obesity in adulthood for newborns who are born via cesarean section (8). Few publications have explored the association among cesarean section delivery, obesity, and T2DM. Alternatively, studies have analyzed the risk of T2DM in patients born by cesarean section with or without exposure to breastfeeding (9). In Mexico, we have found no evidence of research analyzing these factors simultaneously. Therefore, this study aimed to demonstrate that cesarean section delivery and nonexposure to breastfeeding favor the development of obesity and T2DM.

MATERIAL AND METHODS

In this analytical cross-sectional study, patients with T2DM who visited the Mexican Diabetes Association in Jalisco and Hospital Civil de Guadalajara Dr. Juan I. Menchaca were included from January 1, 2022, to October 31, 2022. Patients from both locations participated. Patients aged over 18 years with normal weight, overweight or obesity were included, regardless of sex. Informed consent was obtained from all participants. The exclusion criteria encompassed individuals with a history of congenital or genetic diseases, pregnant and/or lactating women with T2DM, individuals born via cesarean section due to aggravated maternal or fetal clinical conditions, mothers with drug addiction, and individuals who received medications for medical reasons. Patients with incomplete records and individuals who were unable to undergo anthropometric measurements were also excluded.

The following equation was utilized for sample size calculation: $n = (Z - \alpha/2 + Z - \beta)^2 * p (1 - p) / e^2$, where $\alpha/2$ is the level of significance or probability of type 1 error ($0.05 / 2 = 1.96$), β is 80 % power (0.84), and p is a probability of 50 % due to a lack of knowledge of the true prevalence of cesarean section delivery. In addition, e^2 is the accepted error of the true frequency of cesarean section delivery $(0.1)^2$. The probability of exclusions was 30 % = 46 with an $n = 200$. Nonprobabilistic sampling was carried out at the included sites. The general characteristics of the patients were considered. including the socioeconomic level, evaluated by the index of the Mexican Association of Market and Opinion Intelligence Agencies (AMAI), which considers seven index levels (10), a history of direct family members with T2DM and anthropometric measurements. In addition, the diet type in the first semester of life and the delivery method were determined.

MEASURING INSTRUMENTS AND TECHNIQUES

Data on the direct anthropometric indicators, weight, and height were obtained, and the body mass index (BMI) was estimated. Weight and body composition were measured using the Tanita Body Composition Analyzer instrument, model TBF-410GS (Tokyo, Japan). Height measurement was performed with a Seca wall stadiometer, model 213 (Seca, Hamburg, Germany). Mea-

surements were taken with the subject standing, without shoes or anything on the head. The subject stood with their back upright and their head, shoulders, buttocks, and heels together while touching the vertical surface of the instrument. Care was taken to ensure weight distribution on both feet; both arms were kept at the sides in a relaxed manner, and the axis of the eye and the external auditory canal were aligned horizontally. The patient was asked to inhale deeply and then lower the moving part of the stadiometer, and the measurement closest to 0.1 cm was recorded. Once the patient's weight and height were obtained, the BMI was estimated in points.

STATISTICAL ANALYSIS

The Kolmogorov-Smirnov test was utilized to verify the normal distribution of the variables. Descriptive statistics for quantitative variables (average and standard deviation) and for qualitative variables (percentages and frequencies) were obtained. Subsequently, the unpaired Student's t test was employed to illustrate the contrast between two independent samples in quantitative variables with a normal distribution, while nonparametric association tests such as the chi-square test were used for the analysis of qualitative variables. The results indicating a significant association are expressed as odds ratios to estimate their epidemiological significance.

ETHICAL CONSIDERATIONS

The research did not pose any risk to the study subjects, and the protocol adhered to the guidelines of the Declaration of Helsinki, as per its latest revision during the 64th Annual Assembly organized by the World Medical Association (2013). Informed consent was obtained from the selected patients, and the protocol was submitted to the Bioethics and Research Committee of the Nuevo Hospital Civil de Guadalajara Dr. Juan I. Menchaca (Opinion no. 17CI14 039 116).

RESULTS

The majority of participants were women (63.8 %). Average age was 57.8 ± 12.7 years. The average age at the diagnosis of T2DM was 46.2 ± 12.5 years. When dividing the sample into women and men, there was no significant difference (46.7 and 45.3 years, respectively). The time elapsed since the diagnosis of T2DM showed a median of 10 years (range: 1-44 years). The majority of patients were in the sixth stage of life. The age difference according to sex and diagnosis of T2DM was not significant (women, 58.0 ± 12.9 years; men, 59.4 ± 12.6 years).

Most of the patients (43.6 %) included in the study were married by civil law and some were married by religion. The number of patients distributed by sex and marital status appears in table I. A significant association was observed with a greater number of civil and religious marriages and common-law marriages in men and a higher percentage of widows ($p = 0.01$). In particular, it was observed that widowhood was five times more frequent in women than in men [OR = 5.2 (CI, 1.53, 18.1), $p = 0.004$], while civil and/or religious marriage and common-law union vs. other marriage types showed a frequency almost three times higher in men than women [OR = 2.77 (1.5, 5.12), $p < 0.001$].

The majority of patients (28 %) were at socioeconomic level C. The average age at the time of diagnosis of T2DM in patients who were born vaginally was 46.7 ± 12.1 years, while in patients who were born by cesarean section, it was 30.7 ± 15.5 years ($p = 0.001$). Furthermore, when the BMI category was divided between normal weight and overweight *vs.* obesity.

Table I. Number of patients described and distributed by marital status

Civil status	Females, *n* (%)	Males, *n* (%)	*p*
Civil and religious marriage	54 (38.8)	41 (51.9)	0.010
Civil marriage	11 (7.9)	6 (7.6)	
Religious marriage	1 (0.7)	0 (0)	
Free union	8 (5.8)	13 (16.5)	
Separate	6 (4.3)	0 (0)	
Divorced	8 (5.8)	3 (3.8)	
Single mother or father	5 (3.6)	2 (2.5)	
Widower	24 (17.3)	3 (3.8)	
Single	22 (15.8)	11 (13.9)	
Total	139 (100)	79 (100)	

Statistical test: Chi-square. Civil and/or religious marriage and free union vs. others: men vs. women [OR = 2.77 (IC, 1.5, 5.12), p *< 0.001].*

Table II. Number of patients distributed by type of delivery method and BMI category

Birth type	Obesity		Normal weight and overweight		*p*
	n	%	*n*	%	
Via cesarean section delivery	6	6.6	1	0.8	0.02
Via vaginal delivery	85	93.4	126	99.2	
Total	91	100	127	100	

Statistical test: Chi-square. Cesarean section delivery increased the probability of obesity by nine times [OR = 8.9 (CI, 1.05, 75.2), p *= 0.02].*

Tabla III. BMI score classification divided by sex. The number of female and male patients with normal weight, overweight and obesity was 218

	Females	Males	*p*
BMI			0.031
Normal weight	20 (14.5 %)	18 (22.8 %)	
Overweight	51 (37.0 %)	37 (46.8 %)	
Obesity	67 (48.2 %)	24 (30.4 %)	
Total	139 (100 %)	79 (100 %)	
Normal vs. *obesity*			0.020
Normal weight	20 (23.0 %)	18 (42.9 %)	
Obesity	67 (77.0 %)	24 (57.1 %)	
Total	87 (100 %)	42 (100 %)	
Overweight vs. *obesity*			0.027
Overweight	51 (43.2 %)	37 (60.7 %)	
Obesity	67 (56.8 %)	24 (38.3 %)	
Total	118 (100 %)	61 (100 %)	

*Statistical test: Chi-square (*p *= 0.102). The frequency of overweight was twice as high in males than in females [OR = 2.02 (CI, 1.07, 3.8),* p *= 0.029]; the frequency of obesity was 2.5 times higher in females [OR = 2.5 (CI, 1.14, 5.5),* p *= 0.02].*

The frequency of births via vaginal was 96.8 % and via cesarean section delivery 3.2 %. It was observed that cesarean section delivery increased the probability of obesity by nine times [OR = 8.9 (CI, 1.05, 75.2), $p = 0.02$] in patients who developed T2DM, as shown in table II. No significant association was observed between the type of delivery method and the different types of feeding during the infancy stage FBF (65.6 %), PBF (23.8 %) and human milk substitutes (HSM) (10.5 %).

A larger proportion of patients were overweight (40.8 %) or obese (41.8 %). When dividing patients by the BMI score and sex, a significant association was observed. Obesity predominated in women, and overweight was more common in men. The frequency of obesity was 2.5 times higher in females [OR = 2.5 (CI, 1.14, 5.5), $p = 0.02$], while overweight was twice as common in men [OR = 2.02 (CI, 1.07, 3.8), $p = 0.029$], as shown in table III.

DISCUSSION

The average age at T2DM diagnosis was 46.2 years, while globally, the diagnosis typically occurs at an older age (55 to 59 years). In a study carried out by Tinajero et al. (11) (2021) worldwide, it was observed that T2DM manifests itself at an earlier age in men than in women. However, in our study, upon dividing the sample by sex, we found that the average age of diagnosis in women was 45.3 years vs. that of 46.7 years in men. The average age at T2DM diagnosis showed significant differences between patients delivered by cesarean section versus vaginally. In patients born by cesarean section, T2DM diagnosis occurred at a younger age compared to those born vaginally (30.7 *vs.* 46.7 years, respectively) ($p = 0.001$). A similar finding was previously reported (9). In our study, it was found that the probability of obesity was approximately nine

times higher in patients born via cesarean section than in patients born vaginally. Although higher, this result aligns with an international study (12), where patients born via cesarean section showed a twofold risk of being overweight or obese at the age of 20 years in the Danish population.

In the group of patients studied, the delivery method (vaginal delivery vs. cesarean section) was not associated with the type of feeding in the first six months of life (FBF, PBF human milk substitutes). This result contrasts with what was reported by other authors, where higher BF rates were found after vaginal birth vs. cesarean section delivery (13,14). When analyzing the type of diet of our patients in the first six months of life, it was found that the frequency of FBF was 65.6 %, while national surveys reported a similar frequency of 68.8 % in 2018. It was observed that in the majority of the patients studied, continuous breastfeeding lasted for an average of 12 months; this finding coincides with what is described in the ENSANUT (15,16). There was no relationship between the type of feeding and BMI, suggesting that, in the studied population, the protective effect of BF against overweight and obesity was not present. Similar results were obtained in another study carried out in Mexico (17). Therefore, we consider that more information is needed to adequately interpret these results on the potential effect of the type of diet on BMI in patients with T2DM.

It was observed that a greater proportion of patients (82.6 %) were overweight (40.8 %) or obese (41.8 %). An analysis of these data, dividing the patients by sex, showed that women were almost three times more likely to be obese than men, while men showed a higher frequency of overweight (46.8 %). These data coincide with what was reported by the ENSANUT in 2022, where the majority of women were obese (41.0 %), while the majority of men were overweight (41.2 %) (18).

STRENGTHS AND LIMITATIONS

Strengths: the information obtained in our study revealed that cesarean section delivery increased the probability of obesity by nine times in patients with T2DM. This information has not been previously documented in our country.

Limitations: the frequency of cesarean section delivery was lower than expected (3.2 %). Additionally, there could be a memory bias among the studied participants related to the frequency and duration of breastfeeding.

CONCLUSIONS

Patients with T2DM who were born via cesarean section were nine times more likely to present with obesity in adulthood than those born vaginally. Therefore, it is necessary to carry out cohort studies that demonstrate a causal relationship between cesarean section delivery and T2DM.

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ARÁN

Nutrición Hospitalaria

Trabajo Original

Obesidad y síndrome metabólico

Efectos del zinc y resveratrol como moduladores de la respuesta a la leptina en adultos con obesidad

Effects of zinc and resveratrol as modulators of leptin response in adults with obesity

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Resumen

Introducción: el tejido graso es un órgano con función endocrina donde se identifica la hormona leptina (LEP). Este péptido regula el apetito, el sistema inmunológico, las funciones vasculares y la sensibilidad a la insulina. El zinc (Zn) y el resveratrol (RES) tienen efectos potenciales sobre el tejido adiposo.

Objetivo: conocer si la administración combinada de Zn y RES tiene algún efecto sobre la cuantificación de la leptina en sangre en personas con obesidad.

Métodos: estudio experimental longitudinal, diseño ensayo clínico controlado, aleatorio, doble ciego. Formación aleatoria de cuatro grupos: T1 (Zn 50 mg), T2 (control), T3 (RES 500 mg), T4 (Zn 50 mg y RES 500 mg) con un período de suplementación de 60 días. Se tomaron muestras sanguíneas y se cuantificaron glucosa (GLU), leptina (LEP) y lípidos (HDL, LDL, TGL) antes y después de la exposición a los elementos del estudio.

Resultados: edad 34 (± 7) años. En pruebas T, significancia en GLU (p = 0,04) y LEP (p = 0,055). Por grupos de exposición: GLU en T1 (p = 0,03) y T2 (p = 0,031); en la LEP, el T4 (p = 0,024). Lípidos por grupos: HDL en T3 (p = 0,039) y T4 (p = 0,014). ANOVA, HDL (p = 0,06). Pearson, HDL (p = 0,07) y LDL (p = 0,09).

Conclusión: el zinc y el resveratrol demostraron ser agentes prometedores en la modulación de la señalización de la leptina y la glucosa, lo que confirma que funcionan de manera proporcional y brindan beneficios para la salud cardíaca, aunque se necesita más tiempo de exposición para ver si afectan a la homeostasis del equilibrio energético.

Palabras clave:

Adipoquinas. Tratamiento de la obesidad. Homeostasis energética. Suplementación mineral. Antioxidante.

Abstract

Introduction: fat tissue is an organ with endocrine function, where the hormone leptin (LEP) is identified. This peptide regulates appetite, the immune system, vascular functions and insulin sensitivity. Zinc (Zn) and resveratrol (RES) have potential effects on adipose tissue.

Objective: to know if the combined administration of Zn and RES has any effect on blood leptin quantification in obese people.

Methods: longitudinal experimental study, controlled clinical trial design, randomized, double blind. Randomized formation of four groups: T1 (Zn 50 mg), T2 (control), T3 (RES 500 mg), T4 (Zn 50 mg and RES 500 mg) with a supplementation period of 60 days. Blood samples were taken and glucose (GLU), leptin (LEP) and lipids (HDL, LDL, TGL) were quantified before and after exposure to the study elements.

Results: age 34 (± 7) years. In T-tests, significance in GLU (p = 0.04) and LEP (p = 0.055). By exposure groups: GLU at T1 (p = 0.03) and T2 (p = 0.031); at LEP at T4 (p = 0.024). Lipids by groups: HDL at T3 (p = 0.039) and T4 (p = 0.014). ANOVA, HDL (p = 0.06). Pearson, HDL (p = 0.07) and LDL (p = 0.09).

Conclusion: zinc and resveratrol showed promise as agents in modulating leptin and glucose signaling, confirming that they work in a proportional manner and provide benefits for cardiac health, but more exposure time is needed to see if they impact energy balance homeostasis.

Keywords:

Adipokines. Treatment for obesity. Energy homeostasis. Mineral supplementation. Antioxidant.

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INTRODUCCIÓN

El sobrepeso y la obesidad están caracterizados por la Organización Mundial de la Salud (OMS) como uno de los principales problemas sanitarios del siglo XXI, estando a punto de ser considerados una epidemia mundial dada su prevalencia, que se incrementa de forma continua y sustancial década tras década (1). Este mismo organismo señala el elevado factor de riesgo que representa la obesidad en la predisposición a enfermedades no transmisibles, entre las que se encuentran las enfermedades cardiovasculares, la diabetes, los trastornos del aparato locomotor y algunos cánceres, sin olvidar los daños psicológicos que padecen las personas que la padecen (2).

El tejido graso sigue causando grandes expectativas dentro de la comunidad científica puesto que, aparte de las funciones fisiológicas que se le atribuyen, se ha demostrado que es un órgano con función endocrina responsable de la secreción de adipoquinas, que actúan como hormonas o mensajeros que participan en diversos procesos fisiológicos (3). Dentro de las adipoquinas se identifica la leptina (LEP), un péptido que afecta a la homeostasis del apetito, regulando el peso corporal, el sistema inmune, las funciones vasculares y la sensibilidad a la insulina (4).

Los niveles séricos de LEP están determinados por el porcentaje de grasa corporal de cada individuo (5). Por esta razón, los individuos obesos presentan elevados niveles de LEP en sangre que, a su vez, crean un estado de saturación, impidiendo su adecuada detección a nivel cerebral y caracterizando lo que se conoce como resistencia a la leptina (RL) (6). La RL, en consecuencia, compromete el mecanismo de la saciedad. Con este mecanismo básico de regulación alterado, los individuos con resistencia a la leptina presentan una mayor probabilidad de aumento de peso.

Algo notable es, que entre la LEP y la insulina existe una perfecta homeostasis, donde la LEP inhibe la producción de insulina en las células β del páncreas, mientras que la insulina estimula la producción de LEP en el adipocito (7-9). Sin embargo, en una situación de baja sensibilidad y RL se pierde esta homeostasis natural, lo que lleva también a desequilibrios en el metabolismo de la glucosa, favoreciendo el surgimiento de la diabetes *mellitus* de tipo 2 (10).

Aunado a esto se encuentra el estado crónico de inflamación que presenta el adipocito en las personas con obesidad y que está directamente relacionado con su alteración y afecta negativamente a los procesos metabólicos naturales del organismo (11).

Debido a los mecanismos anteriormente mencionados, el interés de la comunidad científica por estudiar biomoléculas que puedan ayudar en los procesos de regulación de la leptina sin comprometer otros mecanismos naturales del organismo, con la intención de utilizarlas como apoyo en el tratamiento y/o prevención de la obesidad, ha ido en aumento.

Entre las moléculas estudiadas se pueden destacar el zinc (Zn) y el resveratrol (RES), por tener comprobados efectos potenciales sobre la salud, incluidos los factores relacionados con la obesidad (12-16).

Se afirma que las bajas concentraciones de Zn en sangre se relacionan con un aumento de la incidencia y de la prevalencia de la obesidad (17). Además, se ha mencionado que este elemento tiene la capacidad de reducir los niveles de LEP en sangre, por lo que la ingesta de este mineral a las dosis adecuadas podría controlar la obesidad, al favorecer de forma indirecta los procesos metabólicos relacionados (18).

Por otro lado, el RES es un antioxidante de comprobada actividad frente a los efectos adversos del tejido adiposo inflamado (11). Este polifenol mejora las condiciones de las vías hepáticas, favorece la oxidación de las células β, reduce la expresión del gen de la LEP y disminuye su sensibilidad para regular de manera positiva esta vía metabólica (19,20).

En la actualidad se ha comprobado la efectividad de la asociación de Zn y RES en otros contextos clínicos (21,22); sin embargo, no se han encontrado evidencias científicas relacionadas con la obesidad. Por ello, el objetivo de esta investigación fue conocer si la administración combinada de Zn y RES tiene o no algún efecto sobre la cuantificación de la leptina en sangre en personas con obesidad.

MATERIALES Y MÉTODOS

CONSIDERACIONES ÉTICAS

El estudio se apegó a lo dispuesto en la Constitución Política de los Estados Unidos Mexicanos y en la Ley General de Salud en Materia de Investigación (23). Considerando lo establecido en el Título II, relacionado con los aspectos éticos de la investigación con seres humanos, se contó con la autorización del Comité de Ética de la Facultad de Enfermería y Nutriología (FEN) de la Universidad Autónoma de Chihuahua (UACH), en la Ciudad de Chihuahua, además de la aprobación del Comité de Ética de la Universidad Iberoamericana Internacional (UNINI) y la firma del consentimiento informado de los participantes.

DISEÑO EXPERIMENTAL

El tipo de estudio es experimental y longitudinal, con un arreglo factorial de tratamientos de 2^2 en forma de diseño de ensayo clínico controlado y aleatorizado a doble ciego, con corte cuantitativo. Los tratamientos evaluados fueron: T1 (Zn, 50 mg), T2 (control), T3 (RES, 500 mg) y T4 (Zn, 50 mg y RES, 500 mg), teniendo un periodo de suplementación de 60 días. Los participantes seleccionados fueron exentos del uso de medicamentos antinflamatorios, esteroides, quimioterapéuticos, radioterapéuticos y anorexígenos; se consideró que se ubicaran entre los niveles de obesidad moderada y morbilidad, de acuerdo con los puntos de corte establecidos para el IMC por la OMS (24); los rangos de edad se establecieron tomando en cuenta la Norma Oficial Mexicana NOM-035 (25) y los criterios del Instituto Mexicano de Seguridad Social (26), donde se marcan las edades promedio de inicio del hipogonadismo en mujeres y hombres, para disminuir el sesgo por las alteraciones metabólicas propias de estas etapas. El estudio se inició con 52 participantes (13 por

tratamiento), de los cuales declinaron 15 durante el tiempo de exposición a los agentes del estudio, quedando una población de 37 participantes, ubicados 8 en T1, 7 en T2, 9 en T3 y 13 en T4.

MUESTREO SANGUÍNEO

Las muestras sanguíneas se tomaron antes y después de los 60 días correspondientes al periodo de suplementación, después de un ayuno de doce horas. Se utilizó la técnica de venopunción en el antebrazo y el fluido sanguíneo se almacenó en tubos Vacutainer de color rojo, previamente preparados con anticoagulante y etiquetados; después se centrifugó en un equipo Thermo Scientific para la decantación y sedimentación de los componentes, y se separaron las alícuotas para los diferentes análisis. Para la cuantificación glucosídica y el perfil de lípidos se utilizaron métodos colorimétricos y enzimáticos por medio de un espectrofotómetro modelo Genesys 10S VIS, marca Thermo Scientific, con los reactivos recomendados en el manual de uso de dicho equipo. Para la cuantificación de la hormona leptina se utilizó la técnica ELISA con el kit Human Leptin Instant, marca Invitrogen, en un espectrofotómetro marca Thermo Scientific, utilizando microplacas Multiskany para su lectura.

MEDIDAS ANTROPOMÉTRICAS

La talla se tomó con un estadímetro de pared marca SEGA® con los criterios recomendados por la *International Society for the Advancement of Kinanthropometry* (27). Para el peso y el cálculo del IMC se utilizó un equipo de impedancia magnética In-Body 270®, el cual se maniobró conforme a las instrucciones del manual de uso del equipo.

ANÁLISIS ESTADÍSTICO

Se utilizó un modelo de análisis de la covarianza (ANCOVA) con el objetivo de controlar determinados efectos de las variables continuas capaces de sesgar los resultados al incrementar la varianza dentro de los grupos. Se realizó un análisis descriptivo antes y después de la aplicación de los tratamientos, obteniéndose estadísticos de tendencia central, de dispersión y de asociación (coeficiente de correlación de Pearson) y utilizándose tablas y gráficos para el resumen de los datos. Se realizaron pruebas de la t de Student para las muestras no independientes (pareadas en el tiempo) con el fin de evaluar si la aplicación de cada uno de los tratamientos había provocado o no cambios significativos en las variables de respuesta medidas en los pacientes. Se hicieron análisis de la varianza univariados (ANOVA) y multivariados (MANOVA) para evaluar las diferencias entre los efectos (cambios) de los tratamientos. Por otro lado, se construyeron tablas de contingencia para las variables de respuesta cualitativas, que se analizaron mediante la prueba del chi cuadrado para determinar si las respuestas categóricas mostraban asociación con los niveles de los tratamientos; posteriormente, en caso de existir dicha asociación, esta se representó mediante un análisis de correspondencias. Los análisis estadísticos se realizaron mediante los programas informáticos Minitab 19® y SAS 9.4® (procedimientos CORR, MEANS, GLM y CORRESP).

RESULTADOS

La tabla I muestra los estadísticos de tendencia central y de dispersión para las variables de respuesta consideradas en el presente estudio y evaluadas al inicio del experimento.

Se puede observar que los participantes tenían una edad promedio de 34,6 (EE: ± 1,3) con una variación en la edad del 22 %. En los datos antropométricos, la altura promedio de los participan-

Tabla I. Valores iniciales de estadísticas descriptivas de tendencia central y dispersión de las variables consideradas en el estudio

Variable (Inicial)	Abrev.	Mín.	Máx.	Media	Mediana	Error STD	Coef. de variación (%)
Edad (años)	EDAD	18,0	50,0	34,6	36,0	1,3	22,0
Talla (cm)	TALLA	150,0	190,0	169,3	170,0	1,7	6,0
Peso (kg)	PESO_I	67,7	165,1	110,7	109,9	3,9	21,6
Índice de masa corporal	IMC_I	30,0	58,5	38,5	37,8	1,1	17,6
Glucosa (mg/dl)	GLU_I	95,1	304,9	120,1	115,7	5,6	28,5
Colesterol total (mg/dl)	COLT_I	96,4	273,3	205,4	210,8	6,5	19,3
Triglicéridos (mg/dl)	TGL_I	150,7	274,4	130,4	121,0	8,3	38,8
Colesterol HDL (mg/dl)	HDL_I	15,0	139,4	62,8	60,2	4,4	42,5
Colesterol LDL (mg/dl)	LDL_I	5,0	211,7	115,7	121,5	7,6	39,7
Leptina (ng/ml)	LEP_I	4,0	71,7	23,3	18,0	2,9	76,0

I: dato inicial.

tes fue de 169,3 cm. Llama la atención que la talla fue la variable que, de inicio, presentó el menor porcentaje de variación (6 %), al contrario que el nivel inicial de leptina, que mostró un 76 % de variación. Se observa que el peso máximo encontrado fue de 165,1 kg. Esta variable y las variables MME, ACT y MLG alcanzaron porcentajes de variación que oscilaron entre el 20,3 % y el 21,6 %. La media del IMC (μ = 58,5) se posiciona en la obesidad mórbida. Se observa que el porcentaje de valor máximo encontrado para la MGC es del 90,1 %, con una porción media de μ = 45,7 %.

En los parámetros bioquímicos se encontró que el valor máximo de la GLU era de 304,9 mg/dl, con una media de este mismo indicador de μ = 120,1 mg/dl. Con respecto al perfil lipídico, en los TGL se observaron niveles máximos de 274,4 mg/dl, así como una media de cuantificaciones séricas de μ = 130,4 mg/dl. Las sustancias cerosas como el COLLDL y el COLHDL proyectaron una media de μ = 115,7 mg/dl y μ = 62,8 mg/dl, con valores máximos de 139,4 mg/dl y 211,7 mg/dl, respectivamente. El resultado máximo obtenido para la hormona LEP es de 71,7 ng/ml, en contraste con su mínima de 4,0 ng/ml, llamando la atención su media de μ = 23,3 ng/ml.

Entre los indicadores con los porcentajes de variación más elevados se encuentran COLHDL, COLLDL, TGL, y en mucha menor proporción COLT, COLLDL y NGV.

La tabla II presenta los estadísticos de cambio de tendencia central y dispersión para la diferencia entre sus valores iniciales y finales por cada tratamiento, donde se observa que, al hacer el análisis de las diferencias entre los grupos, las medias de la variable PESO en el T2 y el T4 obtuvieron una disminución de μ = -0,200 kg en los dos grupos. Llama la atención que las diferencias entre cambios encontradas en el IMC_C, en sus valores mínimos, en todos los tratamientos mostraron una respuesta protectora, de la misma manera que sus medias a excepción de en T1. Este mismo impacto se observó en el ACT_C tanto en sus valores mínimos como en su media, localizándose una excepción en la media en el T1. En los datos antropométricos, en el grupo con el T4, la MGC_C y la GC_C presentan una disminución mayor de sus valores mínimos, con -5,3 y -3,8 puntos porcentuales, respectivamente.

Tabla II. Estadísticas descriptivas de tendencia central y dispersión del cambio en las variables consideradas en el estudio, por tratamiento

Variable	Tratamiento	Mín.	Máx.	Media	Mediana	Error STD
PESO_C	T1	-1,700	2,500	0,437	0,650	0,587
	T2	-4,700	3,200	-0,086	-0,200	0,995
	T3	-1,600	1,400	0,100	0,500	0,344
	T4	-4,000	2,600	-0,146	-0,200	0,505
IMC_C	T1	-0,600	8,700	1,250	0,150	1,100
	T2	-2,700	2,000	-0,057	0,000	0,546
	T3	-2,400	0,400	-0,666	-0,300	0,343
	T4	-2,100	2,000	-0,155	-0,200	0,321
ACT_C	T1	-7,500	2,700	-1,140	-0,500	1,040
	T2	-4,600	1,100	-0,514	0,500	0,812
	T3	-9,300	1,300	-0,810	0,000	1,090
	T4	-1,500	5,300	0,585	0,300	0,484
MGC_C	T1	-1,900	3,300	0,925	1,050	0,567
	T2	-1,800	2,200	0,771	1,400	0,516
	T3	-2,000	2,400	-0,544	-0,600	0,428
	T4	-5,300	7,500	0,354	0,300	0,886
MME_C	T1	-5,800	0,000	-1,125	-0,350	0,701
	T2	-3,900	0,800	-0,543	-0,100	0,654
	T3	-7,600	3,800	-0,440	-0,100	1,000
	T4	-1,100	4,000	0,408	0,200	0,366

(Continúa en página siguiente)

Tabla II (Cont.). Estadísticas descriptivas de tendencia central y dispersión del cambio en las variables consideradas en el estudio, por tratamiento

Variable	Tratamiento	Mín.	Máx.	Media	Mediana	Error STD
GC_C	T1	0,500	3,600	1,513	1,100	0,397
	T2	-2,000	3,000	0,771	0,800	0,616
	T3	-1,600	2,000	-0,200	-0,400	0,409
	T4	-3,800	1,600	-0,369	0,000	0,470
NGV_C	T1	0,000	1,000	0,375	0,000	0,183
	T2	-1,000	2,000	0,429	0,000	0,369
	T3	-2,000	4,000	0,222	0,000	0,521
	T4	-2,000	0,000	-0,154	0,000	0,154
MLG_C	T1	-9,900	22,900	-0,040	-0,750	3,560
	T2	-6,500	1,400	-0,860	0,300	1,110
	T3	-28,200	5,900	-3,870	-0,100	3,480
	T4	-1,900	7,200	0,862	0,400	0,646
GLU_C	T1	-47,570	9,580	-18,260	-23,480	6,930
	T2	-73,940	-7,700	-23,370	-10,850	9,170
	T3	-34,900	22,800	-8,940	-8,230	6,580
	T4	-44,400	153,200	-2,200	-11,500	13,500
COLT_C	T1	-62,000	68,200	-3,300	-7,700	14,000
	T2	-23,340	25,050	-9,650	-19,790	6,670
	T3	-37,800	59,300	11,400	8,700	10,600
	T4	-29,800	65,700	10,770	9,720	7,770
TGL_C	T1	-41,700	70,700	8,500	2,100	13,500
	T2	-67,800	71,100	-12,900	-32,800	19,400
	T3	-50,390	21,300	-12,550	-17,840	9,050
	T4	-29,600	97,300	17,200	15,400	10,700
HDL_C	T1	-57,300	25,190	-17,970	-14,210	9,940
	T2	-74,600	66,200	-8,500	-14,800	18,200
	T3	-39,900	88,200	23,500	38,700	13,500
	T4	-28,280	54,570	16,470	12,630	7,540
LDL_C	T1	-36,000	50,300	13,000	12,900	11,000
	T2	-50,800	61,800	1,500	11,000	16,700
	T3	-85,400	77,500	-5,900	-16,000	15,500
	T4	-59,430	30,100	-9,140	-6,090	7,980
LEP_C	T1	-12,600	85,400	18,600	7,100	11,000
	T2	-12,960	15,170	2,500	2,440	3,430
	T3	-27,670	35,900	-1,450	-1,600	5,770
	T4	-19,660	23,490	6,080	5,300	3,440

C: diferencia alcanzada como resultado del tratamiento (antes y después); IMC: índice de masa corporal; ACT: agua corporal total; MGC: masa grasa corporal; MME: masa musculoesquelética; GC: grasa corporal; NGV: nivel de grasa visceral; MLG: masa libre de grasa; GLU: glucosa sérica; COLT: colesterol total; TGL: triglicéridos; HDL: colesterol HDL; LDL: colesterol LDL; LEP: leptina sérica; T: tipo de tratamiento.

Tabla III. Resultados de la prueba de la T para evaluar cambios significativos en las variables de interés, por tratamiento

	General		T1		T2		T3		T4	
Variable (cambio)	Media	Valor *p*	Media	Valor *p*	Media	Valor *p*	Media	Valor *p*	Media	Valor *p*
PESO_C	0,051	0,860	0,437	0,480	-0,085	0,882	0,100	0,528	-0,146	0,988
IMC_C	0,043	0,888	1,250	0,292	-0,057	0,960	-0,667	0,108	-0,154	0,899
GLU_C	-11,330	0,047	-18,260	0,034	-23,371	0,031	-8,936	0,267	-2,248	0,729
COLT_C	4,040	0,423	-3,300	0,822	-9,651	0,486	11,444	0,310	10,773	0,123
TGL_C	2,380	0,717	8,500	0,550	-12,855	0,731	-12,551	0,320	17,176	0,589
HDL_C	6,010	0,342	-17,970	0,114	-8,540	0,452	23,523	0,039	16,471	0,014
LDL_C	-1,560	0,797	13,000	0,276	1,457	0,598	-5,924	0,250	-9,135	0,403
LEP_C	6,280	0,055	18,600	0,135	2,502	0,603	-1,452	0,925	6,077	0,024

C: diferencia alcanzada como resultado del tratamiento (antes y después); IMC: índice de masa corporal; GLU: glucosa sérica; COLT: colesterol total; TGL: triglicéridos; HDL: colesterol HDL; LDL: colesterol LDL; LEP: leptina sérica; T: tipo de tratamiento.

En los bioquímicos, se observa que, en la GLU_C en todos los grupos, los valores mínimos y las medias disminuyeron, destacando los grupos T2 (-73,940 mg/dl) y T1 (-47,570 mg/dl), que obtuvieron los marcadores más altos con respecto a los valores mínimos, mientras que sus medias sobresalen (T2: μ = -23,370 mg/dl; T1: μ = -18,260 mg/dl). En el perfil lipídico se vieron disminuidos todos los valores mínimos de todas las variables; con respecto a las medias, en el COLT_C (μ = -9,650 mg/dl), el COLLDL_C (μ = -8,500 mg/dl) y los TGL_C (μ = -12,900 mg/dl) del grupo T2 también se observó una disminución protectora. Para la variable LEP, la disminución también se registró en todos los valores mínimos y en todos los grupos de estudio, destacando la protección en la media del grupo T3 (μ = -1,450 mg/dl).

Al realizar el análisis descriptivo de tendencia central y de dispersión del cambio de las variables consideradas en el estudio, por tratamiento, se pueden observar más de cerca las diferencias entre los grupos de estudio. En los datos antropométricos, la variable PESO_C del T4 fue la que logró una mayor disminución tanto de sus valores mínimos y máximos (-4,000; -2,600 kg) como de su media (μ = -0,146 kg). En el IMC_C se observa un declive protector de los valores mínimos en todos los grupos, así como en la media del grupo T3 (μ = -0,666).

La tabla III muestra los resultados de la prueba de la t de Student para evaluar cambios significativos en las variables de interés, por tratamiento (muestras pareadas en el tiempo). Se encontró que, en el grupo suplementado con Zn (T1), la GLU llegó a un resultado protector ($p = 0,03$) y en los niveles lipídicos hubo una buena respuesta de las LDL ($p = 0,135$) y HDL ($p = 0,114$), así como de la LEP ($p = 0.135$). En el grupo de control (T2) se observa que, en la GLU, el resultado fue significativo ($p = 0,031$); en el grupo que fue suplementado con resveratrol (T3), el colesterol-HDL se posiciona como factor protector ($p = 0,039$). En los participantes con la interacción conjugada del zinc y el resveratrol (T4), el colesterol-HLD ($p = 0,014$) y la LEP ($p = 0,024$) alcanzaron la significancia deseada.

Al someter los datos al análisis ANOVA (Tabla IV), se observó que únicamente dentro de los datos antropométricos, en los valores de cambio por tratamiento, la GC_C fue significativamente diferente entre los grupos ($p = 0,032$); además, en los datos bioquímicos se observó una tendencia muy cercana a la significancia esperada en el HDL_C ($p = 0,06$).

DISCUSIÓN

Jura y cols. (28) describen en sus hallazgos que, debido al aumento de la esperanza de vida, la prevalencia de la obesidad ha aumentado en los grupos de mayor edad (28). La evidencia de cambios en la adiposidad relacionados con la edad ha llevado a algunos investigadores a sugerir que la obesidad puede considerarse un estado de disfunción metabólica prematura similar al envejecimiento (29). En este sentido, la edad promedio de nuestra población fue de 34 (μ ± 7,6) años, lo que establece que los patrones de obesidad no necesariamente requieren edades avanzadas, sino que esta problemática de salud pública se está manifestando en los diferentes grupos etarios, afectando severamente al metabolismo desde edades tempranas.

En relación al género de nuestros participantes, se identificó que aproximadamente las tres cuartas partes de la población son mujeres. Estos resultados apoyan los datos arrojados en la última Encuesta Nacional de Salud y Nutrición (ENSANUT), donde las mujeres se posicionan a la delantera en esa afección metabólica (30). Por lo tanto, la predisposición de riesgo de este grupo de población va en aumento y no solo con respecto a las complicaciones metabólicas que la obesidad genera sino que esta problemática se repolariza en otros ámbitos, como lo evidencian

Tabla IV. Análisis ANOVA con variables de cambio por tratamiento y valor de *p*

Variable	General	TN1	TN2	TN3	TN4	*p*
PESO_C	0,051 ± 0,29	0,437 ± 0,587[a]	-0,086 ± 0,995[a]	0,1 ± 0,344[a]	-0,1460 ± 0,505[a]	0,905
GLU_C	-11,330 ± 5,51	-18,263 ± 6,928[a]	-23,371 ± 0,166[a]	-8,936 ± 6,583[a]	-2,248 ± 13,534[a]	0,540
COLT_C	4,040 ± 4,99	-3,269 ± 13,994[a]	-9,651 ± 6,672[a]	11,444 ± 0,555[a]	10,773 ± 7,771[a]	0,394
TGL_C	2,380 ± 6,52	8,471 ± 13,505[a]	-12,856 ± 19,396[a]	-12,551 ± 9,047[a]	17,1761 ± 0,74[a]	0,234
HDL_C	6,010 ± 6,23	-17,969 ± 9,942[a]	-8,54 ± 18,181[ab]	23,523 ± 3,535[b]	16,4717 ± 0,542[b]	0,060
LDL_C	-1,560 ± 6,03	13,001 ± 11,003[a]	1,457 ± 16,663[a]	-5,924 ± 15,528[a]	-9,1357 ± 0,983[a]	0,592
LEP_C	6,280 ± 3,17	18,614 ± 11,009[a]	2,5033 ± 0,428[a]	-1,4525 ± 0,767[a]	6,077 ± 3,438[a]	0,172

C: diferencia alcanzada como resultado del tratamiento (antes y después); GLU: glucosa sérica; COLT: colesterol total; TGL: triglicéridos; HDL: colesterol HDL; LDL: colesterol LDL; T: tipo de tratamiento. Letras diferentes en la misma fila indican que los tratamientos son estadísticamente diferentes ($p < 0,05$*).*

Gretebeck y cols. (31), quienes muestran que la inactividad física y la obesidad pueden exacerbar la pérdida de la independencia y la incapacidad funcional en las mujeres, especialmente en las actividades que implican la función de las extremidades inferiores.

Se ha documentado que la obesidad es un importante factor de riesgo para el desarrollo de la diabetes de tipo 2. Se atribuye que el exceso de tejido adiposo puede causar resistencia a la insulina y cambios en el metabolismo de la glucosa (32). Las células β del páncreas son figuras clave para mantener el equilibrio en el metabolismo de la glucosa. Los resultados protectores en la cuantificación de la glucosa de nuestra población ($p = 0,003$) pueden respaldar los resultados de varios estudios que suplementaron con RES y Zn, como los encontrados por Palsamy y cols., quienes afirman que el RES tiene una fuerte actividad sobre estas células β debido a la acción que ejerce en los hidroperóxidos, compuestos que se encuentran aumentados en el islote pancreático en presencia de diabetes, reduciendo significativamente estos marcadores oxidativos después de la exposición (33). En este sentido, Chabosseau y cols. (34) afirman que los iones Zn^{2+} son fundamentales para la síntesis, el empaque y la secreción de la insulina en las células β del páncreas ya que el contenido alterado de insulina pancreática se asocia con todas las formas de DM.

En otras vías de investigación con RES se logró la disminución del glucagón posprandial, descubriendo que esto puede ser un factor protector en el tratamiento de la diabetes de tipo 2, ya que los niveles altos de esta hormona contribuyen a la hiperglucemia (35). Se suma a esto lo encontrado por Sin y cols. (36), los cuales pudieron observar que hay una mejor captación de glucosa en las células de los músculos debido a los cambios de la actividad enzimática, que pueden promover glucólisis y síntesis de glucógeno. Zeng y cols. aseveran que el RES estimula rápidamente la translocación endógena de la proteína-quinasa activada por monofosfato de adenina (AMPK), considerada como un sensor de la energía celular que contribuye a regular el balance energético y la ingesta calórica, mediando en la homeostasis de la glucosa (37).

Como ya se mencionó anteriormente, la insulina es inversamente proporcional a la leptina; con respecto a esta última hormona, pero en el estado de obesidad, la respuesta de la insulina puede verse afectada por la baja sensibilidad o resistencia a la leptina. Se aprecia que el grupo expuesto a RES y Zn en forma conjunta (T4) logró afectar de forma positiva a este biomarcador, comprobándose esta sinergia. Por ello se propone realizar estudios con periodos de tiempo más prolongados, para poder confirmar el impacto en la homeostasis del balance energético.

Otro factor que comúnmente se manifiesta en las personas con obesidad es la dislipidemia, la cual se relaciona con los eventos cardiovasculares. El colesterol-HDL ("colesterol bueno") puede tener un efecto altamente protector en estos pacientes. Al respecto, los tres grupos expuestos en nuestro estudio tuvieron grandes bondades en sus cuantificaciones séricas, coadyuvando en el descontrol metabólico con este tipo de lipoproteínas. Este hallazgo refuerza lo encontrado en varios estudios que aseveran este mismo hallazgo (38-40). Los análisis detallados de los niveles de leptina, glucosa y perfiles de lípidos en sangre mostraron información crucial sobre los efectos de la suplementación con zinc y resveratrol en los adultos con obesidad. Los hallazgos más significativos obtenidos fueron la disminución de los niveles séricos de leptina y glucosa, confirmando que trabajan de forma proporcional, con un efecto positivo en sus sistemas. La disminución observada en los niveles de leptina en los grupos de intervención sugiere un papel prometedor de estas sustancias en la modulación de la señalización de la leptina. Esta hormona desempeña un papel fundamental en la regulación del apetito y el balance energético, y los presentes resultados indican que el zinc y el resveratrol podrían estar ejerciendo influencias positivas en estos sistemas.

En general, el zinc y resveratrol mostraron ser agentes prometedores en la modulación de la señalización de la leptina y la glucosa, confirmando que trabajan de forma proporcional y que aportan beneficios para la salud cardiaca; sin embargo, se sugiere evaluar mayores tiempos de exposición para valorar con mayor contundencia el impacto sobre la homeostasis del balance energético.

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ARÁN

Nutrición Hospitalaria

Trabajo Original

Obesidad y síndrome metabólico

Evaluation of the nutritional status of morbid obesity patients in the first six months after sleeve gastrectomy

Evaluación del estado nutricional de pacientes con obesidad mórbida en los primeros seis meses después de una gastrectomía en manga

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Abstract

Objective: in recent years, bariatric surgery has gained popularity as a treatment for obesity worldwide. While patients do experience weight loss after surgery, it is important to be aware that serious nutritional deficiencies may also occur. This study was conducted to evaluate the nutritional status of morbidly obese patients in the first six months after sleeve gastrectomy.

Methods: the study was planned as a retrospective study. The data of 76 patients aged 19-64 years who had undergone bariatric surgery and were followed by a dietitian for at least 6 months were included in the study. Preoperative and postoperative biochemical parameters and anthropometric measurements of the patients were taken.

Results: the lowest body weight of the patients was found at postoperative month 6 (81.74 ± 14.83 kg), the body weight at the preoperative period (115.86 ± 21.28 kg) and postoperative month 1 (100.39 ± 18.28 kg), and the body weight at postoperative month 1 was statistically lower than at the preoperative period. The preoperative body weights and BMI values of the patients were higher than at postoperative months 1 and 6, and the postoperative month 1 values were higher than at postoperative month 6 ($p < 0.05$). The lowest fasting blood glucose (83.48 ± 8.44 mg/dL), HbA1c (4.96 ± 0.95 %), and Homa-IR (3.34 ± 0.92) were observed at the postoperative month 6. Compared with the preoperative period, the iron level of the patients increased from 69.54 ± 29.82 µg/dL to 96.52 ± 25.39 µg/dL in postoperative month 6, vitamin D levels from 14.48 ± 8.70 µg/dL to 23.96 ± 4.79 µg/dL. While preoperative blood triglyceride and LDL values were statistically higher than in postoperative months 1 and 6, the HDL value was lower ($p < 0.05$).

Conclusion: as a result, after sleeve gastrectomy, patient body weight decreased, and blood lipid profile and diabetes symptoms improved.

Keywords:

Gastrectomy. Bariatric surgery. Nutritional status.

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Resumen

Objetivo: en los últimos años, la cirugía bariátrica ha ganado popularidad como tratamiento de la obesidad en todo el mundo. Si bien los pacientes experimentan pérdida de peso después de la cirugía, es importante tener en cuenta que también pueden producirse deficiencias nutricionales graves. Este estudio se realizó para evaluar el estado nutricional de pacientes con obesidad mórbida en los primeros seis meses después de la gastrectomía en manga.

Métodos: el estudio se planificó como un estudio retrospectivo. Se incluyeron en el estudio los datos de 76 pacientes de entre 19 y 64 años sometidos a cirugía bariátrica y seguidos por un dietista durante al menos 6 meses. Se recogieron los parámetros bioquímicos y las medidas antropométricas preoperatorias y postoperatorias de los pacientes.

Resultados: el peso corporal más bajo de los pacientes se encontró en el mes 6 postoperatorio (81,74 ± 14,83 kg), el peso corporal en el período preoperatorio (115,86 ± 21,28 kg) y el mes 1 postoperatorio (100,39 ± 18,28 kg), y el peso corporal en el mes 1 postoperatorio fue estadísticamente menor que en el período preoperatorio. Los pesos corporales preoperatorios y los valores de IMC de los pacientes fueron superiores a los de los meses 1 y 6 del postoperatorio, y los valores del mes 1 del postoperatorio fueron superiores a los del mes 6 del postoperatorio ($p < 0,05$). Los valores más bajos de glucosa en sangre en ayunas (83,48 ± 8,44 mg/dL), HbA1c (4,96 ± 0,95 %) y Homa-IR (3,34 ± 0,92) se observaron en el mes postoperatorio 6. En comparación con el período preoperatorio, el nivel de hierro de los pacientes aumentó de 69,54 ± 29,82 µg/dL a 96,52 ± 25,39 µg/dL en el mes postoperatorio 6 y los niveles de vitamina D de 14,48 ± 8,70 µg/dL a 23,96 ± 4,79 µg/dL. Aunque los valores preoperatorios de triglicéridos en sangre y LDL fueron estadísticamente mayores que en los meses 1 y 6 postoperatorios, el valor de HDL fue menor ($p < 0,05$).

Conclusión: como resultado, después de la gastrectomía en manga, el peso corporal de los pacientes disminuyó, el perfil de lípidos en sangre y los síntomas de la diabetes mejoraron.

Palabras clave:

Gastrectomía. Cirugía bariátrica. Estado nutricional.

INTRODUCTION

The prevalence of obesity, characterized by excessive fat accumulation in the body, is increasing worldwide. Obesity is an important risk factor for many diseases such as diabetes, cardiovascular diseases, cancer, metabolic syndrome, and psychological disorders (1). The main treatment for obesity is diet and lifestyle changes. Pharmacotherapy is used in patients who cannot lose bodyweight with these two methods. The bariatric surgery (BC) method is discussed in patients who do not experience a higher rate of body weight loss and permanent body weight loss (2).

Recently, bariatric surgery has become popular in the treatment of obesity worldwide and in our country. The fact that patients experienced faster body weight loss and improvements in comorbid diseases with this method compared to other treatment methods led to an increase in the number of patients choosing this method (3). It has been reported that the morbidity associated with bariatric surgery is less than 1 % when performed by an experienced center (2). However, bariatric surgery is not applied to every patient, and this method may be preferred if the patient has some indications (1). Primarily, it is deemed suitable to follow up the patient who is decided to have bariatric surgery by the endocrinology unit for at least six months. In addition, for bariatric surgery to be performed, the patient must have: a) body mass index (BMI) ≥ 40 kg/m^2 or b) BMI ≥ 35 kg/m^2 and at least one comorbidity such as obesity-related hypertension, dyslipidemia, type-2 diabetes *mellitus,* or sleep apnea (2).

Bariatric surgery includes surgical techniques that ensure body weight loss by reducing stomach volume, shortening and/or bypassing the intestinal segment, or using both methods. Sleeve gastrectomy (SG), adjustable gastric band (AGB), gastric bypass, and biliopancreatic diversion with duodenal switch (BPD-DS) are the most commonly applied bariatric surgical methods (2).

Sleeve gastrectomy is a volume-limiting method and a procedure in which the greater curvature of the stomach is removed. In this method, the stomach is reduced, and appetite also decreases due to a decrease in the level of some orexigenic hormones (2). Besides, significant body weight loss, ease of surgical technique, and maintaining the integrity of the pyloric sphincter are among the advantages of this method (4). In this method, the risk of malnutrition is low, and dumping syndrome does not occur. However, leaks in the stapler line, being an irreversible method, and limited long-term (5-10 years) data are among the disadvantages of this method (2).

Despite the postoperative improvement in the health status of the patients, serious nutritional deficiencies may occur in these patients. Especially insufficient energy intake, reduced stomach volume, nausea, vomiting, sudden weight loss, and irregular use of dietary supplements lead to nutritional deficiency in patients (5). Some studies have reported that calcium, iron, vitamin B12, folate, and vitamin D deficiencies can be seen in these patients due to nutritional deficiencies (6,7). Considering the gender, age, dietary habits, physical activity levels, psychology, and physiological conditions of the patients before and after the surgery, providing adequate and balanced nutrition is among the basic principles of the diet (8). After bariatric surgery, anthropometric measurements (body weight, height, etc.) and biochemical parameters should be followed regularly in order to evaluate the nutritional status of the patient (5). For this reason, this study was conducted to evaluate the nutritional status of morbidly obese patients in the first six months after sleeve gastrectomy.

MATERIALS AND METHODS

RESEARCH PLAN

Data from 75 patients aged 19-64 years who applied to the General Surgery Obesity and Metabolic Surgery clinic and were followed up for six months were included. The study includes no intervention, and only the patient data were collected from the hospital computer. The data were collected between February 2022 and December 2022. The research was planned as

a retrospective study. This study is an observational study. The study was approved by Ankara Yıldırım Beyazıt University Health Sciences Ethics Committee. The study started with a total of 87 patients, but 12 patients who did not attend regular doctor and dietitian check-ups were excluded.

The surgical technique to be performed was determined based on the results of preoperative examinations, assessments, and interviews from the anesthesia and endocrine departments, the patient's biomedical measurements (BMI, fat percentage, internal fat percentage), and the patient's informed consent.

Inclusion criteria for the study included: a) data of patients aged 19-64 years; b) data of patients with BMI ≥ 40 kg/m^2 or BMI ≥ 35 kg/m^2 and at least one comorbidity such as obesity-related hypertension, dyslipidemia, type 2 diabetes *mellitus,* and sleep apnea (2); c) data of patients who underwent sleeve gastrectomy; d) volunteering.

Exclusion criteria in the study were: a) data of patients who were not deemed suitable for surgery by the physician and to whom a surgical technique different from sleeve gastrectomy was applied; b) data of patients who were not followed up by a dietitian for six months after surgery; c) data of patients with gastrointestinal inflammatory bowel disease; d) data of patients with psychiatric disorders diagnosed by a physician; e) data of patients with cancer, pregnant and lactating women, alcohol or drug addiction.

ANTHROPOMETRIC MEASUREMENTS

Bodyweight (kg) and body composition (body fat mass (kg), lean body mass (kg), bone mass (kg), body fat ratio (%), body water ratio (%), and abdominal adiposity coefficient) measurements of the patients were taken with a Tanita MC 780 body analyzer.

The body mass index of the patients was calculated by dividing their body weight by the square of their height (body weight / height [kg/m^2]) (9,10). The WHO classification was used in the evaluation, and those with BMI < 18.5 kg/m^2 were considered underweight, those with BMI at 18.5-24.99 kg/m^2 were considered normal, those with BMI at 25.0-29.99 kg/m^2 were considered slightly overweight, and those with BMI ≥ 30 kg/m^2 were considered obese (11).

BIOCHEMICAL PARAMETERS

Preoperative and postoperative (months 1 and 6) fasting blood glucose, HbA1C, insulin, creatinine, GFR, ALT, AST, iron, calcium, vitamin B12, 25-OH-vitamin D, HDL, LDL, and triglyceride values were collected from the hospital system. This values were collected during the week before surgery.

NUTRITION PLAN

The data of patients treated with a nutrition plan following the nutritional principles of the American Society for Metabolic and Bariatric Surgery (ASMBS) by a dietitian were included in the study (12). Patients were given vitamin and mineral supplements in accordance with the recommendations of this guideline after bariatric surgery.

STATISTICAL ANALYSIS

The statistical analyses were performed using the SPSS (IBM SPSS Statistics 24) software suite. Independent-sample t-test (t-table value) statistics were used to compare the measured values of two independent groups regarding the data with a normal distribution. The Mann-Whitney U-test (Z-table value) statistics were used to compare the measurement values of two independent groups regarding the data that did not have a normal distribution. Pearson's χ^2 test statistics were used according to the expected value levels in examining the relations between two qualitative variables.

RESULTS

The data of 76 individuals, 50 women and 26 men, were included in the study. Women were 32.38 ± 8.55 years old and men were 39.19 ± 11.90 years old, with a mean age of 34.71 ± 10.27 years. Age, height, body weight, and lean mass values of men are significantly higher than women. Fat mass values of women are significantly higher than men (Table I).

Table I. Preoperative age, height, and bodyweight of patients by gender

	Women (n = 50)	Men (n = 26)	Total (n = 76)	*p*
	$\bar{X}$ ± S.S.	$\bar{X}$ ± S.S.	$\bar{X}$ ± S.S.	
Age (year)	32.38 ± 8.55	39.19 ± 11.90	34.71 ± 10.27	$p = 0.01$
Height (cm)	163.56 ± 6.18	176.89 ± 8.42	168.11 ± 9.43	$p = 0.00$
Bodyweight (kg)	108.88 ± 17.57	129.29 ± 21.65	115.86 ± 21.28	$p = 0.00$
Body fat mass (kg)	45.33 ± 5.77	37.35 ± 5.62	42.60 ± 6.85	$p = 0.00$
Lean body mass (kg)	54.74 ± 10.24	76.02 ± 10.21	62.02 ± 14.37	$p = 0.00$

While 57 (75 %) of individuals did not have food addiction, 19 (25 %) had it (Table II and Fig. 1).

The preoperative body weights of women and men were significantly higher than the values obbtained at months 1 and 6 postoperatively. The body weights of the participants at month 1 postoperatively were significantly higher than the values at month 6 in the postoperative period.

The preoperative BMI values of women and men were significantly higher than the values at months 1 and 6 postoperatively. BMI values at postoperative month 1 were significantly higher than those at postoperative month 6 (Table III).

While the difference in body weight of men before surgery and at both the 1st and 6th months after surgery is greater than that of women, there is no statistically significant difference in BMI (Table IV).

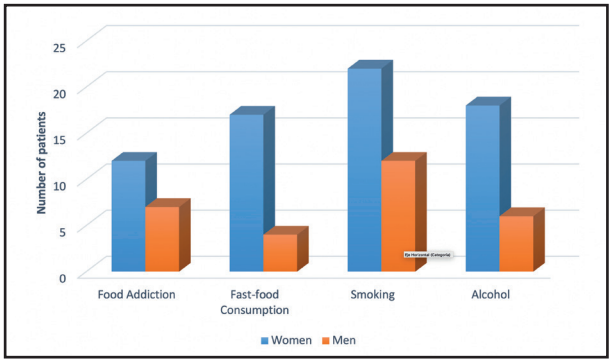

Figure 1.

Preoperative chronic disease, alcohol, smoking, and eating habits of the sleeve gastrectomy patients.

Table II. Preoperative alcohol, smoking, and eating habits of the sleeve gastrectomy patients

	Women (n = 50)		Men (n = 26)		Total (n = 76)		*p*
	n	%	*n*	%	*n*	%	
Food addiction							
Yes	12	24.0	7	26.9	19	25.0	$p = 0.78$
No	38	76.0	19	73.1	57	75.0	
Fast-food consumption							
Yes	17	34.0	4	15.4	21	27.6	$p = 0.09$
No	33	66.0	22	84.6	55	72.4	
Smoking							
Yes	22	44.0	12	46.2	34	44.7	$p = 0.86$
No	28	56.0	14	53.8	42	55.3	
Alcohol							
Yes	18	36.0	6	23.1	24	31.6	$p = 0.25$
No	32	64.0	20	76.9	52	68.4	

Table III. Changes in body mass index and body weight of patients before and after surgery

	Pre-op(1)			Post-op 1 month(2)			Post-op 6 month(3)			p (Women)	*p* (Men)	*p* (Total)
	Women (n = 50)	Men [n = 26]	Total (n = 76)	Women (n = 50)	Men [n = 26]	Total (n = 76)	Women (n = 50)	Men [n = 26]	Total (n = 76)			
	$\bar{X} \pm$ S.S.	$\bar{X} \pm$ S.S.	$\bar{X} \pm$ S.S.	$\bar{X} \pm$ S.S.	$\bar{X} \pm$ S.S.	$\bar{X} \pm$ S.S.	$\bar{X} \pm$ S.S.	$\bar{X} \pm$ S.S.	$\bar{X} \pm$ S.S.			
Weight kg	108.88 ± 17.57	129.29 ± 21.65	115.86 ± 21.28	94.76 ± 15.69	111.20 ± 18.29	100.39 ± 18.28	77.34 ± 13.55	90.18 ± 13.65	81.74 ± 14.83	$p = 0.00$	$p = 0.00$	$p = 0.00$
	$p = 0.00$			$p = 0.00$			$p = 0.00$			[1-2,3] [2-3]	[1-2,3] [2-3]	[1-2,3] [2-3]
BMI kg/m^2	40.75 ± 6.46	41.14 ± 4.97	40.88 ± 5.96	35.47 ± 5.77	35.41 ± 4.23	35.45 ± 5.26	28.96 ± 5.08	28.71 ± 2.94	28.87 ± 4.44	$p = 0.00$	$p = 0.00$	$p = 0.00$
	$p = 0.56$			$p = 0.87$			$p = 0.53$			[1-2,3] [2-3]	[1-2,3] [2-3]	[1-2,3] [2-3]

BMI: body mass index.

Table IV. The difference and percentage of body weight and BMI loss of the patients between preoperative and post-operative 1st and 6th month

	1 mo-preop difference		*p*	6 mo-preop difference		*p*
	Women $\bar{X} \pm$ S.S.	Men $\bar{X} \pm$ S.S.		Women $\bar{X} \pm$ S.S.	Men $\bar{X} \pm$ S.S.	
Weight kg	-14.1 ± 4.60	-18.1 ± 6.41	*0.00*	-31.5 ± 6.94	-39.1 ± 11.08	*0.00*
BMI kg/m^2	-5.3 ± 1.76	-5.7 ± 1.91	0.41	-11.8 ± 2.56	-12.4 ± 3.21	0.66
% Weight and BMI loss	-12.9 ± 4.12	-13.8 ± 4.19	0.72	-28.9 ± 4.85	-29.8 ± 5.26	0.61

BMI: body mass index.

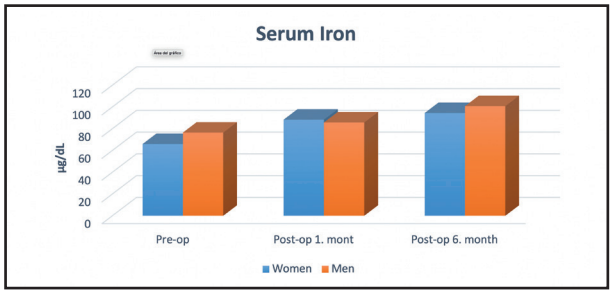

Figure 2.

Pre-and postoperative serum iron levels of patients.

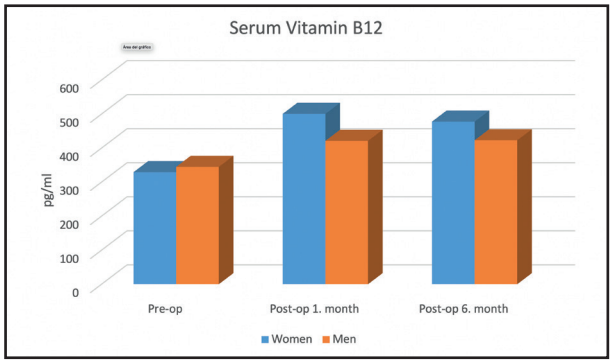

Figure 3.

Pre-and postoperative serum vitamin B12 levels of patients.

Glucose level (83.48 ± 8.44 [mg/dL]) at month 6 postoperatively was found to be statistically lower compared to month 1 postoperatively (88.48 ± 10.16 [mg/dL]) and the preoperative (107.29 ± 13.89 [mg/dL]) period. Preoperative HbA1c, creatinine, AST and ALT values were higher than the values obtained at months 1 and 6 postoperatively. In addition, glucose and HbA1c values in month 1 in the postoperative period were found to be higher than at postoperative month 6. Preoperative GFR and insulin values were significantly lower than at months 1 and 6 postsurgery ($p < 0.05$) (Table V).

The highest Homa-IR value was detected in the preoperative period. Vitamin D and HDL values were significantly lower than the values seen at months 1 and 6 postoperatively (Table V). Furthermore, LDL and triglyceride values were at their highest level in the preoperative period ($p < 0.05$) (Table V).

Preoperative iron concentration was found to be lower than at month 1 postsurgery and month 6 postsurgery. In addition, iron levels at month 1 of the postoperative period was found significantly lower than at month 6 postoperatively (Fig. 2). Preoperative B12 was significantly lower than at months 1 and 6 in the postoperative period (Fig. 3). There was no statistically significant difference between the pre- and post-operative periods in serum vitamin B12 and serum iron levels both of men and women (Figs. 2 and 3).

DISCUSSION

After 2014, sleeve gastrectomy, one of the bariatric surgery methods, started to gain popularity. The reason for this is that this method provides an improvement in comorbid diseases accompanying obesity as well as body weight loss. Therefore, this study was conducted to evaluate the nutritional status of morbidly obese patients in the first six months after sleeve gastrectomy (13).

In patients with morbid obesity, bariatric surgery is an effective method in providing long-term and permanent body weight loss (14,15). In a study, patients who had bariatric surgery were found to have lower body weight, BMI, lean body mass, and body fat mass in months 1, 3, and 6 compared to the preoperative period (5). In numerous studies on sleeve gastrectomy, postoperative body weight and BMI values were found to be lower than in the preoperative period (16-18). Similarly, in this study, the body weight and BMI values of the patients on months 1 and 6 postoperative were found to be lower than in the postoperative period. The preoperative BMI value decreased from 40.88 ± 5.96 kg/m^2 to 28.87 ± 4.44 kg/m^2 at the end of 6 months.

Since the plasma lipid profile improves after bariatric surgery, a decrease is observed in the morbidity and mortality of cardiovascular diseases (19). In some studies conducted on patients with sleeve gastrectomy, it was found that triglyceride, LDL, and total cholesterol decreased and HDL increased after surgery (20-23). In this study, similar to the literature, the lowest LDL value (98.38 ± 14.07 mg/dL) and triglyceride value (89.31 ± 18.23 mg/dL), as well as the highest HDL value (50.89 ± 4.97 mg/dL), were observed in month 6 postoperative.

Table V. Comparison of preoperative and postoperative biochemical parameters

Biochemical parameters	Pre-op(1)	Post-op 1 month(2)	Post-op 6 month(3)	*p*
	$\bar{X}$ ± S.S.	$\bar{X}$ ± S.S.	$\bar{X}$ ± S.S.	
Glucose (mg/dL)	107.29 ± 13.89	88.48 ± 10.16	83.48 ± 8.44	*p = 0.00 [1-2,3][2-3]*
HbA1c (%)	17.32 ± 7.80	5.97 ± 5.51	4.96 ± 0.54	*p = 0.00 [1-2,3][2-3]*
Insulin (µU/ml)	5.69 ± 1.26	11.14 ± 2.03	6.78 ± 2.23	*p = 0.00 [1-2,3][2-3]*
Creatinine (mg/dL)	110.79 ± 18.53	1.67 ± 7.71	0.92 ± 1.35	*p = 0.00 [1-2,3]*
GFR (mL/dak/1.73 m^2)	0.72 ± 0.22	105.63 ± 9.44	107.72 ± 15.59	*p = 0.00 [1-2,3]*
AST (U/L)	20.31 ± 7.77	17.28 ± 2.59	15.25 ± 3.18	*p = 0.00 [1,2-3]*
ALT (U/L)	26.44 ± 13.44	17.63 ± 3.81	15.43 ± 2.92	*p = 0.00 [1,2-3]*
Calcium (mg/dL)	9.11 ± 0.68	7.83 ± 2.15	9.94 ± 10.49	*p = 0.00 [1-2]*
HOMA-IR	9.83 ± 40.31	3.35 ± 0.39	3.34 ± 0.92	*p = 0.00 [1-2,3]*
Vitamin D (µg/dL)	14.48 ± 8.70	16.06 ± 4.87	23.96 ± 4.79	*p = 0.00 [1,2-3]*
LDL (mg/dL)	135.09 ± 27.70	112.89 ± 17.57	98.38 ± 14.07	*p = 0.00 [1-2,3][2-3]*
HDL (mg/dL)	46.55 ± 9.26	49.99 ± 3.65	50.89 ± 4.97	*p = 0.00 [1-2,3]*
Tg (mg/dL)	132.34 ± 49.89	105.93 ± 20.47	89.31 ± 18.23	*p = 0.00 [1-2,3][2-3]*

AST: aspartate aminotransferase; GFR: glomerular filtration rate; CRP: C-reactive protein; ALT: alanine aminotransferase; HOMA-IR: Homeostatic Model Assesment Insulin Resistant; HDL-C: high density lipoprotein; LDL-C: low density lipoprotein; Tg: triglicerides.

In morbidly obese patients with type 2 diabetes, blood glucose and insulin levels improve after bariatric surgery (24). Two years after bariatric surgery, 38.1 % of obese patients with type 2 diabetes resolved their diabetes, and 10 % had a decrease in their symptoms. In the study, fasting blood glucose has changed from 172.6 ± 63.5 mg/dL to 132.4 ± 5.7 mg/dL, HbA1c value from 7.7 % to 6.5 %, and HOMA-IR value decreased from 4.6 to 3.2 (25). In another study, the postoperative insulin and HbA1C values were found to be lower than in the preoperative period (15). In the study conducted by Zhang et al. (17), fasting and postprandial glucose values after surgery (1st year) were found to be lower than in the preoperative period. In addition, the HbA1c value decreased from 5.9 % to 5.4 %. In this study, when the preoperative period and postoperative month 6 were compared, the fasting glucose value decreased from 107.3 ± 13.8 mg/dL to 83.1 ± 8.44 mg/dL, HbA1c value decreased from 17.5 % to 4.9 %, and the HOMA-IR value decreased from 4.6 to 3.1. In addition, the highest insulin value in the study was observed in the postoperative month 1. It is thought that the patients' liquid and puree diet during the first month, their fruit juice and protein powder intake during this period, the lack of sufficient water consumption, and the lack of physical activity caused an increase in insulin levels in the first month. Also, this shows that the bariatric surgery method provides an improvement in the diabetic symptoms of the patients.

After bariatric surgery, macro and micronutrient deficiencies, especially iron, are observed in patients (26). In one study, preoperative iron and ferritin levels were lower than in the postoper-

ative period, while iron-binding capacity was found to be higher (15). In another study, the plasma iron level of individuals who had a sleeve gastrectomy increased continuously in the postoperative 12-month period (27). In this study, similarly, iron levels on months 3 and 6 postoperative were found to be higher than in the preoperative period. It is thought that the reason iron and ferritin levels were higher in the postoperative period compared to the perioperative period is due to the regular administration of mineral supplements to the patients in this study.

In the bariatric surgery method, a decrease in the absorption of food-induced B12 may occur (28). In the study of Barzin et al. (27), vitamin B12 level was found to be significantly higher in the postoperative period (12th month) than in the preoperative period. In this study, the lowest B12 level was observed in the preoperative period. Regular B12 supplementation to patients undergoing bariatric surgery resulted in an increase in the level of the vitamin.

In the literature, it has been shown that bone density decreases in patients after bariatric surgery and that these patients may have osteoporosis risk (15). The reason for this may be a decrease in body weight and/or nutrient absorption (29). Therefore, it is very important to control the levels of micronutrients such as vitamin D and calcium in postoperative patients (5). In the study conducted by Batar and Alphan (5), vitamin D and calcium levels were found to be higher in the postoperative period than in the preoperative period. In another study, an increase in serum vitamin D levels was observed in the first 6 months after bariatric surgery. Serum calcium value was found to be higher in months 1, 3, and 6 compared to the preoperative period. The lowest serum PTH value was observed in month 6 (17). In this study, the highest level of vitamin D was detected in month 6 postoperative (23.96 ± 4.79 µg/dL) and the lowest in the preoperative period (14.48 ± 8.70 µg/dL). In the study, the lowest calcium value was found in postoperative month 1. It is thought that the reason why the lowest calcium value is observed in month 1 is due to the fact that the patients do not use calcium sources and supplements sufficiently due to the postoperative stress.

Bariatric surgery in morbidly obese patients results in long-term weight loss and improvement in liver function tests. In the study conducted by Aksoy et al. (16) on patients who had sleeve gastrectomy, AST and ALT values were found to be lower in the postoperative period (12th month) than in the preoperative period. In another study, the ALT value of the patients before sleeve gastrectomy decreased from 27.8 ± 19.9 U/L to 25.8 ± 12.4 U/L at the end of 6 months, while the AST value decreased from 23.7 ± 12.8 U/L to 24.7 ± 7.8 U/L. In this study, similar to the literature, AST and ALT values on month 6 postoperative were found to be lower than in month 1 postoperative and the preoperative period.

The strengths of this study include detailed data collection, long-term follow-up and multifaceted analysis. Preoperative and postoperative biochemical parameters and anthropometric measurements were examined during the six-month follow-up period. However, because the study was conducted in a single center and only 76 patients were included This study contributes to the literature on the long-term nutritional status of morbid obesity patients after sleeve gastrectomy.

In this study, the body weight and BMI values of the patients decreased after bariatric surgery. There was also improvement in patients' diabetic symptoms and lipid profiles. Macro and micronutrient deficiencies can be seen in patients after bariatric surgery. Therefore, nutritional supplements should be recommended to patients under the supervision of a doctor. The treatment of these patients should be carried out by a multidisciplinary team including a dietitian, doctor, psychologist, physiotherapist, and nurse, and the patients should be checked at regular intervals.

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Trabajo Original

Obesidad y síndrome metabólico

Cross-cultural validation and Spanish translation of the Boston Interview to evaluate severely obese patients seeking metabolic/bariatric surgery

Validación transcultural y traducción al español de la Entrevista Semiestructurada Boston para la evaluación de pacientes con obesidad severa candidatos a cirugía metabólica/bariátrica

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Abstract

Introduction: obesity is a global health problem. Metabolic/Bariatric surgery (MBS) has proven to be one of the most effective methods for treating the most severe forms. However, a thorough evaluation and preparation of people seeking MBS is necessary. In Spain, there are no standardized interviews to carry out the psychosocial assessment of people seeking MBS. The Boston Interview for MBS (BIBS) is a recognized and flexible tool to evaluate the psychosocial factors.

Objective: to present the process of translation into Spanish and cross-cultural adaptation of the BIBS.

Materials and methods: the reverse translation procedure was followed. To validate the translation, a multidisciplinary group of experts was formed. They were asked to rate the clarity of wording and cultural adaptation of the translation items. In addition, the translated interview was used to evaluate 173 patients seeking MBS who rated their satisfaction with the interview experience.

Results: the evaluation of the translation by a group of experts was favorable (global mode and median were 3-excellent, IQR of 1). The overall percentage agreement of the adequacy of "cultural adaptation" of the text was 85.8 % (95 % CI, 0.784, 0.932) and of the "clarity of wording" was 84.7 % (95 % CI, 0.7644; 0.9286). Furthermore, it was well accepted by the majority of the patients interviewed (p(50) 10 out of 10).

Conclusions: the Spanish translation of the BIBS is available for the assessment of Spanish-speaking people seeking MBS. It was rated as having good fidelity to the original English version, and was deemed highly satisfactory by patients.

Keywords:

Obesity. Morbid/Severe obesity. Psychological evaluation. Metabolic/ Bariatric surgery. Cross-cultural validation.

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Resumen

Introducción: la obesidad es un problema de salud mundial. La cirugía metabólica/ bariátrica (CMB) ha demostrado ser uno de los métodos más eficaces para tratar las formas más severas. Sin embargo, es necesaria una buena selección y preparación de los pacientes que optan a una CMB. En España no existen entrevistas estandarizadas para realizar la evaluación psicosocial de estos pacientes. La Entrevista de Boston para CMB (BIBS) es una herramienta reconocida y flexible para evaluar los factores psicosociales.

Objetivo: presentar el proceso de adaptación transcultural y traducción al español de la BIBS.

Material y método: se siguió el procedimiento de traducción inversa. Para validar la traducción, se formó un grupo multidisciplinar de expertos. Se les pidió que valoraran la claridad de la redacción y la adaptación cultural de los ítems traducidos. Posteriormente se usó para entrevistar a 173 pacientes que solicitaban MBS y a quienes se les pidió su valoración.

Resultados: la traducción fue valorada favorablemente por el grupo de expertos (moda y mediana globales: 3-excelente, IQR de 1). El porcentaje global de acuerdo sobre la "adaptación cultural" del texto fue del 85,8 % (IC 95 %: 0,784; 0,932) y sobre la "claridad de la redacción" fue del 84,7 % (IC 95 %: 0,7644; 0,9286). Además, la entrevista fue bien calificada por los pacientes entrevistados (*p*(50) 10 sobre 10).

Conclusiones: se consideró que la versión traducida era comparable a la versión original en inglés y los pacientes se mostraron satisfechos. La traducción al español de la BIBS está disponible para su uso.

Palabras clave:

Obesidad. Obesidad mórbida/severa. Evaluación psicosocial. Cirugía metabólica/bariátrica. Validación transcultural.

INTRODUCTION

Obesity is a health condition that affects millions of people worldwide, and its treatment is a challenge that requires a multidisciplinary approach.

According to the Spanish agency for food safety (Agencia Española de Seguridad Alimentaria y Nutrición, AESAN) and the National epidemiology center of health (Instituto Carlos III, ISCIII), in 2023, 4.9 % of the adult population residing in Spain suffers from severe obesity (mass index (BMI) > 35 kg/m^2) and 1 % have a BMI > 40 (1).

The World Health Organization (WHO) highlights that obesity is responsible for 10-13 % of deaths worldwide (2). When compared to medical treatment, metabolic/bariatric surgery (MBS) has proven to be one of the most effective treatments for patients with severe obesity (3). MBS maintains its effectiveness after the intervention and reduces the risk of other associated comorbidities (4). In fact, studies provide evidence of a substantial reduction in mortality in patients with severe obesity who undergo MBS, along with reduced healthcare utilization and a drop in direct medical costs (2,5).

Worldwide, the number of MBS procedures performed exceeded 800,000 in 2019 (6). According to the ENRICA study, "Estudio de Nutrición y Riesgo Cardiovascular en España" (7), the number of MBS interventions performed has been increasing in Spain, reaching 6,000-7,000 procedures per year in 2023. According to estimates, Spain had over 11,000 patients awaiting MBS in 2022 (8).

MBS improves quality of life and perceived health status, with changes observed in the first year and benefits retained for up to ten years or more (9). However, it is not always the most appropriate treatment for all patients (10). Not all people undergo MBS have a favorable outcome (11) and indeed, for many patients, weight recurrence is a compelling problem that arises between 1 and 3 years after surgery. In addition, in smaller subsets of patients, MBS is associated with an increased risk for substance abuse, self-harm and suicidal ideation, attempts or suicidal death (9). For these reasons, it is necessary to establish careful assessment and preparation procedures for individuals who are seeking MBS.

Rates of psychopathology for any psychiatric disorder across the lifespan are elevated in people seeking MBS, being close to 50 % for the 45-59 age group study (12). The most common psychiatric disorders in this population are affective and anxiety disorders, as well as binge eating disorders (13). Preoperative psychopathology may pose a challenge to adjustment and adherence after surgery as it is associated with longer hospital stays, increased complications and readmission rates (14). Patients behaviors after surgery also influence substantially long-term outcomes (14). While there is a dearth of strong, consistent evidence that pre-operative mental health conditions or eating disorders are associated with postoperative weight outcomes (15), some studies show that patients with greater social complexity showed a greater increase in BMI at 10 years after surgery relative to those without (11). Further, when eating pathology and depression symptoms recur after MBS, poorer weight loss outcomes were reported (9).

Therefore, preoperative psychosocial evaluation is crucial for optimizing the outcomes of patients seeking MBS. It is a way to identify strengths and vulnerabilities and develop recommendations to enhance surgical outcome (14). As early as 1991, the NIH Consensus Statement recommended that patients seeking MBS should be evaluated by a "multidisciplinary team with access to medical, surgical, psychiatric, and nutritional expertise" (5). Since then, the value of such evaluations has continued to be emphasized (5,16,17).

Bauchowitz et al. (2005) reported that the majority of pre-MBS programs (86.4 %) required a psychological evaluation to approve the procedure (18). However, the current view of the goal of the pre-MBS psychosocial assessment is not to provide a dichotomous recommendation about "clearance" — rather, the goal is to assess for risk factors and potential challenges to the patient smoothly navigating the demands of surgery, body image changes, and lifestyle changes required after surgery. Examples include uncontrolled psychiatric symptoms, active substance abuse, severe stressors, economic challenges, etc. Furthermore, when such potential challenges are identified in the pre-operative assessment, the goal is to address them, to optimize post-operative outcomes (5). One factor that complicates the assessment of patients seeking MBS is that in many settings,

there is little connection and/or sparse communication between the evaluating mental health clinician and the MBS team. For instance, Bauchowitz et al. (2005) found that only 25.9 % of MBS programs had their own mental health professional on staff, while 65 % referred patients to mental health professionals in the community.

In this context, the Boston Interview for Bariatric Surgery (BIBS) (19) is a valuable tool in the psychosocial assessment process of people seeking MBS. It provides a framework for exploring psychosocial dimensions, allowing mental health professionals from diverse backgrounds to obtain a more complete picture of the patient's readiness for surgery and the lifestyle changes that will follow. Its content areas align closely with the American Society of Metabolic and Bariatric Surgery (ASMBS) recommendations for the psychological assessment of people seeking MBS (20). It is designed to provide a standardized but flexible and individualized way of working that allows mental health professionals to gather consistent and comparable information on known psychological factors that may influence the outcome of intervention. In addition, it can provide a standardized and agreed method for collecting data for research and a reliable guide to professionals who are training in the psychosocial assessment of people seeking MBS.

The BIBS has been translated into Italian and is recommended by the Italian Society of Obesity Surgery (SICOB) (2011) as one of the tools to adopt for preoperative psychological assessment (21).

In 2023, almost 500 million people worldwide will have Spanish as their mother tongue, representing 6.2 % of the world's population. It is the second-most common native language based on number of speakers (22). However, despite the prevalence of Spanish in the world, there is no standardized interview model in Spanish to assess the psychological readiness of people seeking MBS. This represents a barrier for Spanish-speaking patients seeking MBS treatment. Adapting tools that are already used in other countries would allow the implementation of the knowledge acquired, save efforts in the development of a tool and have greater validity and generalizability as data are taken from different population (23). Even though most guidelines assume that theoretical constructs are similar in both cultures (conceptual equivalence) and that therefore a semantic and linguistic adaptation suffices (23), cross-cultural adaptation is fundamental to guarantee the adequacy of an instrument in a different culture, ensuring that it remains equivalent to the original version, while being relevant to the cultures in which it is being used (24). The cross-cultural adaptation involves not just converting words from one language to another, but also accounting for differences in cultural contexts, expressions, and sensitivities, using forward and back translations and committee consensus approaches to resolve ambiguities or discrepancies and to reach agreement to adapt terms culturally (23). This approach ensures that linguistic and cultural nuances are accurately conveyed and potential misinterpretations or misunderstandings stemming from cultural disparities can be minimized.

The translation of the BIBS into Spanish is an important step to make the preoperative psychosocial assessment more accessible to patients and more standardized for the use of professionals. It is the aim of this paper to present the process of translation into Spanish and cross-cultural adaptation of the BIBS.

MATERIAL AND METHODS

The Boston Interview for Bariatric Surgery (BIBS) consists of an initial introductory section in which basic sociodemographic information is collected and 7 sections that evaluates dietary history and eating habits, screen for eating disorders, medical history and the knowledge about specific surgical procedures, including the risks and post-surgical regimen, motivation and expectations for the surgery, strength of patient´s support systems and relationships, and finally, a psychiatric evaluation. It should be noted that, having been published in 2008, the BIBS includes material relating only to the two procedures most commonly performed at that time, the laparoscopic adjustable gastric band and the Roux-en-Y gastric bypass (RYGB) (Annex 1: https://www.nutricionhospitalaria.org/anexos/05254-01.pdf).

The original version of the BIBS was translated following the back-translation procedure based on the suggested principles for translation and interculturality of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) (25-28). The steps followed are summarized in figure 1.

The research was carried out after having requested the relevant authorization from the ethics committee of the University Hospital Puerta de Hierro Majadahonda in Madrid (HPHM Madrid, Spain. PI: 75/22).

Figure 1.

Steps to translate the Boston Interview for Metabolic/Bariatric Surgery (BIBS).

Dr. Sogg, the first author of the original, English-language version of the BIBS, was contacted to request her permission/authorization to translate and adapt it. As the BIBS in its revised version was updated in 2008 (19), it was recommended by the author to update some of the items using the DSM-5 as well as to implement the suggested criteria for "night eating syndrome". In addition, it was agreed to update the information included in the section "Understanding surgical procedures, risks and postoperative regimen", to add the types of bariatric interventions used in our setting: vertical sleeve gastrectomy and gastric bypass.

Two independent bilingual professionals whose native language was Spanish translated the original version of the BIBS into Spanish (Annex 2: https://www.nutricionhospitalaria.org/anexos/05254-02.pdf). Both versions were collated to create a common version that was reviewed by a group of experts (3 psychiatrists with experience in the evaluation of severe obesity) and consensus corrections were introduced following a methodology similar to the e-Delphi (29). Once the final version was agreed upon, a native bilingual translator other than the initial translator, who was not involved in MBS assessments, retranslated it into English. This version was compared with the original English version, focusing on conceptual equivalence and linguistic consistency, prioritizing the comprehensibility and meaning of the content, rather than literal equivalence of the verbiage. No significant discrepancies were observed between the two versions. Finally, the translated version was shared with the authors of the BIBS and their suggestions were incorporated to establish the definitive Spanish version.

Since this interview is designed as a support for the clinician who adapts the questions to the context and reality of each patient, and since there is no standard measure of comparison established in the MBS population, expert judgment was used to verify that it was understandable and culturally adapted to our environment. A group of experts from different specialties (general surgeons, endocrinologists, psychologists and psychiatrists) was formed; including professionals accustomed to evaluating patients who were people seeking MBS. The input of professionals who are knowledgeable about MBS but are not mental health clinicians was included since some sections of the interview focused on technical and nutritional aspects of the surgery. Finally, three men and six women between 35 and 55 years of age, which was considered sufficient (29), formed the group of experts. Of them, three were endocrinologists with specialization in nutrition, three were general surgeons dedicated to metabolic surgery, two were psychiatrists, and one was a psychologist with specialization in the MBS evaluation.

An online survey was designed grouping the questions into 23 sections by thematic content and length. In each section, respondents were asked if the questions were understandable (clarity of wording) and appropriately culturally adapted using a Likert scale with ratings 0 to 3 (0: deficient, 1: acceptable, 2: good, and 3: excellent). The first four sections were only assessed by the mental health specialists (psychiatrists and psychologist) as these sections focused on specific aspects of mental health evaluation. In addition to the Likert scale questions, a free response section was added to suggest changes in the translation to improve comprehension and adaptation. In this last section, the comments offered were grouped into four categories (1. no modifications, 2. typographic mistakes, 3. slight suggestions that did not modify the original meaning, and 4. comments proposing changes in the meaning of the original question). Except for this last category, the suggestions made were introduced in the translated final version. Again, an e-Delphi methodology (29) was used to collect the experts' responses. Only one round of questions was necessary because the assessment was good and the agreement high. It was considered that the response rates in a second round would not be much different from the results already obtained.

The translated interview was also used to evaluate 173 patients who were people seeking MBS referred to the mental health service of the HPHM from June 2022 to December 2024. No patient refused to participate in the study. Only those patients who were already being treated by other mental health professionals were excluded as the evaluation was preferably done by their Mental Health providers. After the interview, all of the people interviewed were asked to rate their satisfaction with the interview experience on a Likert scale of 0-10 (0: very dissatisfied and 10: very satisfied). It is repeatedly proposed in the literature, that people seeking MBS may be biased in their reporting because they fear a negative evaluation that may prevent them from having surgery (30,31). To minimize this bias, assessments from people seeking MBS were anonymized with a code, and it was explained to them that it would have no influence on their subsequent evaluation or care.

The sociodemographic characteristics of the people seeking MBS evaluated were: 111 women (64.2 %) and 62 men (35.8 %), aged between 18 and 63 years (mean: 46.93, SD: 10.94). Of these, 130 came from Spain (75.1 %), 35 came from Latin America (20.2 %) and the remaining subjects had other nationalities—8 (4.6 %). In relation to level of education: no education or basic education, 35 (20.3 %); university, 55 (31.4 %); and secondary education, 83 (vocational training and high school: 48.3 %). Of the patients evaluated, 14 (8.1 %) did not answer the satisfaction survey. The sociodemographic characteristics of those who did not answer were similar to those who responded, with no statistically significant differences being found between the two samples in relation to age, education or sex.

STATISTICAL ANALYSIS

The data is presented as absolute and relative frequencies for categorical variables and as mean and standard deviation or median and 25th and 75th percentiles for numerical variables. The percentage of agreement between the different medical specialties was estimated with the corresponding 95 % confidence interval.

The statistical analysis was performed with the Stata v18 statistical package (StataCorp. 2023. Stata Statistical Software: Release 18. College Station, TX: StataCorp LLC).

RESULTS

RESULTS OF THE ANALYSIS OF THE BIBS BY THE GROUP OF EXPERTS

From the analysis of the surveys carried out by the group of experts, the median scores in each section ranged from 2: good to 3: excellent (Table I), except for sections 3 (writing) and 4 (writing and adaptation), which were rated 1: acceptable. The overall median rating of the quality of writing was 2: good, and for cultural adaptation was 3: excellent. The overall mode and median were 3: excellent. The overall IQR (interquartile range) was 1 for both questions, which was considered consensus (29).

Table I. Medians of the evaluations of each section for "clarity of wording" and "cultural adaptation" (n = 173)

Section	Median clarity	Median adaptation
S1. Psychiatric evaluation	2	2
S2. Psychiatric history	2	2
S3. Substance use history	1	2
S4. Mental status examination	1	1
S5. Initial instructions	3	3
S6. Sociodemographic data	3	3
S7. Weight history	3	3
S8. Weight loss attempts	3	2
S9. Daily eating patterns	3	3
S10. Disordered eating behavior	3	3
S11. Binge eating	3	3
S12. Compensatory (purging) behaviors	2	2
S13. Snacking	2	2
S14. Night eating syndrome	3	3
S15. Weight attributions	3	3
S16. Medical history	2	2
S17. Surgical procedure knowledge	2	2
S18. Surgical risks knowledge	2	2
S19. Post-surgical regimen knowledge	2	2
S20. Motivation	3	3
S21. Expectations	3	3
S22. Adherence	3	3
S23. Social supports	2	2
Global median	2 (2;3 IQR: 1)	3 (2,3 IQR: 1)

0: poor; 1: acceptable; 2: good; 3: excellent.

In addition, the percentages of agreement in each section were obtained. Table II shows the percentages obtained in relation to cultural adaptation and clarity of wording.

As it can be seen in the table, only in section 4 was the clarity of writing considered deficient by one of the evaluators. The section with the lowest rate of agreement for cultural adaptation was the one related to history taking and psychopathological examination (33 % agreement). In the remaining sections of cultural adaptation, the percentage of good/excellent had a range of 66.7 % to 100 %.

For clarity of wording, sections 3 and 4 related to substance use history and psychopathological history and examination, were the sections with the lowest ratings. In the rest of the sections, the percentage of good/excellent for clarity of writing ranged from 66.6 % to 100 %.

Table III shows the percentages of agreement for the different groups of specialists. There were no relevant differences ($p < 0.05$) between the various specialists. The overall percentage of agreement rating the question on the cultural adaptation of the text as good/excellent was 85.8 % (95 % CI, 0.784, 0.932). The percentage of overall agreement rating it as good/excellent was 84.7 % (95 % CI, 0.7644; 0.9286).

In the qualitative evaluation (Table IV), the comments offered were grouped into 4 categories: no modifications, spelling errors found, suggestions for improved wording without altering the original meaning of the text, and comments that questioned the original question by proposing changes in question meaning.

Section 4, on the collection of background information and psychopathological examination, showed the highest level of dissatisfaction (66 % of the raters asked for greater detail), followed in this case by section 9, which was concerned with daily food intake (55 % of raters suggested more detail).

RESULTS OF PATIENT ASSESSMENTS AFTER EVALUATION WITH BIBS

As interviews were conducted, no difficulties in comprehension were evident. The items were clear and understandable for patients. A total of 148 patients (93.1 %) responded with a score of 9 or 10 (with 10 representing "highly satisfied") on the interview assessment. The median of the evaluations (p50) in both the Hispanic and Spanish populations did not differ, with the score obtained being 10 (10; 10).

The survey was equally well rated among the population with different levels of education (100 % with primary education, 90.79 % with VET or high school, 92.31 % with university studies), as well as among the people coming from Latin America (100 % rated 9 or 10) and the native Spanish population (91.53 % rated 9 or 10) (Fig. 2 and 3).

Table II. Agreement for each section on "cultural adaptation" and "clarity of wording" (n = 3 for S1 to S4 for highlighted results, n = 9 for the rest)

	Cultural adaptation			Clarity of wording		
Sections of the BIBS	**Deficient**	**Fair**	**Good/ Excellent**	**Deficient**	**Fair**	**Good/ Excellent**
S1. Psychiatric evaluation		1 (33.3 %)	2 (66.7 %)		1 (33.3 %)	2 (66.7 %)
S2. Psychiatric history		1 (33.3 %)	2 (66.7 %)		1 (33.3 %)	2 (66.7 %)
S3. Substance use history		1 (33.3 %)	2 (66.7 %)		2 (66.7 %)	1 (33.3 %)
S4. Mental status examination		2 (66.7 %)	1 (33.3 %)	1 (33.3 %)	1 (33.3 %)	1 (33.3 %)
S5. Initial instructions			9 (100.0 %)			9 (100.0 %)
S6. Sociodemographic data			9 (100.0 %)			9 (100.0 %)
S7. Weight history			9 (100.0 %)			9 (100.0 %)
S8. Weight loss attempts			9 (100.0 %)			9 (100.0 %)
S9. Daily eating patterns		1 (11.1 %)	8 (88.9 %)		2 (22.2 %)	7 (77.8 %)
S10. Disordered eating behavior		1 (11.1 %)	8 (88.9 %)		1 (11.1 %)	8 (88.9 %)
S11. Binge eating		1 (11.1 %)	8 (88.9 %)		1 (11.1 %)	8 (88.9 %)
S12. Compensatory (purging) behavior		2 (22.2 %)	7 (77.8 %)		1 (11.1 %)	8 (88.9 %)
S13. Snacking		1 (11.1 %)	8 (88.9 %)		1 (11.1 %)	8 (88.9 %)
S14. Night eating syndrome			9 (100.0 %)			9 (100.0 %)
S15. Weight attributions			9 (100.0 %)			9 (100.0 %)
S16. Medical history			9 (100.0 %)			9 (100.0 %)
S17. Surgical procedure knowledge		1 (11.1 %)	8 (88.9 %)		1 (11.1 %)	8 (88.9 %)
S18. Surgical risks knowledge		3 (33.3 %)	6 (66.7 %)		4 (44.4 %)	5 (55.6 %)
S19. Post-surgical regimen knowledge		1 (11.1 %)	8 (88.9 %)		2 (22.2 %)	7 (77.8 %)
S20. Motivation		1 (12.5 %)	7 (87.5 %)		1 (12.5 %)	7 (87.5 %)
S21. Expectations		1 (11.1 %)	8 (88.9 %)		1 (11.1 %)	8 (88.9 %)
S22. Adherence			9 (100.0 %)			9 (100.0 %)
S23. Social supports			9 (100.0 %)			9 (100.0 %)

DISCUSSION

Adapting a semi-structured interview to another language may seem a simple process but it is complex, not only because of the difficulties inherent in translation (32) but also because once it has been translated, it is difficult to objectively check that it has been done properly and that the properties of the original instrument are maintained. Unlike what happens with questionnaires or scales, in which the psychometric properties of the instrument can be evaluated once it has been translated and adapted, with a semi-structured interview there are no objective values that allow comparison of the original and translated versions. Furthermore, systematic reviews highlight the scarcity of psychometric assessment instruments for people seeking MBS (33) that can serve as valid comparators.

Table III. Percentages of agreement for the different groups of specialists related to "clarity of wording" and "cultural adaptation" (n = 23)

	"Clarity of wording"	"Cultural adaptation"
General surgeons	82.46 % (95 % CI, 0.679; 0.970)	82.46 % (95 % CI, 0.679; 0.970)
Endocrinologist	82.46 % (95 % CI, 0.679; 0.970)	78.95 % (95 % CI, 0.636; 0.943)
Psychiatrist/ psychologist	93.0 % (95 % CI, 0.829; 0.100)	93.0 % (95 % CI, 0.829; 0.100)
Global	84.7 % (95 % CI, 0.7644; 0.9286)	85.8 % (95 % CI, 0.784, 0.932)

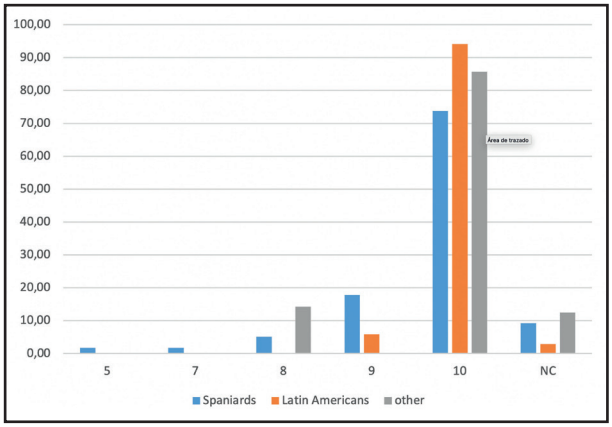

Figure 2.

Relative frequencies of ratings by language (n = 173). Ratings from 0 to 10 (0-deficient to 10-excellent).

Table IV. Clarification from experts (n = 3 for S1 to S4 for highlighted results, n = 9 for the rest)

	No change	Spelling	Content nuances	Restructure text
S1. Psychiatric evaluation	1 (33.3 %)		2 (66.6 %)	
S2. Psychiatric history			2 (66.6 %)	1 (33.3 %)
S3. Substance use history			2 (66.6 %)	1 (33.3 %)
S4. Mental status examination			1 (33.3 %)	2 (66.6 %)
S5. Initial instructions	7 (77.8 %)		1 (11.1 %)	1 (11.1 %)
S6. Sociodemographic data	8 (88.9 %)		1 (11.1 %)	
S7. Weight history	6 (66.7 %)			3 (33.3 %)
S8. Weight loss attempts	6 (66.7 %)			3 (33.3 %)
S9. Daily eating patterns	4 (44.4 %)			5 (55.5 %)
S10. Disordered eating behavior	7 (77.8 %)		2 (22.2 %)	
S11. Binge eating	7 (77.8 %)	1 (11.1 %)		1 (11.1 %)
S12. Compensatory behaviour	5 (55.6 %)		2 (22.2 %)	3 (33.3 %)
S13. Snacking	5 (55.6 %)		2 (22.2 %)	2 (22.2 %)
S14. Night-eating syndrome	7 (77.8 %)			2 (22.2 %)
S15. Weight attributions	7 (77.8 %)		1 (11.1 %)	1 (11.1 %)
S16. Medical history	7 (77.8 %)		1 (11.1 %)	1 (11.1 %)
S17. Surgical procedure knowledge	4 (44.4 %)	4 (44.4 %)		1 (11.1 %)
S18. Surgical risks knowledge	4 (44.4 %)	1 (11.1 %)	3 (33.3 %)	1 (11.1 %)
S19. Post-surgical regimen knowledge	6 (66.7 %)		2 (22.2 %)	1 (11.1 %)
S20. Motivation	6 (66.7 %)		3 (33.3 %)	
S21. Expectations	6 (66.7 %)		2 (22.2 %)	1 (11.1 %)
S22. Adherence	7 (77.8 %)		1 (11.1 %)	1 (11.1 %)
S23. Social support	6 (66.7 %)		2 (22.2 %)	1 (11.1 %)

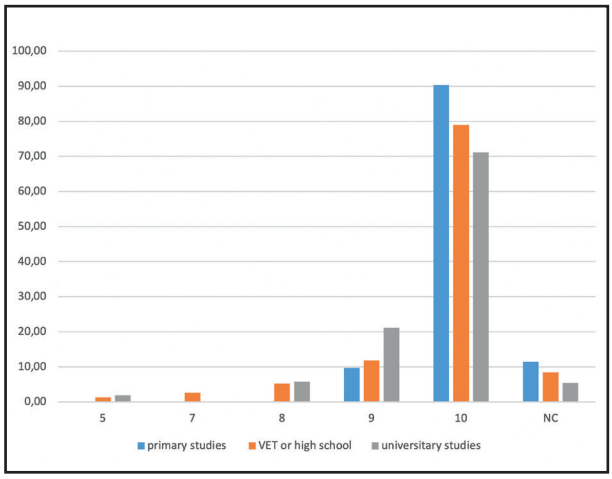

Figure 3.

Relative frequencies of ratings by educational level (n = 173). Ratings from 0 to 10 (0-deficient to 10-excellent).

Two questionnaires, the Bariatric Interprofessional Psychosocial Assessment Suitability Scale (BIPASS) (13) and the Revised Master Questionnaire (MQR) (34), have been developed to assist in the assessment of people seeking MBS, but neither of them has a validated Spanish version. The aim of a psychosocial assessment interview of people seeking MBS is not a numerical output, but guiding a conversation to observe the strengths or difficulties in coping with post-surgical requirements as well as determining the degree of mental health support that is required (20,35,36). Validating a translation means establishing that both versions, translated and original, are equivalent not only in semantic terms, that is, in conveying the original idea, but also in their conceptual equivalence and in their applicability to individuals in their respective cultures (32).

To translate the BIBS, it was decided to adopt the previously described translation-back-translation method (25-27), although some authors such as Walde and Wölm recommend the use of the TRAPD method: "Translation, Review, Adjudication, Pretest and Documentation" (37). The TRAPD method advocates evaluating the questionnaire in the target population rather than comparing the original and back-translated versions, as they argue that such a comparison provides only limited and potentially misleading information about the quality of the text in the target language (32,37). In our case, and given that it is not possible to easily evaluate the BIBS, the back-translation method was considered more appropriate as it allowed us to confirm with the original authors that the translation maintained its original meaning. However, as Kristjansson et al. point out, back-translation, while allowing semantic equivalence to be determined, does not guarantee conceptual equivalence or cultural fit (32). Therefore, as the interview is utilized by practitioners, qualitative validation using expert judgement was considered necessary. Expert judgement has been used in research to validate an instrument subjected to translation and standardization procedures in order to adapt it to different cultural meanings (38-40).

In relation to the methods for collecting the information provided by experts, it was decided to use the Delphi method (29), a technique that offers a high level of interaction between experts through an iterative process, while allowing anonymity and the use of virtual technology, bridging geographical distances. The Delphi technique incorporates the use of an anonymous questionnaire that is answered autonomously, but sharing decisions through the researcher, who aggregates the opinions provided.

The selection of the number of experts depends on aspects such as ease of access to them or the possibility of knowing enough experts on the subject matter of the research (39). Finding mental health experts trained in the assessment of people seeking MBS in Spain was complex as there is no formal/recognized area of specialization in this field. Therefore, a multidisciplinary group of experts was selected that included mental health professionals who had experience or regularly performed this task, endocrinologists with expertise in nutrition, and surgeons specialized in metabolic surgery. Only sections 1 to 4 (psychiatric assessment and history, including personal psychiatric and substance use history) were exclusively assessed by mental health professionals.

The difficulty in finding mental health experts in the field of metabolic surgery, on the other hand, highlights the need for training and also the need for a semi-structured interview that can help mental health professionals to understand which aspects are relevant during this type of interview, facilitating a greater identification and standardization of criteria.

In the qualitative assessment (Table IV), most of the comments offered were in relation to the lowest-rated sections, those relating to the psychopathological examination and general clinical history taking (Section 4), which is generally carried out in the initial assessment. This section is less detailed in the original English version of the BIBS as it is expected that the mental health clinician has training in administering a general mental health evaluation, and therefore it is left to the expertise of the assessing professional. They were also rated lowest by the experts both in terms of clarity of wording and cultural adaptation. Almost all comments offered in the qualitative assessment in Section 9, referring to daily eating patterns, were reviewed and introduced in the definitive translated version. The rest of the results obtained from the group of experts were favorable, with consensus among most experts, who were satisfied with the translation, confirming that the equivalence between the original meaning and the Spanish translation had been achieved. Moreover, it was well accepted by the majority of the 173 patients seeking MBS who were evaluated using the translated version of BIBS, thus proving its acceptability.

Although the interview translation was designed with the Spanish population in mind, no differences were found between the ratings of the interviews conducted with Latin Americans (p50, 10), nor were there any difficulties in their comprehension. However, given that the experts who were asked to evaluate this came from Spain, it would be advisable to test its fit in populations in which the evaluators are Latin Americans.

Despite its limitations, such as the difficulty in finding experts and the need to extend its validation to mental health professionals from Latin America, this study represents a significant advance in the psychosocial assessment of people seeking MBS, as it is the first work to propose the cultural adaptation and translation of BIBS into Spanish. To date, no other instruments in Spanish could guide a multidimensional assessment of people seeking MBS. It is also an aim of this study to propose a method for translating into other languages semi-structured interviews for which there is no gold standard.

In the future, it will be necessary to implement our knowledge of the factors that worsen post-surgical prognosis, and to develop instruments to identify patients at higher risk of unfavorable outcome after surgery, thus facilitating appropriate and efficient interventions. Future research could also adapt the BIBS to other Spanish-speaking populations.

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ARÁN

Nutrición Hospitalaria

Trabajo Original

Obesidad y síndrome metabólico

Effects of a functional yogurt enriched with soluble dietary fiber or vegetable proteins on appetite profile. An acute randomized controlled clinical trial

Efectos de un yogur funcional enriquecido con fibra dietética soluble o proteína vegetal sobre el perfil del apetito. Ensayo clínico controlado, aleatorizado y de corta duración

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Abstract

Introduction: designing functional foods to control appetite could be a useful strategy for managing overweight and obesity. Fiber and proteins could be interesting ingredients to consider.

Objectives: to evaluate the appetite profile of two experimental yogurts (fiber-enriched [FEY] and vegetable protein-enriched [PEY]) versus a control yogurt (CY) in a group of overweight/obesity people.

Material and methods: an acute, randomized, double-blind, crossover clinical trial was carried out in a group of twelve healthy overweight/obesity type I people; randomized to consume 3 yogurts in a different order for 3 acute study days. The appetite profile (1. hunger, 2. satiety, 3. fullness, 4. prospective food consumption, 5. desire to eat something fatty, salty, sweet or savoury) was assessed using a Visual Analog Scale (ranging from 0 "not at all" to 10 "extremely") at 12 moments in each acute study. Additionally, total food consumption in an ad libitum lunch was assessed.

Results: FEY produce a significantly lower desire to consume any food at 30 (1.50 ± 0.42) and 60 minutes (2.78 ± 0.42) after consumption compared to PEY (3.46 ± 0.53; 4.33 ± 0.54) and CY (3.27 ± 0.69; 4.0 ± 0.78) respectively ($p < 0.016$). Also, FEY consumption produced a higher satiety and fullness and a lower desire to ingest something fatty, salty or savory after 90 minutes consumption compared to the other products, but the difference was not significance.

Conclusion: FEY might be a good functional food prototype to control appetite in overweight and obese people.

Keywords:

Obesity. Appetite. Energy intake. Satiety. High fiber foods. Protein.

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Informed consent statement: informed consent was obtained from all subjects involved in the study.

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Resumen

Introducción: el diseño de alimentos funcionales para controlar el apetito podría ser una estrategia útil para controlar el sobrepeso y la obesidad. La fibra y algunas proteínas podrían ser ingredientes interesantes a tener en cuenta.

Objetivos: evaluar el perfil del apetito de dos yogures experimentales (enriquecido en fibra [YEF] y enriquecido en proteínas vegetales [YEP]) frente a un yogur de control (YC) en un grupo de personas sanas.

Material y métodos: se llevó a cabo un ensayo clínico agudo, aleatorizado, doble ciego y cruzado en un grupo de doce personas sanas con sobrepeso/obesidad de tipo I; aleatorizadas para consumir los 3 yogures en un orden diferente. El perfil del apetito (1. hambre, 2. saciedad, 3. plenitud, 4. consumo prospectivo de alimentos, 5. deseo de comer algo graso, salado, dulce o salado) se evaluó mediante una escala visual analógica (de 0 "nada" a 12 "extremadamente" puntos) en 12 momentos del estudio agudo. Además se evaluó el consumo total de alimentos en un almuerzo ad libitum.

Palabras clave:

Obesidad. Apetito. Ingesta energética. Saciedad. Alimentos ricos en fibra. Proteínas.

Resultados: el consumo de YEF produjo un menor deseo de ingerir algún alimento a los 30 (1,50 ± 0,42) y 60 minutos (2,78 ± 0,42) después de su consumo, comparado con el YEP (3,46 ± 0,53; 4,33 ± 0,54) y el YC (3,27 ± 0,69; 4,0 ± 0,78), respectivamente ($p < 0,016$). Además, con el consumo de YEF se produjo una mayor saciedad y plenitud y un menor deseo de ingerir algo graso, salado o sabroso desde los 90 minutos posteriores a consumir el yogur en comparación con el YEP y el YC, aunque las diferencias no fueron significativas.

Conclusión: el YEF podría ser un buen prototipo de alimento funcional para controlar el apetito en personas con sobrepeso y obesidad.

INTRODUCTION

Overweight and obesity have become one of the most relevant public health problems worldwide. Excess weight is a risk factor for numerous pathologies, highlighting metabolic syndrome, type 2 diabetes *mellitus* and cardiovascular diseases. For this reason, it is important to seek for strategies that help reduce body weight. It is a fact that the accumulation of body fat that defines obesity is fundamentally a reflection of positive energy balance, where energy consumed as food intake exceeds that energy expended (1). Regulation of appetite and control of satiety to reduce the food intake could be a nutritional strategy aiming to prevent obesity development (2).

The intensity and duration of the hunger and satiety effects are determined by different factors, including the nutrient composition of foods and beverages (2). Among the nutritional components with "satiating power" fiber or protein are typically a good choice for promoting satiety (3). Dietary fiber could promote weight loss mainly through three mechanisms: by promoting a decrease in energy intake through increased satiety, and/or reducing efficiency in the absorption of energy nutrients, and/or improving glucose tolerance and decreasing insulin levels (4). Moreover, diets with a high fiber content require more chewing time, which slows down swallowing speed. Also, in the stomach, soluble fibers, as a consequence of their viscosity, slow down gastric emptying and increase gastric distention, providing longer periods of satiety sensation (5) Finally, high fiber intake may affect gut hormone secretion, independent of glycemic response, and has been associated with lower BMI and consequently a lower risk and progression of type 2 diabetes, cardiovascular disease, and cancer (6).

Furthermore, different studies have documented that protein intake could have greater satiety potential and lead to greater weight loss compared to other macronutrients. Different studies have described that protein produces an increase in satiety hormones and activate metabolic signals that reduce appetite (7,8).

Because of this, carrying out strategies that increase the consumption of food components such as fiber and protein being harnessed to interact with the physiology to naturally limit calorie intake could be of great interest to control the mechanisms of satiety and appetite and consequently achieve benefits in controlling body weight (1,2).

According to this, designing functional foods enriched in these nutrients could be very useful as a strategy to promote satiety and control weight (9). Different studies have evaluated the satiating power of natural foods or functional foods designed to optimize their satiating effectiveness, improve long-term satiety, and facilitate body weight control (10-12). Such functional foods include dairy products (yogurts), cereals, ready-to-eat meals, and even snack foods (chocolate bars). Among these, dairy products and specially yogurt do not provide a high caloric load and are easy to consume "between meals" (mid-morning, afternoon snack) for most of the population, so they are usually a food of choice to be consumed at those times of the day (11). Moreover, yogurt naturally has a high protein content and also possesses rheological and organoleptic properties that could contribute to reinforce its potential to positively influence satiety (8,11). In addition, different studies have described the health benefits of yogurt and fermented milks due their high nutritional value, leading to an ideal vehicle for functional foods development (11,13).

Currently to date there are few clinical trials that have evaluated the satiating effect of functional foods of dairy products, particularly yogurts enriched with fiber or protein intended to have satiating effects.

Based on these facts, an acute study was conducted to evaluate the satiating properties of two functional yogurts (yogurt with inulin, wholegrain oat flour, rye bran, and poppy seeds added); yogurt with pea protein) using a hunger and satiating Visual Analog Scale in a group of healthy overweight subjects.

MATERIALS AND METHODS

STUDY DESIGN

An acute, randomized, double-blind and crossover clinical trial was designed to evaluate the satiating properties of two experimental yogurt prototypes (an enriched-in-fiber yogurt and a pro-

tein-enriched yogurt) versus a control yogurt in a group of healthy overweight people.

Subjects were randomized by sex and were assigned to one of the three products of the study (fiber-enriched yogurt [FEY], protein enriched yogurt, [PEY] and control yogurt [CY]). All the yogurts were already commercialized products made from cow milk with the following characteristics: FEY (natural yogurt with inulin, wholegrain oat flour, rye bran and poppy seeds added) was selected because of a European approved nutritional claim of "high fiber content" (contains at least 6 g of fiber per 100 g); PEY (Greek yogurt with pea protein) was selected because pea protein was an alternative, sustainable plant-based high quality protein with low allergenicity (14) and potential satiating power (15), and because of a European approved nutritional claim of "source of protein" (at least 12 % of the energy value of the food is provided by protein); and CY (natural yogurt).

Each subject underwent 3 experimental phases, attending 3 visits, with a washout period of 7 days between them, in which they took the assigned yogurt.

The nutritional composition of each yogurt is specified in table I. All study products (experimental and placebo) were supplied by the company DELAFRUIT SLU (formerly known as Go Fruselva SL) in a "yogurt" container of 125 grams.

The containers of the 3 yogurts were only distinguished by an identification number established by the company (yogurt 1, 2 and 3), without the research team knowing at any time which one was which, in order to guarantee the double blind approach.

Once the study was completed, unblinding was performed, non-compliance with the protocol was verified, and the data was reviewed and analyzed.

SUBJECT SELECTION AND ALLOCATION

A total of 12 healthy overweight and obesity type 1 volunteers (6 men and 6 women), were recruited through the Clinical Nutrition and Dietetics Unit of La Paz University Hospital (HULP) in Madrid, Spain. The inclusion criteria were: ages between 18 and 50, BMI between ≥ 25 and < 35 kg/m^2, with an education level sufficient to understand the study. All of the subjects signed an informed consent. The exclusion criteria were: BMI < 25 or ≥ 35 kg/m^2; subjects who followed a vegetarian diet pattern or had a fiber intake ≥ 30 g/day ; individuals with diabetes *mellitus,* dyslipidemia or arterial hypertension under drug treatment; smoking or alcohol use > 2-3 servings/day in the case of men, and > 1 serving/day in women; having lost or gained more than 4 kg or adhered to weight loss diets in the last 6 months; subjects with gastrointestinal diseases affecting the digestion or absorption of nutrients; and pregnant or breastfeeding women. Finally, subjects with intense physical activity, allergies or lactose intolerance, celiac disease or gluten intolerance, and those who rejected the consumption of the foods included in the study (yogurt, potato omelette and bread) were not included.

All 12 volunteers were randomized into one of the three study sequences based on their sex (Fig. 1). The randomization procedure was carried out by the HULP Biostatistics Unit by assigning an "identification number" according to a randomization table to consume the 3 study yogurts in a different order (Y1-Y2-Y3: $n = 4$; Y3-Y1-Y2: $n = 4$; Y2-Y3-Y1: $n = 4$).

The research protocol was approved by the HULP Clinical Research Ethics Committee (code 5007) under the regulations described in the Declaration of Helsinki (16).

Table I. Experimental and control composition of yogurt per 100 g

		FEY	PEY	CY
Energy	kcal	103	101	67
Total fat	g	1.1	2.9	1.8
Saturated fat	g	0.7	1.9	1.2
Protein	g	1.3	3.7	2.1
Total carbohydrate	g	11	14	10
Sugars	g	8.0	8.7	7.8
Fiber	g	8.6	1.8	1.0
Sodium	g	0.03	0.084	0.1

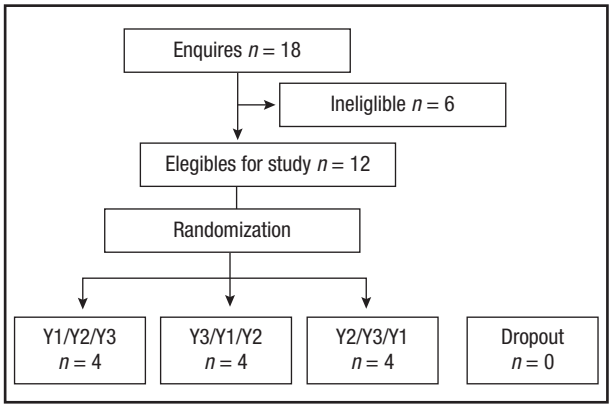

Figure 1.

Consort flow diagram of the recruitment, enrollment, and random assignment processes.

CONDUCTION OF THE STUDY

This study was carried out according to European Food Safety Authority requirements (17). All the participants delivered the signed informed consent to participate and were scheduled to attend to 3 visits in the HULP clinical Research and clinical trials Unit. In each visit, the following protocol was followed (Fig. 2).

– Just after arrival: blood pressure and heart rate measured, anthropometric study, dietary study, physical activity study, 1st blood collection (BC) and 1st appetite profile evaluation (APE).

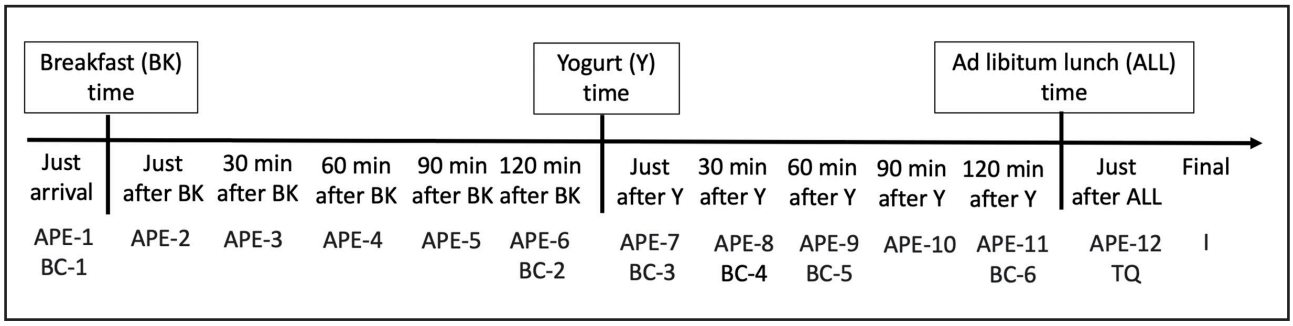

Figure 2.

Diagrammatic representation of the experimental protocol in each visit (BC: blood collection; APE: appetite profile evaluation; TQ: tolerance questionnaire; I: instructions for exit).

- Breakfast time: including milk (200 ml), white bread (60 g), grated tomato (30 g), extra virgin olive oil (10 g) and orange juice (200 ml). Participants had a maximum of 15 minutes for consumption.
- Just after breakfast: 2nd APE.
- 30 min after breakfast: 3rd APE.
- 60 min after breakfast: 4th APE.
- 90 min after breakfast: 5th APE.
- 120 min after breakfast: 2nd BC and 6th APE.
- Yogurt time (P1, P2 o P3). Participants had a maximum of 10 minutes to eat their assigned yogurt according to the randomization scheme.
- Just after the yogurt: 3rd BC, 7th APE and a product sensory perception evaluation.
- 30 min after the yogurt: 4th BC and 8th APE.
- 60 min after yogurt: 5th BC and 9th APE.
- 90 min after yogurt: 10th APE.
- 120 min after yogurt: 6th BC and 11th APE.
- Ad libitum lunch time: including potato omelette and bread. Participants were able to eat as much of the food offered as they wanted and 500 ml of water in a maximum time of 20 minutes.
- Just after lunch: 12th APE and a tolerance questionnaire to the product consumed was collected.

As shown in figure 1, appetite sensation ratings were obtained at 12 specific time-points throughout the entirety of the testing visit. During the visit, no eating or drinking was allowed during the 4 hours of the intervention; reading, studying, talking or listening to music was allowed, but they were not allowed to sleep. It is important to highlight that the formulation of the yogurt consumed as a snack was the only methodological characteristic that was different between each visit.

Before finishing the visit, the researchers gave them a 24-h record to complete with all the foods they consumed throughout the day of the intervention in order to control the overall food consumption during the acute study day.

Finally, the participants were instructed to maintain their usual activity and food consumption pattern until the next visit. Also, to control this aspect, researchers gave them a 72-h food record, a food frequency questionnaire and the "International Physical Activity Questionnaire" short form (18) to be completed 3 days prior to the next visit 7 days later.

OUTCOMES

For the present article the primary outcome was the appetite profile assessment using the validated Visual Analog Scale (VAS) and the secondary outcome was the total food consumption in the ad libitum lunch offered in each visit. Further variables will be explored in future articles.

APPETITE PROFILE EVALUATION

The appetite profile was assessed using a validated VAS ratings on sensation of hunger, satiety, fullness, prospective food consumption, desire to eat something fatty, salty, sweet or savoury, and palatability of the meals (Raben et al., 1995).

Subjects rated appetite profile sensations using a 10-cm scale ranging from 0 ("not at all") to 10 ("extremely") (19,20). This questionnaire was completed in twelve moments according to the previous described protocol.

The appetite was also controlled assessing the total food consumption in the ad libitum lunch offered in each visit such as detailed in the previous protocol (Fig. 1) using a weighed record. Researcher served a weighed homogeneous ad libitum lunch and subjects were given a self-served ad libitum lunch at each visit on the study day. The lunch consisted of bread and a Spanish omelette made with potatoes, onions and eggs, cooked in olive oil. Subjects were instructed to eat until pleasantly satiated. The staff at the study site weighed any remaining food, and total food consumption in the ad libitum lunch (g) was calculated.

Finally, two scores related with appetite profile was calculated: the composite appetite score (CAS = [satiety + fullness + (l00 - prospective food consumption) + (100 - hunger)] / 4) as a global measure of satiety (19), and the appetite score (AS = [desire to eat + hunger + (100 – fullness) + prospective food consumption] / 4) as a global measure of the motivation-to-eat (21).

COMPLIANCE VARIABLES

Participants were instructed to maintain their usual physical activity and food consumption pattern between visits. To control

this aspect, researchers given them a 72-h food record, a food frequency questionnaire and the "International Physical Activity Questionnaire" in the short format (18) to be completed 3 days prior to the next visit 7 days later. These questionnaires were given to the subjects at the end of the screening visit and at the end of visit 1 and visit 2 of the intervention study. In addition, blood pressure and heart rate measures and anthropometric variables (weight, height and waist circumference) also were controlled during the study. Weight was measured on a digital scale for clinical use (capacity, 0-150 kg) and height using a millimeter-precision stadiometer. Finally, the waist circumference was determined at the narrowest point between the last rib and the iliac crest, with the tape close to the skin, without compression.

STATISTICS METHODS

This being a pilot study, the sample size was chosen taking into account the study by Hess et al. 2011 (22).

The qualitative results have been expressed as absolute frequencies and percentages and the quantitative data as mean and standard deviation or median and quartiles. Before any statistical analyses, all variables were checked for normality using the Shapiro-Wilk test. To analyze the crossover study of the data, the area for each subject per treatment is calculated. In order to determine this, the tracking curve is parameterized with polygons and the total area is calculated as the sum of all the partial areas. To study areas and temporal evolution and rule out a cross effect or treatment period effect, a mixed variance model was fitted that included sequence, treatment and period. Post hoc multiple comparisons were performed to detect changes due to treatment at each time point and the Bonferroni correction was applied. Friedman's non-parametric analysis of variance was carried out for the study of the influence of time in each of the treatments. For the study of the influence of treatment, the Wilcoxon signed rank test were evaluated at each time. In both cases the Bonferroni correction is applied. All statistical tests were considered bilateral and, as significant values, those p less than 0.05. Data was analyzed with the statistical program SAS 9.4 (SAS Institute Inc., Cary, NC, USA) and SPSS 25.

RESULTS

A diagram based on the selection and crossover random assignment of the participants who were involved in the study is shown in figure 2. A total of 18 people were interested in participating; 6 people did not meet the selection criteria, a total of 12 met the selection criteria and were randomized to carry out the study. Throughout the clinical trial, no individual dropped out of the study. All participants completed testing according to protocol.

Baseline demographic, anthropometric characteristics of the healthy adult volunteers are shown in table II. No significant differences were found among the subjects included in each sequence of the yogurt consumption. Moreover, the participants maintained their dietary and physical activity patterns during the week prior to each visit without significant changes observed in the results obtained in the questionnaires used (data not shown).

The mean age of the population was 33.6 ± 10.7 years and the sample was homogeneously distributed, being 50 % female and 50 % male in each sequence. The mean BMI was 30.02 ± 1.5 kg/m^2, that is, the mean of the population presented grade I obesity and mean waist circumference was 92.2 ± 21.6 cm, indicating a slightly elevated cardiovascular risk (CCi > 90 cm). The mean blood pressure was normal, being within the normal range for the population (120/80 mmHg). According to the physical activity, 50 % of the participants performed low physical activity (< 60 min/day). All study volunteers also reported sitting for 6-7 hours per day.

Figure 3 presents mean values of appetite profile at specific time-points during the testing visit using the VAS questionnaire. After analyzing the results in the primary outcome, significant differences were observed for some items included in the appetite

Table II. Baseline demographic, anthropometric characteristics of the healthy adult volunteers according to randomization (XSD)

Characteristic	Total	Sequence 1 FEY/CY/PEY	Sequence 2 CY/PEY/FEY	Sequence 3* PEY/FEY/CY
Gender M/F (%)	6 (50)/6 (50)	2 (50)/2 (50)	2 (50)/2 (50)	2 (50)/2 (50)
Age (years)	33.6 ± 10.7	33.75 ± 12	29.7 ± 11.3	37.25 ± 10.4
BMI (kg/m^2)	30.02 ± 1.5	29.5 ± 1.14	30.5 ± 1.7	30.0 ± 1.8
Waist circumference (cm)	92.2 ± 21.6	96.2 ± 4.3	80.3 ± 34.5	100.1 ± 14.5
Blood pressure (mmHg)				
Diastolic pressure	68.42 ± 8.1	72.5 ± 11.3	69.2 ± 7.3	63.5 ± 2.1
Systolic pressure	103.4 ± 9.7	106.7 ± 11.1	104.7 ± 11.5	98.7 ± 6.4
Dietary energy intake (kcal/day)	1971.2 ± 473.7	1951.7 ± 405.1	1940.5 ± 603.8	2021.5 ± 473.7

**There were no significant differences among sequences in baseline characteristics.*

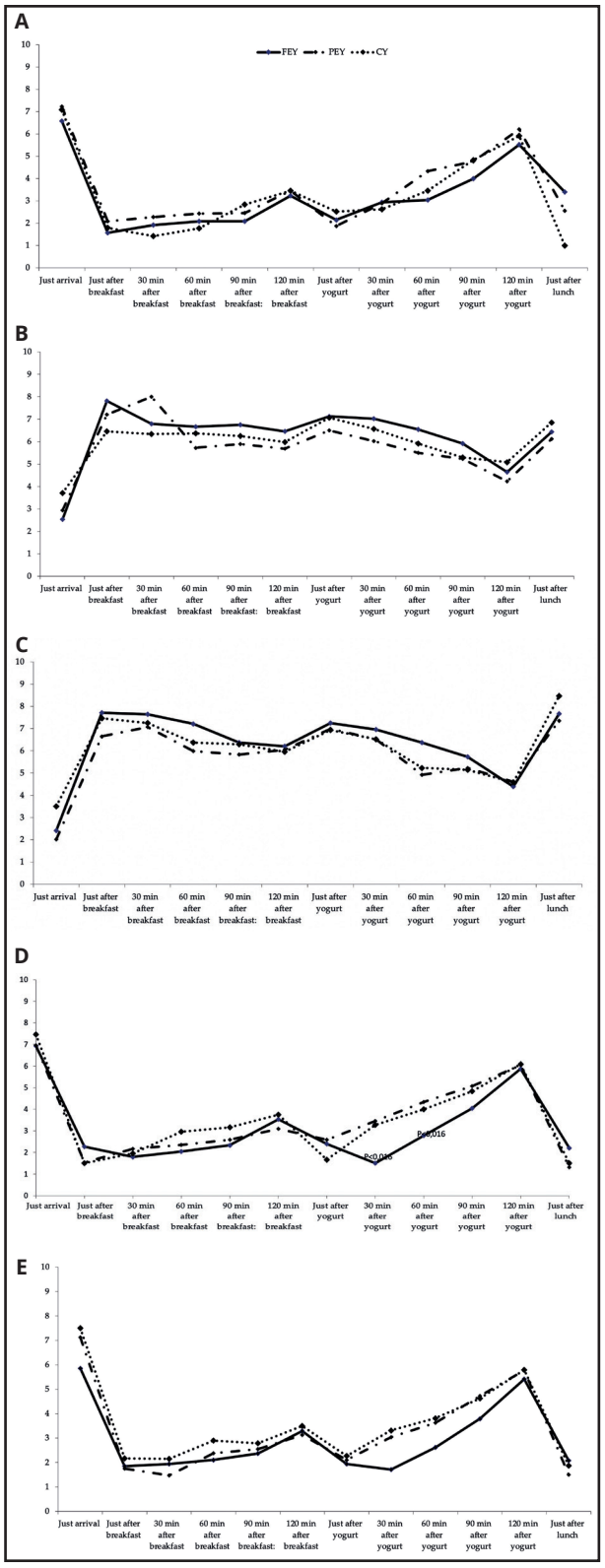

Figure 3.

VAS scores (0-10) for sensation of hunger (A), satiety (B), fullness (C), prospective food consumption (D) and desire to eat something fatty, salty, sweet or savoury, and palatability of the meals (E) after consumption of FEY, PEY and CY in differents moments in the acute study.

profile evaluation between the consumption of the different study products using the VAS questionnaire.

Concerning the hunger sensation, FEY consumption produced a lower hunger sensation than PEY and CY both at 30, 60 and 90 minutes after yogurt consumption. However, no significant differences were observed (Fig. 3A). Also, no significant differences were observed related to the sensation of satiety or fullness, however, FEY produced a greater sensation of satiety (Fig. 3B) and fullness (Fig. 3C) than PEY and CY both at time 30, 60 and 90 min after yogurt consumption.

Regarding question four of the VAS (prospective food consumption) (Fig. 3D), the participants presented a statistically significant lower desire to consume any food when they consumed FEY versus PEY and CY, both at 30 minutes after yogurt consumption (FEY: 1.50 ± 1.53; PEY: 3.46 ± 1.92; CY 3.27 ± 2.48, $p < 0.016$), and 60 minutes after yogurt consumption (FEY: 2.78 ± 1.50; PEY: 4.33 ± 1.95; CY: 4.00 ± 2.80, $p < 0.016$). The desire to consume any food was also lower at 90 minutes after FEY consumption versus PEY and CY, but in this moment, the difference was not significant.

Figure 3E presents the results of the VAS regarding desire to eat something fatty, salty, sweet or savoury. The consumption of the FEY showed a lower desire to eat something fatty, salty, sweet or savory at 30, 60, 90, and 120 minutes after yogurt consumption, compared to PEY and YC. Despite of this, the differences are not statistically significant.

According to the total food (Spanish omelette and bread) consumed ad libitum in the acute study visit, it was higher when participants consumed CY (313.67 ± 121.35 g) versus FEY (281.5 ± 92.40 g) and PEY (250.5 ± 100.86 g). However, these differences were not significant. Moreover, the correlation values of CAS just before ad libitum lunch time with total food ad libitum was inverse, both for the total sample and for each treatment (total sample: -0.09; FEY: -0.19; PEY: -0.06; CY: -0.22, non-significant). Therefore, higher satiety (higher CAS) corresponds to lower food consumption in the ad libitum meal. Regarding the association of AS just before ad libitum lunch time with ad libitum food intake, positive correlations were observed (total sample: 0.13; FEY: 0.31; PEY: 0.15; CY: 0.30, non-significant), meaning that higher motivation-to-eat leads to a greater amount of food consumed ad libitum. However, none of the correlations were significant.

DISCUSSION

The present study shows that the design of functional yogurts enriched with fiber, might have a positive effect on the modulation of appetite and specifically on prospective food consumption, aiming this as a strategy to induce a negative energy balance and therefore prevent obesity development and its consequences.

In a recent systematic review of 136 intervention studies (107 acute, 29 long-term) evaluating the effects of various fiber interventions on appetite (23), it has been found that these effects can differ according to the type of fiber used. Specifically, this

review concludes that only alginate and guar gum (viscous soluble fibers), as well as oat fiber (one of the fibers included in the FEY prototype of our study), predominantly showed positive results in improving appetite profiles in acute studies. This review also mentions that dextrin intake had positive effects on appetite control in chronic studies.

Several mechanisms have been described on how dietary fiber contributes to increasing the sensation of satiety and reduces energy intake (24). For viscous soluble dietary fibers (such as the β-glucan present in the oats of FEY), their physiological effects are primarily due to their water-holding capacity. This property directly increases the fiber's volume and viscosity, which may cause delayed gastric emptying, nutrient absorption and increased volume of gastrointestinal contents, thereby subsequently influence satiety (24,25).

Moreover, soluble fiber is fermented by bacteria in the colon producing short-chain fatty acids (SCFAs) (26), and altering the secretion of gut hormones to enhance satiety (27). These SCFAs play a crucial role in regulating appetite and satiety by stimulating specific receptors in the enteroendocrine cells of the intestine, triggering the release of appetite-regulating peptides such as peptide YY (PYY) and glucagon-like peptide 1 (GLP-1), thus enhancing the sensation of satiety (28).

In the case of the fiber in our FEY prototype, it is a mixed fiber. Therefore, our study design does not enable the assessment of the individual effects of each fiber type; instead, the observed effects are due to the combined action of all the fibers.

Regarding, fiber doses in which benefits are observed, Mah et al. (23) mention that positive effects on appetite profiles are seen with a dose of 2 g of alginate, > 3 g of guar gum, and 5 g of oat fiber. In our clinical trial, the FEY included a total of 10.75 g per serving (8.6 g/100 g) from the addition of inulin, whole oats, whole rye bran, and poppy seeds. Hence, FEY is a mixture of soluble and insoluble fibers.

On the other hand, Mah et al. (23) reported that most acute studies assess appetite using VAS within a range of 2 to 4 hours post-consumption of the product. In our study, we evaluated the appetite profile during the 2 hours following the consumption of the assigned prototype, making the design suitable for our purposes. Nonetheless, including a longer evaluation period could be of interest to assess the effect over a longer-term.

In regards to the considerable variability found, Mah et al. conclude that, unfortunately, the current evidence to date is not consolidated, and is highly varied due to the many differences in methodology employed for evaluating the effects on appetite (type of fiber, dose used, and evaluation times) (23). Consequently, the effects of individual fibers on satiety may not be predictable and requires testing (29).

Our study contributes to enhance the knowledge on the effects of prototype that include fiber mixtures on appetite profile. In fact, when evaluating prospective food consumption, a decrease in VAS ratings was observed in the participants who consumed FEY, being this a statistically significant difference, although this was not accompanied by a significant reduction in the ad libitum lunch. Moreover, associations between higher global satiety score with lower food consumption in the ad libitum meal and a higher global motivation-to-eat score leads to a greater amount of food consumed ad libitum were observed in total sample, and with FEY, PEY and CY; however, these effects were not companied by a significant reduction or increase in food intake at the ad libitum lunch respectively. This often occurs because food cannot be expected to act like a drug (30). Indeed, other authors have described that increased ratings of satiety and fullness were not companied by a decrease in subsequent energy intake. These findings were likely because of other physiologic effects as well as psychological and environmental factors that influence food intake (17).

Related to the protein intake, in a recent systematic review and meta-analysis of 68 clinical trials (49 acute studies and 19 long-term studies) conducted by Kohanmoo et al., found that acute interventions, in which appetite was assessed during the hours following protein consumption, showed a decrease in appetite, a reduction in ghrelin, and an increase in CCK and GLP-1. However, there are still numerous limitations for long-term effects (31).

Acute trials assessed the effect of proteins on appetite shortly after consumption (< 5.5 hours, with a minimum evaluation time mostly at 3 hours), whereas in long-term trials, the intervention period ranged from 3 days to 9 months. The protein supplementation range used in the studies was within 8.5-130 g per day. Finally, regarding the type of protein, Kohanmoo et al. also found significant variability, with whey protein being the most studied among other animal-based proteins (casein, milk, yogurt, beef, turkey, and egg) or plant-based proteins (soy, wheat, gluten, pea), or products containing protein blends (31).

In the present acute study, no differences were observed concerning the appetite profile after the consumption of PEY compared to the other prototypes. These findings could be due to several reasons: evaluation time of the appetite profile, protein doses, type of protein, food matrix, the characteristic of the study sample, among others. On one hand, the evaluation time of the appetite profile using the VAS after yogurt consumption in our study was 120 minutes, which is shorter than the minimum time used in most acute studies reviewed by Kohanmoo et al. (> 3 hours). It is possible that a longer time duration may be required to observe the effects of protein consumption. On the other hand, the protein dose consumed with the 125 g of PEY was 4.63 g/serving (3.7 g/100 g). This dose was lower than the range used in the trials included in the review by Kohanmoon et al. (8.5 to 130 g/day) (27). The dose used in PEY was low primarily because pea protein can cause changes in organoleptic perception, such as an increase in bitter and astringent flavors (32). In fact, the product was designed on a Greek yogurt base to improve the sensory perception of the product by the consumer. Despite this drawback, pea protein was chosen as functional ingredient for PEY because, in recent years, plant-based proteins have gained attention as a better option compared to animal proteins among consumers seeking for more sustainable foods and for health reasons. Moreover, it is a high-quality protein with easy availability and low allergenicity. Recent studies also highlight its solubility, water and oil retention capacity, emulsifying

abilities, gelling properties, and viscosity. Likewise, it has been noted to have a greater satiating power than other types of proteins (whey protein, maltodextrin) (33). The appetite-suppressing effects of peas may be related to high amounts of protein which may delay gastric emptying, attenuate glucose absorption and concentration and stimulate the release of appetite-regulating hormones (27,33). In this context, certain effects are related to smaller peptides formed during protein fermentation. These peptides are linked to the production of appetite-regulating hormones, as well as involved in slowing gastric emptying, thereby prolonging the sensation of fullness after meals. (14). Therefore, many companies seek to leverage these characteristics to design functional foods.

In the context of the food matrix, yogurt per se, is a satiating food that may favorably influence energy balance and body composition (34). Zemel et al, reported in a 1-year intervention, the most consistent evidence to demonstrate that yogurt can favorably influence weight control, during which, African American participants consumed 1 serving of yogurt per day showing an average loss of fat body weight of 4.9 kg (35). Chapelot and Payen studied the effects of isocaloric portions of liquid yogurt and chocolate bars on appetite sensations (36). Their results showed that yogurt consumption resulted in a more pronounced effect on hunger, the desire to eat, and feelings of fullness. Although, these appetite sensations were not accompanied by significant delays in requesting the next meal or a reduction in ad libitum energy intake at the subsequent meal (36). Additionally, the flexibility of yogurt structure allows it to accommodate supplementation of ingredients, for example, fibers, proteins, bacterias that also have the potential to promote negative energy balance (34). Therefore, using yogurt as a study source seems to be a very good option in satiety studies, but also a great snacking option for in between meals.

Consequently, more interventional studies are needed, but also future research in the line of satiating products with proteins should take into consideration to use higher doses than those used in this work.

The main strength of the present study is the well-conducted acute clinical trial with a good design based on the EFSA recommendations. However, a limitation that must be considered when interpreting the results of the present study is the sex of the participants. Although sex was considered in the randomization procedure, the study was not designed to determine sex differences. Nevertheless, other studies have reported differences in the biological response to meal ingestion or appetitive responses and food intake, due to the phase of the menstrual cycle. In the present study did not determine the menstrual phase of the female participants which also may have masked an effect on our outcome measures. Future studies that are powered to identify sex differences, that use carefully developed inclusion/exclusion criteria that are chosen with thought to their sex and gender impact, and control for the phase of the menstrual cycle, should be conducted to robustly determine sex gender effects of this type of intervention (37). Other limitation was that the fat content in PEY was higher than in the other yogurts. Pea protein its richness in amino acids with a variety of bioactivities that can enhance saltiness, umami, and kokumi (38). Nonetheless, the practical application of pea protein and its hydrolysates in food industry are limited due to their poor sensory perception, such as undesirable green and beany flavor, or the bitterness and astringency (30). The company decided to use a Greek yogurt that contains a little more of fat to mask the taste. Another limitation is that in the present article hormonal parameters are not presented to confirm the effects on appetite control, however these results will be analyzed in a future article. Therefore, the results should be interpreted with caution.

CONCLUSIONS

The results of the present study suggest that a yogurt enriched in fiber might be a good prototype functional food to control appetite and reduce total consumption in overweight and obese people. Therefore, these foods might be integrated as an alternative functional food within a hypocaloric weight control diet. Despite this, it is necessary to carry out more studies that explore the effects on biochemical variables and carry out long-term interventions to be able to gain more insight into the impact of these products on body weight control and their function in the appetite profile.

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ARÁN

Nutrición Hospitalaria

Trabajo Original

Obesidad y síndrome metabólico

Cambios en el peso, la composición corporal, los parámetros metabólicos y la vitamina D en sujetos con obesidad de grado 3 y 4 tratados con liraglutida 3 mg

Changes in weight, body composition, metabolic parameters and vitamin D in subjects with grade 3 and 4 obesity treated with liraglutide 3 mg

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Resumen

Introducción: la obesidad de grado 3 y 4 es una enfermedad crónica y progresiva. La liraglutida a dosis de 3 mg podría ser una terapia adyuvante eficaz en estos sujetos.

Objetivos: evaluar los cambios en la pérdida de peso, la composición corporal, los parámetros metabólicos y los niveles de vitamina D en sujetos con obesidad de grado 3 y 4 tratados 8 meses con liraglutida 3 mg.

Métodos: a 67 sujetos con IMC ≥ 40 kg/m^2 se les determinaron los parámetros antropométricos, de composición corporal y metabólicos, así como los niveles de vitamina D basales y tras 8 meses de tratamiento con liraglutida 3 mg.

Resultados: se evidenció una reducción significativa del peso, el IMC y la circunferencia abdominal tras 8 meses de tratamiento con liraglutida ($p < 0,001$), con un porcentaje de pérdida de peso medio del 13,04 % y una media de pérdida de peso de 14,99 kg al finalizar la intervención. Los datos de la composición corporal final mostraron una mejoría significativa del porcentaje de grasa y masa grasa (kg) ($p < 0,001$). La pérdida media de masa muscular fue de 2,02 kg ($p = 0,213$). El índice de grasa visceral (IGV) saludable (< 13) aumentó hasta el 67,17 % ($p < 0,001$) a los 8 meses. Hubo una reducción significativa de la presión arterial ($p < 0,001$) y una mejoría de las variables bioquímicas estudiadas. Hubo un incremento significativo de la 25-OH-vitamina D ($p < 0,001$) al finalizar la intervención.

Conclusiones: el tratamiento con liraglutida fue seguro y eficaz en los pacientes con obesidad, con impacto positivo en la pérdida de peso, los niveles de vitamina D y otros factores de riesgo cardiovascular.

Palabras clave:

Obesidad. Composición corporal. Liraglutida. Vitamina D.

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Confirmamos que el manuscrito ha sido leído y aprobado por todos los autores nombrados y que no hay otras personas que cumplan con los criterios de autoría pero que no figuran en la lista.

Cumplimiento de normas éticas: todos los involucrados en estudios realizados con participantes humanos estuvieron de acuerdo con los estándares éticos del comité de investigación institucional y/o nacional y la declaración de Helsinki de 1964 y sus enmiendas posteriores o estándares éticos comparables.

Todos los participantes incluidos en el estudio entendieron la información relacionada con el estudio, entendieron y firmaron un consentimiento informado por escrito.

Contribuciones de los autores: J. B. escribió el manuscrito, recogió y analizó los datos y dio la aprobación final a la versión. J. N. contribuyó a la discusión, revisó el manuscrito y dio la aprobación final a la versión.

Conflicto de interés: los autores declaran no tener conflicto de interés.

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Abstract

Introduction: grade 3 and 4 obesity is a chronic and progressive disease. Liraglutide 3 mg could be an effective adjuvant therapy in these subjects.

Objectives: to evaluate changes in weight loss, body composition, metabolic parameters and vitamin D levels in subjects with grade 3 and 4 obesity treated for 8 months with liraglutide 3 mg.

Methods: a total of 67 subjects with a BMI ≥ 40 kg/m^2 had anthropometric parameters, body composition, metabolic parameters and vitamin D levels determined at baseline and after 8 months of treatment with liraglutide 3 mg.

Results: a significant reduction in weight, BMI and abdominal circumference was evident after 8 months of treatment with liraglutide ($p < 0.001$), with a mean percentage of weight loss of 13.04 % and a mean weight loss of 14.99 kg at the end of the intervention. The final body composition data showed a significant improvement in the percentage of fat and fat mass (kg) ($p < 0.001$). The average loss of muscle mass was 2.02 kg ($p = 0.213$). The healthy visceral fat index (VGI) (< 13) increased to 67.17 % ($p < 0.001$) at 8 months. There was a significant reduction in blood pressure ($p < 0.001$) and an improvement in the biochemical variables studied. There was a significant increase in 25-OH vitamin D ($p < 0.001$) at the end of the intervention.

Conclusions: Treatment with liraglutide was safe and effective in patients with obesity with a positive impact on weight loss, vitamin D levels and other cardiovascular risk factors.

Keywords:

Obesity. Body composition. Liraglutide. Vitamin D.

INTRODUCCIÓN

La obesidad es una enfermedad crónica, progresiva y recurrente. Se asocia a una serie de alteraciones como la resistencia a la insulina y un riesgo cardiovascular elevado. Es la enfermedad endocrino-metabólica más frecuente y en el siglo actual tenemos una creciente epidemia mundial de obesidad (1-4) que mata cada año a 2,8 millones de personas según la Organización Mundial de la Salud (OMS) (5). Actualmente hay más de 670 millones de personas con obesidad. Estimaciones futuras plantean que cerca de mil millones de personas sufrirán obesidad para el año 2030 (6).

La obesidad como enfermedad produce un gran impacto en la salud en general y deterioro de la salud metabólica en particular. Los estudios epidemiológicos a gran escala han demostrado que la mortalidad por todas las causas aumenta de forma lineal a medida que aumenta el exceso de grasa corporal, debido fundamentalmente a las enfermedades cardiovasculares (ECV) y el cáncer. La reducción del exceso de peso se ha mostrado claramente eficaz para reducir estas complicaciones (7). La modificación de los patrones de alimentación y del estilo de vida sigue siendo la piedra angular de la estrategia para perder peso, pero con determinados grados de obesidad es insuficiente para alcanzar los objetivos deseados. Con el descubrimiento de nuevos fármacos antiobesidad (FAO) seguros y eficaces, como los agonistas del receptor del péptido-1 similar al glucagón (AR GLP-1), el futuro del tratamiento de la obesidad como enfermedad pasa por la terapia conductual (dieta y estilo de vida saludable), los fármacos antiobesidad y la cirugía bariátrica (8). Los ensayos SCALE demostraron que el tratamiento con 3 mg de liraglutida en personas con obesidad fue eficaz para reducir el peso corporal. Una pérdida ponderal del 5 al 15 % en un período de 6 a 12 meses en personas con obesidad es un objetivo realista y alcanzable, que se traduce en un menor riesgo asociado a la obesidad y en beneficios comprobados para la salud tanto física como mental (9). La tendencia de la pandemia de obesidad condiciona una mayor incidencia de formas más graves de esta enfermedad y a edades cada vez más tempranas. La obesidad de grado 3 y la obesidad de grado 4, que se definen según el consenso de la Sociedad Española para el Estudio de la Obesidad por un IMC ≥ 40 kg/m^2 y ≥ 50 kg/m^2, respectivamente (10), se caracterizan por tener un exceso de tejido adiposo, en particular de tejido adiposo visceral (TAV), con serias consecuencias sobre la salud (11), además del incremento del gasto sanitario. Aproximadamente, 400 000 personas en España tienen obesidad grado 3 o 4 (20), siendo más prevalente en mujeres y en la franja de edad de 55 a 60 años (12,13). A día de hoy, la cirugía bariátrica es el tratamiento más efectivo cuando el IMC es igual o superior a 40 kg/m^2, ya que comporta una pérdida de peso significativa y sostenida, y una mejora de las comorbilidades relacionadas y la calidad de vida. Sin embargo, la cirugía bariátrica no está exenta de ciertos riesgos, ni es accesible a todos aquellos que la necesitan, especialmente tras la pandemia de COVID, donde las listas de espera quirúrgicas para esta intervención han aumentado de forma significativa.

Los objetivos de este estudio fueron evaluar los cambios que genera una intervención durante 8 meses con liraglutida 3 mg en la pérdida de peso, la composición corporal, los parámetros metabólicos y los niveles en sangre de vitamina D en sujetos con obesidad de grado 3 y 4.

MATERIAL Y MÉTODOS

SUJETOS

Se incluyeron 67 pacientes de forma consecutiva que cumplían los siguientes criterios de inclusión: un IMC ≥ 40 kg/m^2; no tener diagnóstico de diabetes; haber estado bajo tratamiento con liraglutida 3 mg durante un período de 8 meses; disponer de un seguimiento con parámetros antropométricos y de composición corporal, y determinaciones analíticas al inicio y al final de la intervención.

Este estudio se realizó según la Declaración de Helsinki (14). Los sujetos participantes rellenaron un consentimiento informado y lo firmaron.

ANÁLISIS ANTROPOMÉTRICO

Las medidas antropométricas de peso, talla y circunferencia abdominal (CA) se registraron con instrumentos calibrados de

acuerdo con un protocolo estandarizado. El peso corporal (kg) y la talla (m) se midieron usando una báscula (Seca 711, SECA Deutschland, Hamburgo, Alemania) con tallímetro. La CA (cm) se midió después de una espiración normal, tomando como referencia el punto medio entre la última costilla y la cresta iliaca según el criterio de la OMS (15). Se tomaron dos medidas antropométricas y en todas ellas el paciente estaba en ropa interior y descalzo. El peso y la talla se utilizaron para calcular el IMC, expresado en kg/m^2 (16). Para la determinación del porcentaje de masa grasa (MG) y masa libre de grasa (MLG) se realizó el análisis de la composición corporal mediante bioimpedancia eléctrica con un equipo bicompartimental (TANITA 420-MA, Biológica Tecnología Médica SL, Tokio, Japón) (17). El índice de grasa visceral (IGV) y el porcentaje de agua corporal total (ACT) también se calcularon mediante el equipo bicompartimental TANITA. Para ello se concertó una cita a fin de que los participantes cumplieran las recomendaciones necesarias para un correcto análisis (es decir, no comer alimentos 3 horas antes de la medición; no beber nada 30 minutos antes; no realizar deporte o actividad física moderada o intensa 12 horas antes; no beber café, té, coca cola o cualquier otra bebida estimulante o energética 4 horas antes; no ingerir bebidas alcohólicas 24 horas antes; no fumar 30 minutos antes; y comunicar si tomaba algún fármaco que pudiera causar retención de líquidos (17).

Se precisó también el tabaquismo (fumador, exfumador o no fuma) y se determinó el nivel de actividad física según la duración de la práctica de ejercicios físicos (*jogging,* caminar a ritmo rápido, baile, aeróbicos y jardinería): regular (150 minutos a la semana o 30 minutos día), escasa (< 150 minutos a la semana o < 30 minutos día) y no práctica, según el cuestionario MEDLIFE (MEDIterranean LIFEstyle Index) (18).

DETERMINACIÓN DE LA TENSIÓN ARTERIAL

Se registraron tres mediciones de la tensión arterial con esfigmomanómetro aneroide (Welch Allyn DS45, Nueva York, Estados Unidos) en el brazo derecho después de 5 minutos de estar en reposo y en posición sentado. En el presente análisis se utilizó el promedio de la segunda y la tercera medición.

PARÁMETROS BIOQUÍMICOS

Se extrajeron muestras de sangre para la determinación de la glucosa en ayunas, colesterol total, colesterol HDL, colesterol LDL, triglicéridos y 25-OH vitamina D. Todas las medidas se tomaron después de un ayuno nocturno (al menos 8 h de ayuno). Se calcularon los índices aterogénicos basado en la relación colesterol total/c-HDL y triglicéridos/c-HDL.

PARÁMETROS SOCIODEMOGRÁFICOS Y CLÍNICOS

Se registró si los pacientes recibieron lactancia materna, tenían obesidad en la infancia, el tiempo de evolución de la enfermedad y si tenían antecedentes familiares de obesidad y de diabetes *mellitus* de tipo 2 (DM2). Se registró el nivel de estudios y el estado civil, así como la situación laboral.

INTERVENCIÓN

El plan nutricional incluyó una dieta cuantitativa estructurada y personalizada, según la preferencia de los pacientes, con una reducción promedio de 500 kcal/día de la tasa metabólica inicial calculada, ajustada por la actividad física. Además, también se prescribió un mínimo de 150 minutos de ejercicio por semana.

Respecto a la titulación de liraglutida, los pacientes iniciaron con una dosis de 0,6 mg/día durante la primera semana, aumentaron a 1,2 mg/día la segunda semana, a 1,8 mg/día la tercera semana, a 2,4 mg/día la cuarta semana y hasta 3 mg/día a partir de la quinta semana. Cuando dejó de tolerarse debido a efectos secundarios gastrointestinales, la dosis se redujo nuevamente al régimen anterior.

ANÁLISIS ESTADÍSTICO

Los datos se analizaron con el SPSS 25.0 (SPSSInc., Il EE. UU). Se calcularon la media y la desviación estándar (DE) de las variables sociodemográficas estudiadas. Se utilizó la prueba de la t de Student para comparar las medias de las variables estudiadas antes y después del tratamiento. Los valores de p inferiores a 0,05 indican una diferencia significativa entre las dos medidas. Para encontrar posibles relaciones por la pérdida de IMC realizamos una regresión lineal múltiple donde la variable respuesta es la diferencia entre el IMC final y el IMC basal (ΔIMC = IMC2 - IMC1).

RESULTADOS

De los 67 pacientes incluidos en el estudio, el 79,1 % (53/67) eran mujeres. La edad media fue de 46,76 años. El 85,07 % de los sujetos estudiados tenían más de 15 años de evolución de la obesidad, un 88,06 % declararon antecedentes familiares de obesidad y el 62,69 % tenían antecedentes familiares de DM2. Por otra parte, el 77,61 % no realizaban ejercicio físico regular, en el 19,4 % dicho ejercicio era escaso y solo el 2,99 % de los pacientes tenían una práctica de ejercicio regular. Con respecto a los hábitos tóxicos, solo el 11,84 % de los sujetos declararon fumar. En cuanto al estado civil, solo un 5,97 % de los sujetos incluidos tenían pareja estable. Estos resultados están representados en la tabla I.

Tal y como se muestra especificado en la tabla II, en relación a los datos antropométricos, tanto el peso como la CA y el IMC mejoraron de forma significativa tras 8 meses de tratamiento con liraglutida ($p < 0,001$). Se objetivó un porcentaje de pérdida de peso (PP%) de un 13,04 % y una media de pérdida de peso (PP) de 14,99 kg.

[Nutr Hosp 2024;41(5):1003-1009]

Tabla I. Características sociodemográficas y antecedentes de obesidad de los sujetos participantes en el estudio

	Sujetos (*n* = 67)
Edad (media y DE)	46,76 ± 13,37
Sexo	
Mujeres	53 (79,10 %)
Hombres	14 (20,90 %)
Estado civil	
Soltero	37 (55,22 %)
Casado	4 (5,97 %)
Divorciado/viudo	26 (38,81 %)
Profesión	
Cualificada	49 (73,13 %)
No cualificada	18 (26,87 %)
Nivel educativo	
Universitario	6 (8,96 %)
Técnico	35 (52,24 %)
Estudios básicos o sin estudios	26 (38,81 %)
AFO	
Sí	59 (88,06 %)
No	8 (11,94 %)
AFDM2	
Sí	42 (62,69 %)
No	25 (37,31 %)
Obesidad en la infancia	
Sí	32 (47,76 %)
No	35 (52,24 %)
Lactancia materna	
Sí	38 (56,72 %)
No	29 (43,28 %)
Tiempo de evolución de la obesidad	
< 5 años	0
5-15 años	10 (14,93 %)
> 15 años	57 (85,07 %)
Actividad física	
Regular	2 (2,99 %)
Escasa	13 (19,40 %)
No práctica	52 (77, 61 %)
Tabaquismo	
Fuma	8 (11,94 %)
Exfumadora	4 (5,97 %)
No fuma	55 (82,09 %)

Los datos se representan como media ± DE o porcentajes (%). AFO: antecedentes familiares de obesidad; OM: obesidad mórbida; OE: obesidad extrema; AFDM2: antecedentes familiares de diabetes de tipo 2.

Al analizar los datos de composición corporal obtenidos al inicio y final de la intervención se demostró una reducción significativa ($p < 0,001$) con la MG (% y kg), la MLG (%) y el ACT (%). Sin embargo, al analizar la masa muscular no se evidenció una pérdida significativa tras el tratamiento con liraglutida. Por otra parte, el IGV saludable, que al inicio del estudio se presentaba en solo un 5,7 % de los pacientes, aumentó significativamente y mostró una mejoría significativa ($p < 0,001$) al final de la intervención, lográndose en el 67,17 % de los pacientes. También las cifras de tensión arterial sistólica y diastólica se redujeron de forma significativa ($p < 0,001$) al final de la intervención.

En relación a los parámetros bioquímicos, se observó una tendencia a la mejoría, aunque sin alcanzar la significancia estadística. Por otra parte, se observó un aumento significativo ($p < 0,001$) de los niveles de 25-OH vitamina D al comparar los valores al inicio y final del estudio. Estos datos están representados en la tabla II.

Con el fin de buscar posibles relaciones con la pérdida de peso, realizamos una regresión lineal múltiple donde la variable de respuesta era la diferencia entre el IMC final y el IMC basal (ΔIMC = IMC2 - IMC1). El mejor modelo de regresión indicaba una excelente relación lineal entre ΔIMC y PP%, ΔMLG y Δc-HDL (Ad R2 = 0,887, $p < 0,001$) (Tabla III).

Tal y como se muestra en la tabla IV, se puede observar cómo el PP% fue la más relevante entre las variables explicativas (estimación estándar, -0,97), explicando por sí mismo el 87 % (R = 0,935) de la varianza del modelo.

DISCUSIÓN

El tratamiento de la obesidad, en especial cuando el IMC es superior a 40 kg/m^2, representa un difícil desafío que los profesionales han de afrontar, no solo por la creciente prevalencia sino también por la dificultad para lograr su remisión a largo plazo. Entre las principales dianas destacan, por un lado, mantener al paciente metabólicamente saludable, disminuyendo en lo posible el riesgo cardiometabólico, previniendo o tratando las complicaciones si ya están presentes, y el otro, restaurar la calidad de vida mermada y mejorar el estado funcional y la autoestima. La meta a conseguir, de un 15 % de reducción del peso, debe ser uno de los propósitos del profesional, recomendando todas las estrategias terapéuticas disponibles en nuestras manos, como ocurre en otras enfermedades crónicas regidas por parámetros de control. Además del peso como variable de control principal, es importante también tener en cuenta los objetivos de los cambios de estilo de vida, la mejoría de la composición corporal y la reducción del perímetro de la cintura.

El uso de fármacos antiobesidad tiene efectos beneficiosos sobre el peso y la composición corporal. Los estudios SCALE valoraron la pérdida de peso en sujetos con obesidad y sin diabetes, aunque con un IMC ≤ 40 kg/m^2 (19). En nuestro estudio se incluyeron pacientes con obesidad y un IMC ≥ 40 kg/m^2, y se observó una considerable reducción del peso corporal (kg) y el IMC (kg/m^2), y también una disminución significativa de la CA (cm) con un PP% de alrededor del 13 %.

Tabla II. Evolución de los parámetros antropométricos, de composición corporal y bioquímicos antes y después del tratamiento con liraglutida 3 mg durante 8 meses

	Basal media ± DE	Después de la intervención media ± DE	*p*
Medidas antropométricas			
Peso (kg)	115,43 ± 17,47	100,44 ± 16,56	< 0,001
Talla (m)	1,61 ± 0,09	1,61 ± 0,09	
CA (cm)	125,12 ± 11,22	113,78 ± 11,40	< 0,001
IMC (kg/m^2)	44,25 ± 4,53	38,47 ± 4,40	< 0,001
Valoración de la pérdida de peso			
PP (kg)		14,99 ± 5,33	< 0,001
PP (%)		13,04 ± 4,09	< 0,001
Composición corporal			
MG (%)	46,64 ± 4,54	41,24 ± 4,97	< 0,001
MG (kg)	52,42 ± 8,84	41,72 ± 8,39	< 0,001
MLG (%)	53,42 ± 4,53	58,57 ± 5,09	< 0,001
MM (kg)	57,10 ± 9,20	55,08 ± 9,32	0,213
ACT (%)	39,46 ± 3,73	42,18 ± 4,05	< 0,001
IVG saludable > 13 (n, %)	4 (5,7 %)	45 (67,17 %)	< 0,001
IVG alto ≥ 13 (n, %)	63 (94,3 %)	22 (32,83 %)	< 0,001
Tensión arterial			
Sistólica (mmHg)	141,97 ± 20,19	133,20 ± 11,34	0,002
Diastólica (mmHg)	92,10 ± 10,43	86,54 ± 7,14	< 0,001
Parámetros bioquímicos			
Glucosa en ayunas (mg/dL)	101,91 ± 22,13	96,94 ± 18,73	0,152
Colesterol total (mg/dL)	201,88 ± 39,46	192,13 ± 33,23	0,115
c-HDL (mg/dL)	46,11 ± 12,74	46,87 ± 10,87	0,695
c-LDL (mg/dL)	131,71 ± 36,07	124,46 ± 31,85	0,176
Triglicéridos (mg/dL)	137,88 ± 87,91	125,22 ± 63,35	0,328
Colesterol total / c-HDL	4,68 ± 1,57	4,28 ± 1,24	0,104
Triglicéridos / c-HDL	3,35 ± 2,79	2,92 ± 1,94	0,302
Vitamina D (ng/mL)	16,70 ± 5,56	24,08 ± 5,16	< 0,001

Los datos se representan como media ± DE o porcentajes (%). IMC: índice de masa corporal; CA: circunferencia abdominal; PP (%): porcentaje de pérdida de peso; PP (kg): pérdida de peso en kilogramos; MG: masa grasa; MLG: masa libre de grasa; MM: masa muscular; ACT: agua corporal total; IGV: índice de grasa visceral; c-HDL: colesterol de lipoproteínas de alta densidad; c-LDL: colesterol de lipoproteínas de baja densidad.

Tabla III. Modelo de regresión lineal

				Pruebas del modelo general			
Modelo	**R**	**R²**	**R² ajustado**	**F**	**Df1**	**Df2**	***p***
1	0,945	0,893	0,887	172	3	62	< 0,001

Tabla IV. Variables del modelo de regresión lineal

Predictor	Estimado	EE	t	*p*	Estimado estándar
Intercept	0,0533	0,2887	0,185	0,854	
% PP	-0,4789	0,0247	-19,412	< 0,001	-0,9682
MLG2-MLG1 %	0,0877	0,0376	2,330	0,023	0,1133
C-HDL2-C-HDL1	-0,0530	0,0235	-2,258	0,027	-0,0974

Esta pérdida de peso fue principalmente resultado de una importante reducción de la masa grasa. La liraglutida a dosis de 3 mg, inyectada una vez al día por vía subcutánea, demostró inducir una reducción significativa del peso corporal a expensas principalmente de la masa grasa total y la masa grasa visceral, con una pérdida de peso significativa a lo largo de todo el estudio (± 15 kg), y solo hubo una discreta disminución no significativa de la masa muscular (2 kg). El mantenimiento de la MM y su funcionalidad tiene una destacable importancia para prevenir la recuperación ponderal tras la intervención. El estudio de los efectos sobre la composición corporal a medio y largo plazo es importante a la hora de decidir qué tratamiento indicar a un paciente con obesidad, en particular cuando el IMC es superior a 40 kg/m^2. Existen estudios que demuestran que la liraglutida es efectiva y segura en el tratamiento de pérdida de peso de los sujetos con obesidad, pero existe poca información sobre la modificación de la composición corporal para poder valorar objetivamente cómo influye este tratamiento en los diferentes compartimentos del cuerpo humano (20).

En relación a la masa magra y la probabilidad de que los sujetos con IMC superior a 40 kg/m^2 se sometan a cirugía bariátrica, se ha visto que, independientemente de la técnica quirúrgica realizada, se puede producir una rápida pérdida de peso que incluya una disminución de la masa magra superior al 20 %, con el impacto negativo que pueda generar esta pérdida a corto plazo, así como en la recuperación ponderal posintervención (21-23). Por tanto, es imprescindible el abordaje nutricional con la finalidad de preservar dicha masa muscular. Conservar la masa magra en un tratamiento de pérdida de peso se ha convertido en un objetivo indispensable para evitar la recuperación del peso, mejorar el estado de insulinorresistencia, producido no solo por el depósito de grasa a nivel del hígado sino también por el depósito de grasa a nivel del compartimento muscular (mioesteatosis), y por tanto evitar un deterioro de la salud metabólica que favorece el desarrollo de la enfermedad del hígado graso asociado al metabolismo, la DM2, la enfermedad cardiovascular, las neoplasias y las enfermedades neurodegenerativas (22-24). En nuestro estudio se demostró una mínima pérdida de masa muscular no significativa al final de la intervención, dato destacable si finalmente los sujetos estudiados deciden someterse a la cirugía bariátrica.

Como han demostrado otros estudios realizados con liraglutida en personas con obesidad (25), además de la pérdida de peso, en nuestro estudio se observó también una disminución significativa en las cifras de tensión arterial sistólica y diastólica y de los niveles de glucosa en ayunas, así como también una mejoría del perfil lipídico (26).

En relación a la vitamina D, se observó un incremento significativo de sus niveles séricos al final de la intervención. La deficiencia de vitamina D se ha convertido en una pandemia global que afecta al género humano en su totalidad y a los sujetos con obesidad en particular, provocando un gran impacto en la salud de los individuos con dicho déficit. De hecho, existe una relación inversa entre el contenido de grasa corporal y los niveles séricos de 25OHD (27), tal y como se demostró en este estudio. Vimeswaran et al., han demostrado que un IMC más alto conduce a niveles más bajos de vitamina D, y los efectos de 25OHD en el IMC probablemente sean pequeños (28). Podemos afirmar también que la vitamina D es más baja en las personas con obesidad que en los sujetos sin obesidad. Esto se debe más a un modelo volumétrico dilucional que a un problema de síntesis cutánea, exposición al sol o ingesta dietética deficiente. La $1,25(OH)_2$-D es una vitamina liposoluble y se distribuye por el tejido adiposo y muscular, el hígado y el suero. Todos estos compartimentos aumentan de volumen en la obesidad, por lo que los niveles séricos más bajos de estos sujetos probablemente reflejen un efecto de dilución volumétrica mientras que las reservas corporales en el tejido graso de vitamina D pueden ser adecuadas (29). A pesar de menores niveles de 25OH vitamina D, los adultos con obesidad no tienen mayor recambio óseo ni menor densidad mineral ósea (DMO). Cabe destacar que los pacientes sometidos a cirugía bariátrica tienen niveles bajos de vitamina D, pero también disminución de sus reservas, por lo que tienen pérdida ósea y disminución de la DMO después de la cirugía. Estos cambios importantes en el metabolismo óseo llevan a un aumento del riesgo de fracturas. La evaluación del riesgo de fracturas debe formar parte de la evaluación del paciente que se va a someter a cirugía bariátrica (30). Sin embargo, todavía no está claro que la suplementación con vitamina D muestre beneficios sobre el perfil metabólico adverso de las personas que conviven con la obesidad (29). Por otra parte, en nuestro trabajo, este incremento de la vitamina D se debió fundamentalmente a la disminución de la masa grasa generada por la pérdida de peso que se produjo con el tratamiento con liraglutida.

Sabemos que nuestro estudio tiene limitaciones. En España, los tratamientos contra la obesidad no son reembolsados por el sistema nacional de salud y, por tanto, las personas que acuden a una clínica de adelgazamiento pueden tener un estatus sociocultural más alto y dar lugar a un sesgo de selección. Sin embargo, aportamos datos, no solo antropométricos sino de composición corporal, del efecto de la liraglutida a dosis de

3 mg en pacientes con un IMC superior a 40 kg/m^2, grupo de población poco representado en los ensayos clínicos. Nuestro estudio muestra la eficacia y la seguridad de la liraglutida en los pacientes con IMC superior a 40 kg/m^2, y podría plantearse una alternativa beneficiosa en cuanto a una pérdida ponderal significativa y la adopción de hábitos de vida saludables en espera de una cirugía bariátrica, especialmente desde que las listas de espera de este tipo de cirugías se han incrementado desde la pandemia de COVID.

Los efectos adversos considerados "muy frecuentes" que se presentaron durante los 8 meses de tratamiento con liraglutida fueron náuseas, estreñimiento, cansancio y, con menor frecuencia, eructos, diarrea y gases. Dichos efectos adversos disminuyeron con el tiempo y en ningún caso impidieron alcanzar la dosis máxima de 3 mg y concluir los 8 meses de tratamiento.

CONCLUSIONES

El tratamiento con liraglutida fue seguro y eficaz en los participantes con IMC superior a 40 kg/m^2. La liraglutida tuvo un impacto positivo en la pérdida de peso y mejoró significativamente la composición corporal, así como otros factores de riesgo cardiovascular y los niveles séricos de vitamina D. Los efectos adversos fueron leves y limitados en el tiempo. Sin embargo, son necesarios más estudios para evaluar la eficacia y seguridad a más largo plazo en estos grados de obesidad.

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Trabajo Original

Valoración nutricional

Correlation of physical function and physical activity with muscle mass measured with computed tomography in adult hemodialysis patients

Estudio de correlación de la funcionalidad física y la actividad física con la masa muscular medida con tomografía computarizada en pacientes adultos en hemodiálisis

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Abstract

Background: muscle mass (MM) plays an important role in the physical function of hemodialysis patients; however, muscle mass measurement can be unreliable and expensive. In contrast, the measurement of physical function (PF) is simple and inexpensive and may serve as an alternative. The aim of this study was to correlate the measurement of MM by computed tomography (CT) with physical function measurements and physical activity (PA) levels in HD patients.

Methods: this was a cross-sectional study that included 38 HD patients from a single HD clinic. Each participant had a CT scan to measure mid-thigh muscle mass. Physical function tests were assessed using the six-minute walk test (SMWT), handgrip strength (HGS) test, 5 x sit-to-stand test (STS5), timed up and go test (TUGT) and Short Physical Performance Battery (SPPB), while physical activity levels were measured using the Godin-Shephard leisure-time physical activity questionnaire. Correlation analysis was used to examine the relationship between variables.

Results: handgrip strength was strongly positively correlated with thigh muscle area ($r = 0.656$, $p \leq 0.001$) and weakly correlated with arm muscle area ($r = 0.396$, $p = 0.002$), SMWT ($r = 0.373$, $p = 0.004$), SPPB ($r = 0.269$, $p = 0.041$) and physical activity ($r = 0.323$, $p = 0.013$). There was also a trend for an inverse correlation between handgrip strenght and TUGT ($r = -0.235$, $p = 0.076$). Positive correlations were found between the thigh muscle area and the SPPB ($r = 0.339$, $p = 0.009$) and PA ($r = 0.293$, $p = 0.025$), while there was a trend for an inverse correlation between thigh muscle area and STS5 ($r = -0.256$, $p = 0.052$).

Conclusion: several measures of PF and strenght were correlated with objectives measurements of MM, thus provide options for low-cost measurements related to muscle mass.

Keywords:

Hemodialysis. Muscle mass. Handgrip strength. Physical function. Computed tomography.

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Resumen

Antecedentes: la masa muscular (MM) juega un papel importante en la funcionalidad física de los pacientes en hemodiálisis; sin embargo, la medición de la masa muscular en esta población de pacientes puede ser poco confiable y costosa. Por el contrario, la medición de la función física (FF) es simple, económica y puede servir como alternativa. El objetivo de este estudio fue correlacionar la medición de la MM mediante tomografía computarizada (TC) con la funcionalidad física y los niveles de actividad física (AF) en pacientes en HD.

Métodos: se realizó un estudio transversal que incluyó a 38 pacientes en HD de una clínica de hemodiálisis. Se utilizó la TC para medir la masa muscular del muslo medio de cada participante. Se midió la funcionalidad física con la prueba de la caminata de seis minutos (SMWT), la dinamometría de mano (HGS), la prueba de sentarse y levantarse cinco veces (STS5), la prueba de levantarse y caminar (TUGT) y la Batería de Desempeño Físico Corto (SPPB), mientras que los niveles de actividad física se midieron utilizando el cuestionario de actividad física de Godin-Shephard "Leisure-Time Physical Activity Questionnaire". Se utilizó un análisis de correlación para examinar la relación entre las variables.

Resultados: la dinamometría de mano se correlacionó positiva y fuertemente con el área muscular del muslo ($r = 0,656$, $p \leq 0,001$) y débilmente con el área muscular del brazo ($r = 0,396$, $p = 0,002$), SMWT ($r = 0,373$, $p = 0,004$), SPPB ($r = 0,269$, $p = 0,041$) y actividad física ($r = 0,323$, $p = 0,013$). También se encontró una correlación inversa no significativa entre la dinamometría de mano y el TUGT ($r = -0,235$, $p = 0,076$). Se encontró una correlación positiva entre el área muscular del muslo y el SPPB ($r = 0,339$, $p = 0,009$) y la AF ($r = 0,293$, $p = 0,025$), mientras que se encontró una correlación inversa no significativa entre el área muscular del muslo y STS5 ($r = -0,256$, $p = 0,052$).

Conclusión: varias medidas de la función física y la fuerza se correlacionaron con mediciones objetivas de la masa muscular, proporcionando así opciones para mediciones de bajo costo relacionadas con la masa muscular.

Palabras clave:

Hemodiálisis. Masa muscular. Dinamometría de mano. Funcionalidad física. Tomografía computarizada.

INTRODUCTION

Skeletal muscle tissue is one of the major tissues affected by chronic kidney disease (CKD) (1). It is well known that individuals undergoing hemodialysis (HD) experience loss of muscle mass (MM) due to many factors, including the dialysis procedure *per se*, which induces a catabolic state, as well as insufficient food intake; multiple endocrine disorders; persistent inflammation; metabolic acidosis; and physical inactivity, among other fractors (2).

The loss of muscle mass also reduces physical function (PF) (3), and reductions in MM and PF are directly associated with premature death, poor quality of life, frailty, disability and hospitalizations (1,4-8).

Low level of physical activity (PA) are a common feature in dialysis patients (9) and this may be either a cause or consequence of the reduced MM in this population (10).

The measurement of MM can be complicated, as a patient´s hydration status can impact assessment techniques such as anthropometry and bioelectrical impedance. While there are accurate methods for determining MM that are not influenced as much by hydration status, including computed tomography (CT) and magnetic resonance imaging (11), these techniques are relatively costly, so have limited clinical application.

The measurement of PF and handgrip strength (HGS), which can be an indirect measurement of MM functionality, is low cost and easy to perform. PF can be evaluated by different clinical methods, such as the six-minute walk test (SMWT), HGS, 5 x sit-to-stand test (STS5), timed up and go test (TUGT), or Short Physical Performance Battery (SPPB). The relevance of measuring PF in HD patients has been described in some studies. Isomaya et al. (4). showed that low MM alone was not associated with an increased risk of mortality, but low muscle function (muscle strength) irrespective of the appropriate muscle stores increased the risk of mortality by 98 %. They concluded that muscle atrophy does not explain the alterations in muscle function (4) and that MM and PF are two domains of skeletal muscle tissue that can be affected by different factors (12). In similar studies, younger HD patients with greater mid-thigh muscle area had poorer PF measured with the six-minute walk test than elderly subjects with smaller muscle area who were not on dialysis. This was not explained by the size of the muscle mass or comorbid conditions (3).

Given this background, our primary aim was to determine the correlation between the measurement of MM by CT and simple and low-cost PF tests and PA assessments. As a secondary analysis, we explored the correlation between the measurements of anthropometrics with CT, PF and PA as well as the correlation between muscle strength measured with HGS and anthropometrics, CT muscle mass and PA.

MATERIALS AND METHODS

STUDY DESIGN AND PATIENTS

This was a cross-sectional study that was conducted in accordance with the ethical standards described in the1964 Declaration of Helsinki. This study was approved by the ethics committees with the registration number DI/18/105-B/04/021. Informed consent was obtained from all subjects involved in the study. The inclusion criteria were as follows: regular HD two or three times a week, age > 18 years and ability to perform physical function tests. Patients with amputation, hospitalization in the last 3 months, unsatisfactory attendance at HD sessions, pregnancy, severe dyspnea, femoral fistula and orthopedic or neurological compromises or cognitive alterations affecting their participation in the study were excluded.

PHYSICAL FUNCTION TESTS

PF was assessed using the five repetitions of the sit-to-stand test (STS5), which measures the muscle strength of lower limbs, and the Short Physical Performance Battery (SPPB) (13), which measures the global function of patients. These PF tests were

chosen because both provide information about lower extremity function, which we want to compare with the MM of the mid-thigh muscle. The STS5 measures the time taken to complete 5 repetitions of the sit-to-stand test. To conduct this test, we used a chair with a height of 42 cm that was placed next to a wall, and we asked patients to fold their arms across their chest and stand up and sit down five times as quickly as possible. We record time from the initial sitting position to the final standing position. The SPPB is a well-validated test and measures three different dimensions of PF: 4-meter gait speed, chair stand (STS5), and standing in three different positions for assessment of balance. Each of these tasks are assigned a score ranging from 0 to 4, with 4 indicating the highest level of performance. The scores from each tasked are summed, providing a final score with a range of 0 to 12, where the highest scores indicated better PF (13).

Other measurements for PF were the SMWT and TUGT. The SMWT involved walking back and forth along a 22 m course (two 10-m straight lines connected by two 1-m curves) in a corridor for 6 min. We used the protocol of the American Thoracic Society. Subjects were allowed to rest in case of fatigue or pain. For the TUGT, we asked the patient to rise from a standard armchair, walk 3 meters, turn around, and return and sit down again, with time to complete the task measured in seconds.

HANDGRIP STRENGTH

Although the measurement of MM was performed in the mid-thigh muscle, we also measured handgrip strength using a hand dynamometry (Smedley III; Takei Scientific Instruments, Niigata City, Japan). Patients were seated in a relaxed position with shoulders adducted with neutral rotation, elbow in a 180° extension, forearm and wrist in a neutral position and they were asked to squeeze the dynamometer as hard as they could for 5 seconds (14). The measurement was taken 3 times, and the average of the 3 measurements was recorded as the handgrip strength. We used the European Working Group on Sarcopenia in Older People II (EWGSOP II) criteria to evaluate the muscle strength (15).

For patients who had a fistula, the measurement was performed with the hand opposite to the fistula; for patients with a catheter, the measurement was performed using the dominant hand.

PHYSICAL ACTIVITY

To assess PA, we used the physical activity questionnaire of the University of Laval, which has been shown to be sensitive and reproducible in our population (16). This questionnaire lists nine different types of activities, assigns each of them a caloric expenditure, and measures the kilocalories from PA in 24 hours. We measured PA on a different day of the weekend or the HD session.

MUSCLE MASS ASSESSMENT AND NUTRITIONAL STATUS

Acquisition of images was performed twice using 2 identical CT scanners (Siemens Somatom 128 slices, 2011) without the use of iodinated contrast. Measurements of the muscle tissue were performed at workstations (Carestream Vue PACS) at half of the femur in each patient. The protocol used was a 0.8 mm slice thickness with a 3 mm reconstruction in a soft tissue window. The CT scanner tube voltage was on average between 100 and 120 kV, exposure varied from 50 to 200 mAs, and a soft tissue kernel was used.

A freehand ROI tool was used to draw the margins of the muscle tissue and aponeurosis to calculate the thigh muscle area (quantity of muscle mass) and intramuscular lipid content via attenuation (density values), expressed in Hounsfield units (17). Any increment would express the substitution of fat tissue for muscle in the measured area (Fig. 1).

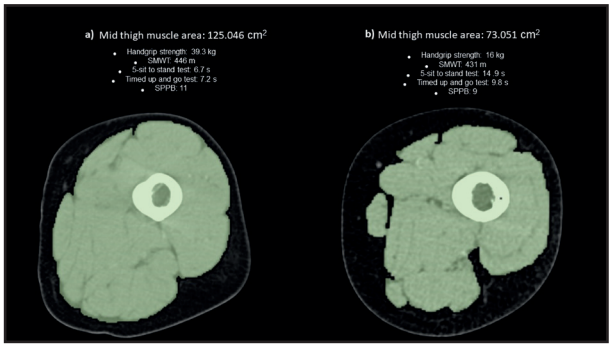

Figure 1.

Representative computed tomography images of the mid-thigh muscle area and physical function tests of two hemodialysis patients.

Anthropometric measurements were taken with a Lange skinfold caliper by a trained dietitian (G.M.A.) to estimate mid-arm muscle circumference and arm muscle area; these measurements were performed before the HD sessions when the patients were close to their dry weight. According to Heymsfield et al., we decided to use the bone-free arm muscle area and the arm muscle circumference formulas to evaluate and classify the muscle mass, also the midarm circumference was measured midway between the tip of the acromion and olecranon process (18). The following formulas were used to estimate mid-arm muscle circumference and bone-free arm muscle area (16):

- Mid-arm muscle circumference: Mid arm circumference – (π x triceps skinfold thickness)
- Bone-free arm muscle area:
  - Males = [(midarm circumference (cm) - π x triceps (cm)]^2 / 4 π) - 10
  - Females = [(midarm circumference (cm) - π x triceps (cm)]^2 / 4 π) - 6.5

Nutritional status was evaluated using the malnutrition inflammation score (MIS). This is a validated tool frequently used to assess the malnutrition status of patients. A higher score reflects a more severe degree of malnutrition and inflammation (19).

STATISTICAL ANALYSIS

To evaluate the distribution of each quantitative variable, we used the Kolmogorov-Smirnov test, and according to the data distribution, we report the data as the means with standard deviations or medians with interquartile ranges. Categorical variables are presented as absolute numbers and proportions. To evaluate the direction and strength of the association between the muscle mass measured with the CT and the PF tests, we used Pearson's correlation coefficient, and a p-value < 0.05 was considered statistically significant. SPSS version 21.0 was used to analyze the data.

RESULTS

BASELINE CHARACTERISTICS

We analyzed 38 patients with a mean age of 33 ± 10.8 years, 52.6 % ($n = 20$) of the patients were male, and the etiology of kidney failure was unknown in most cases (71.1 %). Baseline scores for all PF tests are shown in table I.

CORRELATION BETWEEN THIGH MUSCLE AREA, PHYSICAL ACTIVITY, AND PHYSICAL FUNCTION TESTS

Positive correlations were found between mid-thigh muscle area and SPPB (r = 0.339, $p = 0.009$) (Fig. 2) and physical activity (r = 0.293, $p = 0.025$) (Fig. 3). An inversely correlation was also found between mid-thigh muscle area and STS5 (r = -0.256, $p = 0.052$) (Fig. 4). No significant correlations were found between the thigh muscle area and the six-minute walk test nor the TUGT.

CORRELATION BETWEEN ARM MUSCLE AREA AND MID-ARM CIRCUMFERENCE AND PHYSICAL FUNCTION TESTS AND PHYSICAL ACTIVITY

Arm muscle area was significantly correlated with physical activity (r = 0.323, $p = 0.013$), and no statistical correlations were found with the PF tests. Mid-arm muscle circumference was positively correlated with physical activity, but this correlation was not statistically significant (r = 0.249, $p = 0.059$). No correlations were found with the PF tests.

CORRELATION OF HANDGRIP STRENGTH WITH ANTHROPOMETRICS, CT AND PA

Handgrip strength was positively correlated with arm muscle area measured with anthropometrics (r = 0.396, $p = 0.002$),

Table I. Demographics, body composition, laboratory and physical function characteristics of the study population

Patient characteristics	Total ($n = 38$)
Age (years)	33 ± 10.8
Sex	
Male, *n* (%)	20 (52.6)
Etiology, n (%)	
Unknow	27 (71.1)
Diabetes mellitus	3 (7.9)
Glomerulopathy	1 (2.6)
Hypertension	4 (10.5)
Other	3 (7.9)
Frequency of dialysis (n/%)	
2 times per week	32 (84.2)
3 times per week	6 (15.8)
Dialysis vintage (years)	2 (1, 3.2)
Uresis (ml/24 h)	85 ± 26
Comorbidities, n (%)	
Diabetes	2 (7.9)
Hypertension	38 (100)
Vascular access, n (%)	
Catheter	16 (42.1)
Arteriovenous fistula	22 (57.9)
Weight (kg)	56.6 ± 8.2
Body mass index (kg/m^2)	21.9 ± 2.9
Anthropometrics	
Arm muscle circumference (mm)	246.30 ± 64.7
Arm muscle area (cm^2)	35 ± 14.65
Computed tomography	
Mid-thigh muscle area (cm^2)	100 ± 20
Muscle attenuation (HU)	53 ± 4
MIS (score)	5.1 ± 2.7
Physical function tests	
Six-minute walk (m)	408 ± 64.1
Time up and go (s)	8.2 ± 1.5
5t-sit to stand (s)	9.4 ± 2.7
Short Physical Performance Battery (score)	10.8 ± 1.3
Handgrip strength (kg)	24.7 ± 9.3
Physical activity (kcal from PAQ)	2398 ± 725
Hemoglobin (g/dl)	10.19 ± 2.1
Creatinine (mg/dl)	13 ± 4.1
Albumin (g/dL)	4.2 ± 0.43
Phosphorus (mg/dl)	5.7 ± 2.3
Potassium (mmol/L)	5.4 ± 0.99
CRP (mg/L)	11.7 ± 20.6

Data are indicated as absolute number (percentage), mean ± standard deviation. Fat mass is presented as a percentage of body weight from anthropometry. HU: Hounsfield units; CRP: C-reactive protein; MIS: malnutrition inflammation score.

mid-thigh muscle area measured with CT (r = 0.656, $p = 0.000$) (Fig. 5), SMWT (r = 0.373, $p = 0.004$), SPPB (r = 0.269, $p = 0.041$) and physical activity (r = 0.323, $p = 0.013$) and was negatively correlated with the TUGT (r = -0.235, $p = 0.076$).

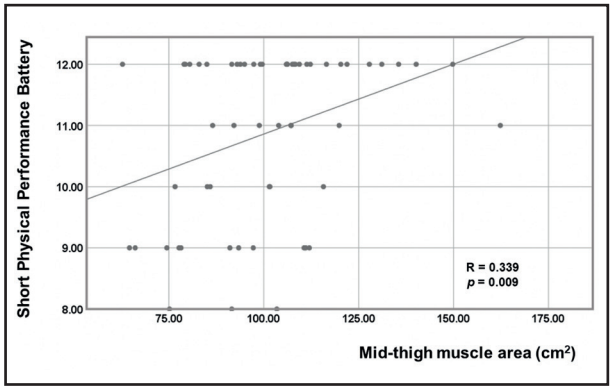

Figure 2.

Correlation between the mid-thigh muscle area measured with computed tomography and the Short Physical Performance Battery.

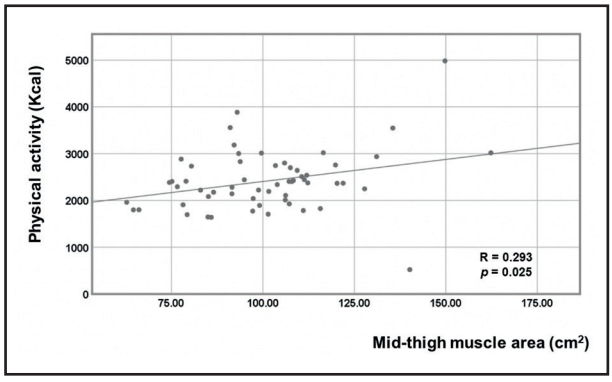

Figure 3.

Correlation between the mid-thigh muscle area measured with computed tomography and physical activity.

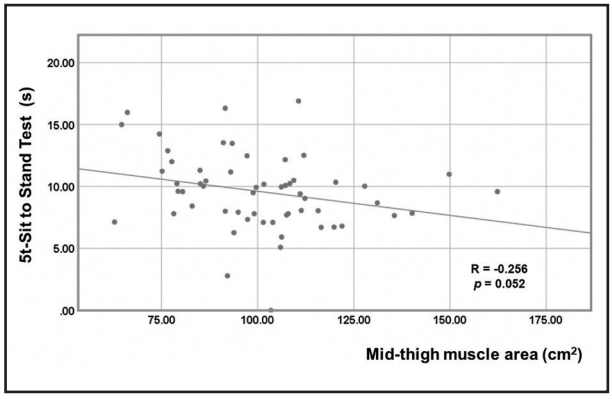

Figure 4.

Correlation between the mid-thigh muscle area measured with computed tomography and the 5 x sit-to-stand test.

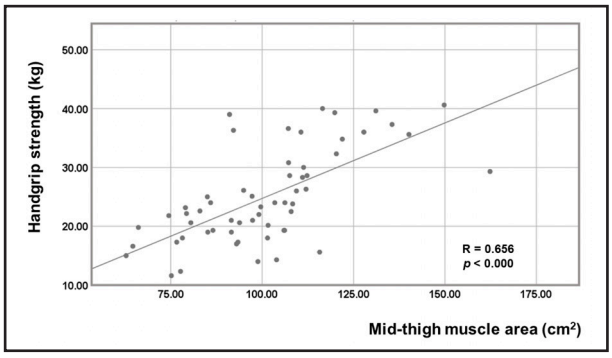

Figure 5.

Correlation between the mid-thigh muscle area measured with computed tomography and handgrip strength.

CORRELATION OF ARM MUSCLE AREA AND MID-ARM MUSCLE CIRCUMFERENCE WITH THIGH MUSCLE AREA

The mid-thigh muscle area was significantly correlated with the arm muscle area (r = 0.431, $p = 0.001$) and arm muscle circumference ($p = 0.357$, $p = 0.006$).

DISCUSSION

The primary finding in this study was that handgrip strength was strongly and significantly correlated with mid-thigh muscle area and with arm muscle area, it was also correlated with different PF tests, such as SMWT, SPPB, and TUGT, and a positive correlation with physical activity was also found. In addition, significant correlations were found between the mid-thigh muscle area and PF measurements obtained with the SPPB and STS5, and physical activity.

It is sometimes difficult to measure muscle mass in HD patients, in part because typical measurement techniques such as bioelectrical impedance analysis can be affected by patient´s hydration status. By contrast, other techniques such as dual-energy X-ray absorptiometry, magnetic resonance imaging and computed tomography are considered to be the "gold standard" reference methods for muscle mass evaluation, but their use is mainly confined to research purposes because they are either too expensive or inaccessible (20). As a result, physical function tests are often used as a proxy to assess muscle function, but few studies have examined how well these functional tests correlate with muscle mass measurements in this patient population (11).

Reduction in muscle mass and function are directly associated with premature death, poor quality of life, frailty, disability and hospitalizations (1,4-8). According to Roshanvaran et al., poor physical function measured with the six-minute walk test, TUGT, gait speed and handgrip strength are associated with an increase in all-cause mortality (5).

Improvement of both domains of muscle mass (muscle size and muscle quality) is important for dialysis patients because both are strong predictors of mortality; low muscle mass increased the risk of mortality by 98 % (HR: 1.98, 95 % CI: 1.01 to 3.87), and low muscle strength increased the risk of mortality by 23 % (HR: 1.23, 95 % CI: 0.56 to 2.67). Skeletal muscle dysfunction leads to mobility limitation and loss of functional independence, which can be translated to poor quality of life (4,3,21). Johansen et al. reported that dialysis patients were weaker and less active and walked more slowly than sedentary controls, although the quantity of muscle mass was not significantly different between the two groups (10). In this study, dialysis subjects had less contractile tissue and a poorer quality of muscle mass due to increased intramuscular fat infiltration (10). Other similar studies showed that younger dialysis patients (49.2 ± 15.8 years) with a greater mid-thigh muscle area (106.2 ± 26.8 cm^2) had poorer physical function than non-hemodialysis elderly subjects (75.3 ± 7.1 years) with a smaller muscle area (96.1 ± 2.1 cm^2), and this difference was not explained by muscle mass or comorbid conditions (3).

Taken together, our study adds to the literature suggesting that these low-cost functional measurements can provide valuable information related to the muscle mass of HD patients.

One of the interesting findings of this study was that HGS strongly correlated with the mid-thigh muscle area measured with CT and with different PF tests, but in other studies, this measurement was associated with the risk of malnutrition and inflammation (22).

A meta-analysis of prospective cohort studies evaluated the association between HGS and all-cause mortality in CKD patients found that the summary risk ratio of all-cause mortality in patients with low HGS was 1.88 (95 % confidence interval, 1.51-2.33; $p < 0.001$), while the summary risk ratio of all-cause mortality associated with a 1-kg unit increase in HGS was 0.95 (95 % confidence interval, 0.93-0-97; $p < 0.001$) (23).

These results suggest that HGS could be a strong predictor of malnutrition, inflammation, and all-cause mortality, as well as providing valuable information regarding the muscle mass of HD patients.

Our study has some limitations. First, due to the small sample size do not allow for the conclusion that the measurement of PF can represent the quality of muscle mass at any age in this patient group. Second, the patients did not undergo familiarization with the different PF tests, which may yield a biased result due to the poor standardization of the patients at the time of the tests.

CONCLUSION

The measurement of MM in HD patients is challenging due to frequent changes in the hydration status. Our data suggest that the evaluation of HGS and other low-cost and easy- to-perform PF measurements can provide important information related to MM. Additional studies are needed that include patient populations with larger sample sizes, across a wider age range, and including patients across the spectrum of kidney disease.

PRACTICAL APPLICATIONS

The measurement of physical function and handgrip strength are both low cost and easy to perform, and both measurements can give clinicians important information about the muscle mass of patients who are undergoing chronic hemodialysis.

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Trabajo Original

Valoración nutricional

Association between protein energy wasting and peritoneal membrane transport in peritoneal dialysis

Asociación entre desgaste proteico energético y tipo de transporte peritoneal en diálisis peritoneal

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Abstract

Background: fast peritoneal transport (FT) has been associated with peritoneal albumin loss and protein energy wasting (PEW); however, this relationship has not been fully studied.

Aim: the aim of this study was to analyze the differences in nutritional parameters between fast-transport peritoneal membrane (FT-PET) and slow-transport peritoneal membrane (ST-PET), and analyze the association between FT-PET and PEW in peritoneal dialysis (PD) patients.

Methods: a cross-sectional study of patients on PD. Peritoneal transport characteristics were assessed using the peritoneal equilibration test (PET). Malnutrition inflammation score (MIS) was used for PEW identification. Clinical and biochemical characteristics between patients with and without PEW were assessed. Association between FT-PET status and PEW were evaluated using univariate and multivariate logistic regression.

Results: a total of 143 patients were included. FT-PET group showed a higher prevalence of hypoalbuminemia, edema, lower phase angle, lower energy intake, and higher values of MIS score. FT-PET was significantly associated with PEW on univariate (OR: 3.5, 95 % CI: 1.56-7.83, $p = 0.002$) and multivariate models (OR: 2.6, 95 % CI: 1.02-6.6, $p = 0.04$). This association was maintained in patients where baseline PET was performed after initiating PD therapy (OR: 6.2, 95 % CI: 1.01-38.6, $p = 0.04$).

Conclusion: FT-PET is associated with PEW evaluated by MIS score. Clinical trials to study nutritional interventions personalized to peritoneal-membrane transport characteristics should be designed.

Keywords:

Peritoneal dialysis. Protein-energy wasting. Malnutrition. Peritoneal transport.

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Resumen

Antecedentes: las características del transporte peritoneal rápido se han asociado a una mayor pérdida de albúmina peritoneal, así como a un mayor riesgo de presentar desgaste proteico energético (DPE); sin embargo, está relación no está esclarecida en la literatura.

Objetivo: el objetivo de la investigación fue analizar las diferencias de indicadores nutricionales entre la membrana peritoneal con transporte rápido y la membrana peritoneal con transporte lento, así como analizar la asociación entre el transporte peritoneal rápido y el diagnóstico de DPE en pacientes con diálisis peritoneal.

Métodos: estudio transversal. Las características del transporte peritoneal se evaluaron mediante la prueba del equilibrio peritoneal (PET). Se utilizó la escala de malnutrición e inflamación (MIS) para la identificación del DPE. Se evaluaron las diferencias entre las características clínicas y bioquímicas en pacientes con y sin DPE. La asociación entre pacientes con transporte rápido y DPE se evaluó mediante regresión logística.

Resultados: se incluyeron un total de 143 pacientes. El transporte peritoneal rápido mostró una mayor prevalencia de hipoalbuminemia, edema, menor valor de ángulo de fase e ingesta energética y mayor puntaje MIS. El transporte peritoneal rápido se asoció con la presentación de DPE en el modelo univariado (OR: 3,5, IC 95 %: 1,56-7,83, $p = 0,002$) y en el análisis multivariado (OR: 2,6, IC 95 %: 1,02-6,6, $p = 0,04$). Esta asociación persiste independientemente del momento de realización del PET (OR: 6,2, IC 95 %: 1,01-38,6, $p = 0,04$).

Conclusión: el transporte peritoneal rápido se asoció con mayor riesgo de DPE evaluado mediante la herramienta MIS. Se requieren de ensayos clínicos para diseñar la intervención nutricional más óptima según las características del PET.

Palabras clave:

Diálisis peritoneal. Desgaste proteico-energético. Desnutrición. Transporte peritoneal.

BACKGROUND

Maintenance peritoneal dialysis (MPD) is considered an excellent long-term kidney replacement therapy (RRT) for chronic kidney disease (CKD) (1). Peritoneal transport is routinely measured to adjust prescription parameters and associated with outcomes such as protein energy wasting (PEW) and malnutrition. PEW is highly prevalent in PD patients, reported in up to 80 % and 33 % in continuous ambulatory peritoneal dialysis (CAPD) and automated peritoneal dialysis (APD), respectively (2,3). The etiology of PEW is multifactorial; uremia, low protein-energy intake, inflammation, metabolic acidosis, nutrient loss during RRT (4), overhydration and comorbidities are some of the key factors associated with PEW.

Both types of PD (CAPD and APD) are associated with advantages and similar outcomes (5). The decision for choosing a PD modality for individual patients should take into account local resources, the person's wishes regarding lifestyle, and the family's/caregivers' wishes if they are providing assistance (6).

Peritoneal-membrane transport is assessed by the peritoneal equilibration test (PET), which provides data about clearance and ultrafiltration (UF) capacity; both characteristics are considered for PD prescription (7,8). PET study categorizes peritoneal-membrane as a slow transporter (ST-PET) and as fast transporter (FT-PET) (9,10).

The International Society of Peritoneal Dialysis suggest that the first PET should be performed 6–12 weeks after PD started, with routine evaluation of membrane function (11).

There is controversial data with regard to the association of peritoneal-membrane transport with nutritional status (12). Some studies report that FT-PET could affect nutritional status (12,13), increase the risk of all-cause mortality (14,15) and is associated with lower levels of serum albumin, lower phase angle and a higher rate of malnutrition (16). Other studies (17-19) report higher all-cause mortality and PD discontinuation in diabetic nephropathy PD patients with FT-PET. Contrary of this evidence, other authors found not an association between FT-PET and nutritional status or clinical outcomes (20,21). At this time, the evidence of association between FT-PET and PEW is not clear, and studies not include patients on APD. Additionally, the use of malnutrition inflammation score (MIS) as a tool for PEW is limited.

The aim of this study was to analyze the differences in nutritional parameters between FT-PET and ST-PET, and analyze the association between FT-PET and PEW using MIS tool in MPD.

METHODS

A cross-sectional study was conducted. All consecutive incidence and subsequent PD patients who were seen in the Nephrology Department of the National Institute of Cardiology for performed PET study from January 2018 to January 2022 were eligible for enrollment, despite the etiology of the PET study. Patients with active infections, had incomplete biochemical/nutritional data, amputations, pacemakers or implantable cardioverters were excluded. The study was performed in accordance with the Declaration of Helsinki and was approved by the Ethics Committee of the National Institute of Cardiology (#20-1195). Written informed consent was obtained.

DATA COLLECTION

Demographic and clinical data (age, etiology of CKD, diabetes status, dialysis vintage (months between the date initiation of PD and the date of study entry), PD prescription, urine output, UF in 24 hours and systolic blood pressure) were collected from electronic medical records. The rate of glucose absorption from dialysis solutions was estimated as 40 % for APD and 60 % for CAPD, according to the Academy of Nutrition and Dietetic recommendations (22).

SAMPLE SIZE

Sample size was estimated using the double population proportion formula in Stata Intercooled V14.0 by considering difference in the proportion of PEW of at least 25 % between groups,

according to the Liu Y et al. report (16), assuming a significance level of 5 % and a power of 80 %, the final simple calculated to be included in the study was 116 patients. However, we included 154 patients who had a PET study.

PERITONEAL EQUILIBRATION TEST (PET)

The peritoneal equilibration test (PET) was performed and interpreted using the classification proposed by Twardowski, who used solutions at 2.5 % glucose (23,24), and peritoneal-membrane transport was categorized as fast if peritoneal creatinine clearance rate (D/PCr) was 0.81-1.03; fast average transporter was defined as D/PCr of 0.68-0.80, slow average transporter as D/PCr of 0.56-0.67, and slow transporter as a value of D/PCr equal to 0.34-0.56. For the analysis, slow/slow average were considered ST-PET, and fast/fast average transporters were considered FT-PET (25). Causes for PET study were reported (baseline study, poor solute clearance despite urea clearance dose, overhydration, follow up after peritonitis event, and routine follow up).

BIOCHEMICAL ANALYSIS

Blood samples were obtained the same day of PET study under fasting conditions. Lipid profile (total cholesterol and triglycerides), serum electrolytes (phosphorus, potassium and sodium), uremic toxins (blood urea nitrogen-BUN, creatinine), glucose, HbA1c and C-reactive protein (CRP) were determined. Residual kidney function (RKF) was calculated using creatinine and CKD-EPI formula or considered loss of RKF if urine output was < 200 ml (26). Low albumin concentrations were defined as a serum albumin level < 3.8 g/dL) (27) and inflammation was defined as a CRP > 3 mg/dL (28).

NUTRITIONAL ASSESSMENT

A trained renal dietitian performed a nutritional assessment on the same day of PET study.

The malnutrition inflammation score (MIS) is a validated tool used for assessing the nutritional status of patients that consists of four main parts: patients related medical history, physical examination, BMI and laboratory parameters. Score 0 of the MIS in each part denotes normal nutrition status while score 3 denotes severe nutritional deficit. The sum of all components ranges from 0 (normal) to 30 (severely abnormal) (29). PEW was defined as a result ≥ 8 points (30).

Weight and height were measured (Seca model 700; Seca, Hamburg, Germany) using standard procedures described by Lohman et al. (31). Body composition was assessed using a multi-frequency device (InBody S10®, InBody Co., Ltd., Seoul, Korea). Measurements were performed with the patient in a supine position. Eight adhesive electrodes were used: one on each wrist, one on the distal part of the third metacarpal bone of each hand, one on the central part of each ankle and one on the distal part of the second metatarsal bone in each foot. Phase angle (PhA), fat-free mass (FFM), extracellular water (ECW), intracellular water (ICW), total body water (TBW) and extracellular water/total body water ratio (ECW/TBW) were obtained. Fat-free mass index (FFMI) (FFM/height^2) and body mass index (BMI) (body weight/height^2) were calculated using estimated dry weight. An ECW/TBW ratio > 0.385 was considered as overhydration status (32). Ideal body weight was calculated as m^2 x 24 (< 60 years old) or 25 (> 60 years old). Values derived from TBW or ECW were recalculated with a healthy ECW/TBW of 0.385 to dry weight obtention. Low PhA (< 4.64°) (3) was categorized according to previous cut-off values for PD Mexican population (3). Low BMI was defined as < 23 kg/m^2 (27).

Handgrip strength (HGS) was assessed using a hydraulic hand dynamometer (Jamar, Columbia, MD, USA) with the patient seated and arms at 90° and slightly away from the trunk. Three attempts of 3 seconds in each hand were performed. The highest value of each side was reported (33).

Dietary intake was assessed using a 3-day food record (one weekend day and two weekdays). Food intake was converted into nutrients using data from the Tables of Composition of Mexican Foods (34). Energy (kcal) and protein (g) intake were estimated. Low protein intake (< 0.8 g/kg) was calculated using the ideal body weight (27).

STATISTICAL ANALYSIS

Statistical analysis was performed using Stata Intercooled (Version 14, STATA Corporation, College Station, TX, USA). Normality was verified with the Shapiro-Wilk test. Descriptive statistics were used to analyze categorical variables (absolute and relative frequency) and quantitative variables (mean and standard deviation (SD) or median and interquartile range (IQR)). Differences between ST-PET and FT-PET were analyzed using Student's t-test, Mann-Whitney U-test, or χ^2 test. Univariate logistic regression was used to evaluate the association between FT and PEW (yes/no). Multivariate regression models were performed and fitted to the data using backward stepwise selection. Analyzed variables were retained in the model if they had a *p*-value less or equal to the maximum *p*-value selection criteria of 0.1. Results were expressed as odds ratio (OR) and 95 % confidence interval (95 % CI). Statistical significance was defined as $p < 0.05$.

RESULTS

A total of 143 patients with MPD were included in this analysis. From the total sample, 74 (52 %) correspond to baseline PET studies. There were 70 (49 %) women with a median age of 40 (30-53) years, and 43 (30 %) had type 2 diabetes; 105 (73 %) patients were on APD; 89 (62 %) had FT-PET. The baseline characteristics are shown in table I. No differences in PEW were detected between the APD and CAPD groups (Supplementary Table I).

Table I. Demographic and clinical data of chronic kidney disease patients on peritoneal dialysis

Variable	Total (*n* = 143) *n* (%)
Age (years)	40 (30-53)
Sex (%)	
Female	70 (49 %)
Male	73 (51 %)
PD modality	
Automated peritoneal dialysis	105 (73 %)
Continuous ambulatory peritoneal dialysis	38 (27 %)
Vintage dialysis (months)	16 (4-44)
CKD etiology	
Unknown	50 (35 %)
Type 2 diabetes *mellitus*	43 (30 %)
Glomerulopathy	14 (10 %)
Hypertension	6 (4 %)
Cardiorenal syndrome	10 (7 %)
Renal hypoplasia	4 (3 %)
Lithiasis	3 (2 %)
Uric acid	4 (3 %)
Systemic lupus erythematosus	3 (2 %)
Polycystic kidney disease	6 (4 %)
Indication for PET-study	
Baseline study	74 (52 %)
Poor solute clearance	23 (16 %)
Overhydration	15 (10 %)
Follow up after peritonitis event	21 (15 %)
Routine follow up	10 (7 %)
PET-creatinine	
High	31 (22 %)
Medium high	58 (40 %)
Medium low	11 (8 %)
Low	43 (30 %)

PET: peritoneal equilibration test; CKD: chronic kidney disease; PD: peritoneal dialysis.

DIFFERENCES IN PERITONEAL TRANSPORT CHARACTERISTICS

The differences between FT-PET and ST-PET were evaluated (Table II). In FT-PET, a higher frequency of PEW (44.3 % *vs* 18.5 % $p = 0.002$) and higher overhydration determined by ECW/TBW (0.400 ± 0.013 *vs* 0.393 ± 0.013; $p = 0.002$) were observed in comparison to the ST-PET group, as were significant differences for PhA (4.27° ± 0.94 *vs* 4.79° ± 0.95; $p = 0.001$).

Additionally, FT-PET was associated with lower albumin concentrations (3.61 *vs* 3.90 g/dl; $p < 0.001$) and a higher prevalence of hypoalbuminemia (70 % *vs* 35 %, $p < 0.001$). Lower energy intake was observed in the FT-PET group (28.12 *vs* 32.5 kcal/kg ideal body weight; $p = 0.007$) and a trend toward lower protein intake (23 vs 11 %; $p = 0.07$).

ASSOCIATION BETWEEN PEW AND FAST PERITONEAL TRANSPORT

Univariate logistic regression analysis demonstrated an association between PEW and triglycerides (OR: 0.99, 95 % CI: 0.98 to 0.99), PhA (OR: 0.2, 95 % CI: 0.1 to 0.4), overhydration (OR: 1.5, 95 % CI: 1.2 to 1.8) and FT-PET (OR: 3.5, 95 % CI: 1.56 to 7.3) (Supplementary Table II). In the multivariate analysis, FT-PET is associated with PEW (OR: 2.6, 95 % CI: 1.02 to 6.6, $p = 0.04$) after adjusting to energy intake, overhydration, age, diabetes, sex, dialysis vintage, UF and RKF.

Additionally, when only individuals with baseline PET-study were assessed, the association remains (OR: 6.26, 95 %, CI: 1.01-38.65, $p = 0.04$) (Table III).

DISCUSSION

This cross-sectional study found that FT-PET is an independent risk factor for PEW in MPD patients.

Our result was consistent with some previous studies; Liu Y et al. concluded that baseline faster peritoneal transport was independently associated with worse nutritional status evaluated by subjective global assessment (OR: 3.43, 95 % CI: 1.69 to 6.96, $p < 0.01$) and PEW score (OR: 2.40, 95 % CI: 1.08 to 5.31, $p = 0.03$) in CAPD patients (16).

Supplementary Table I. Differences between automated and continuous ambulatory peritoneal dialysis

	Automated peritoneal dialysis *n* = 105	Continuous ambulatory peritoneal dialysis *n* = 38	*p*-value
Age (years)	38.9 ± 13.6	49.5 ± 17	< 0.001*
Sex (%)			
Female	55 (52 %)	15 (40 %)	0.17
Male	50 (48 %)	23 (60 %)	

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Supplementary Table I. Differences between automated and continuous ambulatory peritoneal dialysis

	Automated peritoneal dialysis ***n*** **= 105**	**Continuous ambulatory peritoneal dialysis** ***n*** **= 38**	***p*-value**
Vintage dialysis (months)	27 (7-47)	5.5 (3-10)	0.001
Systolic blood pressure (mmHg)	148 ± 30	143 ± 25	0.29
Ultrafiltration (ml/day)	954 ± 488	932 ± 575	0.82
Urine output (ml/day)	50 (0-400)	315 (0-900)	0.04*
MIS score	7 (5-10)	8 (6-9)	0.25
PEW (*n* [%])	36 (34 %)	13 (35 %)	0.92
Actual weight (kg)	63.5 ± 12.4	60.8 ± 12.3	0.24
ECW/TBW (L)	0.394 ± 0.013	0.405 ± 0.013	< 0.001*
Dry weight (kg)	61.9 ± 12.0	57.6 ± 11.6	0.06
BMI (kg/m^2)	23.7 (21.4-25.8)	22.3 (20.7-24.5)	0.10
BMI < 23 kg/m^2	44 (42 %)	22 (57 %)	0.09
Phase angle (°)	4.6 ± 0.97	4.0 ± 0.91	0.004*
Phase angle < 4.64°	59 (48 %)	27 (71 %)	0.01*
FFMI (kg/m^2)	17.7 ± 2.3	17.6 ± 2.4	0.78
Handgrip strength right arm (kg)	21.5 (12.5-31)	19.5 (10-22)	0.005*
Handgrip strength left arm (kg)	19.5 (14-30)	16 (8-22)	0.008*
Albumin (g/dL)	3.7 ± 0.4	3.5 ± 0.6	< 0.001*
Albumin < 3.8 (g/dL)	55 (52 %)	26 (68 %)	< 0.08
Total cholesterol (mg/dL)	187.4 ± 47.4	192 ± 56.2	0.62
Creatinine (mg/dL)	14.1 ± 4.8	10.5 ± 5.0	< 0.001*
Phosphorus (mg/dL)	6.4 ± 2.0	5.3 ± 1.5	0.002*
Glucose (mg/dL)	94 (87-101)	89 (83-112)	0.30
BUN (mg/dL)	58.1 ± 16.8	60.9 ± 21.3	0.41
Potassium (mmol/L)	4.6 ± 0.7	4.6 ± 0.8	0.66
Sodium (mmol/L)	138.3 ± 3.3	137.1 ± 3.5	0.06
Triglycerides (mg/dL)	139 (104-200)	147 (129-232)	0.17
CRP (mg/dL)	2.7 (1.1-8)	3.3 (0.9-6.4)	0.67
CRP > 3 mg/dL	35 (48 %)	13 (52 %)	0.72
HbA1c (%)	5.3 (5-6.1)	5.5 (5.1-7.5)	0.24
RKF (ml/min/1.73^2)	0 (0-3.6)	3 (0-5.9)	0.01*
Energy from dialysate (kcal)	326 (259-326)	277 (184-382)	0.37
Energy intake (kcal/day)	1915 ± 596	1568 ± 524	0.002*
Energy intake (kcal/kg IBW)	31.1 ± 9.5	26 ± 8.5	0.004*
Protein intake (g/day)	70.6 (57 - 88)	59 (48.6-72.4)	0.007*
Protein intake < 0.8 g/kg IBW	16 (15 %)	10 (27 %)	0.11

*Mean ± SD; Median (IQR), n(%). MIS: malnutrition inflammation score; PEW: protein energy wasting; ECW/TBW: extracellular water/total body water; BMI: body mass index; FFMI: fat free mass index; BUN: blood urea nitrogen; CRP: C-reactive protein; HbA1c: hemoglobin glycosylated; RKF: residual kidney function; IBW: ideal body weight. *p-value < 0.05.*

Table II. Clinical and nutritional differences between fast and slow transporters

	Total sample *n* = 143	FT-PET *n* = 89	ST-PET *n* = 54	*p*-value
Age (years)	40 (30-53)	41 (31-55)	39 (28-51)	0.45
Sex (%) Female Male	 70 (49 %) 73 (51 %)	 44 (49 %) 45 (51 %)	 26 (48 %) 28 (52 %)	0.88
Vintage dialysis (months)	16 (4-44)	15 (4-42)	22 (3-44)	0.80
Systolic blood pressure (mmHg)	147 ± 29	148 ± 26.6	145 ± 33	0.63
PD modality Automated PD Continuous ambulatory PD	 105 (73 %) 38 (27 %)	 59 (66 %) 30 (34 %)	 46 (85 %) 8 (15 %)	0.01*
Ultrafiltration (ml/day)	949 ± 508	928 ± 504	965 ± 517	0.76
Urine output (ml/day)	110 (0-667)	150 (0-500)	105 (0-900)	0.43
MIS score	7 (5-10)	8 (5-11)	6 (4-8)	0.002*
PEW (n (%))	49 (34.5 %)	39 (44.3 %)	10 (18.5 %)	0.002*
Anthropometrics and body composition				
Actual weight (kg)	62.8 ± 12.4	63.3 ± 12.3	62.0 ± 12.6	0.53
ECW/TBW (L)	0.397 ± 0.013	0.400 ± 0.013	0.393 ± 0.013	0.002*
Dry weight (kg)	60.8 ± 12.0	61.0 ± 11.9	60.4 ± 12.2	0.78
BMI (kg/m^2)	23.4 (21.2-25.7)	22.8 (21-25.2)	23.9 (21.6-26.5)	0.19
BMI < 23 kg/m^2	66 (46.4 %)	46 (52.2 %)	20 (37 %)	0.07
Phase Angle (°)	4.47 ± 0.98	4.27 ± 0.94	4.79 ± 0.95	0.001*
Phase angle < 4.64°	77 (54 %)	56 (63.6 %)	21 (38.8 %)	0.004*
FFMI (kg/m^2)	17.7 ± 2.3	17.8 ± 2.4	17.4 ± 2.2	0.33
Handgrip strength right arm (kg)	20 (12-29)	20 (12-28)	22 (16-30)	0.19
Handgrip strength left arm (kg)	18 (12-27)	18 (12-26)	19.5 (13-28)	0.21
Biochemical parameters				
Albumin (g/dL)	3.7 (3.4-3.9)	3.6 (3.2-3.9)	3.9 (3.6-4.2)	< 0.001*
Albumin < 3.8 (g/dL)	81 (56.6 %)	62 (70 %)	19 (35 %)	< 0.001*
Total cholesterol (mg/dL)	184 (156-212)	188 (160-216)	175 (155-207)	0.27
Creatinine (mg/dL)	13.2 ± 5.1	12.8 ± 5.1	13.8 ± 5.1	0.26
Phosphorus (mg/dL)	6.4 (4.7-7.2)	6.4 (4.5-7.2)	6.4 (4.9-7.1)	0.47
Glucose (mg/dL)	92 (84.4-101)	91.1 (84-101)	93.6 (87.2-100.4)	0.73
BUN (mg/dL)	58.8 ± 18.1	57.8 ± 19.0	60.5 ± 16.5	0.40
Potassium (mmol/L)	4.6 ± 0.7	4.6 ± 0.7	4.6 ± 0.8	0.59
Sodium (mmol/L)	138 ± 3.4	137.7 ± 3.4	138.5 ± 3.2	0.15
Triglycerides (mg/dL)	143 (107-206)	142 (106-197)	153 (112-236)	0.20
CRP (mg/dL)	2.7 (1.0-8)	2.5 (0.8-6.5)	3.8 (1.3-8.9)	0.22
CRP > 3 mg/dL	48 (49 %)	29 (33 %)	19 (35 %)	0.31
HbA1c (%)	5.3 (5.0-6.1)	5.3 (5-6.4)	5.3 (5.0-5.8)	0.49
RKF (ml/min/1.73^2)	1 (0-4.1)	2.5 (0-4.15)	0 (0-4.1)	0.57
Diet information				
Energy from dialysate (kcal)	323 (245-367)	326 (245-374)	306 (228-340)	0.15
Energy intake (kcal/day)	1824 ± 596	1751 ± 585	1942 ± 600	0.06
Energy intake (kcal/kg IBW)	29.8 ± 9.5	28.1 ± 8.9	32.5 ± 9.8	0.007*
Protein intake (g/day)	68.7 (54.6-85.9)	69.6 (51-87)	68 (57.7-82.6)	0.66
Protein intake < 0.8 g/kg IBW	26 (18 %)	20 (23 %)	6 (11 %)	0.07

*Mean ± SD; Median (IQR), n (%). FT-PET: fast-transporter peritoneal equilibration test; ST-PET: slow-transporter peritoneal equilibration test; MIS: malnutrition inflammation score; PEW: protein energy wasting; ECW/TBW: extracellular water/total body water; BMI: body mass index; FFMI: fat free mass index; BUN: blood urea nitrogen; CRP: C-reactive protein; HbA1c: hemoglobin glycosylated; RKF: residual kidney function; IBW: ideal body weight. *p value < 0.05.*

Supplementary Table II. Univariate analysis of variables associated with PEW

Variable	Univariate analysis		
	OR	IC 95 %	*p*-value
Triglycerides	0.99	0.98-0.99	0.009*
Overhydration	1.5	1.2-1.8	< 0.001*
Phase angle	0.2	0.1-0.4	< 0.001*
Ultrafiltration	0.99	0.998-0.999	0.045*
Hemoglobin	0.8	0.7-0.9	0.05
Dialysis vintage	1.0	0.99-1.01	0.44
C-reactive protein	1.0	0.98-1.04	0.20
Age	1.0	0.98-1.03	0.53
Diuresis	0.9	0.99-1.0	0.18
Number of dialysis exchanges	0.9	0.68-1.43	0.95
Icodextrin use	0.7	0.25-2.31	0.63
Diabetes *mellitus*	2.0	0.9-4.2	0.05
Sex (woman)	1.1	0.5-2.2	0.77

**p-value < 0.05.*

Table III. Association between fast transporters and protein energy wasting

Model	OR	95 % CI	*p*-value
Model 1	3.5	1.56-7.8	0.002*
Model 2	2.6	1.02-6.6	0.04*
Model 3	6.2	1.01-38.6	0.04*

Model 1: crude. Model 2: adjusted to energy intake (kcal/kg), overhydration, age, diabetes, sex, dialysis vintage, ultrafiltration and residual kidney function. Model 3: Model 2 + only individuals with baseline PET-study (n = 89).

The prevalence of PEW detected in our sample (34.5 %) was lower in comparison to others reports; the prevalence in Liu Y et al was 56.7 % (62.6 % in FT-PET vs. 45.2 % in ST-PET) (16) in CAPD patients. Our cohort characteristics could explain these differences, as our sample is younger and had lower comorbidities such as diabetes.

Our findings suggest that FT-PET is associated with poor nutritional status; however, by the cross-sectional nature of the study, causality is difficult to establish. Cooper et al. found a strong association between protein losses through PD in FT-PET and greater intraperitoneal inflammation compared to ST-PET (35). In our study, patients with FT-PET had significantly lower albumin concentrations, documented hypoalbuminemia in 70 % of patients *vs* 35 % for ST-PET.

Several mechanisms could explain this association; a) FT-PET patients are more likely to have fluid overload, b) low serum albumin was secondary to protein loss due to higher peritoneal exchanges, c) lower dietary intake mediated by increased absorption calories from dialysate solutions and d) inflammation and production of advanced glycation products.

Other authors didn't find an association between PET and nutritional outcomes; Szeto and colleagues report that PET is not associated with longitudinal changes of nutritional parameters and did not find an association between peritoneal membrane characteristics and albumin or fat-free mass (20). Similarly, Harty et al in a cross-sectional study of CAPD patients report the absence of a relationship between nutritional status and PET results (21).

PhA is a parameter obtained using bioelectrical impedance analysis that is associated to oxidative stress and nutritional status (36). In our study, we observed low values of PhA (4.27 ± 0.94 vs 4.79 ± 0.95, $p = 0.001$) for FT vs ST- PET. Similarly, Liu Y et al. report higher PhA values in ST-PET patients (6.27 ± 0.47 vs 6.15 ± 0.39, $p \leq 0.05$) (16). Han BG et al. report an association between low PhA (< 4.5°) and higher risk of PEW in a sample of 80 patients with CKD without RRT and 80 PD patients (37).

An association between FT-PET and overhydration was reported (38). Fluid overload has been implicated in cardiovascular disease in PD patients and depending on the type of hydration parameters used, the reported prevalence of fluid overload ranged from 53.4 to 72.1 % (39). In our sample, we found FT-PET patients had higher overhydration evaluated by ECW/TBW (0.400 ± 0.013 L vs 0.393 ± 0.013 L, $p = 0.002$). Excessive hydration could result in hemodilution and a decrease in serum albumin concentration; hypoalbuminemia causes a reduction in plasma oncotic pressure that exacerbates fluid accumulation in extracellular space. Other factors that decrease albumin concentrations are chronic systemic inflammation (28).

PD solutions with high glucose concentration were used to achieve fluid removal, translating to higher energy absorbed by dialysate. In our study observed a difference in higher estimated absorption of calories form dialysate in FT- PET without statistical significance. Additionally, it has been documented a lower food intake secondary to alteration in appetite signals by the dialysate dextrose absorption (40). Similar to Guan JC et al. (7), we observed a lower energy intake (kcal/kg ideal body weight) in FT-PET and a higher proportion of patients with low protein intake without statistical significance ($p = 0.07$).

Considering these results (hypoalbuminemia, overhydration, low PhA, lower energy intake and higher PEW prevalence), the individualization of nutritional therapy according to the peritoneal membrane characteristics may impact in clinical outcomes.

This study has some limitations. The nature of the study (cross-sectional) does not allow direction of causality, our cohort was enrolled at a single center and not every participant had PET-study at baseline however, sub-analyses including only those subjects with baseline PET were consistent with the main results.

CONCLUSION

Patients with FT-PET on PD had worse nutritional status in comparison to ST-PET. FT-PET is a risk factor for PEW evaluated by MIS score. Clinical trials to study personalized nutritional interventions to peritoneal-membrane transport characteristics should be designed.

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ARÁN

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Trabajo Original

Valoración nutricional

Comparison of repeatability of subjective appetite sensations in men and women at different menstrual cycle phase

Comparación de la repetibilidad de las sensaciones subjetivas de apetito en hombres y mujeres en diferentes fases del ciclo menstrual

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Abstract

Introduction: appetite can be measured through subjective sensations of appetite (SSA), which can be assessed by means of scales, the most relevant being the visual analog scales (VAS).

Objective: to analyze the repeatability of VAS in men and women in follicular phase (FF) and luteal phase (LF) of the menstrual cycle

Materials and methods: 34 men and women were included. VAS of subjective appetite sensations (SAS) were applied before and after standardized breakfast in two sessions.

Results: women LP showed intra-class correlation coefficient (ICC) values greater than 0.5, and most of VAS in women FP and men showed ICC values greater than 0.7. The ICC of hunger and desire to eat were different between men and women LP. Comparisons of these ICC´s showed that only hunger and desire to eat were different between men and women.

Conclusion: repeatability of VAS was similar between men and women in different stages of menstrual cycle. This is the first study to assess repeatability of VAS in women in LP and to objectively compare the repeatability of VAS to evaluate SAS.

Keywords:

Visual analogue scales. Hunger. Satiety. Questionnaires. Test-retest reliability.

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Resumen

Introducción: el apetito se puede medir a través de sensaciones subjetivas del apetito (SSA), las cuales pueden evaluarse mediante escalas, siendo las más relevantes las escalas analógicas visuales (EAV).

Objetivo: analizar la repetibilidad de las EAV en hombres y mujeres en fase folicular (FF) y fase lútea (FL) del ciclo menstrual.

Material y métodos: se incluyeron 34 hombres y mujeres. Se aplicaron las EAV para las SSA antes y después de un desayuno estandarizado en dos sesiones.

Resultados: las mujeres FL mostraron valores de coeficiente de correlación intraclase (CCI) superiores a 0,5 y la mayoría de EAV de mujeres FF y hombres mostraron valores de CCI superiores a 0,7. La comparación de los CCI mostró que solo hambre y el deseo por comer fue diferente entre hombres y mujeres.

Conclusión: la repetibilidad de las EAV fue similar entre hombres y mujeres en diferentes etapas del ciclo menstrual. Este es el primer estudio que evalúa la repetibilidad de las EAV en mujeres FL y que compara objetivamente la repetibilidad de EAV para evaluar SSA.

Palabras clave:

Escalas análogas visuales. Hambre. Saciedad. Cuestionarios. Aplicación y reaplicación.

INTRODUCTION

Appetite is the action that covers the entire field of food intake, ranging from selection and motivation to preference (1). It is influenced by several psychological and physiological factors such as emotional states, hormones, epigenetics (2), menstrual cycle, age, and sex, among others (3).

Appetite can be measured through subjective appetite sensations (SAS) such as hunger, fullness, satiety, desire to eat, and prospective food consumption (4). It is possible to measure SAS through scales and one of the most relevant tools for this purpose are the visual analogue scales (VAS) (5). However, before using them, it is necessary to evaluate their repeatability (6) to assure consistency in their use when they are applied in more than one occasion to the same group of people (7,8). VAS have been developed and validated it in the English language (5), which makes it difficult to be applied in other populations. Therefore, it has been suggested to adapt them considering specific language and cultural context (9).

Moreover, owing the variability in SAS according to menstrual cycle and sex, it is important to consider these variables when VAS are used (10). The menstrual cycle, which normally lasts 28-32 days, consists of a follicular phase (FP) made up of 12 to 14 days, in which low concentrations of estrogens and progesterone are present; 1 day of ovulation in which the concentration of luteinizing hormone increases because of increased estradiol; and a luteal phase (LP) lasting between 12 and 14 days, characterized by high concentrations of estrogens and progesterone (10). Some studies had reported that during the FP hunger or food consumption is lower compared to LP (11-14), but other authors had reported less hunger in LP (3). Furthermore, Brennan et al. found that energy intake was different between the menstrual cycle phases. Participants reported less hunger in FP than in LP, and demonstrated that energy intake in young healthy women is highly repeatable during FP (11).

On the other hand, Gregersen et al. reported that appetite ratings were not influenced by BMI, diet or weight, but they differed according to age and sex, and women had significantly higher satiety and fullness ratings than men (3). To our knowledge, we have not found any study in the literature that studies repeatability in men and in women in the different phases of the menstrual cycle. Therefore, the aim of this study was to analyze the repeatability of VAS scores in men and in women in the follicular and luteal phases of the menstrual cycle. We hypothesized that men and women in LP and in FP would experience different SAS after intake of a standardized meal.

MATERIALS AND METHODS

STUDY POPULATION

Thirty-four participants were recruited using posters and flyers from August to December 2019. The study was carried out in the Instituto de Nutrigenética y Nutrigenómica Traslacional at Universidad de Guadalajara. We hypothesized that men and women at different menstrual cycle phase present differences in repeatability of subjective appetite sensations. The sample size was calculated with a statistical power of 80 %, according to the study of Horner et al., who considered a sample size between 36 and 73 to detect a 10 mm change in the VAS of a paired design (15). Inclusion criteria were men and women aged 18-25 years, with normal weight, with a regular breakfast habit. Women were included if they had a regular menstrual cycle (28-32 days). A woman was considered in the follicular phase (FP) when she was within the first 5-7 days of the onset of menstruation, and in the luteal phase (LP) when she was at 20-24 days after the first day of menstruation (10) as reported in a medical record. Exclusion criteria were subjects who followed a vegan or vegetarian diet, food allergies, elite athletes, being under treatment for weight loss, receiving medications that alter appetite, smokers, having respiratory symptoms, and women who were pregnant, breastfeeding or using contraceptives. Forty-two subjects were included in the study and signed the informed consent—5 of these did not meet all the inclusion criteria, and 3 abandoned the study in the re-test session. Finally, only 34 participants that completed all sessions were included. This study was approved by the Ethics and Biosafety Committees of the Health Sciences University Center of the Universidad de Guadalajara (Register number: CI-03619). All participants signed an informed consent, and all procedures were performed according to the Declaration of Helsinki (16).

ANTHROPOMETRIC MEASUREMENTS

Anthropometric measurements were performed after 10 h of fasting, without shoes and with light clothes. Height was determined using a stadiometer with a precision of 0.1 cm and a measuring range up to 205 cm (SECA® stadiometer, SECA GMBH & Co., Hamburg, Germany; model 213). Body composition was analyzed by electrical bioimpedance (Inbody 370, Biospace Co., Seoul, Korea, 250 kg capacity, 0.1 kg precision). Waist circumference was measured in the narrowest diameter between the last rib and the iliac crest using a Lufkin Rosscraft® tape (Lufkin Rosscraft® metal tape measure, NV, USA; model W606, range 0 to 200 cm, accurate to 0.1 cm).

VISUAL ANALOGUE SCALES

The VAS consisted of a straight horizontal line of 100 mm with the words "None" or "Not at all" located at the left end, and at the right end the words "Extremely" or "As much as I have ever felt". Participants were asked to mark a transversal line with an ultrafine point pen (Bic crystal, 0.7 mm) between these two ends according to their appetite sensation in that specific moment. Quantification was done by measuring the distance from the left end of the line to the mark, and then a numerical value was obtained (1,17).

CROSS-CULTURAL ADAPTATION

To address the translation from English to Spanish, a linguist translator participated in the process. Besides, specialists in the area reviewed that the translation of VAS was logical, easy to understand, semantic, and conceptually equivalent, so the desired information could be collected (Fig. 1). After translation and back-translation, the research group reviewed them and evaluated the equivalence with bilingual and monolingual individuals. Subsequently, VAS were applied to a group of nine university students. They were asked whether the instructions were clear on each VAS to ensure their comprehensibility.

BREAKFAST DESIGN

The breakfast fixed meal consisted of a sandwich and simple water. The amount and type of ingredients were as follows: 2 slices of half-baked whole wheat, 1 ½ tablespoon of sour cream, 2 slices of turkey ham (40 g), 1 slice of red tomato, 1 leaf of lettuce, and 250 mL of simple water. The composition of breakfast was 267 kilocalories (42 % carbohydrates, 23 % protein, and 35 % fat). Energy and macronutrient content were analyzed with the Nutritionist Pro™ software (Axxya Systems, Stafford, TX, USA).

STUDY DESIGN

Participants were asked to attend the research unit in two different sessions (test and retest). They attended at 7:40 h with an overnight fast of 10 hours. They were asked to arrive by bus, car, or train and with minimum or no physical activity the day prior to the intervention. At 8:00 h the participants went to a white room with sufficient lighting at room temperature. Qualified nutritionists gave them instructions to fill the VAS. While participants were fasting (from 8:10 to 8:15 h), the VAS were filled. Then, subjects had 10 minutes to eat breakfast. Immediately after, the VAS were filled one more time. Four weeks later, subjects were asked to repeat the same process under the same conditions.

STATISTICAL ANALYSES

Quantitative variables were assessed for normal distribution with the Kolmogorov-Smirnov test and expressed as mean ± standard deviation (SD) or median and interquartile range. Comparisons between groups were performed with one-way ANOVA or the Kruskal-Wallis test. Differences between tests and re-tests were analyzed with the paired t-test or Wilcoxon's test. Repeatability was analyzed through the coefficient of repeatability (CR) and intraclass correlation coefficient (ICC). CR was calculated as $CR = 2 \times SD$, where SD is the SD of the differences between paired data (18).

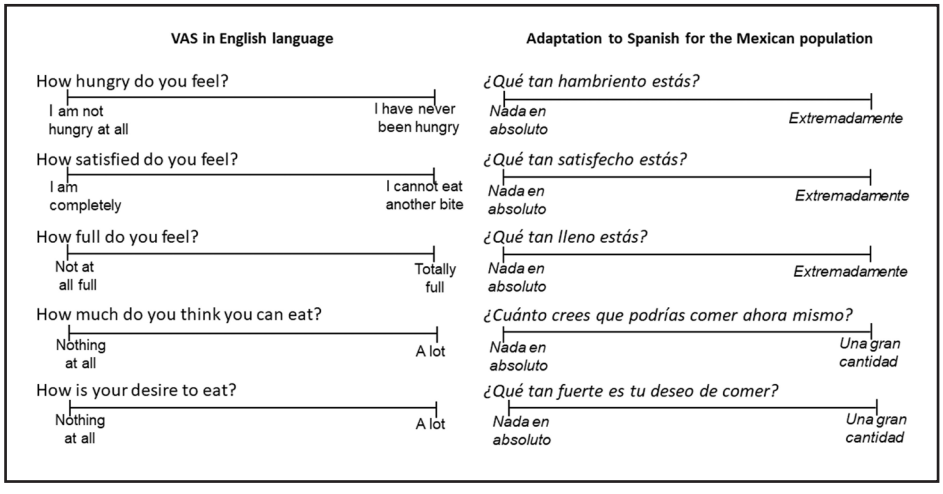

Figure 1.

Cross-cultural adaptation of VAS to the Spanish language.

A Bland-Altman plot was also calculated. ICC was calculated using the two-way mixed model and absolute agreement (19). Excellent repeatability was concluded when ICC > 0.8, good when between 0.7 and 0.8, and moderate when between 0.6 and 0.7 (20). To compare ICC between groups we used the Cocor software version 1.1-3 (21). Data were analyzed using SPSS version 21.0 (IBM Corp., Armonk, NY). Graphics were created with Graphpad Prism version 8.3.1 (GraphPad Software, San Diego, CA).

RESULTS

GENERAL CHARACTERISTICS OF THE STUDY POPULATION

A total of 34 participants (50 % women) were enrolled with a mean age of 21.0 ± 1.4 years. Nine women were at FP and eight women were at LP of the menstrual cycle. All anthropometric variables, except BMI, were different between men and women but not between groups of women. Age was also no different between groups (Table I).

SPANISH ADAPTATION OF VAS

The cross-cultural adaptation of the Spanish version of VAS were easy to fill, comprehensible, well understood, and none of the scale forms remained incomplete or unanswered.

APPLICATION OF VAS

The change (Δ) between post-breakfast and fasting VAS was compared between test and retest sessions and no differences were found. Besides, hunger, desire to eat, and prospective food consumption diminished after breakfast; fullness and satiety increased (Fig. 2).

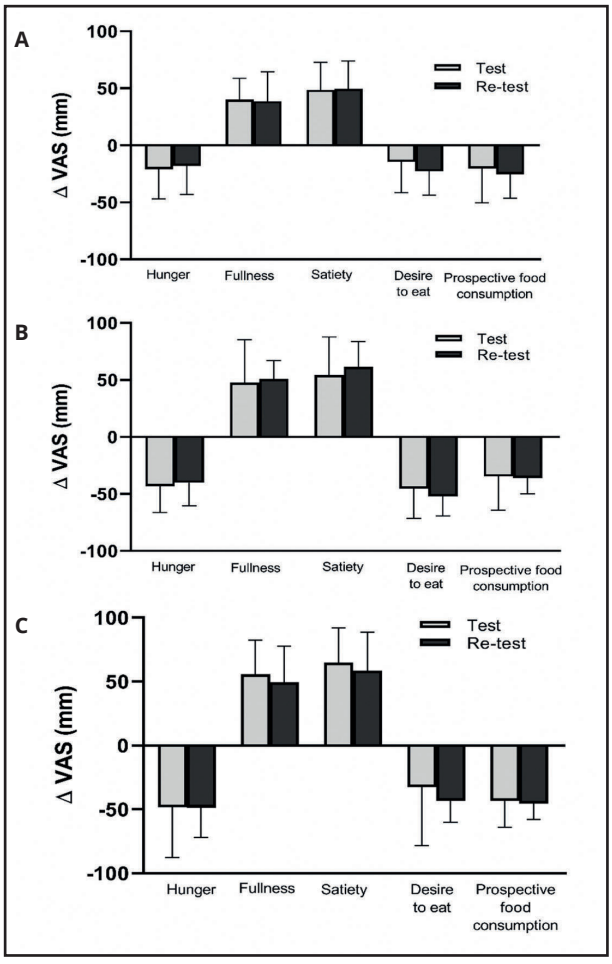

Figure 2.

Changes in subjective appetite sensations in test and re-test sessions. Changes in appetite sensations in men (A), women in follicular phase (B), and women in luteal phase (C).

Table I. Anthropometric characteristics of study population

Variable	Total *n* = 34	Men *n* = 17	Women (follicular phase) *n* = 9	Women (luteal phase) *n* = 8	*p*-value
Age (y)	21.0 ± 1.4	21.2 ± 1.0	21.0 ± 2.1	20.5 ± 1.1	0.471
BMI (kg/m^2)	21.9 ± 1.9	22.4 ± 2.1	21.6 ± 1.7	21.3 ± 1.6	0.382
Waist circumference (cm)	73.6 ± 6.2	77.4 ± 6.0^a	70.7 ± 2.6^b	68.6 ± 4.2^b	*< 0.001*
Body fat percentage (%)	24.5 ± 7.2	19.5 ± 4.5^a	31.3 ± 5.5^b	27.3 ± 6.0^b	*< 0.001*
Fat free mass (kg)	47.7 ± 9.5	55.3 ± 6.1^a	38.7 ± 4.3^b	41.4 ± 5.3^b	*< 0.001*
Skeletal muscle mass (kg)	26.4 ± 5.8	31.1 ± 3.7^a	20.9 ± 2.6^b	22.6 ± 3.1^b	*< 0.001*
Lean mass (kg)	44.6 ± 9.0	52.1 ± 5.8^a	36.4 ± 4.1^b	39.0 ± 5.0^b	*< 0.001*
Total body water (kg)	34.9 ± 6.9	40.6 ± 4.4^a	28.4 ± 3.2^b	30.3 ± 3.9^b	*< 0.001*

Data are expressed as mean ± SD. Superscripts indicate statistical difference, that is, means sharing a superscript "a" show no differences between them; if one mean has superscript "a" and another superscript "b", they are statistically different.

REPEATABILITY OF VAS

Repeatability of the five VAS in fasting ranged at 30-49 in men, 27-37 in women FP, and 37-95 in women LP. In post-breakfast, repeatability ranged within 31-45, 29-52, and 20-75 in men, women FP, and women LP, respectively. When using the ICC, women LP displayed values less than 0.5 in most of the VAS; contrary, most of VAS in women FP and men showed ICC values greater than 0.7; but comparisons of these coefficients of correlation between groups, showed that only the ICC of hunger and desire to eat were different between men and women (Table II).

Finally, Bland-Altman plots are shown in figure 3 for post-breakfast hunger and satiety in the three groups. It was observed that in men one subject was outside of limits of agreement. Besides, in the LP group, the interval agreement for post-breakfast satiety scale was wider when compared with the other groups.

DISCUSSION

In the present study, the adaptation and repeatability of the five VAS used to measure SAS were assessed. The utilization of VAS allowed the evaluation of somatic sensory aspects in a practical and repeatable way, and we were able to translate them for their use in the Spanish language. One of the challenges is the adaptation of scales validated and implemented in other countries. In Spanish-speaking countries few studies related to the adaptation of SAS have been reported—for example, Ozório et al. adapted VAS for assessing appetite in the Portuguese language in Brazil. However, the population involved in that study were exclusively hospitalized cancer patients (22). Further, González-Antón et al. adapted VAS to the Spanish language in Spain to assess appetite sensations and glycemic response (23), which hinders an objective comparison with our study.

Among the parameters used to assess repeatability, the most widely used is the CR (18), but ICC has also been applied successfully to describe repeatability in satiety research (24-26) and it is recognized as a useful tool for an objective evaluation to classify repeatability as high or low (20). Importantly, the use of more than one indicator allows to strengthen the interpretation of results and increase the ability to do comparisons between studies (20).

In this study, the repeatability of VAS was assessed through the CR and ICC indicators in three different groups: men and women both in FP and LP. Regarding the repeatability of VAS in the group of men, it is important to note that although most authors have reported a lower repeatability in fasting scores (5,15,27), our study showed that CR values were very similar for fasting and post-breakfast, with a CR range from 30 to 49. The fullness scale was the most repeatable according to CR, as for both in fasting

Table II. Repeatability of subjective appetite sensations

	Men *n* = 17				Women (follicular phase) *n* = 9				Women (luteal phase) *n* = 8				*p*-values for ICC comparisons		
VAS	Test mean (mm)	Re-test mean (mm)	CR	ICC	Test mean (mm)	Re-test mean (mm)	CR	ICC	Test mean (mm)	Re-test mean (mm)	CR	ICC	*p1* men vs FP	*p2* men vs LP	*p3* FP vs LP
Fasting															
Hunger	51	52	49	0.5	74	77	37	0.2	68	64	90	-0.5	0.477	0.035	0.214
Fullness	19	17	30	0.6	12	7	34	0.3	15	20	41	0.0	0.431	0.183	0.609
Satiety	17	15	43	-0.1	11	6	27	0.5	10	18	37	-0.2	0.183	0.844	0.214
Desire to eat	54	59	45	0.6	71	83	35	0.4	56	60	95	-0.6	0.580	0.007	0.065
Prospective food consumption	70	67	41	0.7	68	80	33	0.6	66	69	38	0.4	0.721	0.394	0.656
Post-breakfast															
Hunger	30	34	39	0.6	31	37	29	0.8	20	16	27	0.7	0.406	0.738	0.702
Fullness	59	56	31	0.7	60	58	52	0.4	71	69	69	0.0	0.363	0.096	0.484
Satiety	66	65	45	0.5	65	67	42	0.6	74	76	75	0.0	0.768	0.291	0.252
Desire to eat	40	36	42	0.6	26	31	29	0.8	24	16	42	0.5	0.406	0.782	0.364
Prospective food consumption	50	41	42	0.5	33	44	39	0.5	23	23	20	0.9	1.000	0.076	0.127

FP: follicular phase; LP: luteal phase.

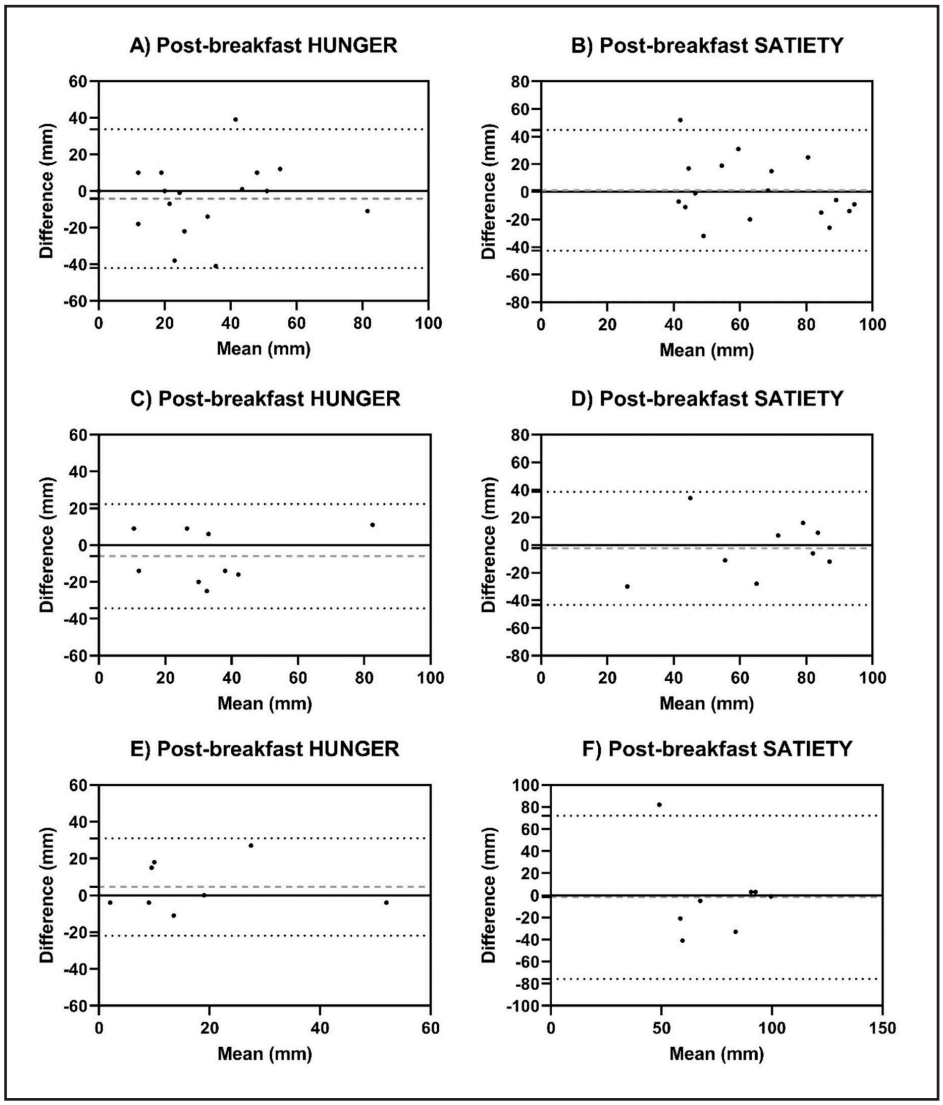

Figure 3.

Bland-Altman plots for hunger and satiety. A and B. Men. C and D. Women in follicular phase. E and F. Women in luteal phase. The black dashed lines represent the 95 % limits of agreement; the grey dashed line indicates mean bias.

and post-breakfast in men. The CR for the fullness scale was similar to those reported by Flint et al. (27) and Raben et al. (28), and smaller than the one reported by Horner et al. during fasting (15). In general, the CRs of VAS of Horner et al. were higher than ours, probably because their study was done in subjects with overweight and obesity (15). Besides, according to the ICC interpretation (20), all applied scales in men (except satiety in fasting) in both fasting and post-breakfast, showed good repeatability.

Repeatability of VAS was also analyzed in women in FP or LP of their menstrual cycle. Regarding the FP group, the study by Tucker et al. also included healthy women in the FP (25). These results agree with ours as for the scales with the best repeatability being hunger and desire to eat, with an ICC between 0.72 and 0.67; nevertheless, our ICC values were higher. Tucker et al. also concluded that the scales were not repeatable because an ICC ranged from 0.18 to 0.40 (25). In our case, fasting and post-breakfast ICC values in this group of women achieved a good and excellent repeatability for most of them. About the CR in the study of Tucker et al., the scores of hunger, fullness, and desire to eat in fasting were similar to those found in this study; the exception was the CR of prospective food consumption, which was lower in this study. The repeatability of VAS to assess SAS in women in LP has not been reported previously.

It has been mentioned that interpretation of repeatability as strong or weak is very subjective (25). The CR scores mean that 95 % of the differences between a test and a re-test will fall within this value, that is, within the limits of agreement proposed by Bland Altman (18); but the ICC values can be classified in categories such as excellent, good, or moderate repeatability (20). In this study, we compared ICC between groups to determine if repeatability of VAS was different between them. In fact, repeatability of the five VAS in fasting and post-breakfast times was similar between men, women in FP, and women in LP. The only exception was fasting hunger and desire to eat between men and women in LP. Some authors have suggested that VAS in appetite research should be used only when women are in the follicular phase due to changes in energy intake and energy expenditure (25,27). Interestingly, no differences were detected

in VAS repeatability between women in different menstrual cycle phases; nevertheless, more studies that corroborate our findings should be design. To our knowledge, this is the first study that report objective comparisons of VAS repeatability scores by sex or different menstrual cycle phases in women in appetite research.

When evaluating the repeatability of VAS, different methodologies are performed such as fixed meal (15) or meal with energy content according to individual needs (27), others give a standardized diet before the intervention (27), while others do not (25), and repeatability tests are made within different time intervals such 3-4 weeks (27) or only 7 days (15). Besides repeatability is calculated with different formulas (15,25). Therefore, it is important to establish standardized criteria to compare studies in a more precise way.

The limitations of this study were the lack of a biochemical markers of menstrual cycle phase and the age of participants due to all were young subjects with normal weight, which does not allow us to generalize the usefulness of this instrument. Future studies are required to assess the repeatability of VAS in the Spanish language populations, including a wider range of ages and BMI.

CONCLUSIONS

In conclusion, the adaption of VAS to assess SAS to the Spanish language was comprehensible and the questions were easy to fill and well understood. Repeatability of the VAS was similar between men and women in different stages of the menstrual cycle. Previously, no study had evaluated repeatability in women in the LP of the menstrual cycle and none of them had compared ICC between groups; therefore, further studies considering these characteristics and with larger sample sizes are needed to corroborate our findings.

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ARÁN

Nutrición Hospitalaria

Trabajo Original

Valoración nutricional

Preoperative nutritional factors as predictors of postoperative early outcomes in colorectal cancer — A prospective cohort study

Factores nutricionales preoperatorios como predictores de resultados postoperatorios precoces en cáncer colorrectal: un estudio prospectivo de cohortes

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Abstract

Introduction: in colorectal cancer (CRC) surgery, preoperative nutritional factors are often overlooked or underestimated. This situation represents a significant deficiency that may negatively affect patients' postoperative recovery processes.

Objective: the objective of this study was to evaluate the impact of preoperative malnutrition, sarcopenia, obesity, and dietary inflammatory potential on early postoperative outcomes in CRC.

Methods: preoperative sarcopenia was identified using European Working Group on Sarcopenia in Older People (EWGSOP2) criteria based on skeletal muscle obtained from computed tomography (CT) scans, and malnutrition was identified using Global Leadership Initiative on Malnutrition (GLIM) criteria. Visceral and subcutaneous obesity were assessed using CT scans. The energy-adjusted dietary inflammatory index (E-DII) was calculated from dietary records.

Results: a total of 121 patients were included in the study, and 45.5 % of them were malnourished according to GLIM, 15.7 % were sarcopenic according to EWGSOP2. Multivariate logistic regression analysis showed that sarcopenia [OR = 3.973 (1.028-15.353), $p = 0.043$], malnutrition [OR = 3.954 (1.479-10.575), $p = 0.006$], and E-DII [OR = 4.955 (1.397-17.571), $p = 0.013$] were independent risk factors for complications. Sarcopenia [OR = 6.894 (1.080-43.998), $p = 0.041$] was also risk factor for long-term hospitalization.

Conclusion: a comprehensive evaluation of preoperative nutrition and related factors in CRC surgery, along with timely interventions, has the potential to significantly reduce postoperative complications and length of hospital stays.

Keywords:

Sarcopenia. Malnutrition. Body composition. Colorectal surgery. Complications.

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Ethics approval: the Non-Invasive Clinical Research Ethics Committee at Hacettepe University gave its permission to this research (GO 21/499). The Declaration of Helsinki was followed in the conduct of the research, and the volunteer participants signed informed permission forms. ClinicalTrials.gov has the NCT06016829 research registration number.

Conflicts of interest: the authors declare that the research was conducted without any commercial or financial relationship that could be interpreted as a potential conflict of interest.

Artificial intelligence: the authors declare that they have not used artificial intelligence (AI) or any AI-enabled technology in the preparation of the manuscript.

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Resumen

Introducción: en la cirugía del cáncer colorrectal (CCR), los factores nutricionales preoperatorios suelen pasarse por alto o subestimarse. Esta situación representa una carencia importante que puede afectar negativamente a los procesos de recuperación postoperatoria de los pacientes.

Objetivo: el objetivo de este estudio fue evaluar el impacto de la desnutrición preoperatoria, la sarcopenia, la obesidad y el potencial inflamatorio de la dieta en los resultados postoperatorios tempranos en el CCR.

Métodos: la sarcopenia preoperatoria se identificó mediante los criterios del Grupo Europeo de Trabajo sobre Sarcopenia en Personas Mayores (EWGSOP2) basados en el músculo esquelético obtenido mediante tomografía computarizada (TC), y la malnutrición se identificó mediante los criterios de la Iniciativa de Liderazgo Global sobre Malnutrición (GLIM). La obesidad visceral y subcutánea se evaluó mediante TC. El índice inflamatorio dietético ajustado a la energía (E-DII) se calculó a partir de los registros dietéticos.

Resultados: un total de 121 pacientes fueron incluidos en el estudio; el 45,5 % de ellos estaban desnutridos según la GLIM, y el 15,7 % sarcopénicos según el EWGSOP2. El análisis de regresión logística multivariante mostró que la sarcopenia [OR = 3,973 (1,028-15,353), $p = 0,043$], la desnutrición [OR = 3,954 (1,479-10,575), $p = 0,006$] y el E-DII [OR = 4,955 (1,397-17,571), $p = 0,013$] eran factores de riesgo independientes de complicaciones. La sarcopenia [OR = 6,894 (1,080-43,998), $p = 0,041$] también fue un factor de riesgo de hospitalización a largo plazo.

Conclusiones: una evaluación exhaustiva de la nutrición preoperatoria y los factores relacionados en la cirugía del CCR, junto con intervenciones oportunas, tiene el potencial de reducir significativamente las complicaciones postoperatorias y la duración de las estancias hospitalarias.

Palabras clave:

Sarcopenia. Desnutrición. Composición corporal. Cirugía colorrectal. Complicaciones.

INTRODUCTION

Colorectal cancer (CRC) is the third most common malignancy and the second leading cause of mortality within the spectrum of all malignant neoplasms (1). Surgery is the main treatment for early-stage CRC. Despite advances in surgical techniques and improved perioperative care, about one third of patients still experience complications after colorectal surgery (2). Surgical treatment can lead to inflammation and metabolic stress. Nutritional factors such as preoperative malnutrition or sarcopenia prevent the patient from tolerating surgical stress and lead to poor postoperative outcomes (3). Preoperative malnutrition is a common occurrence in gastrointestinal cancers. Malnutrition has been reported in approximately 40 % of patients undergoing gastrointestinal surgery (4). Patients undergoing colorectal surgery are more susceptible to malnutrition due to various factors, including inadequate intake caused by intestinal obstruction or cancer-related anorexia, malabsorption, excessive losses from intestinal fistulas and a marked inflammatory response (5). Different diagnostic criteria for malnutrition have been used, but there was no universal consensus. The Global Leadership Initiative on Malnutrition (GLIM) has recently published international consensus-based diagnostic criteria for malnutrition (6). Previous studies have reported that a preoperative diagnosis of GLIM malnutrition in various types of cancer adversely affects postoperative outcomes (7,8).

Computed tomography (CT) scans, a component of CRC cancer screening and therapy protocols, are also used to assess body composition factors such as skeletal muscle and adipose tissue (9). Sarcopenia, a condition marked by a reduction in both the quantity and functionality of skeletal muscle, has been shown to have an adverse impact on postoperative outcomes and survival rates in CRC (10,11). The majority of studies have diagnosed sarcopenia solely on the basis of skeletal muscle mass obtained from CT scans. However, a reduced in muscle strength is the main diagnostic criterion for sarcopenia, according the most recent guidelines published by European Working Group on Sarcopenia in Older People (EWGSOP2) (12). Not only sarcopenia or low skeletal muscle mass but also obesity affects surgical outcomes. Studies examining the effect of obesity on surgical outcomes in CRC based on CT-derived adipose tissue area (visceral or subcutaneous) are more limited and results are conflicting.

The Dietary Inflammatory Index (DII) was developed based on evidence of the relationship between diet and blood markers of inflammation (13). A higher DII score, indicating a diet high in inflammation, was found to correlate with an increased likelihood of developing CRC (14). The effect of dietary inflammatory potential on the outcomes of colorectal surgery has not been extensively studied, except for one research article that examined its impact on the duration of hospitalization (15).

The objective of the study was to evaluate the impact of preoperative malnutrition, sarcopenia (defined by EWGSOP2 criteria), obesity (assessed by CT scan), and dietary inflammatory potential on early postoperative outcomes in patients with CRC.

MATERIAL AND METHODS

STUDY POPULATION

This prospective cohort study included patients scheduled for colorectal surgery at Bilkent City Hospital between July 2021 and December 2022. The following were the inclusion criteria: being diagnosed with CRC; being at least 18 years old; and being planned for colorectal surgical treatment. The following were exclusion criteria: having received neoadjuvant therapy; currently receiving corticosteroid or hormone therapy; distant metastasis; any malignancy other than CRC; autoimmune disease; active infectious disease. The flow chart of the study was shown in figure 1. During the study period, a cohort of 147 consecutive individuals diagnosed with CRC and scheduled for colorectal surgery were included in the study. A total of 26 patients were excluded from the study as a result of surgery cancellation, neoadjuvant therapy, and missing data; as a result, 121 patients remained in the final analysis.

The Non-Invasive Clinical Research Ethics Committee at Hacettepe University gave its permission to this research (GO 21/499). The Declaration of Helsinki was followed in the conduct of the research, and the volunteer participants signed informed permission forms.

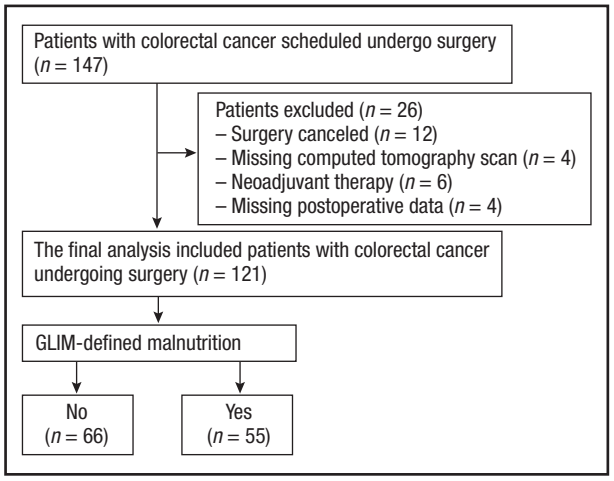

Figure 1.

Flow chart of the patients included and excluded. GLIM: Global Leadership Initiative on Malnutrition.

STUDY PROTOCOL

Researchers performed in-person interviews with patients during a timeframe of 1-3 days before to the operation. During these interviews, a questionnaire was administered that included general information, dietary records, and nutrition screening tests. Body weights were measured with the Tanita BC730 and height was measured using a stadiometer. Patients' self-reported body weights from 1, 3, and 6 months ago were recorded, and if weight loss was observed in the recorded data for the last 1, 3, and 6 months, the percentage of weight loss was calculated. The patients were asked whether the weight loss was intentional. A photographic food atlas was used to obtain the 24-hour dietary recall of patients. Energy and nutrient intakes were determined using the Nutrition Information System (BeBIS, version 8.1) software program.

Tumor location, TNM stage, comorbidities, information about surgery, and postoperative outcomes were obtained from hospital records. In order to assess comorbidities, the Charlson Comorbidity Index (CCI) was used (16).

Biochemical parameters analyzed within 48 hours prior to surgery were recorded from the hospital's data system. The delta neutrophil index (DNI), neutrophil lymphocyte ratio (NLR), and prognostic nutritional index (PNI) were used for the evaluation of systemic inflammation. The DNI was obtained directly from the records as a routine blood count parameter. NLR was calculated by dividing the quantity of neutrophils by lymphocytes. PNI was determined using the following formula: {10 x albumin (g/dL)} + {0.005 x total lymphocyte count}.

MUSCLE STRENGTH

Hand grip strength was measured using a Takei 5401 digital hand dynamometer (Takei Scientific Instruments, Tokyo, Japan) to evaluate muscle strength. The measurement was taken three times from each hand while standing, with the forearm at thigh level and away from the body. The mean of the six measurements was used to determine the grip strength. Low muscle strength was considered to be < 27 kg for males and < 16 kg for females (12).

BODY COMPOSITION ANALYSIS FROM CT SCANS

CT scans taken within one month prior to surgery were received from the Picture Archiving and Communication System (PACS). Body composition analysis was performed on the third lumbar vertebra (L3) cross-sectional area using ImageJ 1.53j (National Institutes of Health, Bethesda, Maryland, USA) following the steps in the protocol detailed previously (17). Hounsfield unit (HU) thresholds specific for skeletal muscle, visceral, and subcutaneous adipose tissue were used in the analyses (Fig. 2). All analyses were performed by a trained researcher (TNYK) blinded to the patient's clinical information. To verify the accuracy and reproducibility of the results, 10 randomly selected patient images were independently analyzed by a second blinded trained researcher (HFY). The intraclass correlation coefficient was 0.99 (95 % CI, 0.98-1.00) for SMA, 1.00 (95 % CI, 0.99-1.00) for SATA and 1.00 (95 % CI, 0.99-1.00) for VATA.

SARCOPENIA AND CT-BASED OBESITY DEFINITION

Skeletal muscle area (SMA) were divided by the square of the patients' height (m^2) to obtain the skeletal muscle index (SMI). The SMI cutoff values determined by Martin et al. (18) were used to identify individuals with low skeletal muscle mass. For females, the cutoff was 41 cm^2/m^2. For males with a BMI < 25, the cutoff was 43 cm^2/m^2. For males with a BMI ≥ 25, the cutoff was 53 cm^2/m^2. Sarcopenia diagnosis was established according the revised criteria of the EWGSOP2, beginning with the identification of probable sarcopenia based on low muscle strength [10]. Within the probable sarcopenic patients, those with low skeletal muscle mass determined by CT have been diagnosed with sarcopenia. As our study did not measure physical performance, we did not evaluate the severity of sarcopenia.

There was no widely accepted CT-based cut-off point to define visceral and subcutaneous obesity. We determined visceral adipose tissue area (VATA) and subcutaneous adipose tissue area (SATA) cut-off points for CT-based obesity diagnosis by receiver operating characteristic (ROC). Figure 3 shows CT images of patients with different body composition from our study sample.

ASSESSMENT OF MALNUTRITION

A systematic two-step approach was used to identify malnutrition in patients. The initial assessment of patients for malnutrition

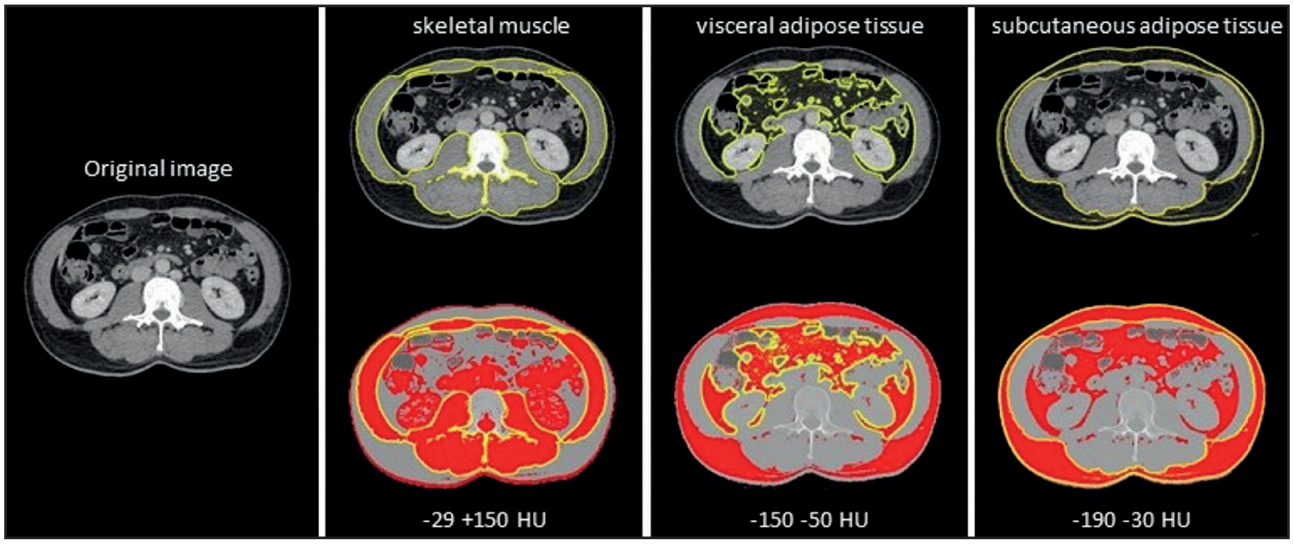

Figure 2.

Body composition analysis from third lumber vertebra cross-sectional area. Hounsfield unit (HU) values for skeletal muscle area, visceral or subcutaneous adipose tissue area were applied for each as indicated in the figure. Then, only the area within the yellow line was calculated from the resulting red area. The red area outside the yellow line was manually selected and subtracted from the final result.

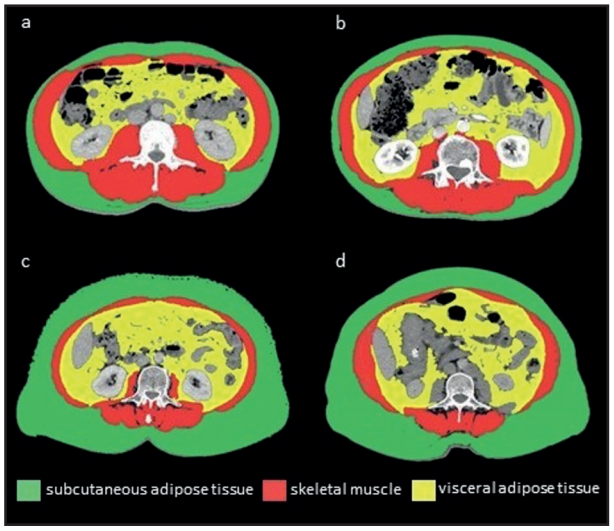

Figure 3.

Computed tomography 3rd lumbar vertebra cross-sectional area images of patients with different body compositions: A. Male with a healthy body composition. B. Male with sarcopenia. C. Female with sarcopenia and visceral and subcutaneous obesity. D. Female with visceral and subcutaneous obesity.

risk was conducted using NRS2002. Patients with scores of 3 or higher were identified as at-risk. Subsequently, these individuals underwent a second evaluation to determine if they met the criteria for a malnutrition diagnosis, using the GLIM criteria. The GLIM criteria required that at least one phenotypic (involuntary weight loss, low BMI, decreased muscle mass) and one etiologic criterion (decreased food intake or assimilation, disease burden/inflammation) be satisfied in order to diagnose malnutrition (6). As cancer met the etiological criterion, the presence of at least one phenotypic criterion was sufficient for the diagnosis of malnutrition in this study.

CALCULATION OF E-DII

We assessed the inflammatory potential of the diet using the Dietary Inflammatory Index (DII) developed by Shivappa et al. based on 24-hour dietary recalls (13). The DII uses 45 food parameters to assess the inflammatory potential of the diet. Since we were able to obtain data on 37 food parameters from 24-hour dietary recalls and the BeBIS program, we included 37 of the 45 food parameters. Food parameters not included were trans fatty acid, flavon-3-ol, flavonones, flavonols, flavones, anthocyanidins, isoflavones, eugenol. By summing the DIIs calculated separately for each food parameter, an overall DII score for the daily diet of individuals is obtained. We used the energy-adjusted E-DII in our research. For the E-DII, the individual's food intakes were calculated per 1000 kcal and adjusted so that the global average food intakes were also per 1000 kcal. E-DII scores were then calculated for each individual following the same formula as in the DII calculation (19). Greater inflammatory potential of the diet was indicated by higher E-DII scores. The E-DII scores were classified into tertiles, with the inflammatory potential progressively increasing from the first tertile to the third tertile.

POSTOPERATIVE OUTCOMES

The postoperative outcomes encompassed the occurrence of complications within a 30-day period and the length of hospital

stays after the surgery. The investigator responsible for monitoring postoperative outcomes was blinded to the results of the preoperative assessments. Postoperative complications were evaluated using the Clavien-Dindo classification (20), and only complications classified as Grade 2 or higher were considered in the analysis. A hospital stay was deemed long-term if it exceeded 7 days.

STATISTICAL ANALYSIS

The sample size was established using the G*Power software program version 3.1, based on the association between nutritional risk status and the frequency of postoperative complications. Accordingly, the minimum sample size for our research was 117 (error rate: 0.05; power: 80 %; effect size: 0.26). The data were analyzed using SPSS v22.0 (Chicago, USA). Statistical significance was determined by a two-sided *p*-value of less than 0.05. Based on data distribution, continuous variables were presented as the mean ± standard deviation (SD) or the median and interquartile range (IQR). The categorical variables were shown as frequencies and percentages. The Chi-square test was used to compare categorical variables, while the Student t-test or Mann-Whitney U-test was utilized to compare continuous variables, according to the normality of the distribution. The cutoff points for VATA and SATA values for defining visceral and subcutaneous obesity were determined separately for males and females using ROC curve analysis, with obesity characterized as BMI ≥ 25 kg/m². For the purpose of identifying risk factors for long-term postoperative hospital stays and complications, univariate logistic analysis was followed by multivariate logistic regression analysis. To identify risk factors for long-term postoperative hospital stays and complications, we conducted univariate logistic analysis followed by multivariate logistic regression analysis.

RESULTS

CLINICAL CHARACTERISTICS

Table I presents the clinical characteristics of the patients. Of the 121 patients included in the study, 55 (45.5 %) were diagnosed with malnutrition according to GLIM criteria. The mean age of the patients was 62.3 ± 12.08 years and the majority of patients (62.8 %) were male. There was no significant difference observed between those with malnutrition and those without in terms of gender, tumor location, stage, stoma presence, operation duration, and postoperative oral feeding time. Malnourished patients had a higher mean age, Charlson comorbidity index, and length of postoperative hospital stay ($p < 0.05$). Postoperative complications (Clavien-Dindo ≥ 2) developed in a total of 39 (32.2 %) patients. The frequency of complications in malnourished patients was 54.5 %, while in without malnutrition patients, it was 13.6 % ($p < 0.05$).

Table I. Clinical characteristics of patients

Variables	Total (*n* = 121)	Malnutrition		*p*
		No (*n* = 66)	Yes (*n* = 55)	
Gender				
Male	76 (62.8 %)	38 (57.6 %)	38 (69.1 %)	0.192
Female	45 (37.2 %)	28 (42.4 %)	17 (30.9 %)	
Age (years)	62.3 ± 12.08	60.0 ± 11.86	65.0 ± 11.88	0.023*
< 65	58 (47.9 %)	36 (54.5 %)	22 (40.0 %)	0.111
≥ 65	63 (52.1 %)	30 (45.5 %)	33 (60.0 %)	
Charlson comorbidity index	4.0 ± 1.72	3.7 ± 1.76	4.4 ± 1.61	0.025*
Tumor location				
Colon	50 (41.3 %)	27 (40.9 %)	23 (41.8 %)	0.919
Rectum	71 (58.7 %)	39 (59.1 %)	32 (58.2 %)	
Surgical approach				
Laparoscopic	51 (42.1 %)	34 (51.5 %)	17 (30.9 %)	0.022*
Open	70 (57.9 %)	32 (48.5 %)	38 (69.1 %)	
TNM stage				
I	18 (14.9 %)	11 (16.7 %)	7 (12.7 %)	
II	47 (38.8 %)	27 (40.9 %)	20 (36.4 %)	0.625
III	56 (46.3 %)	28 (42.4 %)	28 (50.9 %)	

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Table I (Cont.). Clinical characteristics of patients

Variables	Total (*n* = 121)	Malnutrition		*p*
		No (*n* = 66)	Yes (*n* = 55)	
Stoma No Yes	 68 (56.2 %) 53 (43.8 %)	 37 (56.1 %) 29 (43.9 %)	 31 (56.4 %) 24 (43.6 %)	0.973
Clavien-Dindo < 2 ≥ 2	 82 (67.8 %) 39 (32.2 %)	 57 (86.4 %) 9 (13.6 %)	 25 (45.5 %) 30 (54.5 %)	< 0.001*
Operation duration (min)	260.1 ± 71.14	259.5 ± 71.86	260.7 ± 70.92	0.928
Postoperative oral feeding time (days)	2.0 (2.00)	2.0 (2.00)	2.0 (4.00)	0.727
Length of postoperative hospital stay (days)	7.0 (5.00)	7.0 (2.00)	10.0 (7.00)	< 0.001*

**p < 0.05 is significant.*

VISCERAL AND SUBCUTANEOUS OBESITY CUT-OFF VALUES

According to the ROC analysis, the VATA cut-off values indicating visceral obesity were 172.03 cm^2 (AUC = 0.817; 95 % CI, 0.719-0.916; $p < 0.001$) for males and 128.43 cm^2 (AUC = 0.845; 95 % CI, 0.708-0.982; $p < 0.001$) for females. The SATA cut-off values indicating subcutaneous obesity were 145.75 cm^2 (AUC = 0.895; 95 % CI, 0.825-0.965; $p < 0.001$) and 218.81 cm^2 (AUC = 0.875; 95 % CI, 0.772-0.978; $p < 0.001$) in males and females, respectively.

NUTRITIONAL AND INFLAMMATORY PARAMETERS

The nutritional and inflammatory parameters of the patients are presented in table II. The patients' mean BMI was 27.1 ± 5.09 kg/m^2 and those with malnutrition had a lower mean BMI than those without malnutrition ($p < 0.001$). Additionally, SMI, VATA, and SATA were lower in patients with malnutrition. The prevalence of sarcopenia was 27.3 % among patients with malnutrition and 6.1 % in those without malnutrition ($p = 0.001$). The prevalence of visceral and subcutaneous obesity was lower in patients with malnutrition ($p = 0.028$, $p = 0.017$, respectively). There was no significant difference in mean grip strength between patients with and without malnutrition ($p = 0.139$). Nevertheless, the frequency of low grip strength was higher in malnourished patients (45.5 %) ($p = 0.037$). The E-DII was 0.5 ± 1.46 in the patients with malnutrition and -0.2 ± 1.19 in those without malnutrition ($p = 0.010$), and individuals in E-DII tertile 3 (higher pro-inflammatory diet indicator) accounted for approximately half (47.3 %) of the patients with malnutrition. While there was no significant difference in inflammatory biochemical parameters such as DNI and PNI, the frequency NLR ≥ 3 was higher in patients with malnutrition (56.4 %) compared to those without (34.8 %) ($p = 0.018$).

Table II. Nutritional and inflammatory parameters of patients

Variables	Total (*n* = 121)	Malnutrition		*p*
		No (*n* = 66)	Yes (*n* = 55)	
BMI (kg/m^2)	27.1 ± 5.09	28.7 ± 5.14	25.11 ± 4.29	< 0.001*
SMI (cm^2/m^2)	48.6 ± 9.81	51.1 ± 7.94	45.6 ± 11.01	0.002*
VATA (cm^2)	157.4 (115.31)	185.7 (98.63)	139.8 (121.70)	0.027*
SATA (cm^2)	171.7 (134.48)	207.1 (160.10)	144.4 (101.47)	0.001*
Grip strength (kg)	25.8 ± 8.70	26.9 ± 9.20	24.5 ± 7.95	0.139
Low grip strength No Yes	 78 (64.5 %) 43 (35.5 %)	 48 (72.7 %) 18 (27.3 %)	 30 (54.5 %) 25 (45.5 %)	0.037*

(Continues on next page)

Table II (Cont.). Nutritional and inflammatory parameters of patients

Variables	Total (*n* = 121)	Malnutrition		*p*
		No (*n* = 66)	Yes (*n* = 55)	
Low skeletal muscle				
No	76 (62.8 %)	50 (75.8 %)	26 (47.3 %)	0.001*
Yes	45 (37.2 %)	16 (24.2 %)	29 (52.7 %)	
Sarcopenia				
No	102 (84.3 %)	62 (93.9 %)	40 (72.7 %)	0.001*
Yes	19 (15.7 %)	4 (6.1 %)	15 (27.3 %)	
Visceral obesity				
No	55 (45.5 %)	24 (36.4 %)	31 (56.4 %)	0.028*
Yes	66 (54.5 %)	42 (63.6 %)	24 (43.6 %)	
Subcutaneous obesity				
No	56 (46.3 %)	24 (36.4 %)	32 (58.2 %)	0.017*
Yes	65 (53.7 %)	42 (63.6 %)	23 (41.8 %)	
E-DII	0.1 ± 1.35	-0.2 ± 1.19	0.5 ± 1.46	0.010*
E-DII				
Tertile 1 (-3.87 to -0.57)	40 (33.1 %)	27 (40.9 %)	13 (23.6 %)	0.008*
Tertile 2 (0.57 to 0.75)	41 (33.9 %)	25 (37.9 %)	16 (29.1 %)	
Tertile 3 (0.75 to 3.17)	40 (33.1 %)	14 (21.2 %)	26 (47.3 %)	
DNI				
< 0.1	94 (77.7 %)	54 (81.8 %)	40 (72.7 %)	0.232
≥ 0.1	27 (22.3 %)	12 (18.2 %)	15 (27.3 %)	
NLR				
< 3	67 (55.4 %)	43 (65.2 %)	24 (43.6 %)	0.018*
≥ 3	54 (44.6 %)	23 (34.8 %)	31 (56.4 %)	
PNI				
≥ 45	16 (13.2 %)	7 (10.6 %)	9 (16.4 %)	*0.352*
< 45	105 (86.8 %)	59 (89.4 %)	46 (83.6 %)	

*BMI: body mass index; SMI: skeletal muscle index; VATA: visceral adipose tissue area; SATA: subcutaneous adipose tissue area; E-DII: energy-adjusted dietary inflammatory index; DNI: delta neutrophil index; NLR: neutrophil lymphocyte ratio; PNI: prognostic nutritional index. *p < 0.05 is significant*

POSTOPERATIVE OUTCOMES

The results of the logistic regression analysis for risk factors predicting postoperative complications in CRC are shown in table III. Surgical approach ($p = 0.034$), sarcopenia ($p = 0.003$), visceral obesity ($p = 0.041$), malnutrition ($p < 0.001$), E -DII ($p = 0.001$) and NLR ($p = 0.011$) were risk factors associated with complications in univariate analysis. The multivariate analysis revealed that sarcopenia [OR = 3.973 (1.028-15.353), $p = 0.043$], malnutrition [OR = 3.954 (1.479-10.575), $p = 0.006$] and E-DII [OR = 4.955 (1.397-17.571), $p = 0.013$] were independent risk factors to predict postoperative complications.

In the univariate analysis of factors associated with long-term postoperative hospital stay, age ($p = 0.039$), surgical approach ($p = 0.001$), Charlson comorbidity index ($p = 0.023$), postoperative complication ($p < 0.001$) sarcopenia ($p = 0.002$), malnutrition ($p = 0.005$), and NLR ($p = 0.022$) were significant. In the multivariate analysis surgical approach [OR = 2.962 (1.133-7.747), $p = 0.027$], postoperative complication [OR = 16.993 (4.616-62.558), $p < 0.001$] and sarcopenia [OR = 6.894 (1.080-43.998), $p = 0.041$] were independent risk factors for long-term postoperative hospital stay (Table IV).

DISCUSSION

Our study has demonstrated the predictive role of various nutritional parameters in postoperative complications and long-term hospital stay in CRC.

Tabla III. Logistic regression analysis for predicting postoperative complications (Clavien-Dindo ≥ 2) in colorectal cancer

Variables	Univariate analysis			Multivariate analysis		
	OR	95 % CI	*p*	OR	95 % CI	*p*
Gender						
Male	Ref	0.200-1.074	0.073			
Female	0.463					
Age (years)						
< 65	Ref	0.518-2.386	0.787			
≥ 65	1.111					
BMI (kg/m²)	0.934	0.860-1.013	0.100			
< 25	Ref					
≥ 25	0.671	0.308-1.464	0.316			
Tumor location						
Colon	Ref	0.346-1.613	0.457			
Rectum	0.747					
Surgical approach						
Laparoscopic	Ref			Ref		
Open	2.424	1.067-5.509	0.034*	1.557	0.581-4.170	0.379
Charlson comorbidity index	1.160	0.924-1.455	0.201			
TNM stage						
I	Ref					
II	1.342	0.406-4.433	0.630			
III	1.232	0.381-3.984	0.728			
Stoma						
No	Ref					
Yes	1.563	0.725-3.367	0.254			
Operation duration (min)	1.003	0.998-1.009	0.256			
Sarcopenia						
No	Ref			Ref		
Yes	4.762	1.699-13.348	0.003*	3.973	1.028-15.353	0.043*
Visceral obesity						
No	Ref			Ref		
Yes	0.445	0.205-0.968	0.041*	0.586	0.222-1.545	0.280
Subcutaneous obesity						
No	Ref					
Yes	0.547	0.253-1.183	0.125			
Malnutrition						
No	Ref			Ref		
Yes	7.600	3.150-18.339	< 0.001*	3.954	1.479-10.575	0.006*
E-DII						
Tertile 1 (-3.87 to -0.57)	Ref			Ref		
Tertile 2 (0.57 to 0.75)	2.631	0.885-7.817	0.082			
Tertile 3 (0.75 to 3.17)	5.667	1.951-16.462	0.001*	4.955	1.397-17.571	0.013*

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Table III (Cont.). Logistic regression analysis for predicting postoperative complications (Clavien-Dindo ≥ 2) in colorectal cancer

Variables	Univariate analysis			Multivariate analysis		
	OR	95 % CI	*p*	OR	95 % CI	*p*
DNI						
< 0.1	Ref					
≥ 0.1	1.985	0.823-4.790	0.127			
NLR						
< 3	Ref			Ref		
≥ 3	2.773	1.263-6.087	0.011*	1.779	0.676-4.682	0.243
PNI						
≥ 45	Ref					
< 45	1.351	0.629-2.902	0.441			

*BMI: body mass index; E-DII: energy-adjusted dietary inflammatory index; DNI: delta neutrophil index; NLR: neutrophil lymphocyte ratio; PNI: prognostic nutritional index. *p < 0.05 is significant.*

Table IV. Logistic regression analysis for risk factors predicting long-term (> 7 days) postoperative hospital stay in colorectal cancer

	Univariate analysis			Multivariate analysis		
Variables	OR	95 % CI	*p*	OR	95 % CI	*p*
Gender						
Male	Ref					
Female	0.992	0.474-2.074	0.983			
Age (years)						
< 65 years	Ref			Ref		
≥ 65 years	2.153	1.041-4.453	0.039*	1.488	0.459-4.820	0.508
BMI (kg/m²)						
< 25	Ref					
≥ 25	0.569	0.269-1.202	0.140			
Tumor location						
Colon	Ref					
Rectum	1.642	0.792-3.405	0.182			
Surgical approach						
Laparoscopic	Ref			Ref		
Open	3.600	1.683-7.700	0.001*	2.962	1.133-7.747	0.027*
Charlson comorbidity index	1.296	1.037-1.620	0.023*	1.088	0.750-1.578	0.656
TNM stage						
I	Ref					
II	1.611	0.539-4.817	0.393			
III	0.750	0.259-2.175	0.596			
Stoma						
No	Ref					
Yes	1.930	0.931-4.003	0.077			
Operation duration (min)	1.003	0.998-1.009	0.208			

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Tabla IV (Cont.). Logistic regression analysis for risk factors predicting long-term (> 7 days) postoperative hospital stay in colorectal cancer

	Univariate analysis			Multivariate analysis		
Variables	**OR**	**95 % CI**	***p***	**OR**	**95 % CI**	***p***
Postoperative complication						
No	Ref			Ref		
Yes	17.824	5.744-55.308	<0.001*	16.993	4.616-62.558	< 0.001*
Sarcopenia						
No	Ref			Ref		
Yes	10.767	2.363-49.051	0.002*	6.894	1.080-43.998	0.041*
Visceral obesity						
No	Ref					
Yes	0.523	0.253-1.080	0.080			
Subcutaneous obesity						
No	Ref					
Yes	0.561	0.272-1.157	0.118			
Malnutrition						
No	Ref			Ref		
Yes	2.915	1.386-6.131	0.005*	0.722	0.258-2.017	0.534
E-DII						
Tertile 1 (-3.87 to -0.57)	Ref					
Tertile 2 (0.57 to 0.75)	0.864	0.361-2.066	0.742			
Tertile 3 (0.75 to 3.17)	1.353	0.560-3.267	0.502			
DNI						
< 0.1	Ref					
≥ 0.1	1.518	0.637-3.614	0.346			
NLR						
< 3	Ref			Ref		
≥ 3	2.368	1.135-4.940	0.022*	1.723	0.662-4.481	0.265
PNI						
≥ 45	Ref					
< 45	1.414	0.490-4.080	0.521			

*BMI: body mass index; E-DII: energy-adjusted dietary inflammatory index; DNI: delta neutrophil index; NLR: neutrophil lymphocyte ratio; PNI: prognostic nutritional index. *p < 0.05 is significant.*

Malnutrition was diagnosed using the recently validated GLIM criteria for CRC patients in our study (21). The use of the GLIM criteria can provide an objective and standardized assessment of malnutrition and can be an important tool in clinical practice. The prevalence of malnutrition defined by GLIM criteria was 45.5 % in our study. Studies defining malnutrition in CRC using GLIM criteria are still limited. However, in a few recent studies, this prevalence has been reported to be approximately 23.6 % to 60.7 % (22-24). This wide range is thought to be due to differences in age, cancer stage and application of GLIM criteria (such as muscle measurement technique) in the study populations. We also found that the risk of complications was four times higher in patients with malnutrition defined according to GLIM criteria compared to those without. Previous studies have previously shown that malnutrition, as defined by different nutritional screening tools, affects postoperative outcomes in CRC patients (25,26). Furthermore, malnutrition, defined according to GLIM criteria in recent years, has also been shown to negatively affect postoperative outcomes in CRC, similar to our results (22,27,28).

Our findings showed that a high preoperative pro-inflammatory diet increased the risk of postoperative complications. Previously published studies have reported that a high DII score increases the risk of developing CRC (14,29) and is even associated with post-diagnosis mortality (30). As far as we know, this is the first study investigating the impact of dietary inflammatory potential, as assessed by the E-DII, on the risk of postoperative complica-

tions in CRC. However, it has been reported that n-3 polyunsaturated fatty acids taken in the habitual diet in CRC patients lead to a decrease in the frequency of postoperative complications (31). In another study, a high intake of dietary fiber in the preoperative diet was associated with a lower risk of postoperative complications (32). Considering the anti-inflammatory properties of both n-3 fatty acids and dietary fiber, it can be said that these results parallel the findings of our study, which addressed the preoperative diet with the E-DII, incorporating both of these dietary components. In our study, we did not find a significant association between the E-DII and the risk of long-term hospitalization; however, a previous study has shown that an anti-inflammatory DII score reduced the length of hospital stay (15). The DII, being an index created based on the relationship between dietary components and inflammatory processes (13), is likely to have an impact on surgical outcomes. However, studies assessing not only the nutritional status of patients before surgery but also their overall dietary consumption, including nutrient compositions, diet quality, and the inflammatory potential of the diet, are needed.

In our research, we employed CT images at the level of the third lumbar vertebra for the assessment of body composition. As CT scanning is part of the diagnostic process in CRC patients, it does not require additional expenses and radiation exposure. Moreover, it has been widely utilized for the measurement of body composition in cancer patients in recent years. Despite advances in treatment approaches, high mortality rates in colorectal cancer patients highlight the importance of the prognostic role of body composition-related parameters such as sarcopenia and obesity (1,33,34). Our study revealed that the prevalence of sarcopenia according to EWGSOP2 criteria was 15.7 % and, as expected, the prevalence of sarcopenia was higher in malnourished patients. In a recent meta-analysis, the prevalence of sarcopenia, defined on the basis of CT-based low skeletal muscle mass, was reported to be 34 % (35). Similarly, in our study, the prevalence of CT-based low skeletal muscle mass was 37.2 %. However, in the revised sarcopenia criteria, muscle strength has been established as the primary criterion, as it is considered better at predicting adverse outcomes than muscle mass (12). According to our findings, sarcopenia as defined by the revised criteria is an independent risk factor for postoperative complications and long-term hospitalization. Consistent with our findings, previous studies on CRC have reported that preoperative sarcopenia increases the risk of postoperative morbidity and mortality (10,11,33,36). Nevertheless, all of these studies defined sarcopenia based on skeletal muscle mass alone. As far as we know, the association between sarcopenia determined by EWGSOP2 criteria and postoperative outcomes in CRC has not been previously reported. The lack of universally accepted criteria for diagnosing sarcopenia, as well as variations in measurement techniques and cutoffs for skeletal muscle mass in studies, complicates the interpretation of results.

In contrast to sarcopenia, the effect of visceral or subcutaneous obesity on postoperative outcomes has been less studied and remains unclear. A recent meta-analysis reported that CT-derived visceral obesity had no effect on overall postoperative complications and mortality (37). Similarly, in our study, both visceral and subcutaneous obesity showed no significant impact on postoperative complications and length of hospital stay. However, some studies have found that visceral obesity increases the risk of postoperative ileus and general complications (38,39). On the contrary, some studies have shown favorable effects of visceral and subcutaneous obesity on survival in CRC (34,40). In a recent study, no association was found between visceral obesity and survival and length of hospital stay (33). Although the reason for these inconsistent results has not been clearly explained, different methods of determining adipose tissue area between studies, different cutoff values and population-specific factors such as ethnicity may influence clinical outcomes. Furthermore, our study determined CT-based cut-off values for visceral and subcutaneous adipose tissues using ROC curve analysis to overcome the lack of population-specific cut-off values not available in the literature. These cut-off values are important for future studies as they provide confirmatory and comparable data.

Our study has some limitations such as being single-centered and the observational design limiting causal inference. In addition, although our aim was to obtain a 3-day dietary consumption record to assess the preoperative dietary inflammatory potential, we were only able to obtain a 1-day dietary record using the 24-hour recall method due to the preoperative fasting status of the patients. However, unlike most retrospective studies in this field, the strength of our study was its prospective design and comprehensive assessment of preoperative nutritional factors.

CONCLUSION

Preoperative sarcopenia, malnutrition, and inflammatory capacity of the diet can be used as determinants of early outcomes in CRC surgery. As part of perioperative care, it is important to conduct a comprehensive examination of nutrition-related factors, including nutritional status, body composition, and inflammatory capacity of the diet. Timely intervention based on these factors can improve postoperative outcomes, which is beneficial for both patient welfare and hospital costs.

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ARÁN

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Trabajo Original

Epidemiología y dietética

Association of serum 25-hydroxyvitamin D concentrations and myopia in the U.S. Population — Results from the NHANES 2001-2008

Correlación entre la concentración sérica de 25-hidroxivitamina D y la miopía en la población estadounidense: resultados del NHANES 2001-2008

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Abstract

Background: myopia is associated with sight-threatening potential complications, and it becoming increasingly common globally. However, the association between serum 25-hydroxyvitamin D [25(OH)D] concentrations and myopia remains unclear and the evidence is controversial. Thus, this study aimed to investigate the association between serum 25(OH)D concentrations and myopia in the U.S. population.

Subject and methods: this study used the National Health and Nutrition Examination Survey (NHANES) 2001-2008 data. The logistic regression was applied to explore the association between serum 25(OH)D concentrations and myopia.

Results: among the 14,051 participants, the prevalence of myopia was 33.2 % (4,668/14,051). In the multivariate regression models, serum 25(OH)D concentrations as continuous variable were non-significantly associated with the prevalence of myopia (adjusted OR, 0.98 [95 % CI, 0.97-1.00]) after adjusting all covariates. As a categorical variable, serum 25(OH)D compared with the lowest tertile, the adjusted ORs with increasing tertiles were 0.96 (95 % CI: 0.89,1.05) and 0.95 (95 % CI: 0.86, 1.06). In myopia participants, serum 25(OH)D concentrations were also non-significantly associated with the progress of myopia. In stratified analyses, the results remain stable with different ages, sex, and education parameters.

Conclusions: serum 25(OH)D concentrations were non-significantly associated with myopia in the U.S. population. We need more prospective studies to provide evidence.

Keywords:

Myopia. Serum 25-hydroxyvitamin D concentrations. NHANES.

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Ethical approval: the survey protocol for the NHANES was approved by CDC´s National Center for Health Statistics Institutional Research Ethics Review Board. All participants provided written informed consent, and the study was approved by the NCHS Research Ethics Review Board (https://wwwn.cdc.gov/nchs/nhanes/default.aspx).

Availability of data and materials: the NHANES data analyzed in the current study are publicly available.

Disclaimer: the findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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Resumen

Introducción: la miopía se asocia a posibles complicaciones que amenazan la visión y es cada vez más común en todo el mundo. Sin embargo, la relación entre la concentración sérica de 25-hidroxivitamina D [25(OH)D] y la miopía no está clara y la evidencia es discutida. El objetivo del estudio fue determinar la relación entre la concentración sérica de 25(OH)D y la miopía en la población estadounidense.

Objetivo y métodos: se analizaron los datos de la encuesta nacional de salud y nutrición (NHANES) 2001-2008. La relación entre los niveles séricos de 25(OH)D y la miopía se analizó mediante regresión logística.

Resultados: la prevalencia de la miopía fue del 33,2 % en 14.051 participantes (4.668/14.051). En los modelos de regresión múltiple, la concentración sérica de 25(OH)D como variable continua no se correlacionó significativamente con la prevalencia de la miopía después de ajustar todas las covariables (OR ajustado, 0,98 [IC 95 %: 0,97 a 1,00]). Los resultados mostraron que la 25(OH)D sérica era de 0,96 (IC 95 %: 0,89, 1,05) y 0,95 (IC 95 %: 0,86, 1,06), respectivamente. En los participantes con miopía, la concentración sérica de 25(OH)D tampoco se correlacionó significativamente con la progresión de la miopía. En el análisis estratificado, los resultados se mantuvieron estables por edad, sexo y nivel educativo.

Conclusión: la concentración sérica de 25(OH)D no está asociada con la miopía en la población estadounidense. Necesitamos más estudios prospectivos para aportar pruebas.

Palabras clave:

Miopía. Concentración sérica de 25-hidroxivitamina D. NHANES.

INTRODUCTION

Myopia is a complex trait influenced by genetic factors and numerous environmental (1). It has become increasingly common worldwide, most dramatically in urban Asia, and is rapidly inflicting on the United States and Europe (2). In a meta-analysis, it was estimated that the global prevalence of myopia reached 22.9 % in 2010, with a prediction that 49.8 % of the world's population would have it by 2050 (3). As a potentially sight-threatening condition, myopia has had major implications worldwide, both visually and financially (4,5). Therefore, it is important to identify modifiable risk factors for controlling the myopia development, especially preventing low and moderate myopia from developing high myopia.

The risk of myopia is higher with higher socioeconomic status, education, proximity to work, prenatal factors, and urbanization (2,6). Several studies have demonstrated that spending time outdoors has a protective effect on myopia in young adults and school-aged children (7,8). Different aspects of myopia occurrence, development, and clinical treatment have been studied in several studies focusing on metabolomic changes (7,8). Exposure to sunlight produces vitamin D endogenously. Vitamin D status is usually determined by the serum concentration of 25-hydroxyvitamin D [25(OH)D]. The relationship between serum 25(OH)D and myopia is few investigations (9-11). In recent years, the correlation between 25(OH)D and myopia increasingly has paid attentions. However, it remains controversial associated between serum 25(OH)D concentrations and myopia. In some studies, serum 25(OH)D concentration was associated with the prevalence of myopia, but not in all studies (12,13).

Therefore, we exploited this cross-sectional study to evaluate the association of serum 25(OH)D concentrations with myopia in a U.S. population using the National Health and Nutrition Examination Survey (NHANES) database.

SUBJECT AND METHODS

DATA SOURCES AND STUDY POPULATION

In this study, NHANES is an ongoing, two-year-cycle program administered by the Centers for Disease Control and Prevention of the United States. Physical and laboratory exams and standardized interview questionnaires were administered to all participants, including socioeconomic, demographic, and health-related questions. The National Center for Health Statistics Research Ethics Review Board has approved NHANES study protocol. Informed consent is obtained from all participants in writing. The NHANES database is available online with more information and details (https://www.cdc.gov/nchs/nhanes.htm). All reporting followed the Strengthening the Reporting of Observational Studies in Epidemiology guidelines (14).

In this study, we used public data from four cycles of the NHANES (2001-2002, 2003-2004, 2005-2006 and 2007-2008). Between 2001 and 2008, there were 41,658 participants in NHANES. Only participants (aged > 12 years) who underwent an examination of visual function were included. We excluded participants with surgery for myopia, cataract, and unknown surgery.

OPHTHALMIC DATA

In this study, participants aged 12 years or older were asked to undergo a visual function test. Our objective refraction measurements were taken using an autorefractor/keratometer (Nidek ARK-760A, Nidek Co. Ltd., Tokyo, Japan) in non-cycloplegic state and taken as the average of three measurements.

A spherical equivalent was calculated by dividing the cylindrical value by the spherical value. This is commonly used in epidemiological studies as a mean measurement. Myopia was defined as a spherical equivalent of -0.75 diopters (D) or less (low myopia, ≤ -0.75D to > -3D; moderate myopia, ≤ -3D to > -6D; severe myopia, ≤ -6D) (1). Those with a spherical equivalent greater than -0.75D were not considered to have myopia.

BLOOD MEASUREMENT

Liquid chromatography-tandem mass spectrometry was used to measure serum 25(OH)D concentrations, which is more sensitive and specific than immunoassays (15). The limit of detection of serum concentrations was 3.75 nmol/L for 25(OH)D. As mentioned above, NHANES used an imputed value for 25(OH)D when

out of range. There were no values below the limit of detection of 3.75 nmol/L. Serum 25(OH)D concentration was classified as deficient group (< 50 nmol/L), insufficient group (50-75 nmol/L), and sufficient group (≥ 75 nmol/L) in our study. The measurement and assessment of these metabolites are described in detail on the NHANES website (https://wwwn.cdc.gov/nchs/data/nhanes/2009-2010/manuals/lab.pdf).

COVARIATES

In this study, covariates included sex (male or female), age, marital status (married, unmarried and other), education level (less than high school, high school or equivalent, college or above and other), poverty income ratio (PIR) (< 1, ≥ 1), body mass index (BMI) (< 25.0, ≤ 25.0 to < 30, and ≥ 30.0 kg/m^2). Current smokers, former smokers, and never smokers were categorized according to their smoking status. Participants who had smoked more than 100 cigarettes in the past and reported smoking either some days or every day were considered to be current smokers, and who had smoked more than 100 cigarettes during their lifetime but did not smoke currently were considered former smokers. Participants who do not have smoked even 100 cigarettes during their lifetime were considered never smokers. TV or video hours per day was determined by the answer to the following question: "Over the past 30 days, on average, about how many hours per day did you sit and watch TV or videos?" According to answers, it was categorized as none; ≤ 1 hours; 2 hours; or ≥ 3 hours. Using a computer hours per day was determined by the answer to the following question: "Over the past 30 days, on average about how many hours per day did you use a computer or play computer games?" According to answers, it was categorized as none; ≤ 1 hour; or ≥ 2 hours. Dietary calcium intake and dietary magnesium intake were performed before the interview at MEC to collect the previous 24 h dietary information. The season of examination was categorized as summer or winter, according on whether the period of examination was between May to October or November to April, respectively (16).

STATISTICAL ANALYSIS

All normally distributed and skewed continuous variables are expressed as mean and standard deviation (SD) or median and interquartile range (IQR), and categorical variables as frequencies (%). The chi-square test (categorical variables), One-Way ANOVA (normal distribution), and Kruskal-Wallis test (skewed distribution) were used to compare variables. Multivariable logistic regression analyses were adopted to assess the association between serum 25(OH)D concentrations and myopia. We investigated serum 25(OH)D concentrations as a continuous variable and categorical variable. Subgroup analysis examined the relationship between serum 25(OH)D concentrations and the prevalence of myopia according to ages, sex, and education. Odds ratios (ORs) and 95 % CIs were calculated.

Our analyses were conducted using R 4.0 (http://www.R-project.org, The R Foundation) and Free Statistics version 1.4 (17). Statistical significance was determined by a two-tailed test. A *p*-value of 0.05 was considered significant.

RESULTS

BASELINE CHARACTERISTICS OF THE STUDY POPULATION

Four cycles of NHANES, 2001-2002, 2003-2004, 2005-2006, and 2007-2008, were used in our study. The flowchart of participants in the study design is illustrated in figure 1. The full and final data included 14,051 participants who met all inclusion and no exclusion criteria, of whom 4668 (33.2 %) had myopia. Table I shows the demographic, socioeconomic and baseline characteristics of no-myopia and myopia. Included participants had a mean (SD) age of 37.3 (19.6) years, of which 6914 (49.2 %) were males. In the myopic group, the mean (SD) age was 34.2 (17.4) years, and 2155 (46.2 %) were males. In non-myopic group, the mean (SD) age was 38.8 (20.4) years, and 4759 (50.7 %) were males. Age, sex, education level, marital status, BMI, PIR, smoking status, computer hours per day, dietary calcium, dietary magnesium, and season of examination were significantly different between the non-myopic and myopic groups. Compared with the non-myopic group, the myopic group was mostly accounted of females, and more likely to be younger, well-educated, higher income, and higher dietary calcium and dietary magnesium.

ASSOCIATION BETWEEN SERUM 25(OH)D CONCENTRATIONS AND THE PREVALENCE OF MYOPIA

We used regression analysis to identify factors which were associated with the prevalence of myopia in the entire study population. The results of univariate ordinal regression analysis

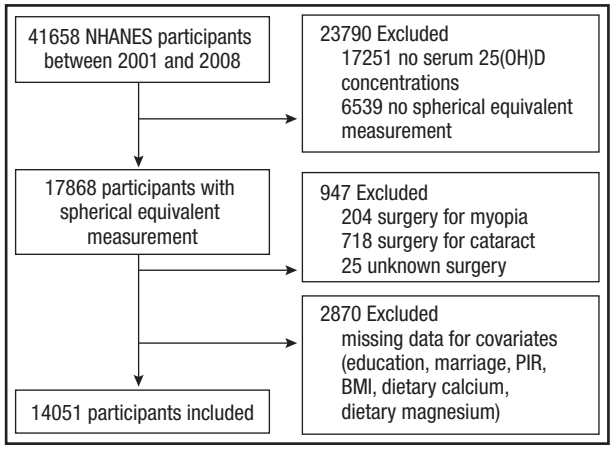

Figure 1.

Flowchart of the inclusion and exclusion criteria.

Table I. Characteristics of participants, NHANES 2001-2008

Characteristic	Total (*n* = 14,051)	Without myopia (*n* = 9,383)	With myopia (*n* = 4,668)	*p*-value
Age, mean ± SD, yrs	37.3 ± 19.6	38.8 ± 20.4	34.2 ± 17.4	< 0.001
Sex, n (%)				
Male	6,914 (49.2)	4,759 (50.7)	2,155 (46.2)	< 0.001
Female	7,137 (50.8)	4,624 (49.3)	2,513 (53.8)	
Education, n (%)				
Less than high school	5,845 (41.6)	4,195 (44.7)	1,650 (35.3)	< 0.001
High school or equivalent	3,217 (22.9)	2,216 (23.6)	1,001 (21.4)	
College or above and other	4,989 (35.5)	2,972 (31.7)	2,017 (43.2)	
Marital status, n (%)				
Married	6,704 (47.7)	4,561 (48.6)	2,143 (45.9)	< 0.001
Unmarried	5,540 (39.4)	3,512 (37.4)	2,028 (43.4)	
Other	1,807 (12.9)	1,310 (14)	497 (10.6)	
PIR, n (%)				
< 1	2,943 (20.9)	2,048 (21.8)	895 (19.2)	< 0.001
≥ 1	11,108 (79.1)	7,335 (78.2)	3,773 (80.8)	
BMI, n (%)				
Underweight/normal	5,693 (40.5)	3,744 (39.9)	1,949 (41.8)	0.001
Overweight	4,318 (30.7)	2,978 (31.7)	1,340 (28.7)	
Obese	4,040 (28.8)	2,661 (28.4)	1,379 (29.5)	
Smoking status, n (%)				
Current smoker	2,385 (23.9)	1,661 (24.6)	724 (22.4)	< 0.001
Former smoker	2,469 (24.7)	1,748 (25.9)	721 (22.3)	
Never smoker	5,139 (51.4)	3,350 (49.6)	1,789 (55.3)	
TV or video hours per day, n (%), h/d				
None	166 (1.7)	111 (1.7)	55 (1.7)	0.113
≤ 1 h	2,971 (30.6)	1,948 (29.9)	1,023 (31.9)	
2 h	2,587 (26.6)	1,723 (26.5)	864 (26.9)	
≥ 3 h	3,999 (41.1)	2,731 (41.9)	1,268 (39.5)	
Computer hours per day, n (%), h/d				
None	3,640 (37.4)	2,678 (41.1)	962 (30)	< 0.001
≤ 1 h	4,200 (43.2)	2,686 (41.2)	1,514 (47.2)	
≥ 2 h	1,884 (19.4)	1,150 (17.7)	734 (22.9)	
Dietary calcium (mg)	905.2 ± 637.7	889.4 ± 624.4	937.0 ± 662.6	< 0.001
Dietary magnesium (mg)	275.8 ± 146.4	273.9 ± 145.2	279.6 ± 148.9	0.031
Season of examination, n (%)				
Winter	6,816 (48.5)	4,680 (49.9)	2,136 (45.8)	< 0.001
Summer	7,235 (51.5)	4,703 (50.1)	2,532 (54.2)	

PIR: a ratio of family income to poverty threshold; BMI: body mass index.

indicated that age, sex, education, marital status, PIR, BMI, computer hours per day, season of examination, dietary calcium, and dietary magnesium were positively associated with the prevalence of myopia (Supplementary Table I).

In the multivariable logistic regression, we observed that the odd ratios (ORs) of serum 25(OH)D concentrations were non-significant in all models ($p > 0.05$ for all) (Table II). There was no clear evidence for an association of serum 25(OH)D concentrations as

Table II. Association between 25(OH)D and the prevalence of Myopia (*n* = 14,051), NHANES 2001-2008

	Myopia (*n* = 4,668)							
	Model 1		Model 2		Model 3		Model 4	
	OR (95 % CI)	*p*-value	OR (95 % CI)	*p*-value	OR (95 % CI)	*p*-value	OR (95 % CI)	*p*-value
25(OH)D * 0.1 nmol/L, (continuous)	1 (0.99-1.02)	0.732	1.01 (0.99-1.02)	0.295	0.99 (0.97-1)	0.098	0.98 (0.97-1)	0.052
25(OH)D, nmol/L Deficient (< 50)	1 (Ref)		1 (Ref)		1 (Ref)		1 (Ref)	
Insufficient (50-75)	0.98 (0.91-1.06)	0.627	1.02 (0.94-1.11)	0.573	0.97 (0.89-1.06)	0.493	0.96 (0.89-1.05)	0.375
Sufficient (≥ 75)	1.06 (0.97-1.17)	0.221	1.1 (1-1.21)	0.062	0.96 (0.87-1.07)	0.488	0.95 (0.86-1.06)	0.344

Adjusted covariates: Model 1: unadjusted; Model 2: adjusted by age, sex; Model 3: Model 2 + education, marital status, PIR, BMI, season of examination; Model 4: Model 3 + dietary calcium, dietary magnesium.

a continuous variable with the prevalence of myopia (adjusted OR, 0.98 [95 % CI, 0.97-1.00]) after adjustment for age, sex, education, marital status, PIR, BMI, season of examination, dietary calcium, and dietary magnesium. We also investigated serum 25(OH)D concentrations as a categorical variable. In contrast, participants in the deficient group had no association with the prevalence of myopia compared with those in the insufficient group and sufficient group (adjusted OR, 0.96 [95 % CI, 0.89-1.05], 0.95 [95 % CI: 0.86, 1.06]) after adjustment for all covariates.

ASSOCIATION BETWEEN SERUM 25(OH)D CONCENTRATIONS AND THE SEVERITY OF MYOPIA

Myopia was classified as low myopic group (≤ -0.75 to > -3D), moderate myopic group (≤ -3 to > -6D), and severe myopic group (≤ -6D). In our study, the 4668 participants were included in the myopic participants with low myopic group (*n* = 3065), moderate myopic group (*n* = 1200), and severe myopic group (*n* = 403). In multinomial logistic regression, there was clear evidence for a non-significant association of serum 25(OH)D concentrations with increasing myopia severity after adjusting all covariates (adjusted OR, 1.02 [95 % CI, 0.99-1.05], 1.00 [95 % CI: 0.96, 1.05]) (Table III).

SENSITIVE ANALYSIS

To render our findings more robust, we excluded the participants without smoking status (*n* = 4328), TV or video hours per day (*n* = 4327), and computer hours per day data (*n* = 4058). The remaining 6613 participants were included. In the multivariable logistic regression, we made additionally adjusted smoking status, TV or video hours per day, and computer hours per day. The results remained stable (Table IV). Serum 25(OH)D concentrations as continuous variable do not associate with the prevalence of myopia (adjusted OR, 0.98 [95 % CI, 0.95-1.00]). Meanwhile, we investigated serum 25(OH)D concentrations as a categorical variable in the remaining 6613 participants. Participants in the deficient group had no association with the prevalence of myopia compared with those in the insufficient group and sufficient group (adjusted OR, 0.97 [95 % CI, 0.85-1.10], 0.95 [95 % CI: 0.81, 1.10]).

We also performed a stratified analyses to robust our findings. We investigated whether the association between serum 25(OH)D concentrations and the prevalence of myopia varied at different ages, sex, and education. In the stratified analyses, the results remain stable (Fig. 2). The multiplicative interactions of serum 25(OH)D concentrations and ages (*p* for interaction = 0.409), serum 25(OH)D concentrations and sex

Table III. Association between 25(OH)D and the severity of myopia (n = 4,668), NHANES 2001-2008

	n	25(OH)D * 0.1, nmol/L (continuous) OR (95 % CI)	*p*-value
Low myopia (≤ -0.75 to > -3 D)	3,065	1 (Ref)	
Moderate myopia (≤ -3 to > -6 D)	1,200	1.02 (0.99-1.05)	0.262
Severe myopia (≤ -6 D)	403	1 (0.96-1.05)	0.902

Adjusted covariates: age, sex, education, marital status, PIR, BMI, season of examination, dietary calcium, dietary magnesium.

Table IV. Association between 25(OH)D and the prevalence of myopia (*n* = 6,613), NHANES 2001-2008

	Myopia (*n* = 2,107)					
	Model 1		Model 2		Model 3	
	OR (95 % CI)	*p*-value	OR (95 % CI)	*p*-value	OR (95 % CI)	*p*-value
25(OH)D * 0.1, nmol/L (continuous)	1.01 (0.99-1.03)	0.499	0.98 (0.96-1.01)	0.123	0.98 (0.95-1)	0.104
25(OH)D, nmol/L						
Deficient (< 50)	1 (Ref)		1 (Ref)		1 (Ref)	
Insufficient (50-75)	1.01 (0.9-1.13)	0.889	0.98 (0.86-1.11)	0.736	0.97 (0.85-1.1)	0.62
Sufficient (≥ 75)	1.11 (0.96-1.27)	0.149	0.95 (0.82-1.11)	0.517	0.94 (0.81-1.1)	0.435

Adjusted covariates: Model 1: unadjusted; Model 2: adjusted by age, sex, education, marital status, PIR, BMI, season of examination, dietary calcium, dietary magnesium; Model 3 + smoking status, TV or video hours per day, computer hours per day.

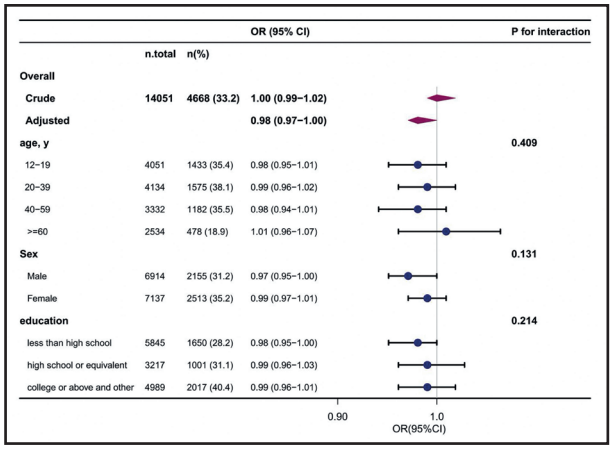

Figure 2.

OR of serum 25(OH)D concentration on the prevalence of myopia by age, sex, and education subgroup.

(*p* for interaction = 0.131), and serum 25(OH)D concentrations and education (*p* for interaction = 0.241) in regard to the prevalence of myopia were not significant.

DISCUSSION

In this study, we investigated the associations between serum 25(OH)D concentrations and the prevalence of myopia in the U.S. population. We found that serum 25(OH)D concentrations were not associated with the prevalence of myopia. In stratified analysis, the results remained stable with different ages, sex, and education. In our analyses, there was scant evidence that serum 25(OH)D concentrations were themselves associated with myopia. Vitamin D could not be a possible target for myopia interventions. It may be not directly involved in the prevalence of myopia, just as a marker of time spent outdoors.

Our findings about serum 25(OH)D concentrations and the prevalence of myopia are consistent with results of some previous studies (18-20). In Specht lO´s case-control study, it observed no statistically significant associations between neonatal 25(OH)D3 and myopia in young adulthood (*n* = 1737) (19). Lingham et al. found that low 25(OH)D concentration was not associated with odds of myopia or spherical equivalent in middle-aged and older western (*n* = 1737) (20). However, our study had much larger numbers of participants (*n* = 14,051) and used sensitive analysis to minimize the potential confounders, and found no relationship between serum 25(OH)D concentrations and the prevalence of myopia.

In a Multicountry European Study, Katie M´s cross-sectional study (*n* = 4166) indicated that in the adjusted analyses, no convincing evidence was reported for an association of 25(OH)D3 concentrations with myopia aged older than *65 years old* (adjusted OR, 0.99 [95 % CI, 0.98-1.00]) (1). Their results are akin to our findings. However, this study only enrolled 4166 patients. And it still overlooked several important confounders, such as dietary calcium intake (17) and dietary magnesium intake (16). Our study had much larger sample size (*n* = 14051) and considered dietary calcium intake and dietary magnesium intake as confounders.

Xiaoman Li et al. conducted a cross-sectional study in China (*n* = 383) and described serum 25(OH)D concentrations were not associated with myopia in the 6-14 years old Chinese children (adjusted OR, 0.99 [95 % CI, 0.97-1.02]) (21). In a cross-sectional observational study Sahira Aaraj et al. found that association of low vitamin D levels and myopia was not significantly in Pakista children aged 5-15 years (22). These phenomenons also can be found in our study, serum 25(OH)D concentrations were non-significantly with myopia in the 12-19 years old U.S. participants (adjusted OR, 0.98 [95 % CI, 0.95-1.00]). Participants (*n* = 4051) aged between 12-19 years old were all included in our study.

In our study, the serum 25(OH)D concentrations were not associated with the prevalence of myopia in different ages. However, some previous studies were inconsistent with our results. Previous national survey studies in Korean populations had observed a

significant association between low serum 25(OH)D concentration and myopia prevalence in Korean adolescents and adults, particularly notable in adolescents with high myopia (23,24). Compared with our study, some pivotal risk factors, such as the season of examination (13) and dietary magnesium intake (16) were not effectively controlled in these studies. In this study, we used stratified analyses to investigated the association between serum 25(OH)D concentrations and the prevalence of myopia varied at different ages, sex, and education. Using different populations may be the other reason for the inconsistency between the two studies.

In some studies, there was a significant association between the prevalence of myopia and vitamin D in young people. In three cohort studies, the prevalence of myopia was significantly associated with vitamin D in children and young adulthood (13,25,26). In a cross-section study, serum 25(OH)D concentration is related to the prevalence of myopia in Chinese children (27). Compared with our study, these studies only included people under the age of 20, whereas our study included the entire population, with much larger sample size ($n = 14,051$). Meanwhile we conducted sensitivity analysis for different ages, the results remain stable with different ages.

It is still unclear the role of serum 25(OH)D concentrations in the prevalence and severity of myopia. In a Mendelian randomization study, it showed that the true contribution of vitamin D levels to degree of myopia is very small. In previous observational studies, the association between vitamin D levels and myopia were likely confounded by time spent outdoors (28). It has been identified as the protective effect of time outdoors on myopia in young adults (7). However, whether 25(OH)D is directly involved in myopia or merely acts as a biomarker of time spent in outdoor activities needs to be verified.

This study has several limitations. First, as a cross-sectional study it could not show causality. Second, we considered many covariates. However, the results may be affected by unmeasured confounding factors. For example, time spent outdoors was not considered in our study because of inadequate data in the NHANES database. We adjusted for possible confounders in order to minimizing the influence of factors which may lead to outcome bias, and we also used stratified analyses. We investigated the association between serum 25(OH)D concentrations and the prevalence of myopia varied at different ages, sex, and education. The result was robust. Finally, non-cycloplegic auto-refractor for myopia assessment may be the other limitation, because the effect of accommodation in adolescents was not excluded. In the NHANES database, the use of cycloplegic medication was also not specified before refracting the subjects. These might lead to classification bias in our study. However, we conducted sensitivity analysis for different ages, it is also robust.

CONCLUSIONS

This study suggests that serum 25(OH)D concentrations were non-significantly associated with myopia in the U.S. population. This might provide some clinical clues, however further randomized controlled studies are required to provide more evidence.

Supplementary Table I. Univariate analysis between 25(OH)D and the prevalence of myopia

Characteristics *n*	OR (95 % CI)	*p*-value
Age, mean ± SD, yrs	0.99 (0.99-0.99)	< 0.001
Sex, n (%)		
Male	1 (Ref)	< 0.001
Female	1.2 (1.12-1.29)	
Education, n (%)		
Less than high school	1 (Ref)	
High school or equivalent	1.15 (1.05-1.26)	0.004
College or above and other	1.73 (1.59-1.87)	< 0.001
Marital status, n (%)		
Married	1 (Ref)	
Unmarried	1.23 (1.14-1.32)	< 0.001
Other	0.81 (0.72-0.91)	< 0.001
PIR, n (%)		
< 1	1 (Ref)	< 0.001
≥ 1	1.18 (1.08-1.29)	
BMI, n (%)		
Underweight/normal	1 (Ref)	
Overweight	0.86 (0.79-0.94)	0.001
Obese	1 (0.91-1.08)	0.917
Smoking status, n (%)		
Current smoker	1 (Ref)	
Former smoker	0.95 (0.84-1.07)	0.379
Never smoker	1.23 (1.1-1.36)	< 0.001
TV or video hours per day, n (%), h/d		
None	1 (Ref)	
≤ 1 h	1.06 (0.76-1.48)	0.731
2 h	1.01 (0.73-1.41)	0.944
≥ 3 h	0.94 (0.67-1.3)	0.699
Computer hours per day, n (%), h/d		
None	1 (Ref)	
≤ 1 h	1.57 (1.42-1.73)	< 0.001
≥ 2 h	1.78 (1.58-2)	< 0.001
Dietary calcium (mg)	1 (1-1)	< 0.001
Dietary magnesium (mg)	1 (1-1)	0.01
Season of examination, n (%)		
Winter	1 (Ref)	< 0.001
Summer	1.18 (1.1-1.27)	

PIR: a ratio of family income to poverty threshold; BMI: body mass index.

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ARÁN

Nutrición Hospitalaria

Trabajo Original

Epidemiología y dietética

Evaluation of depression, anxiety, risky eating behaviors, eating habits and physical activity after the COVID-19 pandemic among adolescents in Mexico City

Evaluación de depresión, ansiedad, conductas alimentarias de riesgo, hábitos alimentarios y actividad física posterior a la pandemia de COVID-19 en adolescentes de la Ciudad de México

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Abstract

Introduction: during the pandemic, an increase in symptoms of depression and anxiety, as well as lifestyle changes in adolescents has been reported.

Objectives: to evaluate anxiety and depression symptoms, risky eating behaviors (REB), eating habits and physical activity after the COVID-19 pandemic in Mexican adolescents; to associate the study variables with the development of REB.

Methods: a study was performed with a sample of 2,710 adolescents. The Hospital Anxiety and Depression Scale (HADS) and the Questionnaire to measure Risky Eating Behaviors were applied; eating habits and physical activity were evaluated. A Multivariate Logistic Regression analysis was performed to evaluate an association between study variables and REB.

Results: it was found that 34.4 % and 47.2 % of the adolescents presented symptoms of depression and anxiety, respectively. Furthermore, 10.6 % had REB and 18.1 % were at risk of REB. The combined prevalence of overweight and obesity was 46.5 %; only 13.1 % of the participants had healthy eating habits and 18.2 % adequate physical activity. Symptoms of depression ($p < 0.0001$), anxiety ($p < 0.0001$), higher BMI ($p < 0.0001$), female sex, excessive consumption of sugary drinks, eating outside the home ($p < 0.0001$), and lifestyle ($p = 0.001$) were associated with REB.

Conclusions: confinement caused chaos on the lifestyle of adolescents as well as their psychological health. It is essential to develop educational programs that involve government authorities, parents and health agencies to reinforce the topics of healthy eating, physical activity and mental health in the country's secondary schools.

Keywords:

COVID-19. Adolescents. Mexico. Anxiety. Depression. Risky eating behaviors.

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Resumen

Introducción: durante la pandemia se han reportado un incremento de síntomas de depresión y ansiedad, así como cambios en el estilo de vida de los adolescentes.

Objetivos: evaluar los síntomas de ansiedad y depresión, conductas alimentarias de riesgo (CAR), los hábitos alimentarios y actividad física posterior a la pandemia de COVID-19 en adolescentes mexicanos; asociar las variables del estudio con el desarrollo de CAR.

Métodos: se realizó un estudio con una muestra de 2710 adolescentes. Se aplicó la Escala Hospitalaria de Ansiedad y Depresión y el Cuestionario para medir Conductas Alimentarias de Riesgo; se evaluaron hábitos alimentarios y actividad física. Se realizó un análisis de Regresión Logística Multivariante para evaluar una asociación entre variables del estudio y CAR.

Resultados: se encontró que el 34,4 % y 47,2 % de los adolescentes presentaron síntomas de depresión y ansiedad, respectivamente. Además, el 10,6 % tuvieron CAR y el 18,1 % riesgo de CAR. La prevalencia combinada de sobrepeso y obesidad fue del 46,5 %, solo el 13,1 % de los participantes tuvieron hábitos alimentarios saludables y un 18,2 % actividad física adecuada. Los síntomas de depresión ($p < 0,0001$), la ansiedad ($p < 0,0001$), el mayor IMC ($p < 0,0001$), el sexo femenino, consumir bebidas azucaradas en exceso, comer fuera de casa ($p < 0,0001$) y el estilo de vida ($p = 0,001$) se asociaron con CAR.

Conclusiones: el confinamiento causó estragos en el estilo de vida de los adolescentes y en su salud psicológica. Es indispensable elaborar programas educativos que involucren a las autoridades gubernamentales, padres de familia e instancias sanitarias para reforzar temas de alimentación saludable, actividad física y salud mental en la educación secundaria del país.

Palabras clave:

COVID-19. Adolescentes. México. Ansiedad. Depresión. Conductas alimentarias de riesgo.

INTRODUCTION

Four years ago, a global pandemic occurred and to this day its consequences continue to be studied not only at the respiratory level, but also in various aspects related to lifestyle. In December 2019, the first case of COVID-19 was identified in Wuhan, China. On March 11, 2020, the World Health Organization recognized the widespread global transmission of COVID-19 and declared it a pandemic, which constituted a global emergency with a high impact on public health (1,2). The first case was detected in Mexico on February 27, 2020 at the National Institute of Respiratory Diseases in Mexico City, and the first death occurred on March 18. On March 24, with 475 confirmed cases, Phase 2 of the "health contingency" was declared with stricter measures of social distancing, confinement and academic restriction (3).

As a result of this situation, educational institutions were required to substitute in-person teaching for virtuality to put social distancing into practice and reduce contagion during the COVID-19 pandemic (4). This social distancing affected a large number of children, adolescents, adults and the elderly in mental health for months or years during and after the pandemic. Various studies mentioned an increase in symptoms of depression and anxiety, post-traumatic stress, suicidal ideation, as well as sleep problems in these populations (1,5).

One of the groups that was identified as most vulnerable to the situation of voluntary confinement were adolescents; this population showed higher levels of depression, stress and anxiety (6). Some research mention that preventing adolescents from interacting and engaging socially with their peers and educators, the prolonged periods of school closures, and the restriction of movement were manifested as emotional restlessness and additional anxiety (7).

On the other hand, there are reports that indicate that some of the direct psychological effects of COVID-19 among children and adolescents included: sleep and appetite disorders, learning difficulties, hyperactivity and irritability. In schoolchildren, distress symptoms such as palpitations, hyperventilation and diarrhea appeared, generally associated with somatization processes; additionally, signs of depression were manifested with feelings of sadness and abandonment.

In the behavioral aspect, emotional and behavioral regressions have been mentioned and described more frequently in preschoolers and young school children, but they also occurred in adolescents. The psychological effects derived from the infectious disease and confinement have lasted beyond their duration (8).

Ochoa et al. (9), in their research, which included cross-sectional longitudinal studies, systematic reviews and meta-analyses, reported that the prevalence of stress in children and adolescents aged 2 to 17 years during the pandemic ranged between 28 % and 34 %. Furthermore, the prevalence of emotional and behavioral problems was 17.6 % (18.6 % for boys and 16.6 % for girls). The prevalence of mild to severe anxiety and depression symptoms was high (37.4% and 43.7 %, respectively).

It is important to mention that psychological alterations such as anxiety and depression may be closely related to risky eating behaviors (REB) (10). In Spain, Samatán and Ruiz (11) reinforce this idea in their study performed with adolescents under 18 years of age who attended the Eating Disorders Unit for the first time, reporting that the adolescent population was the most affected age group (87.1 %), compared to 12.9 % of those under 13 years of age, with a greater contrast between these groups during the COVID-19 pandemic.

In Mexico, Villalobos-Hernández et al. (12) reported the prevalence of REB in Mexican adolescents, based on the results of the National Continuous Health and Nutrition Survey 2022 (ENSANUT): 6.6 % of adolescents presented some degree of REB (5.0 % moderate risk and 1.6 % high risk). These data were similar to those reported in the ENSANUT 2018-2019, in which 7.3 % of adolescents presented some degree of risky eating behaviors, but higher than the prevalence reported in the ENSANUT 2006 (3.9 %), in which the same questionnaire was used to detect REB at the national level before pandemic. Likewise, it was reported that adolescent women were at greater risk and people residing in rural areas at lower risk of suffering from this problem. Derived from these data, the authors (12,13) pointed out the im-

portance of continuing to monitor REBs in national representative surveys, since this problem may lead to negative health repercussions in this population.

Previous studies have identified associations of some psycho-emotional and anthropometric variables with REBs. Radilla et al. (14) conducted a 3-year study prior to the COVID-19 pandemic, which was a randomized controlled trial with an educational intervention to improve eating habits and physical activity. The research was performed in 16 Technical Secondary Schools in Mexico City and involved 2,368 adolescents with the purpose of identifying risk or protective factors of suffering from REB. According to the results, depression and anxiety, as well as being a woman and having a higher body mass index (BMI) were risk factors of suffering from REB, while physical activity measured by the number of steps was a protective factor.

Eating behavior is a human activity related to food intake and depends on internal and external factors of the individual. It has been reported that during confinement, there were changes in the total amount of consumed foods, especially an increase in sweet and salty foods with high energy density. At the same time, there was a decrease in the consumption of vegetables, fruits, and legumes (15-17).

Taking the above into account, the purpose of this research was to evaluate symptoms of anxiety and depression, REB, eating habits and physical activity after the COVID-19 pandemic in Mexican secondary school adolescents, as well as identify associations between study variables and REB.

MATERIAL AND METHODS

An observational, quantitative and descriptive study was performed. In 2022 (transition period after the pandemic), 2,710 first-grade secondary school students were evaluated, with an average age of 12 years, from 33 secondary schools in 12 municipalities in Mexico City.

As inclusion criteria, full-time technical secondary schools were considered, which provided letter of informed consent from participants signed by their parents or guardians and who gave their assent to participate. Students with a diagnosis of diabetes, hypertension, metabolic syndrome and other chronic diseases, who were pregnant or lactating at the time of the intervention, students with acute illnesses and those who did not have authorization or did not want to participate were considered exclusion criteria. The elimination criteria were those students who refused to participate in any component of the study.

Body composition measurements were taken and questionnaires were applied to evaluate symptoms of anxiety and depression, REB, eating habits and physical activity.

ANTHROPOMETRIC EVALUATION

Prior to the application of the questionnaires, anthropometric measurements were taken with the use of an Inbody-270 body composition analyzer (South Korea), and weight status was estimated with the body mass index (BMI) percentiles, proposed by the WHO (18) by using the Who Anthro Plus® program (Switzerland).

INSTRUMENTS

With the purpose of evaluating symptoms of anxiety and depression, the Hospital Anxiety and Depression Scale-HADS, validated in a Mexican population between 12 and 68 years old with eating disorders, were used; Cronbach's alpha of the total scale was 0.88 and of its two subscales > 0.80 (19,20). The scale is self-reported and allows to identify symptoms of anxiety and depression. It consists of fourteen multiple-choice items and two subscales: depression and anxiety, each with seven items. The score for each subscale can vary between 0 and 21, each item presents four response options, ranging from absence or minimal presence = 0 to maximum presence of symptoms = 3. The higher the score obtained from each subscale the greater the intensity or severity of symptoms: 0-7 points absence of symptoms; 8-10 presence of symptoms; 11-21 complete clinical picture.

To evaluate risky eating behaviors (REB), the questionnaire of Unikel et al. (21) was applied, validated in Mexico, Cronbach's alpha = 0.83. The questionnaire is self-reported and easy to apply; it has been used in the ENSANUT 2006, 2012 and 2022 national surveys to evaluate REB in Mexican adolescents (12,13). The questionnaire was developed based on the diagnostic criteria of the DSM-IV and consisted of questions with a Likert scale with four response options: never = 0, sometimes = 1, frequently (twice a week) = 2, very frequently (more than twice a week) = 3, with a cut-off point < 7 no risk, between 7 and 10, moderate risk, and greater than 10 points, high risk. The instrument evaluates the main behaviors that resulted in weight loss over the previous three months, such as: concern about gaining weight, binge eating, the feeling of lack of control when eating, restrictive eating behaviors (diet, fasting, excessive physical activity, and use of weight-loss pills), as well as purgative behavior (self-induced vomiting, use of laxatives, and diuretics).

A self-report questionnaire on eating habits and physical activity was applied, consisting of 31 items, which included the following variables: frequencies of meal times, physical activity and lifestyles, consumption of high-calorie foods, company in food consumption, consumption of vegetables and fruits, place of food consumption, consumption of alcoholic beverages, sugary drinks, plain water and milk, Cronbach's alpha of the total questionnaire was 0.78 (22).

Likewise, eating habits were assessed by self-reported surveys, using 24-hour recall, in which adolescents described in detail at-home measurements of all foods and beverages consumed the previous day. The obtained information was compared with the energy and nutrient reference values of the Mexican System of Equivalent Foods (23) with the purpose of knowing whether the adolescents' diet corresponds to their weight, height, age, and physiological situation.

SAMPLE SIZE

The sample size was established using a base of 119 schools from 16 municipalities in CDMX, of which 46 secondary schools were extended-time schools and therefore met the characteristics required for the intervention during the 2022 school year.

The selection was adjusted to simple random sampling with a finite population and the Murray and Larry formula (24) was used for the calculation: where: *n*: sample size. N: population size, the value of 46 was used (full-time secondary schools). Z: value corresponding to the approximately normal distribution, $Z\alpha = 1.62$; $\alpha = 0.10$. p: expected prevalence of the parameter to be evaluated, if unknown ($p = 0.5$), which increases the sample size. Q: $1 - p$ (if $p = 50$ %, then q = 50 %). i: assumed error (10 %).

$$n = \frac{(1.62)^2\,(46)\,(0.5)\,(0.5)}{0.01\,(46\text{-}1) + (1.62)\,(0.5)\,(0.5)} = \frac{30.1806}{0.85555} = 35.2 \approx 33$$

ETHICAL CONSIDERATIONS

All adolescents participated voluntarily, had the informed consent of their parents or guardians and verbal assent prior to participation. The present study was reviewed and approved by the Research Ethics Committee of the Division of Biological and Health Sciences. The Divisional Council of Biological and Health Sciences of the Universidad Autónoma Metropolitana, Unidad Xochimilco, in session 7/21, held on May 6, 2021 through Agreement 7/21.5.4 of document DCBS.CD.157.21 issued the resolution to approve the research project.

STATISTICAL ANALYSIS

To analyze the sociodemographic data, descriptive statistics were applied with measures of central tendency and dispersion. The average frequency and percentage of data such as age, sex, frequency of food consumption, and results of the questionnaires applied were obtained. Likewise, in order to identify associations with REB in Mexican adolescents, a binomial logistic regression analysis was carried out on all measurements, which were contrasted with the dependent variable (occurrence of REB). The data obtained were analyzed with the SPSS statistical package, version 24.0 for Windows.

RESULTS

From the total of 2,710 students, 1,430 (52.8 %) were female and 1,280 (47.2 %) were male, with an average age of 12 years.

Table I shows the psychological aspects of the adolescents: 34.4 % of them presented symptoms of depression (24.4 % moderate symptoms and 10 % maximum symptoms) and 47.2 % of adolescents presented anxiety symptoms (23 % moderate and 24.2 % maximum symptoms).

With respect to REB, it was observed that the category with the highest incident rate was the practice of excessive exercise to lose weight (37.9 %), followed by concern about gaining weight (35.2 %), eating too much (13.6 %) and dieting to lose weight (9.7 %), with a frequency of at least twice a week. When evaluating REB in total, it was observed that 18.1 % of the adolescents were at moderate risk and 10.6 % at high risk of developing unhealthy behaviors (Table II).

When analyzing the nutritional status of the participants, it was observed that 2,296 (84.7 %) adolescents had an appropriate height for their age, 373 (13.8 %) were at risk of having short height and 41 (1.5 %) had low height for their age. Likewise, 1,264 (46.6 %) adolescents had an adequate weight, 719 (26.5 %) were overweight, 543 (20 %) were obese, and 184 (6.8 %) had low weight for their height.

Regarding the eating habits of adolescents (Table III), it was observed that only 12.9 %, 18.4 % and 20.4 % of adolescents consumed vegetables, fruits and milk, respectively on a daily basis. Regarding the consumption of foods with high energy density, it was found that adolescents consumed sausages (47.7 %), fast food (12.6 %), sweets or chocolates (38 %), bread or cookies (39.7 %) and snacks (30 %) three or more times a week. Likewise, 1.7 % of adolescents reported consuming alcoholic beverages 5 or more times per week and 31.4 % of adolescents consumed drinks with added sugars three or more times per week. On the other hand, only 23.5 % of adolescents consumed seven or more glasses of plain water per day. When analyzing the food and drink consumption of adolescents in total, it was found that only 13.1 % had adequate eating habits.

When investigating the frequency of consumption of main meals (Table IV), it was observed that only 56.9 % eat breakfast, 71.4 % eat lunch and 45.6 % have dinner six or seven days a week. Most adolescents ate their meals at home, generally accompanied by their family, although 45.6 % of adolescents reported snacking alone.

Regarding physical activity (Table V), it was reported that 27 % of adolescents never or almost never do physical activity and 34.4 % do less than two hours a week. When analyzing together the frequency and time of physical activity performed by adolescents, only a low percentage (18.2 %) of them complied with adequate physical activity practice.

In the Multivariate Binary Logistic Regression analysis to identify associations between REB and study variables (Table VI), it was found that symptoms of depression (OR = 2.098; 95 % CI = 1.663-2.436, $p < 0.0001$), anxiety (OR = 2.636; 95 % CI = 2.333-3.149, $p < 0.0001$), higher BMI (OR = 1.877, 95 % CI = 1.425-1.929, $p < 0.0001$), as well as eating breakfast outside the home (OR = 1.704, 95 % CI = 1.208-3.203, $p = 0.012$) increase the probability of presenting REB. Otherwise, a negative association was observed between REB and variables such as being male ($p < 0.0001$), consumption of sugary drinks < 3 times/week ($p < 0.0001$), having dinner at home ($p < 0.0001$), eating snacks at home ($p = 0.25$), active lifestyle and appropriate eating habits ($p < 0.0001$).

Table I. Depression and anxiety in adolescents

		Almost always	Frequently	Rarely	Not at all
		n (%)			
Depression	Always enjoy the same things	906 (33.4)	1022 (37.7)	735 (27.1)	47 (1.7)
	Have the ability to laugh and see the funny side of things	1249 (46.1)	1025 (37.8)	406 (15)	30 (1.1)
	Feel happy	1076 (39.7)	1151 (42.5)	435 (16.1)	48 (1.8)
	Look forward to things	953 (35.2)	785 (29)	794 (29.3)	178 (6.6)
	Able to enjoy a good book, radio or television program	960 (35.4)	1106 (40.8)	507 (18.7)	137 (5.1)
	Feel slow and clumsy	370 (13.7)	567 (20.9)	1097 (40.5)	676 (24.9)
	Have lost interest in your personal appearance	174 (6.4)	362 (13.4)	1083 (40)	1091 (40.3)
Depression	Normal	1777 (65.6)			
	Depression symptoms	661 (24.4)			
	Depression	272 (10)			
Anxiety	Feel tense or nervous	338 (12.5)	761 (28.1)	1116 (41.2)	495 (18.3)
	Feel a kind of fear as if something were going to happen	301 (11.1)	488 (18)	1280 (47.2)	641 (23.7)
	Have a head full of worries	404 (14.9)	653 (24.1)	1152 (42.5)	501 (18.5)
	Experience an unpleasant feeling of nerves and emptiness in your stomach	294 (10.8)	382 (14.1)	1265 (46.7)	769 (28.4)
	Feel restless as if you can't stop moving	293 (10.8)	476 (17.6)	1052 (38.8)	889 (32.8)
	Suddenly feeling great distress or fear	200 (7.4)	391 (14.4)	1245 (45.9)	874 (32.3)
	Able to sit calmly and relax	793 (29.3)	965 (35.6)	738 (27.2)	214 (7.9)
Anxiety diagnosis	Normal	1431 (52.8)			
	Anxiety symptoms	623 (23)			
	Anxiety	656 (24.2)			

Table II. Risky eating behaviors in adolescents

How often in the last 3 months have you had or performed the following behaviors to try to lose weight?					
		Never or almost never	Sometimes	Frequently (2 times a week)	Very frequently (> 2 times a week)
		n (%)			
REB	Concern about gaining weight	848 (31.3)	908 (33.5)	385 (14.2)	569 (21)
	Eating a lot	1115 (41.1)	1227 (45.3)	262 (9.7)	106 (3.9)
	Losing control over what you eat	1712 (63.2)	710 (26.2)	183 (6.8)	105 (3.9)
	Vomiting after eating	2439 (90)	206 (7.6)	30 (1.1)	35 (1.3)
	Fasting	1920 (70.8)	585 (21.6)	136 (5)	69 (2.5)
	Dieting	1590 (58.7)	859 (31.7)	145 (5.4)	116 (4.3)
	Excessive exercise	744 (27.5)	938 (34.6)	529 (19.5)	499 (18.4)

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Table II (Cont.). Risky eating behaviors in adolescents

How often in the last 3 months have you had or performed the following behaviors to try to lose weight?					
		Never or almost never	**Sometimes**	**Frequently (2 times a week)**	**Very frequently (> 2 times a week)**
		***n* (%)**			
REB	Taking pills	2532 (93.4)	120 (4.4)	43 (1.6)	15 (0.6)
	Taking diuretics	2557 (94.4)	79 (2.9)	69 (2.5)	5 (0.2)
	Taking laxatives	2571 (94.9)	100 (3.7)	16 (0.6)	23 (0.8)
REB diagnosis	No risk	1934 (71.4)			
	REB risk	490 (18.1)			
	REB	286 (10.6)			

Table III. Eating habits in adolescents

		Weekly consumption frequency			**Portions consumed per day**		
		Vegetables	**Fruits**	**Milk**	**Vegetables**		**Fruits**
		***n* (%)**			***n* (%)**		
Recommended foods	0 to 2 days	554 (20.4)	466 (17.2)	942 (34.8)	1 portion	591 (21.8)	553 (20.4)
	3 to 4 days	781 (28.8)	650 (24)	820 (30.3)	2 portions	874 (32.3)	764 (28.2)
	5 to 6 days	1025 (37.8)	1095 (40.4)	395 (14.6)	3 portions	1060 (39.1)	1159 (42.8)
	Daily	350 (12.9)	499 (18.4)	553 (20.4)	4 or more portions	185 (6.8)	234 (8.6)
		Weekly consumption frequency					
		Sausages	**Fast food**	**Sweets or chocolates**		**Bread or cookies**	**Snack**
		***n* (%)**					
Calorie foods	5 or more days	346 (12.8)	79 (2.9)	290 (10.7)		273 (10.1)	166 (6.1)
	3 to 4 days	945 (34.9)	264 (9.7)	740 (27.3)		803 (29.6)	648 (23.9)
	1 to 2 days	1239 (45.7)	1844 (68)	1363 (50.3)		1371 (50.6)	1567 (57.8)
	Never	180 (6.6)	523 (19.3)	317 (11.7)		263 (9.7)	329 (12.1)
		Weekly consumption frequency					
		Alcoholic	**Sugary**				
		n (%)					
Beverages	5 or more days	47 (1.7)	387 (14.3)				
	3 to 4 days	63 (2.3)	464 (17.1)				
	1 to 2 days	378 (13.9)	1534 (56.6)				
	Never	2222 (82)	325 (12)				

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Table III (Cont.). Eating habits in adolescents

	Consumption amount per day					
	Water		Alcoholic		Sugary	
		n (%)		*n* (%)		*n* (%)
Beverages	0 to 2 glasses	442 (16.3)	5 or more drinks	86 (3.2)	4 or more glasses	87 (3.2)
	3 to 4 glasses	818 (30.2)	3 to 4 drinks	70 (2.6)	3 glasses	269 (9.9)
	5 to 6 grasses	813 (30)	1 to 2 drinks	272 (10)	2 glasses	1412 (52.1)
	7 or more glasses	637 (23.5)	None or less than 1	2282 (84.2)	1 glass or less	942 (34.8)

		Interpretation of eating habits
		n (%)
Eating habits	Inadequate (< 25.5 points)	271 (10)
	Partially inadequate (≥ 25.5 and < 38.5 points)	2083 (76.9)
	Adequate (≥ 38.5 points)	356 (13.1)

Table IV. Frequency, place and frequent company in food consumption

		Breakfast	Lunch	Dinner	Snack
		n (%)			
Weekly frequency of food consumption	0 to 1 day	308 (11.4)	151 (5.6)	330 (12.2)	533 (19.7)
	2 to 3 days	331 (12.2)	226 (8.3)	352 (13)	645 (23.8)
	4 to 5 days	529 (19.5)	397 (14.6)	792 (29.2)	1075 (39.7)
	6 to 7 days	1542 (56.9)	1936 (71.4)	1236 (45.6)	457 (16.9)
Frequent place of food consumption	At a street stall or the first thing you find	83 (3.1)	61 (2.3)	80 (3)	216 (8)
	In a restaurant or at an established place	64 (2.4)	105 (3.9)	147 (5.4)	146 (5.4)
	Eat away from home (the food I bring from home)	376 (13.9)	274 (10.1)	201 (7.4)	645 (23.8)
	At home	2187 (80.7)	2270 (83.8)	2282 (84.2)	1703 (62.8)
Frequent company for food consumption	Alone	740 (27.3)	362 (13.4)	558 (20.6)	1236 (45.6)
	With acquaintances	72 (2.7)	68 (2.5)	66 (2.4)	109 (4)
	With friends	349 (12.9)	187 (6.9)	128 (4.7)	533 (19.7)
	With my family	1549 (57.2)	2093 (77.2)	1958 (72.3)	832 (30.7)

Table V. Physical activity of adolescents

		n (%)
Frequency of physical activity	Never	87 (3.2)
	Almost never	645 (23.8)
	Frequently	1407 (51.9)
	Very frequently	571 (21.1)

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Tabla V (Cont.). Physical activity of adolescents

		n (%)
Time/week of physical activity	Less than 2 hours	932 (34.4)
	From 2 to less than 4 hours	990 (36.5)
	From 4 to less than 6 hours	438 (16.2)
	6 or more hours	350 (12.9)
Interpretation of physical activity	Inadequate (< 6 points)	1256 (46.3)
	Partially inadequate (≥ 6 and < 9 points)	961 (35.5)
	Adequate (≥ 9 points)	493 (18.2)

Tabla VI. Associations between study variables and risky eating behaviors (REB)* in adolescents

Variables	B	Significance	Exp (B)	95 % C.I. for EXP (B)	
				Lower	Upper
Sex	-0.522	0.000	0.593	0.514	0.902
Diagnosis Z score BMI E	0.630	0.000	1.877	1.425	1.929
Frequency of sugary drinks consumption (< 3 times/week)	-0.511	0.000	0.600	0.606	1.154
Place where you have breakfast (away from home)	0.533	0.012	1.704	1.208	3.203
Place where you have dinner (at home)	-0.792	0.000	0.453	0.390	0.823
Place where you eat snacks (at home)	-0.303	0.025	0.739	0.678	1.240
Active lifestyle	-0.308	0.001	0.735	0.632	0.921
Adequate eating habits	-0.668	0.000	0.513	0.381	0.760
Depression symptoms	0.741	0.000	2.098	1.663	2.436
Anxiety symptoms	0.969	0.000	2.636	2.133	3.149

Risky Eating Behavior Questionnaire (CAR) that has a Likert scale with four response options: never = 0, sometimes = 1, frequently (twice a week) = 2, very frequently (more than twice a week) = 3, with a cut-off point < 7 no risk, between 7 and 10 moderate risk, and greater than 10 points high risk.

DISCUSSION

Based on the analysis of the results with 2,710 adolescents from Mexico City, it was possible to identify the symptoms of anxiety and depression, risky eating behaviors, eating habits and physical activity that this population had during and after the COVID-19 pandemic; it was also possible to identify the associations between study variables and the development of risky eating behaviors.

In this research, it was found that a high number of adolescents presented symptoms of depression (34.4 %) and anxiety (47.2 %). These data coincide with research performed on children and adolescents during the pandemic: in Honduras, some degree of depression (62 %), anxiety (55.9 %) and stress (55.2 %) was reported in the majority of participants (1); in Spain, emotional symptoms and behavioral problems were observed in 69.7 % and in English-speaking populations, symptoms of depression and anxiety were observed in 43.7 % and 37.4 % of participants, respectively (6,9). Angeles and Mazon (25) indicated that during confinement and the year of epidemiological transition, the lack of a varied routine, physical exercise, recreation, seeing friends, going to the park or visiting other family members without restrictions were relevant factors that affected the psychological health of individuals. It is necessary to consider that prolonged boredom or even experiencing different types of domestic violence could also be factors that affected the mental health of adolescents.

Regarding eating behaviors, the results of the present study showed that one in ten adolescents presented a high risk of de-

veloping REB, which was higher than the prevalence reported at the national surveys (ENSANUT) performed previously (3.9 %) and during the pandemic (6.6 %) (12,13). The increase in REB during the years of confinement may be explained by changes in daily routine, increase in symptoms of depression and anxiety, as well as changes in eating habits and decrease in physical activity. Our results also confirmed previously reported data; that women have a higher prevalence of REB than men (12,13,26,27). Regarding the sociocultural characteristics that surround adolescents, it is worth mentioning that at the national level, REBs are observed more frequently in adolescents from urban areas (12,13).

In this study, variables such as symptoms of anxiety and depression, female sex, higher BMI, and eating breakfast outside the home were positively associated with REB. Otherwise, negative associations were observed between REB and variables such as consumption of sugary drinks < 3 times/week, having dinner and snacks at home, active lifestyle and appropriate eating habits. These results coincide with the study by Quiñones et al. (28) performed with 916 adolescents in Peru, in which a higher prevalence of eating disorders was found in female adolescents, as well as in participants who had symptoms of anxiety. According to Canals and Arija (29), generalized anxiety detected in childhood may predict the manifestations of REB and the diagnosis of eating disorders in adolescence. At later ages, anxiety may be considered a risk factor for the development of eating disorders in women but not in men.

Likewise, in the present study, a high prevalence of overweight and obesity was found (combined prevalence 46.5 %, overweight 26.5 %, obesity 20 %), similar to results reported during the pandemic by the ENSANUT Continua 2020-2022 (a combined prevalence of 41.1 %, of which 23.9 % of participants were overweight and 17.2 % were obese) with a sample of 5,421 that represents 17,168,295 Mexican adolescents between 12 and 19 years old (30). This prevalence was higher compared to those reported in national surveys prior to the pandemic: in Mexico, from 2006 to 2018, the combined prevalence of overweight and obesity in adolescents increased from 33.2 % to 38 %, respectively (31).

According to Medina Zacarias et al., 2020 (31), the most important risk factors associated with overweight/obesity in Mexican adolescents were related to family coexistence factors (e.g., living with an overweight adult) and lifestyle factors (spending > 2 hours in front of a screen and having a dietary pattern characterized by sugary drinks, sweets, sweet cereals, desserts, and snacks consumption). Being overweight since childhood and adolescence implies the appearance of chronic diseases from the earliest ages, which results in lower quality of life, loss of productive years and increase in health expenses at the level of the family and the health sector. In addition, children and adolescents with obesity were at greater risk of developing more severe SARS-CoV-2 disease (COVID-19), as well as the multisystem inflammatory syndrome caused by this virus (32).

Furthermore, in the present study, unhealthy lifestyles were observed among the participants: 86.9 % of the adolescents had inadequate or partially inadequate eating habits and 81.8 % presented inadequate or partially inadequate physical activity, results that coincide with those reported by Navarro et al. (33), who in a study involving 470 Mexican adolescents, found that 74.3 % of the participants obtained a low level of physical activity and 54.6 % had unhealthy eating habits. Our results and the study by Navarro (33) have in common the fact that confinement in this population was characterized by changing the routine of individual and family habits. The interruption of in-person school activity was one of the factors that most modified the behavior of the young population. Increased sedentary lifestyle with the development of bad eating habits led to the use of electronic devices, as well as excessive use of social networks and streaming platforms, accompanied by a feeling of boredom and frustration (34).

LIMITATIONS OF THE STUDY

Among the limitations of the study was its cross-sectional design, which does not allow causal interpretation of the associations identified by the statistical models. Additionally, self-reported questionnaires were administered, which are susceptible to response bias. The questionnaires applied to the sample to evaluate anxiety, depression, and risky eating behaviors identified symptoms and tendencies toward risky behaviors, but did not diagnose any clinical condition. However, the instruments applied in the present study have been previously validated in different population groups, including Mexican adolescents with eating disorders, and have been frequently used to identify unhealthy behaviors in national surveys.

It was concluded that confinement wreaked chaos on the lifestyle of Mexican adolescents and their psychological health, demonstrating an association between REB and variables such as female sex, higher BMI, consumption of beverages with added sugars, eating outside the home, and symptoms of anxiety and depression. Therefore, it is important to develop interdisciplinary targeted and coordinated prevention programs for depression, anxiety, and eating disorders to reduce psychological risk factors resulting from social isolation, as well as promote a healthy lifestyle.

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ARÁN

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Trabajo Original

Epidemiología y dietética

Condición de discapacidad y consumo de bebidas azucaradas: análisis de una encuesta poblacional colombiana

Disability status and consumption of sugar-sweetened beverages: analysis of a Colombian population survey

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Resumen

Introducción: según la Organización Mundial de la Salud (OMS), la obesidad se ha triplicado en el mundo, producto de la alta ingesta calórica. Las personas con discapacidad tienen una mayor probabilidad de tener sobrepeso y obesidad.

Objetivos: el objetivo de este estudio fue estimar la asociación entre la condición de discapacidad y el consumo de bebidas azucaradas en pobladores de 18 a más años de edad de Colombia durante el 2017.

Métodos: realizamos un análisis secundario de los datos de la Encuesta Nacional de Calidad de Vida (ECV) 2017 de Colombia. La variable dependiente fue el consumo de bebidas azucaradas y la independiente fue la condición de discapacidad. Adicionalmente se incorporaron variables de confusión. Se realizó una regresión logística ordinal para estimar la magnitud de la asociación. En todos los resultados se consideró el diseño muestral complejo de la ECV 2017.

Resultados: incluimos los datos de 18.957 personas de 18 a más años. El 7,9 % tenían discapacidad y el 64,4 % consumían bebidas azucaradas. Las personas con discapacidad moderada y severa tuvieron, respectivamente, un 18 % y 41 % menos probabilidades de tener un mayor consumo de bebidas azucaradas en comparación con las personas sin discapacidad (OR: 0,82; IC 95 %: 0,72-0,95 y OR: 0,59; IC 95 %: 0,39-0,90). Cuando se estratificó según los grupos de edad, esta asociación permaneció solo en los mayores de 45 años.

Conclusiones: en Colombia, durante el 2017, las personas con discapacidad mayores de 45 años consumieron menos bebidas azucaradas que las personas sin discapacidad.

Palabras clave:

Bebida azucarada.
Personas con discapacidad.
Asociación. América Latina.
Colombia.

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Abstract

Introduction: according to the World Health Organization (WHO), obesity has tripled in the world as a result of high caloric intake. People with disabilities are more likely to be overweight and obese.

Objectives: this study aimed to estimate the association between disability status and consumption of sugar-sweetened beverages in the population aged 18 years and older in Colombia in 2017.

Methods: we conducted a secondary analysis of data from Colombia's 2017 National Quality of Life Survey (ECV). The dependent variable was the consumption of sugar-sweetened beverages, and the independent variable was the disability status. Additionally, confounding variables were incorporated. An ordinal logistic regression was performed to estimate the magnitude of the association. The complex sample design of the 2017 LCS was considered in all results.

Results: we included data from 18,957 persons aged 18 years and older; 7.9 % had a disability, and 64.4 % consumed sugar-sweetened beverages. People with moderate and severe disability were 18 % and 41 %, respectively, less likely to have a higher consumption of sugar-sweetened beverages compared to people without disability (OR: 0.82; 95 % CI: 0.72-0.95 and OR: 0.59; 95 % CI: 0.39-0.90). When stratified by age group, this association remained only in those older than 45.

Conclusions: in Colombia, in 2017, people with disabilities older than 45 years consumed fewer sugar-sweetened beverages than people without disabilities.

Keywords:

Sugar-sweetened beverages. Disabled persons. Association. Latin America. Colombia.

INTRODUCCIÓN

La Organización Mundial de la Salud (OMS) estima que más de mil millones de personas en el mundo tienen alguna discapacidad (1). Las prevalencias de la discapacidad en América Latina varían entre los países (5,3 % a 24,9 %) y dependen de los instrumentos que se usan para su medición (2). En Colombia, según el Departamento Administrativo Nacional de Estadística (DANE), la prevalencia de la discapacidad en el 2020 fue del 5,6 %, lo que equivale a 2,65 millones de personas (3).

La prevalencia mundial del sobrepeso y la obesidad se ha triplicado en los últimos cuarenta años y más de 2.100 millones de personas, lo que corresponde al 30 % de la población, tienen estas condiciones (4).

La evidencia demuestra que existe una relación etiológica entre el consumo de bebidas azucaradas y el aumento de peso (5). Dentro de las calorías consumidas por las personas obesas, las bebidas azucaradas son las que proveen un alto contenido energético, alto índice glucémico y bajo índice de saciedad, que induce a una mayor ingesta de alimentos después de su consumo (6). Por esta razón, se reconoce que el consumo de bebidas azucaradas representa uno de los factores más importantes vinculados al aumento de peso, las enfermedades cardiovasculares y ciertos tipos de cáncer (5). La evidencia obtenida a través de varios metaanálisis sugiere que existe una asociación positiva entre el consumo de bebidas azucaradas y el aumento de peso (7,8).

Colombia es uno de los países que más consume bebidas azucaradas, posicionándose en el puesto 10 en el ranking mundial con un consumo per cápita de 66,5 litros (9). En una revisión sistemática de encuestas poblacionales y subpoblacionales que incluyó 187 países, se encontró que el mayor consumo de bebidas azucaradas ocurría en los países de América Latina y el Caribe, especialmente en Colombia, donde el promedio del consumo fue mayor a tres vasos por día (3,26 vasos en las mujeres y 3,55 vasos en los hombres) en el grupo etario de 25 a 35 años (10).

Diversos estudios han demostrado que las personas con discapacidad tienen una mayor prevalencia de sobrepeso y obesidad. Una revisión de estudios epidemiológicos que buscó estimar la prevalencia de la obesidad en las personas con discapacidad física encontró que las probabilidades de obesidad eran entre 1,2 y 3,9 veces mayores en las personas con discapacidad física en comparación con las personas sin discapacidad (11). Un estudio que incluyó a 1.119 adultos mayores de 20 años con discapacidad intelectual encontró una mayor prevalencia de obesidad (20,7 %) y sobrepeso (28,0 %) sobre todo en las mujeres. Este estudio comparó sus resultados con los datos de la población general y encontró que las mujeres tenían una mayor prevalencia de obesidad (32 %) que las mujeres de la población general (23 %) (12). En otro estudio que utilizó los datos de nueve años (2008 a 2017) del Registro Nacional de Discapacidad de Corea, que incluía a 123.334.034 personas, se encontró que las mujeres con discapacidad tenían más probabilidades de ser obesas en comparación con las mujeres sin discapacidad y que esta probabilidad se incrementaba de acuerdo con los grados de discapacidad; en los hombres ocurría lo mismo pero en menor magnitud (13). De igual forma, en un análisis del NHANES *(National Health and Nutrition Examination Survey)* en dos periodos (2008 y 2010), se concluyó que las personas con discapacidad tienen una mayor probabilidad de exceder el límite diario recomendado para la ingesta de grasas saturadas y productos ultraprocesados en comparación con las personas sin discapacidad (14).

Existe poca información sobre el consumo de bebidas azucaradas en los países andinos como Colombia y, menos aún, sobre su posible asociación con la discapacidad. Se reconoce que el consumo de bebidas azucaradas es uno de los principales factores de riesgo para el sobrepeso y la obesidad, por lo que se han aplicado impuestos a estas bebidas en un intento de reducir estas condiciones, especialmente en los hogares con bajos recursos económicos (15). De igual manera, las personas con discapacidad tienen mayor probabilidad de sobrepeso y obesidad, por lo que es plausible probar la existencia de esta asociación.

Por todo lo anterior, el objetivo de este estudio fue estimar la asociación entre la condición de discapacidad y el consumo de bebidas azucaradas en pobladores de 18 a más años de Colombia durante el 2017. Adicionalmente, evaluamos esta asociación según los grupos de edad, sexo y tipos de discapacidad.

MÉTODOS

DISEÑO Y POBLACIÓN

Se llevó a cabo un análisis secundario de los datos de la Encuesta Nacional de Calidad de Vida (ECV) de 2017. La población estuvo conformada por residentes del territorio nacional de Colombia. Las encuestas se llevaron a cabo en un periodo de siete semanas. La ECV 2017 se ejecutó desde el 1 de octubre al 15 de noviembre del 2017.

CONTEXTO

La ECV 2017 fue realizada por el Departamento Administrativo Nacional de Estadística (DANE). El objetivo de la encuesta fue «obtener información que permita analizar y hacer comparaciones de las condiciones socioeconómicas de los hogares colombianos y hacer seguimiento a las variables necesarias para el diseño e implementación de políticas públicas». La ECV 2017 tiene representatividad nacional, cabecera y centros poblados-rural disperso, con excepción de área rural de San Andrés y la Orinoquia-Amazonia (16).

El marco muestral está dado por un listado de viviendas, hogares y personas obtenidos del Censo General del 2005, que incluyó a personas mayores de 18 años, que pertenecieran a los hogares, y a personas de entre 12 y 17 años, escolares o universitarios. Tiene tres unidades de muestreo: la unidad primaria compuesta por los municipios de 7.000 y más habitantes, la unidad secundaria compuesta por las manzanas de los municipios y la unidad terciaria conformada por segmentos de diez viviendas en promedio (16).

El muestreo de la ECV 2017 fue probabilístico, multietápico, estratificado y de conglomerados. A fin de evitar la repetición de la encuesta en los mismos hogares, se realizó la rotación de la muestra, es decir, que las unidades finales se seleccionaron hasta agotarse y luego, se iniciaron al azar. La forma de recopilar la información fue a través de la entrevista directa. Los datos fueron recopilados en dispositivos móviles a fin de lograr mayor exactitud y calidad (16).

CRITERIOS DE SELECCIÓN

Para este análisis se incluyeron los datos de las personas de 18 a más años de edad, de ambos sexos, y se excluyeron los datos faltantes o incongruentes.

VARIABLES

La variable dependiente fue el consumo de bebidas azucaradas, que se midió con la pregunta «¿Habitualmente consume bebidas azucaradas (gaseosas, refrescos, bebidas de jugos de frutas procesadas, té endulzado, refrescos en polvo)?», cuyas alternativas de respuesta fueron: 1) todos los días de la semana (dos o más veces al día), 2) todos los días de la semana (una vez al día), 3) cuatro a seis veces a la semana, 4) dos o tres veces a la semana, 5) una vez a la semana, 6) menos de una vez por semana y 7) no. Finalmente, esta variable asumió cuatro categorías: consumo alto (categoría 1 y 2), consumo moderado (categoría 3 y 4), consumo bajo (categoría 5 y 6) y no consume bebidas azucaradas (categoría 7).

La variable independiente fue la condición de discapacidad, que se midió con la pregunta «Dada su condición física y mental, y sin ningún tipo de ayuda, usted puede: ¿oír la voz o los sonidos?, ¿hablar o conversar?, ¿ver de cerca, de lejos o alrededor?, ¿mover el cuerpo, caminar o subir y bajar escaleras?, ¿Agarrar o mover objetos con las manos?, ¿entender, aprender, recordar o tomar decisiones por sí mismo(a)?, ¿comer, vestirse o bañarse por sí mismo(a)?, ¿relacionarse o interactuar con las demás personas?, ¿hacer las actividades diarias sin presentar problemas cardiacos, respiratorias?». Adicionalmente, cada pregunta tenía cuatro categorías de respuesta: 1) no puede hacerlo; 2) sí, con mucha dificultad; 3) sí, con alguna dificultad y 4) sin dificultad. Se asumió la condición de discapacidad cuando la persona respondió afirmativamente al menos a una de las categorías 1, 2 o 3, de las nueve preguntas descritas anteriormente. Por último, esta variable tuvo cuatro categorías: sin discapacidad, discapacidad leve, discapacidad moderada y discapacidad severa.

Se incluyeron variables sociodemográficas como el sexo (hombre y mujer), grupos de edad (18-29 años, 30-44 años, 45-59 años, 60 a más años), estado civil (casado/conviviente, viudo/separado/divorciado y soltero), nivel educativo (sin educación/preescolar, primaria, secundaria, y superior), seguro de salud (no y sí), enfermedad crónica «¿Le han diagnosticado alguna enfermedad crónica? (enfermedad de larga duración y prolongados tratamientos como: enfermedades cardiovasculares, hipertensión, asma, bronquitis crónica, gastritis, lupus, cáncer, gota, leucemia, diabetes, etc.)» (no y sí), autopercepción de salud «¿El estado de salud de usted es?» (muy bueno, bueno, regular o malo), consumo de tabaco «¿Actualmente fuma cigarrillos, tabaco?» (no y sí), autoidentificación étnica «De acuerdo con su cultura, pueblo o rasgos físicos, ¿usted se reconoce cómo?» (ninguna, indígena, afrodescendiente).

ANÁLISIS ESTADÍSTICO

Los datos se descargaron de la página web del DANE (17) y luego se importaron al programa STATA versión 16 para Windows. Se efectuó un análisis descriptivo con frecuencias y porcentajes, luego un análisis bivariado en donde se evaluaron las diferencias según el consumo de bebidas azucaradas, con la prueba de Chi cuadrado. También se efectuó un análisis multivariado, en donde se incluyeron a todas las variables y se consideraron dos modelos, uno crudo y uno ajustado. Las variables que resultaron asociadas en el modelo crudo ($p < 0,05$) se incluyeron en el modelo ajustado. Debido a que la variable dependiente posee

cuatro categorías (sin consumo, poco consumo, moderado consumo y alto consumo) se efectuó una regresión logística ordinal y se estimarán odds ratio (OR) con sus intervalos de confianza al 95 % (IC 95 %). Se evaluó la posibilidad de multicolinealidad en las variables del modelo ajustado a través del cálculo manual del factor de inflación de la varianza (VIF, por sus siglas en inglés) (18). El diseño muestral complejo de la ECV se tuvo en cuenta en todos los cálculos realizados. Se utilizó un diagrama de bosque *(forest plot)* para mostrar las diferencias según grupos de edad, sexo y tipos de discapacidad.

PERMISOS Y CONSIDERACIONES ÉTICAS

El proyecto del estudio fue aprobado por la carrera de Medicina Humana de Universidad Científica del Sur y fue exonerado de la evaluación por el comité de ética institucional por tratarse de datos de acceso público, según resolución No. 012-DGIDI-CIENTIFICA-2021. Los microdatos de la ECV 2017 están anonimizados y son de acceso libre, según lo declarado por el DANE (16).

RESULTADOS

La base contenía los datos de 26.500 personas; se excluyeron 43 personas de la variable «seguro de salud» que correspondían a la categoría «no sabe» y se excluyeron 7.500 personas que tenían menos de 18 años, quedando 18.957 conjuntos de datos para el análisis final.

El 53,2 % eran mujeres, la mayoría pertenecían al grupo etario de 30-44 años (29,9 %), estaban casados o eran convivientes (55,5 %), tenían como máximo nivel educativo el secundario (41,0 %). Asimismo, el 17,3 % tenían una enfermedad crónica, el 5,6 % no tenían seguro de salud, el 65,5 % percibían que tenían buena salud, el 8,5 % consumían tabaco y el 7,9 % se identificaban con alguna etnia (1,4 % indígena y 6,5 % afrodescendiente). Finalmente, el 7,9 % refirieron que tenían alguna discapacidad, siendo el 6,8 % de nivel moderado y el 1,1 % de nivel severo. El 64,4 % refirieron que consumían bebidas azucaradas y, de ellos, el 18,7 % tenían poco consumo, el 24,7 % tenían un consumo moderado y el 21 % tenían un alto consumo de bebidas azucaradas (Tabla I).

Tabla I. Características de los pobladores de 18 o más años de Colombia durante el 2017 (n = 18.957)

Características	*n*	%*	IC 95 %
Sexo			
Hombre	8.527	46,8	45,9-47,7
Mujer	10.430	53,2	52,3-54,1
Grupos de edad			
18-29 años	5.046	29,0	28,1-30,0
30-44 años	5.391	29,9	29,1-3,1
45-59 años	4.814	23,6	2,3-24,3
60 a más años	3.706	17,5	16,9-18,1
Estado civil			
Casado/conviviente	10.419	55,5	54,7- 56,4
Viudo/separado/divorciado	3.452	16,9	16,2-17,6
Soltero	5.086	27,6	26,8-28,4
Nivel educativo			
Sin educación/preescolar	728	3,2	2,9-3,5
Primaria	4.211	19,4	18,7-20,1
Secundaria	7.872	41,0	40,1-42,0
Superior	6.146	36,4	35,5-37,3
Seguro de salud			
No	18.019	94,4	93,9-94,8
Sí	938	5,6	5,2-6,1
Enfermedad crónica			
No	15.439	82,7	82,0-83,3
Sí	3.518	17,3	17,7-18,0

(Continúa en página siguiente)

Tabla I (Cont.). Características de los pobladores de 18 o más años de Colombia durante el 2017 (n = 18.957)

Características	*n*	%*	IC 95 %
Autopercepción de salud			
Muy bueno	2.638	16,9	16,1-17, 6
Bueno	12.458	65,5	64,7-66,4
Regular	3.541	16,3	15,7-17,0
Malo	320	1,3	1,1-1,4
Consumo de tabaco			
No	17.457	91,5	91,0-92,0
Sí	1.500	8,5	8,0-9,0
Autoidentificación étnica			
Ninguna	15.892	92,1	91,7-92,6
Indígena	705	1,4	1,2-1,6
Afrodescendiente	2.360	6,5	6,1-6,9
Discapacidad			
Sin discapacidad	17.307	92,1	91,6-92,6
Discapacidad moderada	1.415	6,8	6,4-7,3
Discapacidad severa	235	1,1	0,1-1,3
Bebidas azucaradas			
Sin consumo	7.135	35,6	34,7-36,4
Poco	3.378	18,7	18,0-19,4
Moderado	4.285	24,7	23,9-25,6
Alto consumo	4.159	21,0	20,3-21,8

**Porcentaje ponderado según el diseño muestral de la ECV 2017. IC 95 %: intervalo de confianza al 95 %.*

En el análisis bivariado se observa una disminución de las proporciones de consumo (poco, moderado y alto) de bebidas azucaradas a medida que se incrementan los niveles de discapacidad, siendo esta diferencia significativa ($p < 0,001$) (Tabla II).

En el análisis multivariado, en el modelo crudo se observó que las personas con discapacidad moderada y severa tenían, respectivamente, un 51 % y un 73 % menos probabilidades de presentar un mayor consumo de bebidas azucaradas que las personas sin discapacidad (OR: 0,49; IC 95 %: 0,43-0,56 y OR: 0,27; IC 95 %: 0,18-0,39). En el modelo ajustado por sexo, grupos de edad, estado civil, nivel educativo, enfermedad crónica, seguro de salud, consumo de tabaco y autoidentificación étnica, las personas con discapacidad moderada y severa tuvieron, respectivamente, un 18 % y un 41 % menos de probabilidades de presentar un mayor consumo de bebidas azucaradas en comparación con las personas sin discapacidad (OR: 0,82; IC 95 %: 0,72-0,95 y OR: 0,59; IC 95 %: 0,39-0,90) (Tabla III). En el modelo ajustado no se encontraron indicios de multicolinealidad entre las variables (VIF ≈ 2).

Cuando los modelos ajustados se estratificaron según los grupos de edad, se observó que esta asociación solo era significativa en los grupos de 45 a 59 años (OR: 0,76; IC 95 %: 0,60-0,96) y de 60 a más años (OR: 0,76; IC 95 %: 0,61-0,96). Cuando se estratificó según el sexo, se observó que tanto los hombres como las mujeres tenían una menor probabilidad de presentar un mayor consumo de bebidas azucaradas (hombres OR: 0,75; IC 95 %: 0,60-0,93 y mujeres OR: 0,83; IC 95 %: 0,69-0,98). Cuando se estratificó según los tipos de discapacidad, se observó que la mayoría tenían una menor probabilidad de tener un mayor consumo de bebidas azucaradas, destacando esto en aquellos que tenían dificultades para «comer, vestirse o bañarse por sí mismos» (OR: 0,28 IC 95 %: 0,16-0,50) y «relacionarse o interactuar con las demás personas» (OR: 0,34 IC 95 %: 0,19-0,62) (Fig. 1).

DISCUSIÓN

El 7,9 % de los pobladores de 18 a más años de Colombia refirieron que tenían alguna discapacidad y el 64,4 % admitieron que consumían bebidas azucaradas. En forma global, las personas con discapacidad tuvieron menos probabilidades de presentar un mayor consumo de bebidas azucaradas en comparación con las personas sin discapacidad. Sin embargo, cuando se estratificó según los grupos de edad, esta asociación solo fue significativa en los grupos de 45 a 59 años y de 60 a más años.

Tabla II. Diferencias según el consumo de bebidas azucaradas en pobladores de 18 o más años de Colombia durante el 2017

Características	Bebidas azucaradas				Valor de *p**
	Sin consumo	Poco consumo	Moderado consumo	Alto consumo	
Sexo					
Hombre	2.711 (29,5)	1.406 (17,0)	2.214 (28,1)	2.196 (25,4)	< 0,001
Mujer	4.424 (40,9)	1.972 (20,1)	2.071 (21,8)	1.963 (17,2)	
Grupo de edad					
18-29 años	1.172 (22,0)	853 (17,0)	1.521 (32,7)	1.500 (28,3)	< 0,001
30-44 años	1.650 (29,7)	1.011 (19,7)	1.400 (27,3)	1.330 (23,3)	
45-59 años	2.071 (41,2)	902 (20,8)	928 (20,7)	913 (17,3)	
60 a mas años	2.242 (60,4)	612 (17,0)	436 (12,7)	416 (9,9)	
Estado civil					
Casado/conviviente	3.886 (35,6)	1.976 (20,1)	2.323 (23,8)	2.234 (20,5)	< 0,001
Viudo/separado/divorciado	1.624 (46,4)	617 (18,3)	595 (19,0)	616 (16,3)	
Soltero	1.625 (28,9)	785 (16,0)	1.367 (30,1)	1.309 (25,0)	
Nivel educativo					
Sin educación/preescolar	404 (52,6)	133 (17,2)	88 (14,5)	103 (15,7)	< 0,001
Primaria	1.967 (43,7)	808 (20,0)	752 (19,3)	684 (17,0)	
Secundaria	2.518 (29,7)	1.365 (18,2)	1.964 (27,5)	2.025 (24,6)	
Superior	2.246 (36,2)	1.072 (18,7)	1.481 (25,5)	1.347 (19,6)	
Seguro de salud					
No	6.840 (36,0)	3.217 (18,7)	4.040 (24,6)	3.922 (20,7)	< 0,001
Sí	295 (26,8)	161 (18,7)	245 (27,5)	237 (27,0)	
Enfermedad crónica					
No	5.179 (31,8)	2.758 (18,9)	2.807 (26,5)	3.695 (22,8)	< 0,001
Sí	1.956 (53,5)	620 (17,6)	478 (16,6)	464 (12,3)	
Autopercepción de salud					
Muy bueno	817 (28,3)	421 (15,8)	725 (33,2)	675 (22,7)	< 0,001
Bueno	4.449 (34,5)	2.218 (19,1)	2.987 (24,7)	2.804 (21,7)	
Regular	1.657 (44,7)	692 (20,2)	551 (18,0)	641 (17,1)	
Malo	212 (66,2)	47 (15,9)	22 (5,8)	39 (12,1)	
Consumo de tabaco					
No	6.716 (36,4)	3.146 (19,0)	3.927 (24,6)	3.668 (20,0)	< 0,001
Sí	419 (26,1)	232 (15,3)	358 (26,6)	491 (32,0)	
Autoidentificación étnica					
Ninguna	6.138 (36,0)	2.867 (18,3)	3.614 (24,7)	3.273 (21,0)	< 0,001
Indígena	234 (29,7)	113 (22,1)	134 (21,7)	224 (26,5)	
Afrodescendiente	763 (31,1)	398 (23,6)	537 (25,4)	662 (19,9)	
Discapacidad					
Sin discapacidad	6.202 (34,0)	3.090 (18,7)	4.084 (25,7)	3.931 (21,6)	< 0,001
Discapacidad moderada	770 (51,7)	264 (19,1)	191 (14,7)	190 (14,5)	
Discapacidad severa	163 (68,2)	24 (10,5)	10 (5,8)	38 (15,5)	

**Prueba del chi cuadrado.*

Tabla III. Asociación entre la condición de discapacidad y el consumo de bebidas azucaradas, según el modelo crudo y el ajustado del análisis multivariado

Características	Modelo crudo	Valor de *p*	Modelo ajustado*	Valor de *p*
	OR (IC 95 %)		OR (IC 95 %)	
Discapacidad				
Sin discapacidad	Referencia		Referencia	
Discapacidad moderada	0,49 (0,43-0,56)	< 0,001	0,82 (0,72-0,95)	0,007
Discapacidad severa	0,27 (0,18-0,39)	< 0,001	0,59 (0,39-0,90)	0,014

**Modelo ajustado por sexo, grupos de edad, estado civil, nivel educativo, enfermedad crónica, seguro de salud, consumo de tabaco y autoidentificación étnica. OR: odds ratio; IC 95 %: intervalo de confianza al 95 %.*

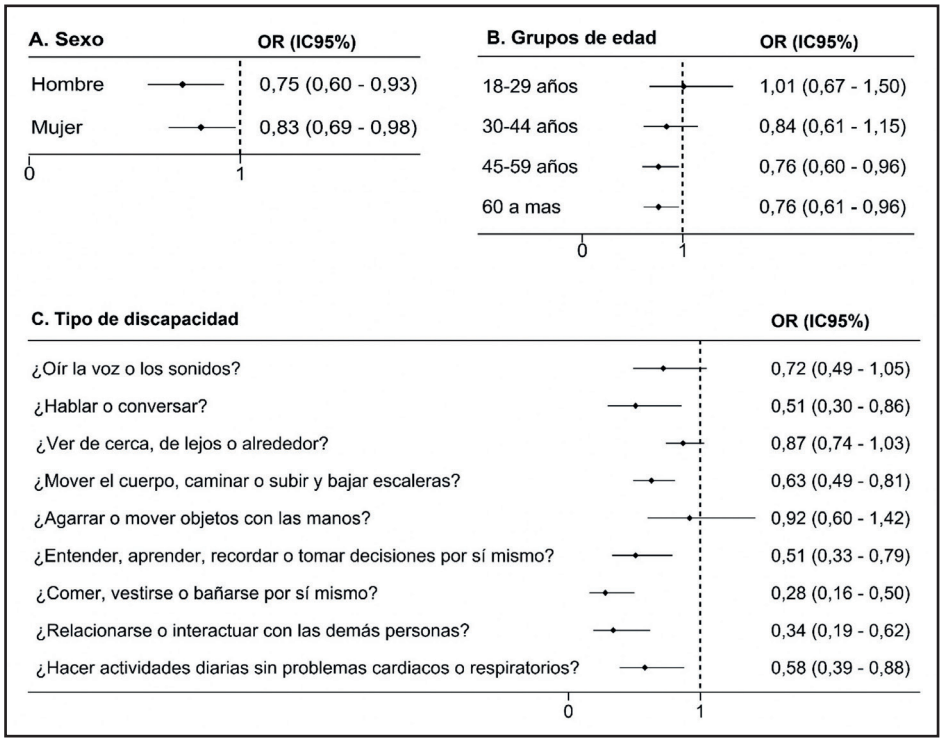

Figura 1.

Asociación entre la condición de discapacidad y el consumo de bebidas azucaradas (modelo ajustado), con estratificación por sexo, grupos de edad y tipos de discapacidad.

En hombres y mujeres, y en la mayoría de los tipos de discapacidad, se observó una menor probabilidad de tener un mayor consumo de bebidas azucaradas.

En el presente estudio, la prevalencia del consumo de bebidas azucaradas fue del 64,4 %. Un estudio poblacional realizado en Colombia ha descrito una prevalencia similar; este trabajo se basó en los datos de la Encuesta Nacional de Situación Nutricional (ENSIN) del 2010, que incluyo a 17.514 sujetos de 5 a 64 años y reportó una prevalencia media del consumo de bebidas azucaradas del 79,2 % (IC 95 %: 75,7-82,8) en los hombres de 18 a 64 años, y del 70,7 % (IC 95 %: 66,0-75,4) en las mujeres de la misma edad (19). Es importante mencionar que la mayoría de los estudios han estimado incidencias por ser cohortes prospectivas o han descrito el consumo a través del promedio de vasos consumidos al día. No se han encontrado datos referidos a la prevalencia del consumo de bebidas azucaradas en poblaciones similares. Este único estudio muestra una proporción ligeramente mayor, por lo que podemos concluir que los resultados hallados son correctos.

Como hallazgo principal, se encontró que las personas con discapacidad tenían una menor probabilidad de consumir bebidas azucaradas en comparación con las personas sin discapacidad. Un resultado similar se reportó en un estudio que analizó los datos de la Encuesta Nacional de Salud y Nutrición de Sudáfrica (SANHANES-1), que incluyó a 15.179 personas de 15 a más años y encontró un menor consumo diario de gaseosas en las personas con discapacidad funcional (7,1 %) en comparación con las personas sin discapacidad (11,0 %) ($p = 0,002$). Sin embargo, en el análisis multivariado de este estudio no se encontró asociación entre estas dos variables (OR: 0,84; IC 95 %: 0,56-1,23) (20).

Sin embargo, en un estudio realizado en 150.760 adultos mayores de 18 años de 23 estados y del distrito de Columbia de los Estados Unidos, se encontró que la prevalencia del consumo de bebidas azucaradas, al menos una vez al día, era significativamente mayor en los adultos con discapacidad (30,3 %) en comparación con aquellos sin discapacidad (28,6 %) (ORa: 1,27; $p < 0{,}001$); este estudio destaca que el consumo de una dieta saludable es difícil en las personas con discapacidad, lo que conlleva una ingesta nutricional inadecuada (21). Asimismo, en un estudio que analizó los datos secundarios del Sistema de Monitoreo y Vigilancia de Australia Meridional (SAMSS) desde el 2008 al 2017 procedentes de 46.302 personas de 16 a 64 años, se encontró que el 21,3 % de las personas con discapacidad consumían bebidas azucaradas en comparación con el 19,4 % que no consumían bebidas azucaradas y que también tenían discapacidad. Este estudio también mostró que las personas con discapacidad consumían, en promedio, 154 mililitros de gaseosas al día, en comparación con los 113 ml que consumían las personas sin discapacidad (22). Al igual que en el trabajo anterior, este estudio no demostró asociación entre la discapacidad y el consumo de bebidas azucaradas en el análisis multivariado.

La poca evidencia disponible sobre esta posible asociación muestra resultados contradictorios, tal como se ha descrito previamente. Hasta donde se tiene conocimiento, este sería el primer estudio que describe un efecto protector de la discapacidad frente al consumo de bebidas azucaradas. No obstante, estos resultados deben tomarse con cautela ya que la medición de la discapacidad es difícil y compleja, sobre todo a nivel poblacional. Se han realizado varios intentos de medir la discapacidad a través de preguntas autorreferidas, recomendadas por el grupo de Washington (23), o a través del uso de la Encuesta Modelo de Discapacidad de la OMS (24), que tienen serias limitaciones para estimar valores de prevalencia o incidencia de la discapacidad, incluyendo sus niveles. Sumado a esto, las encuestas poblacionales no valoran la «funcionalidad», por lo que pueden existir personas con discapacidad moderada o severa que son altamente funcionales, con hábitos semejantes a los de la población general, con una alimentación rica en grasas saturadas y azúcar. Esta amplia variabilidad podría explicar los resultados contradictorios de los estudios previos.

Adicionalmente, esta asociación solo fue significativa en los mayores de 45 años. El padecimiento de enfermedades crónicas y de discapacidad en los adultos mayores (25) podría incrementar el «autocuidado» y la «autogestión» de la salud a través de cambios en los estilos de vida (26), como evitar el consumo de bebidas azucaradas por considerar que son perjudiciales para la salud. El menor consumo de bebidas azucaradas en las personas mayores sería un hallazgo favorable, ya que se ha demostrado que un alto consumo de azúcar se ha relacionado con un menor rendimiento cognitivo y con alteraciones de la función cerebral en los adultos mayores (27), incluidas la enfermedad de Alzheimer (28) y la enfermedad cerebrovascular (29), lo que incrementaría las tasas de discapacidad. En los más jóvenes, las probabilidades de consumo de bebidas azucaradas resultaron ser semejantes entre las personas con y sin discapacidad, y esto puede estar relacionado con una mayor exposición a la publicidad y a la diversidad de sabores que ofrecen estas bebidas (20).

LIMITACIONES

La condición de discapacidad debería determinarla un especialista en medicina física, rehabilitación o geriatría; sin embargo, las preguntas del grupo de Washington se han utilizado ampliamente en la medición de la discapacidad en los estudios poblacionales. La medición del consumo de bebidas azucaradas estaría sujeta a sesgos de recuerdo y de deseabilidad social, lo que podría incrementar o disminuir la prevalencia de esta variable. Algunas variables, como el índice de masa corporal, que podrían estar relacionadas con el consumo de bebidas azucaradas no aparecían en la base de datos analizada. Debido al diseño transversal del estudio, no se puede determinar la causalidad entre las variables principales y, por esta razón, puede existir causalidad reversa, es decir, el consumo habitual de bebidas azucaradas podría condicionar la discapacidad a través del incremento de los años vividos con discapacidad (30). Como fortaleza debemos mencionar que los resultados tienen representatividad de toda la población colombiana.

CONCLUSIONES

En Colombia, durante el 2017, las personas con discapacidad tuvieron menos probabilidades de presentar un mayor consumo de bebidas azucaradas en comparación con las personas sin discapacidad. Esta probabilidad se incrementó de acuerdo con el nivel de discapacidad. Sin embargo, esta asociación solo estuvo presente en los mayores de 45 años. En los grupos etarios más jóvenes, el consumo de bebidas azucaradas resultó semejante entre las personas con o sin discapacidad. Se recomienda la realización de estudios primarios que incluyan la temporalidad de los eventos a fin de confirmar la direccionalidad de las asociaciones halladas en el presente estudio.

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Trabajo Original

Epidemiología y dietética

Association between overall quality of macronutrients and incidence of overweight and obesity in the SUN *(Seguimiento Universidad de Navarra)* cohort

Asociación entre la calidad global de macronutrientes y la incidencia de sobrepeso y obesidad en la cohorte SUN (Seguimiento Universidad de Navarra)

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Abstract

Introduction: no previous large prospective studies have assessed the global quality of macronutrients in association with the risk of overweight/obesity.

Objective: to prospectively assess the association of an overall macronutrient quality index (MQI) with weight change and the incidence of overweight/obesity in the Seguimiento Universidad de Navarra (SUN) cohort.

Methods: the diet of 9,344 Spanish university graduates free of overweight/obesity (mean age: 36.5 [SD, 11.1]) was assessed through a validated 136-item food frequency questionnaire. The MQI was calculated as the sum of the Carbohydrate Quality Index, the Fat Quality Index, and the Healthy Plate Protein Quality Index. Participants were classified into groups (G) according to MQI. Incident overweight/obesity was defined if follow-up questionnaires indicated BMI was ≥ 25 kg/m^2. Multiple linear regression models and Cox proportional hazard models were used to assess the average yearly weight change and the risk of overweight/obesity over follow-up time.

Results: 2,465 cases of incident overweight/obesity were identified (median follow-up: 10.7 years). Increasing MQI was significantly associated with lower annual weight gain (g): β coefficient: -99.0, (95 % CI: -173.6 to -24.5) in the G4 vs G1, p for trend = 0.007. In the fully adjusted model the incidences of overweight/obesity in G4 and G1 were 21.7 % (431 cases) and 29.3 % (954 cases), respectively. The adjusted HR was 0.87 (95 % CI, 0.77-0.98, *p* for trend = 0.036). When we used repeated analyses updating the MQI after 10 years of follow-up, results remained similar.

Conclusions: a significant inverse association between a multidimensional MQI and the risk of overweight/obesity was found in this Mediterranean cohort of adults.

Keywords:

Macronutrient quality. SUN cohort. Weight change. Overweight. Obesity.

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Ethical standards disclosure: voluntary completion of baseline questionnaire was considered to imply informed consent. The study was conducted according to the Declaration of Helsinki, and all procedures involving human subjects were approved by the Institutional Review board of the University of Navarra. The cohort is registered at clinicaltrials.gov as NCT02669602.

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Artificial intelligence: the authors declare not to have used artificial intelligence (AI) or any AI-assisted technologies in the elaboration of the article.

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Resumen

Introducción: ningún estudio prospectivo previo de gran tamaño ha evaluado la asociación entre la calidad global de los macronutrientes y el riesgo de sobrepeso/obesidad.

Objetivo: evaluar la asociación del índice global de calidad de macronutrientes (MQI) con el cambio de peso y la incidencia de sobrepeso/obesidad en la cohorte Seguimiento Universidad de Navarra (SUN).

Métodos: la dieta se evalúo en 9344 graduados universitarios españoles mediante un cuestionario validado de frecuencia de consumo. El MQI se calculó como la suma del índice de calidad de carbohidratos, el índice de calidad de grasas y el índice de calidad de proteínas del plato saludable. Los participantes se clasificaron en cuartiles según el MQI. Se definió la incidencia de sobrepeso/obesidad durante el seguimiento si el IMC era ≥ 25 kg/m^2. Se utilizaron modelos de regresión lineal múltiple y de riesgo proporcional de Cox para evaluar el cambio de peso anualizado y el riesgo de sobrepeso/obesidad durante el seguimiento.

Resultados: 2465 casos incidentes de sobrepeso/obesidad (mediana de seguimiento: 10,7 años). El aumento del MQI se asoció significativamente con un menor aumento de peso anual (g): coeficiente ß: -99,0 (IC 95 %: -173,6 a -24,5) en Q4 *vs.* Q1 (*p* tendencia lineal = 0,007). En el modelo más ajustado, la incidencia de sobrepeso/obesidad en Q4 y Q1 fue del 21,7 % (431 casos) y del 29,3 % (954 casos), respectivamente. El HR ajustado fue 0,87 (IC 95 %, 0,77-0,98, *p* tendencia lineal = 0,036).

Conclusiones: se encontró una asociación inversa significativa entre el MQI multidimensional y el riesgo de sobrepeso/obesidad en esta cohorte mediterránea de adultos.

Palabras clave:

Calidad de macronutrientes. Cohorte SUN. Cambio de peso. Sobrepeso. Obesidad.

INTRODUCTION

Obesity is considered to be a pandemic disease and a major public health problem among adults worldwide because it is associated with much morbidity and mortality derived from most non-communicable diseases (NCDs). Obesity rates have increased dramatically over the last few decades. If trends continue, around two billion adults globally will be obese by 2035 (1). Overweight and obesity increase the risk of cardiovascular diseases (CVD), diabetes, cancers and other health problems (2) and are associated with increased health care costs (3). Its etiology is complex and multifactorial and involves genetic components. However, dietary factors, low physical activity and sedentary lifestyle play important roles in body composition (1).

Thus, identifying dietary patterns, isolated dietary components or foods and macronutrient distribution related to obesity prevention has become a major priority for public health.

The Dietary Guidelines for Americans (DGA) 2020-2025 reflect with moderate evidence that dietary patterns emphasizing vegetables, fruits, and whole grains; seafood and legumes; moderate in dairy products and alcohol; low in sugar-sweetened foods and beverages, and refined grains and lower in meats (including red and processed meats), are associated with favorable outcomes related to the risk of obesity or body weight. Specifically, dietary pattern components associated with these favorable outcomes include lower intakes of saturated fats, cholesterol, and sodium, and higher intakes of unsaturated fats (4).

Notwithstanding, the acceptable macronutrient distribution ranges (AMDR) associated with lower chronic disease risk and adequate micronutrient intake, are: 45-65 %, 20-35 % and 10-35 % of total energy intake (TEI) for carbohydrates, fats and proteins, respectively (5). However, evidence on the relationship between macronutrient distributions aside from the AMDR, and risk of overweight/obesity in adults is scarce and the results are inconsistent or report no significant association (6).

Previous research has classified dietary patterns based on macronutrient proportion into three main types of diets: low carbohydrate, moderate macronutrients and low fat (7).

Nevertheless, the role of macronutrient in obesity remains controversial (8). There is an emerging scientific interest to assess whether the "quality" of macronutrients could be more important than their "quantity" to prevent obesity (9-11).

Diet quality indices have been previously used to assess their association with general obesity or abdominal obesity (12,13). However, diet quality indices based solely on nutrients are less common. Although an adequate balance of macronutrients is a common dimension included in the construction of diet quality indices, specific indices based on the quality dimension of macronutrients are scarce (13,14).

In this context, several *a priori dietary* indices have been developed to evaluate the quality of macronutrients individually (15,16) or globally (16).

Our team has previously investigated the specific role of fat and carbohydrates (17-19) on the risk of obesity. However, no previous large prospective studies have simultaneously assessed the global quality of macronutrients, through a priori and multidimensional dietary index (MQI), in association with risk of overweight/obesity. Thus, we aimed to longitudinally evaluate the association between MQI and average yearly weight change and risk of overweight/obesity, in the "Seguimiento Universidad de Navarra (SUN)" Project.

MATERIAL AND METHODS

DESIGN

The SUN Project (www.proyectosun.es) is a multipurpose, dynamic prospective cohort that began in 1999. The participants of this cohort are all Spanish university graduates of the University of Navarra and other Spanish universities. Its main objective is to evaluate the impact of lifestyle and diet, in particular the Mediterranean Diet (MedDiet), on NCDs such as diabetes, obesity, cancer and CVD. Self-administered questionnaires, at baseline and every 2 years, by mail or web-based, collected information on sociodemographic characteristics, anthropometric measures, lifestyle variables, family and personal medical history, diet and

health- related habits. The overall retention rate is greater than 90% in the SUN cohort. Additional details on this cohort have been described elsewhere.

SUBJECTS

In the SUN cohort, 23,133 participants were included until May 2022, excluding 234 who did not answer the baseline questionnaire before August 31st, 2019 to ensure a minimum follow-up of 2 years; 6,744 participants with a baseline BMI ≥ 25; 1,616 participants with an energy intake outside of the predefined limits established by Willett (men < 800 or > 4,000 kcal/d and women < 500 or > 3500 kcal/d), 3,277 women who were pregnant at the time of enrollment into the cohort or during the follow-up; 562 with prevalent diabetes, CVD, or cancer; 1,319 participants who had no follow-up; and finally 37 participants without information on variables of interest. Thus, our study included a total of 9,344 participants.

The SUN project was conducted according to the principles expressed in the Declaration of Helsinki. Informed consent for their participation in the cohort is implied when an answer to the first questionnaire (Q0) is received and potential candidates are informed of their right to leave the study at any time without consequences. This project was approved by the University of Navarra Institutional Review Committee (approval code 010830) and this cohort was registered at Clinicaltrials.gov as NCT02669602.

DIETARY ASSESSMENT

Dietary variables were assessed at baseline and after 10 years of follow-up through a self-administered 136-item semi-quantitative food frequency questionnaire (FFQ). This FFQ has been previously validated in Spain (22,23) with typical portion sizes specified for each item and with nine categories from "never or almost never" to "≥ 6 times/day". Participants report their frequency of consumption, on average, during the previous year.

Finally, the calculation of dietary intake was performed by a team of trained nutritionists using the Spanish Food Composition Tables (24,25).

Adherence to the MedDiet was measured through the use of two dietary indices: the MDS developed by Trichopolou et al. (26) and the MEDAS with ranges of 0 to 9 points and of 0 and 14 points respectively (27). On the other hand, adherence to the Provegetarian food pattern was calculated according to the score proposed by Martínez-González, et al. (28). In all cases, higher scores indicated greater adherence to each dietary pattern.

EXPOSURE ASSESSMENT: MACRONUTRIENT QUALITY INDEX

The MQI (16) was established based on three sub-indexes: the Carbohydrate Quality Index (CQI), the Fat Quality Index (FQI), and the Healthy Plate Protein Source Quality index (HPPQI) as follows: MQI = CQI + FQI + HPPQI.

This CQI (19) is based on four equally weighted domains: glycemic index (GI), total fiber intake (g/d), ratio of carbohydrates from solid/total (solids + liquids), ratio of carbohydrates from whole grain /total cereals (whole grain + refined). Participants were categorized into quintiles for each of the four components of the CQI. A value (range 1 to 5) was given according to each quintile (only for the GI were the values upside down) and finally, the four values for each participant were added to obtain the CQI.

The FQI (19) was calculated using the following ratio: [monounsaturated fatty acids (MFA) + polyunsaturated fatty acids (PFA)]/ [saturated fatty acids (SFA) + trans fatty acids (TFA)].

Finally, the HPPQI (16) was calculated based on the following ratio HPPQI = (seafood + poultry + legumes + nuts) / (red and processed meat + cheese); according to the Harvard Healthy Eating Plate (29), food groups placed in the numerator and denominator reflect healthy and unhealthy sources of protein, respectively.

To calculate the MQI, participants were classified into quintiles for each sub-index (CQI, FQI, and HPPQI), assigning values from 1 (low quality) to 5 (high quality). All sub-indices were added yielding a MQI score from 3 (low macronutrient quality) to 15 (high macronutrient quality). Finally, Participants were categorized into the following 4 groups to create 4 reasonably equal groups according the MQI: very lowest adherence (MQI from 3 to 7), lowest adherence (MQI from 8 to 9), medium adherence (MQI from 10 to 11) and highest adherence (MQI from 12 to 15).

OUTCOME ASSESSMENT

Self-reported weight was collected at baseline and in all follow-up questionnaires. BMI was calculated from the weight and height reported at baseline and throughout follow-up.

Reliability and validity of participants' self-reported bodyweights had been previously evaluated in a subsample of the cohort (30). Self-reported body weights showed a high correlation with directly measured body weights (*r*: 0.991; 95 % CI: 0.986-0.994). The mean relative error in self-reported weight was 1.45 %.

In this study, incident overweight or obesity was defined as when participants had a baseline BMI < 25 kg/m^2 in Q0 and a BMI ≥ 25 kg/m^2 in any of the successive follow-up questionnaires.

ASSESSMENT OF OTHER VARIABLES

Information of non-dietary variables was also collected at baseline. Physical activity and hypertension have been previously validated in subsamples of this cohort (31). The prevalence and history of several NCDs was ascertained at baseline and updated until the exit of the cohort or until death was reported.

STATISTICAL ANALYSES

We describe the baseline characteristics of participants adjusted for age and sex using the inverse probability weighting method according to groups of the MQI. Proportions and means and standard deviations (SDs) were used to describe categorical and quantitative variables, respectively.

Multiple linear regressions models and Cox proportional hazard models were used to assess the association between MQI and average yearly weight change (in g) and risk of overweight/obesity, respectively, over follow-up time, across groups of adherence to MQI.

We calculated hazard ratios (HRs) and their 95 % CIs. The follow-up time for each participant was defined as the interval between the date of returning the Q0 to the date of the first report of a body weight corresponding to overweight/obesity or the date of the last questionnaire. In all models, age was the underlying time variable.

We performed a crude model and three multivariable model adjusting for well-known potential confounders. In Model 1 we adjusted for sex, year of recruitment (5 categories), and age in deciles. Model 2 was additionally adjusted for baseline BMI (continuous, kg/m^2), smoking habit (continuous, packs/year), physical activity (continuous, MET-h/s), hours spent sitting (continuous, h/d), alcohol consumption (never, < 5 g/d women/< 10 g/d men, 5-25 g/d women or 10-50 g/d men, and > 25 g/d women/> 50 g/d men) and marital status (single, married, widowed and other) and finally Model 3 was additionally adjusted for total energy (continuous, kcal/d), snacking between meals (yes/no), family history of obesity (yes/no), university years (continuous), fast food consumption (continuous, g/d), and special diet follow-up (yes/no). In all analyses, we used the lowest group as the reference category.

We used MQI as a continuous variable, assigning medians to each group, to assess the significance of the linear trend tests.

To evaluate a more realistic assessment of long-term diet during follow-up, we repeated the main analyses with dietary variables included in FFQ-10 after 10 years of follow-up, using updated data and cumulative average MQI.

We assessed the combined effect of adherence to the MedDiet, evaluated through Mediterranean Diet Score (MDS) and Mediterranean Diet Adherence Screener (MEDAS), and the Provegetarian food pattern, with the MQI. For this purpose, we categorized each dietary index by the median, interpreted as "low adherence" and "high adherence", and the MQI in tertiles (T1, T2 and T3). In all analyses, the reference category was the Q1 in MQI and the lowest adherence of MDS, MEDAS or Provegetarian diet.

Finally, the following sensitivity analyses were also performed to assess the robustness of our findings: modifying the energy limits outside the established limits (5th and 95th percentile), modifying the energy limits outside the established limits (1th and 99th percentile), additional adjustment for weight gain ≥ 3 kg in the 5 years before entering the cohort, exclusion of participants who did not answer more than 30 items of the FFQ and finally excluding participants who followed a special diet at baseline.

These analyses were performed using STATA version 15. Any *p*-values < 0.05 were considered statistically significant.

RESULTS

A total of 9344 participants were followed for an average time of 16.0 years (99 719 person-years). During this time, 2465 cases of overweight/obesity were found. Table I represents the age and sex adjusted baseline characteristics of the participants according to MQI groups. The mean score in MQI was 9 (range from 3 to 15), the mean of age was 36.5 years (SD, 11.1) and 64.7 % of participants were women. On average, participants in the highest group of the MQI (range 12 to 15) tended to be single, non-smokers, physically more active, avoided snacks between meals, followed a special diet, used supplementation, and had higher adherence to the MedDiet. On the other hand, participants with lower adherence in the MQI (range 3 to 7) were more likely to be married, current smokers, never consume alcohol, and spent more time sitting.

Table I. Baseline sociodemographic characteristics adjusted for age and sex according to the Macronutrient Quality Index (MQI) groups of participants in the SUN cohort (*n* = 9,344)[1,2]

	G1	G2	G3	G4
n (frequency)	3251	2245	1870	1978
MQI (range)	3-7	8-9	10-11	12-15
MQI (median)	6	9	10	13
Marital status (%)				
Single	45.8	45.1	46.1	48.9
Married	49.3	48.6	48.9	44.6
Widowed	0.9	0.8	1.1	0.7
Others	4.0	5.5	4.0	5.8

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Tabla I (Cont.). Baseline sociodemographic characteristics adjusted for age and sex according to the Macronutrient Quality Index (MQI) groups of participants in the SUN cohort (n = 9,344)[1,2]

	G1	G2	G3	G4
Years at university	5.1 (1.6)	5.1 (1.6)	5.1 (1.5)	5.0 (1.5)
Smoking (%)				
Never	50.6	50.8	52.2	55.9
Current	23.6	23.5	21.6	16.2
Former	25.8	25.8	26.2	27.9
Cumulative smoking habit (packs-year)	5.5 (8.9)	5.2 (8.4)	4.9 (8.3)	4.4 (7.5)
Alcohol intake (g/d)				
Never	20.3	18.1	18.0	19.0
< 5 g/d women/< 10 g/d men	46.0	48.4	47.9	50.8
5-25 g/d women/10-50 g/d men	32.1	32.0	32.3	28.8
> 25 g/d women/> 50 g/d men	1.6	1.6	1.7	1.3
Physical activity (MET s-h/week)	20.7 (22.4)	22.0 (22.5)	24.5 (26.6)	28.7 (28.1)
BMI, baseline (kg/m^2)	22.0 (1.9)	22.1 (1.8)	22.0 (1.9)	21.9 (1.9)
Time spent sitting (h/d)	5.3 (2.1)	5.2 (2.0)	5.2 (2.1)	5.1 (2.0)
Prevalent hypertension (%)	6.3	6.0	6.6	6.7
Prevalent dyslipemia (%)	3.3	3.3	3.6	3.5
Prevalent depression (%)	11.2	10.7	12.0	11.0
Snacking (%)	32.9	31.6	28.8	27.0
Special diet (%)	4.7	5.4	6.7	11.2
Vitamin supplement use (%)	18.0	17.9	21.3	23.6
Adherence MDS (0-9)	3.0 (1.4)	4.0 (1.5)	4.9 (1.5)	5.9 (1.4)
Adherence MEDAS (0-14)	4.9 (1.5)	5.8 (1.5)	6.5 (1.5)	7.7 (1.6)

%: percentage; G: group; BMI: body mass index; MQI: macronutrient quality index. [1]Adjusted by the inverse probability weighting method. [2]Values are expressed as averages ± SD or percentages.

As expected, participants who were in Q4 (best MQI) had a higher consumption of vegetables, fruits, pulse, whole and refined grains, fish, white meat, low-fat dairy products, nuts and olive and a lower consumption of red meats, dairy products and fast-food (Table II). Regarding baseline energy and nutrient intakes, the participants in Q4 (best MQI) reported a higher intake of energy from carbohydrates and had a higher intake of fiber, while participants in Q1 (worst MQI) had a diet with a higher intake of energy from fats, saturated fatty acids, trans fatty acids and cholesterol.

On the other hand, absolute average yearly weight change (g/y) decreased across groups of MQI. Thus, participants with the highest MQI showed a lower weight gain = +336.1 g/y, whereas those with the lowest MQI showed the highest weight change = +514.6 g/y. We found a significant inverse association between the MQI at baseline and weight change in the full multivariable adjusted model. The β coefficient for the fourth group versus the first group was -99.0, 95 % CI: -173.6 to -24.5), p for trend = 0.007 (Table III).

A total of 2,465 cases of incident overweight/obesity were identified, of which 954 were in Q1, 618 in Q2, 462 in Q3, and 431 in Q4. Table IV shows the results of Cox regression analyses carried out to assess the association between MQI and the incidence of overweight and obesity. In general, an inverse association between MQI and the risk of overweight/ obesity was observed in both the crude model and the 3 multivariate models. Point estimates also decreased across the MQI groups. Statistical significance was observed in the Q4 vs Q1 across all models, also showing significant p for trends in both the age- and sex-adjusted model and the 3 adjusted models. Thus, in the more adjusted model, the incidence of overweight/obesity was lower in Q4 with 431 cases (22 %) compared to 954 incident cases (29 %) in Q1. In model 3, the HR and 95 % CI in each category were: 0.99 (0.89-1.10), 0.96 (0.85-1.08) and

Table II. Basal food intake and basal energy and nutrient intake according to the groups of the Macronutrient Quality Index (MQI) (*n* = 9344)

		G1	G2	G3
n (frequency)	3251	2245	1870	1978
MQI (range)	3-7	8-9	10-11	12-15
MQI (median)	6	9	10	13
Food (g/d)				
Vegetables	395.3 (228.4)	505.5 (297.0)	579.5 (363.3)	721.8 (426.1)
Fruits	202.3 (173.9)	273.5 (226.8)	322.5 (251.5)	423.2 (293.5)
Pulse	18.7 (11.1)	22.3 (15.6)	26.1 (23.0)	28.7 (23.9)
Whole grains	3.7 (14.4)	9.3 (26.2)	15.2 (32.7)	31.6 (44.8)
Refined grains	101.0 (72.2)	103.2 (72.3)	105.4 (75.2)	111.7 (72.5)
Fish	73.2 (40.9)	93.0 (50.5)	105.5 (57.0)	123.2 (67.0)
Red meat	95.2 (48.6)	81.0 (44.2)	67.8 (40.5)	49.8 (34.9)
White meat	39.5 (32.1)	47.8 (32.6)	50.6 (41.8)	53.0 (38.5)
Dairy products	286.1 (239.2)	209.9 (190.1)	158.1 (158.9)	111.5 (126.3)
Low- fat dairy products	187.9 (241.4)	213.6 (240.1)	235.7 (238.8)	258.7 (262.3)
Eggs	25.0 (17.2)	24.2 (16.1)	22.7 (13.9)	20.6 (13.4)
Nuts	4.6 (6.3)	6.3 (8.6)	8.5 (11.4)	15.2 (20.1)
Olive oil	14.5 (11.9)	18.4 (15.3)	20.8 (15.4)	24.0 (16.5)
Fast food	25.9 (21.7)	23.0 (20.0)	21.2 (20.5)	16.4 (18.3)
Alcohol	6.2 (8.8)	6.0 (8.7)	5.9 (8.5)	5.5 (8.1)
Energy and nutrients				
Energy (kcal/d)	2360 (611)	2377 (610)	2374 (635)	2370 (603)
Carbohydrates (% E)	42.2 (7.11)	43.6 (6.9)	44.7 (7.2)	46.5 (7.6)
Fiber (g/d)	17.7 (6.4)	21.7 (8.0)	25.0 (9.6)	31.2 (11.1)
Proteins (% E)	18.2 (3.2)	18.1 (3.1)	17.9 (3.5)	17.9 (3.4)
Fats (% E)	37.7 (6.0)	36.5 (6.3)	35.5 (6.7)	33.9 (7.0)
MUFA (% E)	15.9 (3.1)	15.8 (3.7)	15.8 (4.1)	15.5 (4.2)
PFA (% E)	4.9 (1.4)	5.3 (1.5)	5.4 (1.8)	5.3 (1.6)
SFA (% E)	14.6 (3.0)	12.8 (2.4)	11.5 (2.4)	9.6 (2.4)
TFA (% E)	0.5 (0.2)	0.4 (0.2)	0.3 (0.1)	0.2 (0.1)
PFA-n3 (g/d)	2.3 (1.0)	2.5 (1.2)	2.7 (1.3)	2.9 (1.3)
PFA-n6 (g/d)	18.8 (12.5)	18.8 (12.2)	18.0 (12.0)	16.3 (11.2)
Cholesterol (mg/d)	445.0 (198.9)	431.5 (154.3)	401.8 (143.8)	359.4 (137.9)

MQI: macronutrient quality index; %E: percentage of total energy consumed; MUFA: monounsaturated fatty acids; PFA: polyunsaturated fatty acids; SFA: saturated fatty acids; TFA: trans fatty acids; PFA-n3: omega 3 fatty acids; PFA-n6: omega 6 fatty acids.

0.87 (0.77-0.98) for Q2, Q3 and Q4, respectively, compared to Q1, *p* for trend = 0.036.

Spearman's correlation coefficients (r) for the MQI and its components at baseline were calculated. The highest correlation coefficients at baseline were observed between MQI and FQI or CQI, both (r = 0.65), while the lowest correlation was between MQI and HPPQI (r = 0.27).

In order to have a more up-to-date dietary approach, the main analysis was re-analyzed, with repeated measures of diet evaluated with two different methods: updated diet and cumulative diet average (Table V). In both analyses the results are very similar to those obtained when evaluating the diet at baseline. Thus, for model 3 using the updated diet method, the HR and 95 % CI were as follows: 0.96 (0.87-1.06), 0.97 (0.85-1.10) and 0.86 (0.75-0.98) for Q2, Q3 and Q4, respectively, *p* for trend: 0·035. On the other hand, when using the cumulative diet method, these values were 0.99 (0.89-1.10), 0.98 (0.87-1.10) and 0.87 (0.77-0.98) for Q2, Q3 y Q4, respectively, *p* for trend: 0.033. As for the other models, only the highest group presented significance.

Figure 1A, 1B and 1C represent the HRs for the incidence of overweight/obesity according to the combined analysis of MQI and MDS, MEDAS and Provegetarian diet, respectively. For each analysis, participants were categorized into 6 groups according to the MQI and the adherence of each dietary pattern. In all cases, the reference category included the participants with

Table III. Annual weight change (g) in participants without overweight/obesity according to the groups of the MQI· Beta regression coefficients and 95 % confidence intervals (CI)

			G1		G2		G3		*p* for trend
n (frequency)	3251		2245		1870		1978		
Weight change (g/year)	514.6		385.6		408.4		336.1		
	Coef β	**95 % CI**	**Coef β**	**95 % CI**	**Coef β**	**95 % CI**	**Coef β**	**95 % CI**	
Crude model	0 (Ref·)		*-129.1*	*-198.9; -60.2*	*-106.3*	*-179.1; -33.4*	*-178.5*	*-250.1; -107.0*	*< 0.001*
Model 1	0 (Ref·)		*-107.2*	*-176.2; -38.2*	-66.3	-139.7; 7.4	*-117.3*	*-190.1; -43.8*	*0.001*
Model 2	0 (Ref·)		*-108.8*	*-177.4; -40.2*	-58.7	-131.9; 14.5	*-96.7*	*-170.3; -23.1*	*0.008*
Model 3	0 (Ref·)		*-106.5*	*-175.0; -38.1*	-59.5	-132.8; 13.8	*-99.0*	*-173.6; -24.5*	*0.007*

Ref: reference value; MQI: macronutrient quality index; G: groups. Model 1: adjusted for sex, year of recruitment (5 categories) and age deciles (in addition to using age as the underlying time variable). Model 2: was additionally adjusted for BMI (continuous, kg/m²), smoking habit (continuous, packs/year), physical activity (continuous, MET-h/s), hours spent sitting (continuous, h/d), alcohol consumption (never, < 5 g/d women/< 10 g/d men, 5-25 g/d women or 10-50 g/d men, and > 25 g/d women/> 50 g/d men) and marital status (single, married, widowed and other). Model 3 additionally adjusted for total energy, snacking between meals (yes/no), family history of obesity (yes/no), years at university (continuous), fast food consumption (continuous, g/d) and special diet follow-up (yes/no).

Table IV. Incidence of overweight or obesity (BMI ≥ 25 kg/m²) in participants without overweight/obesity at the beginning of the study in relation to the groups of the MQI· Hazard ratios and 95 % confidence intervals

		G1	G2	G3	*p* for trend
Subjects (n)	3251	2245	1870	1978	
Overweight/obesity cases (n)	954	618	462	431	
Person-years	35119	24358	19641	20600	
Overweight/obesity rate/1000 persons years	2.7	2.5	2.4	2.1	
Age-and sex-adjusted	1.00 (Ref)	0.97 (0·87-1·07)	0.92 (0.83-1.04)	*0.83 (0.74-0.93)†*	*0.002*
Model 1	1.00 (Ref)	0.97 (0·87-1·07)	0.92 (0.82-1.03)	*0.82 (0.73-0.93)‡*	*0.001*
Model 2	1.00 (Ref)	0.99 (0·89-1·10)	0.96 (0.86-1.08)	*0.88 (0.78-0.99)**	*0.048*
Model 3	1.00 (Ref)	0.99 (0·89-1·10)	0.96 (0.85-1.08)	*0.87 (0.77-0.98)†*	*0.036*

*Model 1: adjusted for sex, year of recruitment (5 categories) and age deciles (in addition to using age as the underlying time variable). Model 2: was additionally adjusted for BMI (continuous, kg/m²), smoking habit (continuous, packs/year), physical activity (continuous, MET-h/s), hours spent sitting (continuous, h/d), alcohol consumption (never, < 5 g/d women/< 10 g/d men, 5-25 g/d women or 10-50 g/d men, and > 25 g/d women/> 50 g/d men) and marital status (single, married, widowed and other). Model 3 additionally adjusted for total energy, snacking between meals (yes/no), family history of obesity (yes/no), years of university (continuous), fast food consumption (continuous, g/d) and special diet follow-up (yes/no). *p < 0.01. †p < 0.05. ‡p < 0.001.*

the worst MQI and the worst adherence of each dietary pattern (Mediterranean or Provegetarian). The figures show that the lowest risk of developing overweight/obesity was observed in those participants with better MQI (T3) and greater adherence to the Mediterranean or Provegetarian patterns. Thus, for the analysis with MDS, MEDAS or Provegetarian diet, the subjects with the best score in both dietary patterns had a 12 %, 19 % and 15 % lower risk respectively, compared to those with the worst score in both scores. The HR (95 % CI) for participants with higher adherence to the MedDiet measured by MDS or MEDAs (≥ median) and higher MQI (T3) were, respectively 0.88 (0.78-0.99) and 0.81 (0.72-0.92). Similarly, participants with higher adherence to the Provegetarian (≥ median) and higher MQI (T3) had a HR (95 % CI) of 0.85 (0.75-0.97).

Multiple sensitivity analyses were performed to check the robustness of the main findings (Table VI). In general, an inverse association between MQI and the incidence of overweight/ obesity was observed in the different scenarios that were considered, except when excluding participant with 30 or more missing values in the FFQ.

Table V. Analysis of repeated measures after 10 years of follow-up· Hazard ratios and 95 % confidence intervals for the association between MQI and the incidence of overweight/obesity in the SUN cohort

Updated diet		**G1**	**G2**	**G3**	***p* for trend**
Incidence of overweight/obesity	682	907	452	424	
Person/ years	25589	35211	18661	20258	
Age-and sex-adjusted	1.00 (Ref)	0.97 (0.87-1.07)	0.92 (0.83-1.04)	*0.83 (0.74-0.93)**	*0.016*
Model 1	1.00 (Ref)	0.98 (0.89-1.09)	0.95 (0.84-1.08)	*0.84 (0.74-0.95)**	*0.007*
Model 2	1.00 (Ref)	0.96 (0.87-1.07)	0.97 (0.86-1.10)	*0.87 (0.76-0.99)**	*0.043*
Model 3	1.00 (Ref)	0.96 (0.87-1.06)	0.97 (0.85-1.10)	*0.86 (0.75-0.98)**	*0.035*
Cumulative diet average		**G1**	**G2**	**G3**	***p* for trend**
Incidence of overweight/obesity	953	624	469	419	
Age-and sex-adjusted	35477	24576	19431	20234	
Crude model	1.00 (Ref·)	0.93 (0.84-1.03)	0.88 (0.78-0.98)	*0.74 (0.66-0.84)**	*< 0.000*
Model 1	1.00 (Ref·)	0.99 (0.89-1.09)	0.96 (0.86-1.07)	*0.83 (0.73-0.93)**	*0.003*
Model 2	1.00 (Ref·)	1.00 (0.90-1.10)	0.98 (0.87-1.10)	*0.87 (0.77-0.99)**	*0.042*
Model 3	1.00 (Ref·)	0.99 (0.89-1.10)	0.98 (0.87-1.10)	*0.87 (0.77-0.98)**	*0.033*

*Ref: reference value; MQI: macronutrient quality index; G: group. Model 1: adjusted for sex, year of recruitment (5 categories) and age deciles. Model 2: was additionally adjusted for BMI (continuous, kg/m²), smoking habit (continuous, packs/year), physical activity (continuous, MET-h/s), hours spent sitting (continuous, h/d), alcohol consumption (never, < 5 g/d women/< 10 g/d men, 5-25 g/d women or 10-50 g/d men, and > 25 g/d women/> 50 g/d men) and marital status (single, married, widowed and other). Model 3 additionally adjusted for total energy, snacking between meals (yes/no), family history of obesity (yes/no), years of university (continuous), fast food consumption (continuous, g/d) and special diet follow-up (yes/no). *p < 0.05.*

Table VI. Hazard ratio and confidence intervals at 95 % or the association between the Macronutrient Quality Index and the incidence of overweight and obesity of the SUN cohort. Group 4 *vs* group 1

	n	**Events**	**G4 *vs* G1**	***p* for trend**
Main analyses	9344	2465	*0.87 (0.77-0.98)**	*0.036*
Sensitivity analyses				
Exclusion participants with energy intake < 5th percentile and > 95th percentile	9311	2412	*0.87 (0.77-0.98)**	*0.046*
Exclusion participants with energy intake < 1th percentile and > 99th percentile	10144	2622	*0.87 (0.77-0.98)**	*0.014*
Additional adjustment for weight gain ≥ 3 kg in the 5 y before to entering the cohort	9344	2465	*0.87 (0.77-0.98)**	*0.036*
Excluding participant with 30 or more missing values in FFQ	8991	2373	0.88 (0.78-1.00)	0.058
Excluding participants with special diet at baseline	8729	2243	*0.83 (0.73-0.95)**	*0.008*

Adjusted for sex, year of recruitment (5 categories), age deciles, BMI (continuous, kg/m²), smoking habit (continuous, packs/year), physical activity (continuous, MET-h/s), hours spent sitting (continuous, h/d), alcohol consumption (never, < 5 g/d women/< 10 g/d men, 5-25 g/d women or 10-50 g/d men, and > 25 g/d women/> 50 g/d men) and marital status (single, married, widowed and other), total energy, snacking between meals (yes/no), family history of obesity (yes/no), years of university (continuous), fast food consumption (continuous, g/d) and special diet follow-up (yes/no).

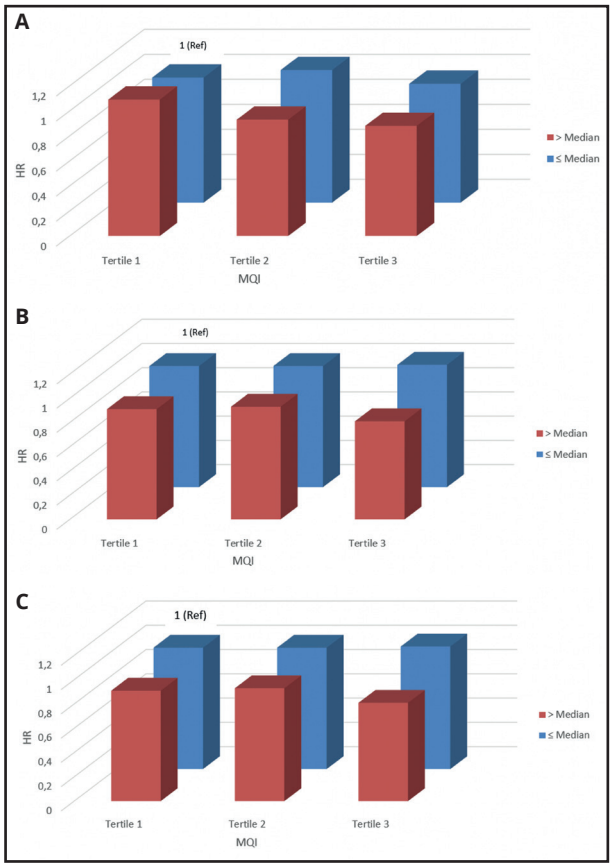

Figure 1.

A. Combined analysis between Adherence to Mediterranean Diet Score and MQI, and the incidence of overweight/obesity among participants in the SUN cohort. B. Combined analysis between adherence to MEDAS and MQI and incidence of overweight/obesity in participants in the SUN cohort. C. Combined analysis between adherence to the Provegetarian Diet Score and MQI and the incidence of overweight/obesity in participants in the SUN cohort (Ref: reference value; MQI: macronutrient quality index; T: tertile. Model stratified by year of recruitment [five categories] and age deciles, and adjusted for sex, BMI [continuous, kg/m^2], smoking habit [straight, packs/year], physical activity [continuous, MET-h/s], hours spent sitting [continuous, h/d], alcohol consumption [never, < 5 g/d women/< 10 g/d men, 5-25 g/d women or 10-50 g/d men, and > 25 g/d women/> 50 g/d men], marital status [single, married, widowed and other], total energy, snacking between meals [yes/no], family history of obesity [yes/no], years of university [continuous], fast food consumption [continuous, g/d], and exceptional diet follow-up [yes/no]).

DISCUSSION

To the best of our knowledge, no previous study has assessed the association between the overall quality of macronutrients, as measured by the MQI, and the incidence of overweight/obesity in a large Mediterranean population. The most important finding was the significant decrease in the risk of overweight/obesity among participants with the best MQI.

Participants in the highest MQI had a higher consumption of vegetables, fruits, legumes, whole grains, fish, white meats, skimmed dairy products, nuts and olive oil, and lower of red and processed meat, fast-food and alcohol. These food groups provide vitamins, minerals, protein, fiber, healthy fats, low calories, and low GI that help prevent overweight and obesity (4,32).

Participants with the best MQI were more likely to meet fiber, SFA, TFA and cholesterol recommendations. In absolute terms, the TEI and percentage of each macronutrient was quite similar across groups, suggesting that the quality is more important than the quantity when assessing the risk of obesity in adults.

Most studies have used individual components or dietary carbohydrates, mainly a load of GI, dietary fiber, or whole grains, instead of a clearly defined multidimensional index to evaluate its effects on the risk of overweight and obesity. In fact, the International Carbohydrate Quality Consortium summarize and disseminate the science around dietary carbohydrate and health with a focus on carbohydrate quality, especially on dietary fiber, GI and whole grains (33). On the other hand, a high consumption of carbohydrates with starch and sugar content is associated with a higher incidence of overweight and obesity and mortality risk. However, there are several previous studies that have used the CQI as a tool to determine dietary carbohydrate quality, and have evaluated its association with several obesity indicators and its role on body fat deposition in different studies. Thus, better overall carbohydrate quality, as assessed by the CQI, has been associated with a lower risk of overweight/obesity (19), favorable changes in visceral and overall adiposity distribution as well as overall and abdominal obesity (18,34).

On the other hand, the ideal proportion of energy derived from fat in the diet and its relation to body weight is not clear (35). The participants with the best MQI had a lower percentage of total dietary fats, MUFA, SFA, TFA and cholesterol, but a higher PUFA percentage from a higher consumption of fish and nuts. Nonetheless, in all four groups the mean TEI from fats was near or even higher than the AMDR (20-35 % TEI), range associated with a reduced risk of inadequate nutrient intakes (5).

Studies on the influence of dietary fat subtypes on obesity began several years ago (36). A systematic literature review in 2012 suggested that the proportion of macronutrients in the diet was not important in predicting changes in weight or waist circumference (37); meanwhile, more recently, the PREDIMED trial concluded that increasing the intake of unsaturated fatty acids at the expense of SFA, proteins, and carbohydrates had beneficial effects on body weight and obesity. This study also recommended high-quality fat diets like the MedDiet, instead of restricting total fat intake (38).

It is reasonable to promote the replacement of SFA with MUFA and PUFA and avoidance of consumption of industrial TFA, to reduce the risk of chronic disease (39). In fact, a scoping review concluded that although most dietary guidelines recommended total fat intakes of 30-35 % of TEI, the replacement of SFA with PUFA and MUFA, and avoidance of industrial TFA, was recommended. Moreover, it was suggested that future guidelines should give recommendations on dietary fat intake and fat quality (40).

In our study, the percentage of energy from sources of protein was very similar across the four categories of MQI, in spite of the

differences in consumption. Thus, participants with the higher MQI consumed more fish, white meat and low-fat dairy products, but less red and processed meat and eggs. These results suggest than the quality could be more important than the quantity of macronutrients to prevent weight gain.

High-protein intake is commonly recommended to help people manage body weight, weight loss or muscle gain (41). However, the relationship between protein intake and cardiometabolic health is complex and influenced by concomitant changes in body weight and overall diet composition. A high-protein, low-carbohydrate and reduced-energy diet has been associated with increased cardiometabolic disease risk, presumably mediated by the changes in the hormonal milieu after high-protein intake (41). Thus, in 2020 a research concluded that as far as the health effects of different diets are concerned, the macronutrient composition, the GI, the sources of nutrients (e.g. plant or animal), the food matrix, and other dietary variables could be important (42).

In addition to analyzing the effect of macronutrients, it is crucial to consider the dietary pattern, as opposed to individual nutrients.

We also found that a higher MQI and adherence to MedDiet was associated with a lower risk of overweight/obesity. In line with this finding, the MedDiet, one of the most studied and well-known high-quality dietary patterns worldwide, has been associated with a wide range of benefits for health. A recent narrative review confirmed that there is strong evidence for its benefits on cardiovascular health, including a reduction in the incidence of cardiovascular outcomes as well as risk factors. In fact, suggestive evidence with moderate effects have shown that the MedDiet is not associated with obesity and does not increase weight gain. Moreover, benefits on weight loss are stronger with energy-restricted MedDiet interventions (43).

Among 6 prospective cohort studies, higher adherence to the MedDiet was associated with a lower risk of overweight and/or obesity. The MedDiet was significantly associated with less weight gain during 5 years of follow-up among 4 cohort studies (44).

On the other hand, the Provegetarian diet has been associated with a lower risk of becoming overweight/obese (45). This association is most likely attributable to a high intake of fruits and vegetables, very low intake of processed meat, with low energy density, but rich in micronutrients and phytochemicals.

Some limitations should be considered. First, the participants are university graduates so our sample may not represent the general Spanish population. However, the generalization of the findings must be based on biological mechanisms and both the level of education and the homogeneity add validity to the results and reduce the likelihood of misclassification bias while increasing internal validity. Second, the FFQ was self-reported and may have a certain degree of measurement bias, but is considered the gold standard in large cohorts and our FFQ has been validated previously (22,23). Third, the MQI was derived from the FFQ and it has not been validated, but it has already been used in previously published studies to evaluate its association with CVD incidence (46), and its three sub-indexes have also been used in previous investigations. Fourth, even though the analyses were adjusted for potential confounders, a certain degree of residual confounding could remain. However, we adjusted for well-known risk-factors of weight gain. Fifth, self-reported outcomes were used, but have been previously validated in this SUN cohort. Finally, a causal association cannot be properly established because of the observational study design.

The strengths of our study include the large sample size, the high retention rate, its prospective design, the large follow-up period and adjustments for many potential confounding factors, a sufficient number of overweight/obesity cases, the use of previously validated questionnaires, the use of repeated measures, and sensitivity analyses.

In this Mediterranean cohort, we found a significant inverse relationship between a higher macronutrient quality, as measured by the MQI, and incidence of overweight/obesity. Furthermore, participants who had greater adherence to the MedDiet and Provegetarian patterns, and presented the highest MQI had a lower incidence of being overweight and obese.

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ARÁN

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Trabajo Original

Otros

Can mindful eating be a psycho-marker of obesity in bipolar disorder?

¿Puede ser la alimentación consciente un psicomarcador de obesidad en el trastorno bipolar?

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Abstract

Background and aim: obesity is a very important problem in individuals with bipolar disorder. The study was aimed to determine the prevalence of obesity in individuals with bipolar disorder and to evaluate the effects of factors affecting eating behavior such as mindful eating, impulsivity and eating disorders on the development of obesity in these individuals.

Methods: this study is a cross-sectional study. A total of 109 individuals (52 female; 57 male) with bipolar disorder who were in a euthymic state at the time of the interview and underwent outpatient follow-up, treatment and monitorization, and 109 age- and sex-matched healthy individuals as the control group were included in the study. The Mindful Eating Questionnaire-30 (MEQ-30), Three-Factor Eating Questionnaire (TFEQ-21), Barratt Impulsiveness Scale 11-Short Form (BIS-11-SF), and Eating Attitude Test-26 (EAT-26) were used, and anthropometric measurements (height, bodyweight, etc.) were taken.

Results: the obesity rate was 50.4 % among the cases and 24.8 % in the control group. Moreover, disinhibition (3.4 ± 0.93), emotional eating (3.5 ± 1.13), and mindfulness (2.6 ± 0.54) scores of individuals with BD were significantly lower than for healthy individuals (3.7 ± 0.82, 4.0 ± 0.93, 2.8 ± 0.55, respectively). The risk of obesity was 5.19 times higher in cases compared to the age- and gender-matched controls (OR = 5.19, 95 % CI (2.01-13.37), $p = 0.001$). The risk of obesity was 2.76 times higher in those with low mindful eating level (OR = 2.76, 95 % CI (1.07-5.47), $p = 0.014$) and 4.29 times higher in those using antipsyhotics/mood stabilizers (OR = 4.29, 95 % CI (1.12-12.24), $p < 0.001$).

Conclusion: a comprehensive education program on mindful eating and healthy eating would be helpful in elucidating the mechanisms of the possible relationships between bipolar disorder-specific risk factors and mindful eating.

Keywords:

Mindful eating. Bipolar disorders. Obesity. Eating disorders. Impulsivity.

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Registration of clinical trials: the present study was conducted in accordance with the Helsinki Declaration. It was approved by an independent review board of the Ege University (Medical Ethics Committee decision no: 22-1.1T/40 date: 14.01.2022). Verbal and written consent was obtained from all the participants.

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Resumen

Antecedentes y objetivos: la obesidad es un problema muy importante en los individuos con trastorno bipolar. El objetivo era determinar la prevalencia de la obesidad en individuos con trastorno bipolar y evaluar los efectos de los factores que afectan a la conducta alimentaria, como la alimentación consciente, la impulsividad y el trastorno alimentario, en el desarrollo de la obesidad de estos individuos.

Métodos: se trata de un estudio transversal. Un total de 109 individuos (52 mujeres; 57 hombres) con trastorno bipolar que se encontraban en estado eutímico en el momento de la entrevista y se sometieron a seguimiento, tratamiento y monitorización ambulatorios, y 109 individuos sanos emparejados por edad y sexo como grupo de control, fueron incluidos en el estudio. Se utilizaron el Mindful Eating Questionnaire-30 (MEQ-30), el Three-Factor Eating Questionnaire (TFEQ-21), la Barratt Impulsiveness Scale 11-Short Form (BIS-11-SF) y el Eating Attitude Test-26 (EAT-26), y se tomaron medidas antropométricas (altura, peso corporal, etc.).

Resultados: la tasa de obesidad fue del 50,4 % en los casos y del 24,8 % en el grupo de control. Además, las puntuaciones de desinhibición (3,4 ± 0,93), alimentación emocional (3,5 ± 1,13) y atención plena (2,6 ± 0,54) de los individuos con BD fueron significativamente inferiores a las de los individuos sanos (3,7 ± 0,82, 4,0 ± 0,93, 2,8 ± 0,55, respectivamente). El riesgo de obesidad era 5,19 veces mayor en los casos en comparación con los controles emparejados por edad y sexo (OR = 5,19, IC 95 % (2,01-13,37), $p = 0,001$). El riesgo de obesidad fue 2,76 veces mayor en los que tenían un bajo nivel de alimentación consciente (OR = 2,76; IC 95 % (1,07-5,47), $p = 0,014$) y 4,29 veces mayor en los que utilizaban antipsicóticos/estabilizadores del ánimo (OR = 4,29; IC 95 % (1,12-12,24), $p < 0,001$).

Conclusiones: un programa educativo integral sobre *mindful eating* y alimentación saludable sería útil para dilucidar los mecanismos de las posibles relaciones entre los factores de riesgo específicos del trastorno bipolar y la comida consciente.

Palabras clave:

Alimentación consciente. Trastornos bipolares. Obesidad. Trastornos alimentarios. Impulsividad.

INTRODUCTION

Bipolar disorder (BD) is a recurrent, long-course disorder that typically begins at a young age with depressive episodes, manic/hypomanic episodes, and mixed mood periods with symptoms of both extremes and with full recovery or subthreshold symptoms between these mood periods, affecting the social and occupational functioning of the person. Genetic, epigenetic, and environmental factors play a role in its etiology (1).

Compared with the general population, individuals with BD have an increased morbidity and mortality rate. This results in a shorter life expectancy of 9-20 years among individuals with BD. Research suggests that the basis for this is an increased risk of metabolic diseases such as autoimmune diseases, overweight and obesity-related diabetes, and cardiovascular diseases, which are associated with more frequent medical comorbidities in individuals with BD (2,3).

Studies report that more than half of individuals with bipolar disorder are overweight or obese. Platzer et al. found that 44.6 % of male individuals with BD were overweight and 31.1 % were obese, while these rates were 21.5 % and 30.7 %, respectively, for female individuals with BD (4). It has been reported that individuals with BD are 1.77 times more likely to be obese than healthy individuals (5). Etiogenic factors of obesity in individuals with BD include potential weight gaining effects of psychotropic drugs (atypical antipsychotics, mood stabilizers), disorders in the neuro-endocrine system and neurotransmitter dysfunction, atypical depression symptoms, poor lifestyle (poor diet quality, sedentary lifestyle), and genetic predisposition for weight gain (4-6).

Obesity in individuals with BD leads to significant health problems. Therefore, it is of great importance to understand the factors underlying eating behaviors that lead to the development of obesity in these individuals. In this study, it was aimed to determine the prevalence of obesity in individuals with bipolar disorder and to evaluate the effects of factors affecting eating behavior such as mindful eating, impulsivity and eating disorder on the development of obesity in these individuals.

METHODS

PARTICIPANTS

The study was designed as a case-control study. A total of 109 outpatients diagnosed with bipolar disorder, 52 females and 57 males, as well as 109 age- and sex-matched healthy individuals as the control group were included in the study. The study was conducted between May-December 2022 in euthymic individuals diagnosed with bipolar disorder by a psychiatrist according to DSM-5 diagnostic criteria, who were followed up, treated, and monitored on an outpatient basis at Manisa Mental Health and Diseases Hospital. Patients between the ages of 18-60, literate, able to communicate verbally in the scales administered, euthymic for the last six months, without metabolic syndrome, and who agreed to participate in the study after being informed were included in the study. Patients with impaired cooperation and cognitive functions due to mental retardation, neurological disease, alcohol, and substance abuse or being under the influence of alcohol or substance at the time of recruitment, and those with schizophrenia or schizoaffective disorder, organicity-related affective disorder, and those who did not have sufficient command of the Turkish language to answer the questions were excluded from the study. As a control group, age- and gender-matched individuals without neuropsychiatric disorders and alcohol and substance abuse, without prenatal and/or postnatal period, who were Turkish citizens and who was born and bred within their families and and Turkish culture for at least 3 generations were included. The present study was conducted in accordance with the Helsinki Declaration. It was approved by an independent review board of the Ege University (Medical Ethics Committee decision no: 22-1.1T/40 date: 14.01.2022). Verbal and written consent was obtained from all the participants.

MEASURES

Anthropometry and BMI

Height was measured, without shoes, feet together, knees straight, heels, hips, and shoulder blades in contact with the ver-

tical surface in the Frankfort position with a stadiometer (Seca mod. 240 CE 0123, Germany), whereas body weight and body composition (% body fat, fat-free mas) was measured with light clothing, without shoes with Accuniq BC310 bioelectric impedance device (SELVAS Healthcare Inc., Daejeon, Korea). Weight and height were used to calculate body mass index (BMI) as weight in kilograms divided by height in meters squared. Weight status was classified according to WHO categories as follows: underweight (BMI < 18.5), normal weight (BMI between 18.5 and 24.9), overweight (BMI between 25 and 29.9), and obesity (BMI ≥ 30).

Mindful Eating Questionnaire (MEQ-30)

The Mindful Eating Questionnaire was developed by Framson et al. in 2009 to assess the level of mindful eating in individuals (7). A Turkish validity and reliability study of the scale was conducted in 2016 by Köse et al. (8). Unlike the original, the Turkish version of the scale consists of 30 items and seven subscales. The high score obtained from each sub-dimension of the scale indicates that the individual has the characteristic assessed by the relevant sub-dimension. Each item was scored between 1 and 5, and the overall total score is obtained from the average of the scores of 7 subscales, and higher scores indicate more mindful eating.

Three-Factor Eating Questionnaire (TFEQ-21)

This scale was first developed by Stunkard and Messick in 1985 to measure behavioral and cognitive components of eating (9). A Turkish validity and reliability study of the questionnaire was conducted by Karakuş et al. (10). Higher scores indicate greater cognitive restraint, binge eating, or emotional eating.

Eating Attitude Test (EAT-26)

It was developed by Garner et al. (1982) to measure the symptoms of anorexia nervosa (11). It was adapted into Turkish by Okumuş and Sertel (2020), and used as a measurement tool in their study and used as a measurement tool in their study (12). In the EAT-26 test, the results are determined by assessing the sum of the scores of the 26 items. The test results in values ranging from 0-53. For EAT-26, 20 points is considered as the cut-off point. Values of ≥ 20 are considered "at risk of eating behavior disorder" and values of < 20 points are considered "without risk of eating behavior disorder".

Barratt Impulsiveness Scale-11-Short Form (BIS-11-SF)

This scale developed by Patton, Standford, and Barratt (1995), and was adapted into Turkish by Tamam, Güleç and Karataş (13,14). When assessing the BIS-11-SF, four different sub-scores are obtained. These are total score, inability to plan, attentional impulsivity, and motor impulsivity scores. The higher the total BIS-11-SF score, the higher the impulsivity level of the patient.

STATISTICS

Data were analyzed with SPSS 26.0 (Statistical Package for Social Sciences IBM-SPSS Inc., Armonk, NY). The conformity of the variables to normal distribution was analyzed using Shapiro-Wilk test. For categorical variables, descriptive statistics were expressed as numbers and percentages, and for continuous variables, mean and standard deviation were used. Differences between groups were evaluated using Student's t-test or Chi-square analysis. Pearson Correlation analysis was used to analyze the relationship between the subjects' BMI with other parameters. Multinominal logistic regression analysis was used to identify risk factors associated with obesity. The results were considered significant at $p < 0.05$.

RESULTS

PARTICIPANTS

A total of 109 outpatients diagnosed with bipolar disorder, 52 females and 57 males, as well as 109 age- and sex-matched healthy individuals (52 F/57 M) as the control group were included in the study. The mean age of the groups was 40.6 ± 10.19 years. The BMI of the patients was 30.4 ± 6.80 kg/m^2 and 26.9 ± 4.92 kg/m^2 in the control group ($p < 0.001$). According to the BMI classification, 50.4 % of the patients were in the obese group, 27.5 % were in the overweight group, and only 19.3 % were in the normal weight group. In the control group, 24.8 % of the individuals were obese and 42.2 % were overweight ($p < 0.001$). Table I presents the sociodemographic characteristics of the participants.

MEASUREMENTS

The results of the questionnaires administered to the participants are presented in table II. When mindful eating was analyzed, the MEQ-30 score of the patients was 3.3 ± 0.52, while the score of the control group was 3.5 ± 0.43 ($p = 0.005$). In MEQ-30 subscale scores, disinhibition, emotional eating and mindfulness scores of the patients were significantly lower than the control group. Similar to Chung et al., an arbitrary cut-off point on the level of mindful eating was made using the mean score to facilitate the interpretation of the study results (15). Therefore, any scores above 3.50 were considered to be a high level of mindful eating. It was determined that 56.9 % ($n = 62$) of the cases and 42.2 % ($n = 46$) of the control group had low mindful eating level ($p = 0.030$). The TFEQ-21 score of the patients (50.4 ± 9.69) was significantly higher than that of the control group (42.6 ± 10.19) ($p < 0.001$). Similarly, it was determined that the BIS-11-SF score and the scores of all subscales were higher in the patients.

Table I. Sociodemographic characteristics of the participants

	Case (*n* = 109)	Control (*n* = 109)	*p*
*Age (years) ($\tilde{x}$ ± SD)	40.6 ± 10.19	40.6 ± 10.19	1.000
Gender, n (%)			
Female	52 (47.7)	52 (47.7)	1.000
Male	57 (52.3)	57 (52.3)	
Marital status, n (%)			
Single	70 (64.2)	27 (24.8)	< 0.001
Married	39 (35.8)	82 (75.2)	
Education, n (%)			
Illiterate	4 (3.7)	-	0.070
Primary	56 (51.3)	44 (40.4)	
High school	33 (30.3)	42 (38.5)	
Bachelor degree	16 (14.7)	23 (21.1)	
Employment, n (%)			
Worker	51 (46.8)	104 (95.4)	*< 0.001*
Unemployed	58 (53.2)	5 (4.6)	
Smoking, n (%)			
Yes	72 (66.1)	54 (49.5)	*0.010*
No	37 (33.9)	55 (50.5)	
†Number of daily cigarettes ($\tilde{x}$ ± SD)	25.5±18.4	15.1±8.23	*< 0.001*
Body weight satisfaction, n (%)			
Satisfied	36 (33.0)	52 (47.7)	*0.021*
Indecisive	25 (22.9)	28 (25.7)	
Dissatisfied	48 (44.0)	29 (26.6)	
*Anthropometric measurements**			
Height (m)	1.68 ± 0.11	1.69 ± 0.98	0.542
Body weight (kg)	85.8 ± 18.97	77.1 ± 16.13	*< 0.001*
Body fat percentage (%)	28.1 ± 14.02	26.1 ± 9.81	0.462
Body fat mass (kg)	26.0 ± 16.11	21.2 ± 9.99	*0.009*
BMI (kg/m^2)	30.4 ± 6.80	26.9 ± 4.92	*< 0.001*
Class of BMI, n (%)			
Underweight	3 (2.8)	2 (1.8)	*0.001*
Normal	21 (19.3)	34 (31.2)	
Overweight	30 (27.5)	46 (42.2)	
Obesity	55 (50.4)	27 (24.8)	

**Student's t-test, p < 0.01; Chi-square test, p < 0.01. Italics fonts indicate significant differences.*

Table III shows the relationships between the subjects' BMI and some parameters. A weak negative correlation was found between BMI and MEQ-30 score (r = -0.233, p = 0.001). There was a weak positive correlation between BMI and TFE21 score and EAT-26 score (r = 0.373, $p \leq 0.001$; p = 0.182, r = 0.007, respectively). While there was a negative weak correlation between MEQ-30 and BIS-11-SF, there was a negative moderate correlation between MEQ-30 score and TFEQ-30 score.

The analysis of group differences in obesity markers showed a higher rate of obesity in cases compared to the control group (OR = 3.06, CI = 1.53-6.10, p = 0.002). After adjusting the data, it was determined that subjects had a higher risk for obesity compared to the control group (OR = 5.19, CI = 2.01-13.37, p = 0.001), those with low mindful eating (OR = 2.76, CI = 1.07-5.47, p = 0.014), and those receiving antipsychotic or mood stabilizing medication (OR = 4.29, CI = 1.12-12.24, $p \leq 0.001$). Multinomial logistic regression analysis results are presented in table IV.

Table II. Assessment of participants' scale results

	Case (*n* = 109) ($\bar{X}$ ± SD)	Control (*n* = 109) ($\bar{X}$ ± SD)	*p*
Mindful Eating Questionnaire-30	3.3 ± 0.52	3.5 ± 0.43	*0.005*
Disinhibition	3.4 ± 0.93	3.7 ± 0.82	*0.011*
Emotional eating	3.5 ± 1.13	4.0 ± 0.93	*0.001*
Eating control	3.8 ± 0.96	4.0 ± 0.83	0.194
Focus	3.4 ± 0.57	3.4 ± 0.44	0.979
Eating discipline	3.3 ± 0.81	3.2 ± 0.8*3*	0.484
Mindfulness	2.6 ± 0.54	2.8 ± 0.55	*0.012*
Interference	3.4 ± 1.06	3.7 ± 0.91	0.125
Three Factor Questionnaire-21	50.4 ± 9.69	42.6 ± 10.19	*< 0.001*
Uncontrolled eating	21.9 ± 5.46	17.9 ± 5.89	*< 0.001*
Cognitive restraint	15.6 ± 3.83	15.1 ± 3.89	0.310
Emotional eating	12.9 ± 4.3	9.6 ± 3.72	*< 0.001*
Barratt Impulsiveness Scale-11-SF	25.2 ± 7.77	21.4 ± 6.51	*< 0.001*
Non-planning	10.3 ± 5.17	8.9 ± 3.95	*0.043*
Motor impulsivity	8.1 ± 3.9	6.4 ± 2.65	*< 0.001*
Attention impulsivity	6.9 ± 3.24	6.0 ± 2.68	*0.041*
Eating Attitude Test-26	14.7 ± 9.73	8.8 ± 6.25	*< 0.001*
	n (%)	***n (%)***	
*Eating disorder risk**			*< 0.001*
≥ 20	27 (24.8)	9 (8.3)	
< 20	82 (75.2)	100 (91.7)	

*Student's t-test; *Chi-square test. Italics fonts indicate significant differences.*

Table III. Assessment of the relationship between BMI and other parameters

	BMI		MEQ-30		BIS-11-KF		TFEQ-21		EAT-26	
	r	***p***	**r**	***p***	**r**	***p***	**r**	***p***	**r**	***p***
BMI	1	-	*-0.233*	*0.001*	0.129	0.058	*0.373*	*< 0.001*	*0.182*	*0.007*
MEQ-30			1	-	*-0.384*	*< 0.001*	*-0.580*	*< 0.001*	0.030	0.655
Barratt-11-SF					1	-	*0.257*	*< 0.001*	0.060	0.379
TFEQ-21							1	-	*0.265*	*< 0.001*
EAT-26									*1*	-

Pearson correlation analysis. Italics fonts indicate significant differences.

DISCUSSION

This study aimed to investigate the level of mindful eating and the factors impacting mindful eating in individuals with BD. In this study, it was revealed that the level of ME (mindful eating) in individuals with BD was lower than in healthy individuals, and they had problems, especially in disinhibition, emotional eating, and mindfulness behaviors. It was found that binge eating, lack of planning, motor impulsivity, and attention impulsivity scores were higher in individuals with BD than in healthy individuals.

Table IV. Result of the multinomial logistic regression for BMI

	Overweight		Obesity	
Variables	**OR (95 % CI)**	***p***	**OR (95 % CI)**	***p***
Crude model				
Group (Ref: Control)				
Case	0.98 (0.49-1.95)	0.978	3.06 (1.53-6.10)	*0.002*
Adjusted model				
Group (Ref: Control)				
Case	1.55 (0.63-3.82)	0.346	5.19 (2.01-13.37)	*0.001*
Gender (Ref: Female)				
Male	1.43 (0.67-3.09)	0.351	1.07 (0.48-2.38)	0.864
Age	1.05 (1.02-1.09)	0.005	1.06 (1.02-1.11)	*0.002*
Education (Ref: Bachelor's degree)				
Primary	0. 84 (0.29-2.39)	0.737	1.43 (0.48-4.28)	0.530
High school	0.74 (0.27-2.06)	0.569	0.68 (0.22-2.08)	0.679
Marital status (Ref: Single)				
Married	2.50 (1.09-5.75)	0.031	2.55 (1.07-5.47)	*0.036*
Smoking (Ref: Yes)				
No	1.06 (0.49-2.31)	0.879	2.42 (1.07-5.47)	*0.034*
Mindful eating (Ref: High)				
Low	1.43 (0.66-3.11)	0.364	2.76 (1.22-6.23)	*0.014*
BIS-11-SF Score	0.99 (0.94-1.04)	0.601	0.99 (0.94-1.04)	0.674
Antipsyhotic/Mood stabilizing medications (Ref: No)				
Yes	1.44 (0.61-3.41)	0.409	4.29 (1.12-12.24)	*< 0.001*
EAT-26 Score	0.99 (0.94-1.04)	0.615	0.99 (0.95-1.05)	0.950

Reference: Underweight/Normal; BIS-11-SF: Barratt Impulsiveness Scale-11-Short Form; EAT-26: Eating Attitudes Test-26. Italics fonts indicate significant differences.

Besides, it was found that the risk of eating behavior disorder was higher in individuals with BD and 50.4 % of these individuals were obese.

Increased obesity rates in individuals with BD is one of the most important problems. In studies, it was found that the risk of obesity was 1.62-1.77 times higher in individuals with BD and the obesity rate ranged between 29 % and 45 %, with abdominal obesity reaching 51.1 % (6,16). Gurpegei et al. found that the risk of obesity was 4.6 times higher in these patients compared to the control group (17). Increased obesity predisposes individuals with BD to insulin resistance, type II diabetes and cardiovascular diseases (16). It is also known that obesity is associated with an increase in the duration of depressive episodes and hospitalization due to depression, worsening of the course of the disease, inability to feel and increased risk of suicide (18). Therefore, combating obesity in individuals with BD is of great importance.

Recently, the determination that mindful eating level is low in individuals with eating disorders and obese people has led to an increased interest in this issue. Studies in different groups have shown that a high level of mindful eating is associated with high diet quality, healthy body mass index (BMI) and waist circumference, and reduced depressive symptoms, risk of food addiction, and binge eating behavior (19-21). In this study, it was determined that individuals with BD had lower levels of mindful eating than healthy individuals. This may exacerbate health risks in individuals with BD and/or add new problems to these risks.

Studies have found that higher ME scores are associated with improved mental well-being and reduced symptoms of depression (21,22). Hence, it may be beneficial to conduct intervention studies to increase mindful eating in individuals with BD. Gidugu and Jacobs reported that restrictive eating behavior, emotional

eating, binge eating, and disinhibition decreased significantly and mindfulness increased significantly in individuals as a result of mindful eating and nutrition education applied for 14 weeks to a group with SMI, including individuals with BD (23).

It has been suggested that individuals with high levels of mindful eating have healthy eating behaviors and healthy eating habits (24). Studies have documented that BMI level increases as the mindful eating level decreases and obese individuals have lower mindful eating levels than normal or lean individuals (32). Considering the level of mindful eating in addition to medication use, poor dietary habits, sedentary lifestyle, and other comorbidities, which have been shown to cause a high prevalence of obesity in individuals with BD, could be helpful in avoiding obesity and obesity-related health risks in this patient group (6,25).

Disinhibition behaviors and socially inappropriate behaviors seen in individuals with bipolar disorder are among the important symptoms of the disease (26). It was determined that the disinhibition (unrestrained eating) score, which is one of the subscales of mindful eating, showed a negative correlation with psychiatric symptoms. The results obtained from this study were found to be consistent with the literature. Boulanger et al. found that disinhibition was associated with binge eating behaviors in individuals with BD, with individuals having approximately two more levels of disinhibition, and patients with BE behaviors tended to eat in response to emotional cues and lacked control over food intake (27). It has been reported that typical antipsychotics, some atypical antipsychotics, and mood stabilizers used in treatment cause insulin resistance, increased appetite, increased body weight, and waist circumference, which is often accompanied by disturbances in executive functions that facilitate dysregulation and disinhibition in food intake (28).

Emotional eating is positively associated with BMI, abdominal obesity, increased waist circumference and body fat percentage, failure of weight loss attempts, increased risk of eating disorders, and deterioration of mental health (29). Martin et al. found that individuals with BD have a higher prevalence of emotional eating and binge eating behaviors than healthy individuals and that this is associated with maladaptive nutritional behaviors (30). In a population of patients with BD and schizophrenia, the prevalence of emotional eating behavior was found to be 49.2 % and patients were found to have high scores on the emotional eating subscale of the TFEQ-21 (31). Emotional dysregulation in individuals with BD is a key feature of the psychopathology of bipolar disorder and is an affective instability associated with a worse course of the illness (e.g., more severe episodes, increased number of hospitalizations). The level of psychological distress and emotional eating are significant predictors of emotional dysregulation (32). Likewise, similar results were obtained in this study and it was determined that the increase in emotional eating behavior was a strong factor in the decrease in mindful eating levels.

One of the most important reasons for weight gain in individuals diagnosed with bipolar disorder is pharmacotherapy. Atypical antipsychotics and mood stabilizers, as well as their combined use, have been associated with increases in overweight and obesity among patients being treated with these drugs. With the initiation of treatment, it was found to cause significant weight gain in all patients, notably in drug-naive patients and more pronounced in lean and normal-weight individuals (33,34). Doane et al. found that 30.4 % of patients who started atypical antipsychotic treatment had clinically significant weight gain (> 7 %) and the obesity rate in this population was 50.7 % (35). In patients receiving mood stabilizers, 8.2 % of lithium users and 8.5 % of valproate users experienced weight gain (36). Antipsychotic agents exert this effect by altering leptin metabolism and the activity of dopaminergic, histaminergic, muscarinergic, and serotoninergic receptors (5-HT2C) that regulate hunger/satiety and appetite. Changes in these receptors can cause hyperphagia behavior in patients and compulsive consumption of palatable foods containing high carbohydrates and fats (37). Davison, meanwhile, found that the rate of cognitive restraint and disinhibition was higher in individuals with mental disorders than in healthy individuals, that mood stabilizers were associated with weight gain, and the use of atypical antipsychotics and mood stabilizers was associated with disinhibition score (38).

LIMITATIONS

The study has some limitations that should be taken into account. Firstly, the scales were administered on the basis of self-report. Participants who completed these scales may have caused self-report bias by reporting socially accepted behaviors instead of some actual eating behaviors (39). Secondly, more systematic approaches are needed to evaluate the effect of the methods used in the treatment of bipolar disorder on eating behavior. Medications used in the treatment are known to have different effects on eating behavior. For instance, while there is a difference between atypical antipsychotics and mood stabilizers in terms of their effect on patients' eating behaviors, there is also a difference between the effects of atypical antipsychotics olanzapine and aripiprazole. Although none of the individuals in our study had a diagnosis of personality disorder, we consider it an important limitation that personality traits and temperament differences have not been studied. We would like to emphasize that the personality and temperament characteristics of the patients should also be examined in future studies to form a more homogeneous group among patients in terms of mindful eating. Finally, the data were obtained from participants receiving outpatient treatment at the same center. It would be useful to conduct comprehensive studies involving different centers.

CONCLUSION

It has been well-established that eating behavior disorders and obesity are common problems in individuals with bipolar disorder. In this study, it was revealed that emotional eating and binge eating behavior, disinhibition, and impulsivity in individuals with BD lead to decreased levels of mindful eating,

adversely affect the eating behavior of individuals and are one of the main factors underlying the high rate of overweight and obesity. It was found that patients with severe mental disorders lost weight, improved their physical functions, and decreased depression levels in physical activity intervention studies combined with healthy nutrition education (40). However, it has been shown that intervention programs that address psychological factors such as mood, anxiety, and stress in addition to nutrition education and physical activity changes are more successful in helping individuals acquire healthy eating habits and eating behaviors. In the mindfulness intervention study, it was shown that emotional eating and binge eating behaviors of individuals with bipolar disorder decreased, and mindful eating levels increased and this intervention practice may be a helpful option for individuals with severe mental disorders. Thus, studies with larger sample groups are needed to elucidate the mechanisms of possible relationships between bipolar disorder-specific risk factors and mindful eating. Mindfulness education designed specifically for individuals with BD can improve physical health and mental well-being.

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ARÁN

Nutrición Hospitalaria

Trabajo Original

Otros

Efectos de D-tagatosa, estevia y sacarosa sobre el pH y la actividad bacteriana oral en estudiantes de odontología. Ensayo controlado y aleatorizado

Effects of D-tagatose, stevia and sucrose on pH and oral bacterial activity in dentistry students. A randomized controlled trial

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Resumen

Introducción: la estevia y la D-tagatosa han demostrado ser capaces de reducir la ingesta total de calorías e hidratos de carbono como sustitutos de la sacarosa, mostrando un efecto estabilizador del pH y la proliferación bacteriana.

Objetivo: evaluar el efecto de D-tagatosa, estevia y sacarosa sobre el pH salival y la actividad bacteriana en estudiantes de odontología.

Metodología: estudio controlado de grupos paralelos y aleatorizados con cegado simple, cuya muestra consideró tres grupos sometidos a un enjuague bucal de D-tagatosa ($n = 10$), estevia ($n = 10$) y sacarosa ($n = 10$). Estas soluciones se suministraron durante 1 minuto en una dosis única concentrada al 6,4 %. La recolección de datos y el análisis consideraron el registro del pH salival 5 min antes de la exposición al edulcorante, inmediatamente tras la expulsión del enjuague bucal y a los 15 min, 30 min, 45 min y 48 horas. El conteo del número final de unidades formadoras de colonias por mL (UFC/mL) utilizó las muestras salivales obtenidas inmediatamente tras la exposición al edulcorante en conjunto con la muestra obtenida a los 30 minutos posteriores, realizándose los cultivos sobre placas de agar.

Resultados: D-tagatosa, estevia y sacarosa presentan diferencias significativas sobre el UFC/mL total a los 30 minutos ($p < 0,001$), mientras que el pH salival plasmó diferencias significativas a las 48 horas posteriores a la suministración ($p < 0,001$).

Conclusión: D-tagatosa, estevia y sacarosa presentan diferencias significativas sobre el UFC/mL total y el pH salival, siendo estos hallazgos un posible indicativo de un efecto inhibidor parcial del metabolismo bacteriano.

Palabras clave:

D-tagatosa. Estevia. Sacarosa. Concentración de iones de hidrógeno. Ensayo de unidades formadoras de colonias.

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Abstract

Background: stevia and D-tagatose have shown a reduction in total calorie and carbohydrate intake as a substitute for sucrose, demonstrating a stabilizing effect on pH and bacterial proliferation.

Objective: to evaluate the effect of D-tagatose, stevia and sucrose on salivary pH and bacterial activity in odontology students.

Methodology: a controlled study of parallel and randomized groups with a single blind, whose sample considered three groups subjected to a mouthwash of D-tagatose ($n = 10$), stevia ($n = 10$) and sucrose ($n = 10$). These solutions were administered over 1 minute in a single 6.4 % concentrated dose. Data collection and analysis considered the recording of salivary pH 5 min before exposure to the sweetener, immediately after expulsion of the mouthwash and 15 min later, 30 min, 45 min and 48 hours. The counting of the final number of colony-forming units per mL (CFU/mL) was counted using the salivary samples obtained immediately after exposure of the sweetener together with the sample obtained 30 minutes later, with the cultures performed on agar plates.

Results: D-tagatose, stevia and sucrose presented significant differences in total CFU/mL at 30 minutes ($p < 0.001$), while salivary pH showed significant differences at 48 hours after administration ($p < 0.001$).

Conclusion: D-tagatose, stevia and sucrose present significant differences in total CFU/mL and salivary pH, these findings being a possible indication of a partial inhibitory effect on bacterial metabolism.

Keywords:

D-tagatose. Stevia. Sucrose. Hydrogen ion concentration. *Streptococcus mutans*. Colony-forming units assay.

INTRODUCCIÓN

Las caries dentales son la enfermedad infecciosa más recurrente a nivel mundial, siendo su etiología atribuida a múltiples factores como el huésped, la saliva, la flora bacteriana y la dieta, entre otros, cuyas implicancias impactan directamente sobre la calidad de vida (1,2).

En cuanto a la prevalencia de la caries dental, durante la última década, en base a los criterios establecidos por la Organización Mundial de la Salud (OMS), se han reportado 578 millones de casos en pacientes con dentición decidual, correspondientes a una prevalencia global del 48 %, siendo Oceanía (82 %), Asia (52 %) y América (48 %) los continentes con mayores casos, mientras que en África (30 %) y Europa (43 %) se han observado las menores prevalencias (3). Estos hallazgos se han atribuido principalmente a los nuevos hábitos alimentarios, donde prácticas culturales como ritos, creencias y valores han promovido la incorporación del azúcar fermentable, atribuida a potenciales riesgos sobre la proliferación de la placa bacteriana y la caries dental (3,4).

En la actualidad se sabe que la placa dental expuesta a azúcares como la sacarosa podría producir ácidos rápidamente, conllevando caídas rápidas del potencial de hidrógeno (pH), seguidas de una recuperación gradual hacia el pH de la placa de referencia (5,6), razón por la cual la industria química y alimentaria, a través de regulaciones aprobadas por organismos como la Administración de Medicamentos y Alimentos (FDA, por sus siglas en inglés), el Códex Alimentario y la Autoridad Europea de Seguridad Alimentaria (EFSA, por sus siglas en inglés), se ha enfocado en la búsqueda y desarrollo de edulcorantes capaces de sustituir tanto el dulzor como los efectos calóricos de los carbohidratos (7,8), siendo los azúcares como la sacarosa sustituidos por edulcorantes no calóricos (ENC) como la estevia y la D-tagatosa, producto de sus posibles efectos sobre parámetros metabólicos en algunas poblaciones de riesgo como los diabéticos y obesos (9-11).

Entre los efectos sistémicos de los ENC se ha observado una contribución al control del aporte calórico, cuyas consecuencias pueden conllevar mejoras sobre la estabilización del pH salival oral relacionado con la inhibición bacteriana (*Streptococcus mutans*) (6,10,12,13), donde la D-tagatosa ha reportado efectos similares a los de la estevia sobre los niveles de glucosa, producto de posibles interferencias sobre la absorción de carbohidratos por causa de la inhibición tanto de la absorción de disacáridos a nivel intestinal como de la gluconeogénesis a nivel hepático, contribuyendo estos mecanismos a reducir los niveles de colesterol, además de estabilizar la placa bacteriana relacionada con el pH salival en comparación con los azúcares fermentables, donde la ingesta diaria recomendada para el esteviol alcanza los 4 mg/kg de peso corporal, mientras que para la D-tagatosa no existen registros de niveles de ingesta a nivel local, a pesar de su masivo consumo (3,11,14,15).

Por esta razón, la finalidad de este estudio fue evaluar el efecto de la D-tagatosa, la estevia y la sacarosa sobre el pH salival y la actividad bacteriana en estudiantes de odontología.

METODOLOGÍA

DISEÑO

Estudio controlado de grupos paralelos y aleatorizados con cegado simple, elaborado en base a la declaración *''Consolidated Standards of Reporting Trials"* (CONSORT) (16). Este protocolo fue aprobado por el Comité de Ética de la Universidad Central de Chile: Acta N° 53/2023, en concordancia a la Declaración de Helsinki (17).

ELEGIBILIDAD

La muestra consideró 30 estudiantes de odontología que fueron invitados a las instalaciones de la Universidad Nacional Andrés Bello, campus Concepción (Chile), donde un profesional especialista en odontología comprobó la pertinencia de la selección del paciente, entregando al participante una breve descripción por escrito del estudio con su objetivo, acompañada de un consentimiento informado que, una vez firmado, permitió evaluar el pH salival y la actividad bacteriana de los participantes sometidos a soluciones edulcorantes. Los participantes cumplieron los siguientes criterios de elegibilidad:

Criterios de inclusión

– Estudiantes de entre 18 a 30 años pertenecientes a la Universidad Nacional Andrés Bello, campus Concepción (Chile).

Criterios de exclusión

– Estudiantes con algún tipo de enfermedad crónica no transmisible y/o enfermedad bucal diagnosticada.
– Estudiantes que no consumen edulcorantes o sacarosa diariamente.
– Estudiantes que declaren poseer algún tipo de reacción alérgica o intolerancia.
– Estudiantes con una puntuación igual o mayor a 4 en 3 o más dientes según la International Caries Detection and Assessment System II (ICDAS II).
– Estudiantes portadores de aparatos de ortodoncia (fija o removible).
– Estudiantes sometidos a terapia antibiótica menor a 4 semanas previo al estudio.
– Estudiantes que no acepten o no firmen el consentimiento informado.

INTERVENCIÓN

Antes de comenzar la intervención se consideró una evaluación de salud oral a través del índice ICDAS II, cuyo uso masificado permite categorizar la caries dental. Este índice considera la presencia y evolución de las caries, además del estado de restauración de la pieza dental, evaluándose el análisis visual y táctil de la pieza dental a través de una escala tipo Likert con valores de 0 a 6, donde 0 denota la pieza libre de caries y 6 la caries penetrante (18). Adicionalmente, a través de un cuestionario estandarizado, se obtuvieron los datos sociodemográficos, permitiendo ambos instrumentos corroborar los criterios de elegibilidad.

La intervención se realizó en las instalaciones de la clínica odontológica perteneciente a la Universidad Nacional Andrés Bello, campus Concepción (Chile). Esta consistió en la suministración de una solución de enjuague bucal con base de sacarosa granulada (lanza, Chile), estevia en sachet (lanza, Chile) y D-tagatosa granulada (AluSweet Biofoods, Chile), donde cada solución suministrada fue preparada al 6,4 % sobre agua destilada de pH neutro, siguiendo recomendaciones previas (19-21).

La suministración de cada solución estuvo a cargo de un profesional especialista en odontología, quien entregó a cada participante una única dosis de 20 mL de enjuague bucal para aplicar durante 1 minuto, distribuyéndose estas tres soluciones entre tres grupos de 10 integrantes asignados de forma probabilística.

RESULTADOS DE INTERÉS

Se obtuvieron seis muestras de 10 mL de saliva por participante, obteniéndose la primera 5 minutos antes de la exposición al edulcorante, mientras que, después de la la eliminación del enjuague, se realizó la obtención de la segunda toma de muestra (0 min), repitiéndose el mismo proceso a los 5, 15, 30, 45 minutos posteriores y valorándose adicionalmente el pH tras 48 horas de aplicada la última solución.

El pH salival fue evaluado por medio del medidor Edge® Blu con Electrodo de pH Bluetooth® Smart - HI2202 (HANNA® Instruments), cuyo calibrado se realizó a través de dos soluciones estándar (7,1 y 10,1 pH), permitiendo obtener lecturas con ± 0,2 mV de exactitud. Las muestras de saliva obtenidas de los participantes se depositaron en potes plásticos con tapa, previamente esterilizadas y rotuladas con números del 1 al 6 para el control de los tiempos, el nombre del estudiante y la inicial del producto designado para la identificación del edulcorante utilizado. Posteriormente, las muestras fueron trasladadas en un 'cooler' al laboratorio de química de la universidad, en donde se trasvasaron a vasos de precipitados que permitieran que la sonda de pH pudiera sumergirse en cada medición, procurando no exceder el máximo nivel de inmersión, para luego agitar la muestra suavemente sobre una vibradora, esperando la estabilización de la lectura y el registro del pH utilizando una planilla Excel según recomendación previa (22).

Por otro lado se realizó un conteo del número final de unidades formadoras de colonias por mL (UFC/mL), para lo cual se procesaron las muestras salivales obtenidas antes de la administración del edulcorante y a los 30 minutos posterior al enjuague. Estas fueron procesadas por el laboratorio de microbiología de la universidad, en donde se trabajaron con un factor de disolución de -7, donde se mezclaron 900 microlitros de agua destilada estéril y 100 microlitros de saliva, que se traspasaron a tubos desechables de 1.5 ml (Eppendorf) por medio de una pipeta graduada en conjunto con puntas de mezclar desechables. De la solución obtenida se extrajeron 50 microlitros para la realización de una siembra sobre placas de agar Mitis Salivarius (Winkler Ltda.). La distribución del contenido sobre el agar se realizó en forma de zig zag con un asa calibrada, plástica, desechable y estéril. Las placas procesadas fueron rotuladas con la inicial del producto utilizado y con el número 1 o 2, dependiendo de si la muestra correspondía a la exposición anterior a la solución o posterior a esta, para luego introducirse en una estufa con ambiente aerobio Labtech modelo LIB-150M, sometiéndolas a 37 °C por 48 horas. Transcurrido el tiempo de incubación se realizó el análisis macroscópico con una lupa Spence (10 x) para el recuento de colonias sobre las placas de Petri y un análisis morfológico de las colonias, considerando los parámetros correspondientes a la adherencia, la coloración (café grisáceas), la superficie (rugosa), la apariencia (vidrio esmerilado), la consistencia (dura) y la ausencia de disgregación de las colonias a la manipulación. Finalmente, todos estos procedimientos permitieron cuantificar las bacterias dentro de un rango de 100 a 1000 UFC/ml y de más de 100.000 UFC/ml (23-26).

ALEATORIZACIÓN

La secuencia de aleatorización se creó usando un generador de secuencia aleatoria 'online' (https://www.alazar.info/genera-

dor-de-secuencia-de-numeros-desordenada), realizándose este proceso de forma estratificada por centro a través de una asignación 1:1, utilizando tamaños de bloque equivalentes. Los participantes se asignaron al azar siguiendo un método simple de aleatorización codificada.

ENMASCARAMIENTO

El enmascaramiento se realizó por el método simple, donde a los participantes solo se les informó de que estarían evaluando tres edulcorantes de forma aleatoria, sin entregar ninguna otra información que diese a conocer el producto designado.

TAMAÑO MUESTRAL

Los 30 alumnos de sexto año inscritos en el periodo de 2023 en la carrera de odontología impartida por la Universidad Nacional Andrés Bello, campus Concepción (Chile), determinaron el tamaño de muestra, donde se estableció un intervalo de confianza (IC) del 95 % y un margen de error del 1 %, obteniéndose un tamaño de muestra ideal de 30 participantes.

ANÁLISIS DE DATOS

Los datos se exportaron al SPSS versión 27.0 para sistema operativo Windows. Para la descripción de variables se utilizaron los estadísticos media y desviación estándar, mientras que para establecer la distribución de los datos se aplicó la prueba de Shapiro-Wilk. Posteriormente, para detectar diferencias entre los grupos de pH en los edulcorantes, se realizaron análisis factoriales mixtos a través de la prueba ANOVA combinada con la prueba de Bonferroni o decDunnet post-hoc, dependiendo de la homogeneidad de las varianzas de las muestras. Finalmente, para todos los análisis se consideró un nivel de significancia bilateral de 0,05.

RESULTADOS

La figura 1 expone el diseño del estudio, en el cual, de un total de 30 estudiantes universitarios inicialmente elegibles, 30 cumplieron los criterios de inclusión y fueron asignados de manera aleatoria al grupo con sacarosa (n = 10), D-tagatosa (n = 10) y estevia (n = 10). Es relevante señalar que no se registraron abandonos a lo largo de la intervención.

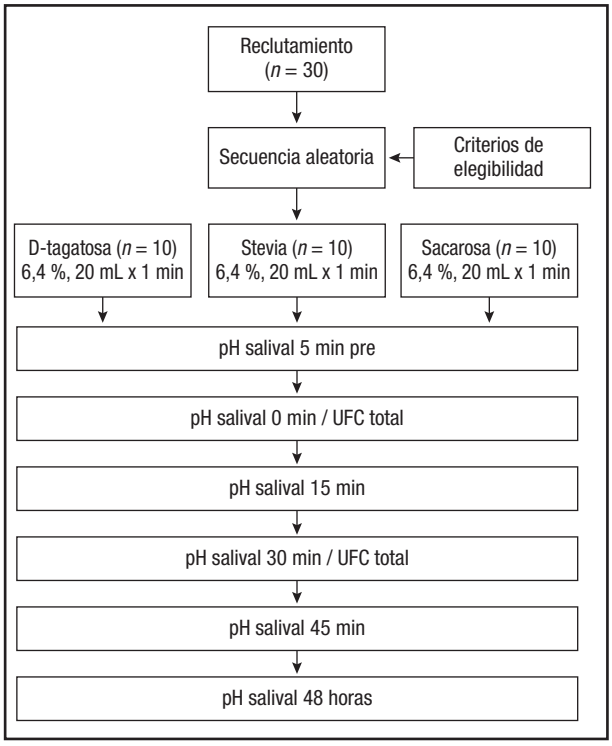

Figura 1.
Diagrama de flujo del diseño del estudio.

En la tabla I se plasman los resultados de las características etarias y de salud oral, apreciándose homogeneidad tanto en la edad (p = 0,492) como en la salud oral (p = 0,456) entre los grupos de edulcorantes.

La tabla II reporta los resultados de pH salival en función del tiempo, donde solo se observan diferencias significativas entre grupos de edulcorantes a las 48 horas posteriores a la suministración ($p < 0,001$). En este contexto, tanto la D-tagatosa ($p < 0,001$) como la estevia (p = 0,001) plasman cambios significativos en comparación con la sacarosa. No obstante, no se aprecian diferencias significativas al comparar ambos edulcorantes entre sí ($p = 0,137$).

Tabla I. Características etarias y orales de la muestra estudiada según los grupos de edulcorantes (n = 30)

Variables	Stevia (n = 10)	D-tagatosa (n = 10)	Sacarosa (n = 10)	F	p
	X ± DS	X ± DS	X ± DS		
Edad	23,10 ± 2,23	22,20 ± 2,48	21,7 ± 3,09	0,728	0,492
ICDAS II	1,40 ± 1,92	2,21 ± 1,31	2,13 ± 1,40	0,809	0,456

X: media; DS: desviación estándar; F: estadístico F. p: valor de p.

Tabla II. Diferencias de pH salival entre grupos de edulcorantes según el tiempo (*n* = 30)

pH salival	Stevia (*n* = 10)	D-tagatosa (*n* = 10)	Sacarosa (*n* = 10)	F	*p*
	X ± DS	X ± DS	X ± DS		
5 min antes	7,48 ± 0,31	7,55 ± 0,32	7,57 ± 0,30	0,240	0,788
0 min	7,41 ± 0,17	7,25 ± 0,51	7,08 ± 0,66	1,156	0,330
15 min	7,59 ± 0,47	7,51 ± 0,30	7,51 ± 0,49	0,118	0,889
30 min	7,66 ± 0,30	7,60 ± 0,27	7,68 ± 0,57	0,096	0,909
45 min	7,57 ± 0,36	7,68 ± 0,26	7,54 ± 0,46	0,367	0,696
48 horas	5,14 ± 0,37	5,37 ± 0,20	4,69 ± 0,77	19,371	< 0,001
Comparación entre grupos edulcorante a las 48 horas					
Par	**Diferencias medias**	**Error estándar**	**IC 95 %**		***p***
			Lim inf.	**Lim sup.**	
Stevia/Sacarosa	0,44600	0,11072	0,1634	0,7286	0,001
D-tagatosa/Sacarosa	0,67800	0,11072	0,3954	0,9606	< 0,001
D-tagatosa/Stevia	0,23200	0,11072	-0,0506	0,5146	0,137

X: media; DS: desviación estándar; F: estadístico F; IC: Intervalo de confianza; Lim inf.: límite inferior; Lim sup.: límite superior; p: valor de p.

Tabla III. Diferencias de UFC total entre grupos de edulcorantes según tiempo (*n* = 30)

pH salival	Stevia (*n* = 10)	D-tagatosa (*n* = 10)	Sacarosa (*n* = 10)	F	*p*
	X ± DS	X ± DS	X ± DS		
0 min	548,50 ± 45,45	582,80 ± 35,03	572,40 ± 41,61	1,847	0,177
30 min	441 ± 47,77	463,60 ± 42,38	668,20 ± 32,89	91,081	< 0,001
Comparación entre grupos edulcorante a las 48 horas					
Par	**Diferencias medias**	**Error estándar**	**IC 95 %**		***p***
			Lim inf.	**Lim sup.**	
Sacarosa/Stevia	227,200	18,547	179,86	274,54	< 0,001
Sacarosa/D-tagatosa	204,600	18,547	0,3954	0,9606	< 0,001
D-tagatosa/Stevia	22,600	18,547	-24,74	69,94	0,701

X: media; DS: desviación estándar; F: estadístico F; IC: Intervalo de confianza; Lim inf.: límite inferior; Lim sup.: límite superior; p: valor de p.

En la tabla III se muestran los valores totales del conteo de UFC/mL, reportándose diferencias significativas entre los 3 grupos de edulcorantes a los 30 min posteriores a la administración ($p < 0,001$). En este sentido, tanto la D-tagatosa ($p < 0,001$) como la estevia ($p < 0,001$) plasman cambios significativos en comparación con la sacarosa. No obstante, no se aprecian diferencias significativas al comparar ambos edulcorantes entre sí ($p = 0,701$).

DISCUSIÓN

El propósito de este estudio fue evaluar el efecto de D-tagatosa, estevia y sacarosa sobre el pH salival y la actividad bacteriana en estudiantes de odontología. Los resultados de las mediciones de pH salival evidenciaron diferencias significativas pasadas 48 horas tras la administración de los tres grupos edulcorantes, mientras que el UFC/mL total solo mostró

diferencias significativas posteriores a los 30 minutos desde la administración del edulcorante.

En cuanto a las medidas basales, se aprecia una homogeneidad que indica que los tres grupos poseían un rango etario similar relacionado con una buena salud oral, reflejada en la ausencia de caries activas y de enfermedad periodontal según la puntuación ICDAS II (18), permitiendo inferir por tanto un bajo nivel de proliferación bacteriana (27,28). No obstante, a pesar de la baja proliferación bacteriana de base, se aprecian también cambios visibles sobre el esmalte dental (ICDAS II < 2) en el grupo sometido a la estevia, mientras que los grupos sometidos a la D-tagatosa y la sacarosa muestran cambios detectables (ICDAS II < 3) (18).

En este contexto, en la literatura se ha reportado que la estevia suministrada como enjuague bucal puede generar efectos inhibitorios sobre la concentración de placa bacteriana luego de una hora desde la suministración, mientras que la D-tagatosa ha mostrado poder reducir la producción de ácido y la síntesis de glucano vinculadas al crecimiento de *S. mutans* y GS5, conllevando la suministración de ambos edulcorantes un posible efecto restaurador del pH oral (11,29,30) y siendo estos hallazgos contradictorios a los reportes del presente estudio, cuyos resultados indican que el pH salival obtenido a las 48 h presenta una acidificación significativa que daría cuenta de un potencial riesgo bucal (pH $\leq$ 6,49) en los tres grupos de edulcorantes en comparación con sus medidas basales (31).

Este comportamiento se podría explicar en parte por la formulación comercial de los tres grupos de edulcorantes, cuyos componentes presentan algunos agentes excipientes como oligosacáridos, que, si bien están destinados a favorecer la consistencia y el sabor del producto, también pueden producir un proceso fermentativo que explicaría el consecuente descenso del pH salival relacionado con un potencial riesgo bucal (31,32). En este contexto, el proceso de inhibición del crecimiento de colonias bacterianas (*S. mutans*, *S. oralis* y *S. gordini*) producto del metabolismo glucolítico, atribuido tradicionalmente a la D- tagatosa y la estevia en forma individual o combinada con glucosa o sacarosa, no sería efectivo por causa de la ineficacia de los formatos comerciales (13,32).

Del mismo modo, esta hipótesis se puede corroborar al observar los reportes del UFC/mL, cuyos valores dan cuenta de un posible efecto inhibitorio de la estevia y la D-tagatosa expresado en la disminución significativa en ambos grupos (Stevia: -107 UFC/mL; D-tagatosa: -119 UFC/mL), mientras que las muestras salivales estimuladas con sacarosa mostraron un significativo aumento (96 UFC/mL), concordando así este comportamiento con los reportes de la literatura (11,13,33).

Los hallazgos del presente estudio están limitados en su validez externa puesto que los suplementos comerciales disponibles en el mercado nacional poseían excipientes (32). Del mismo modo, la exposición de los medios de cultivo se realizó en un ambiente aerobio sin considerar un aislamiento de géneros de *Streptococcus* a través de bacitracina o sacarosa (25). Por estas razones, cabe mencionar que se debe considerar que el presente estudio se llevó a cabo en una única universidad. Por tanto, la generalización de estos hallazgos a otras poblaciones o contextos podría ser limitada y debe tomarse con precaución.

CONCLUSIÓN

Las soluciones de D-tagatosa, estevia y sacarosa solo muestran diferencias significativas sobre el pH salival a las 48 horas, mientras que el UFC/mL total reportó diferencias significativas a los 30 minutos de la administración, siendo estos hallazgos un posible indicativo de un efecto inhibidor parcial del metabolismo bacteriano.

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ARÁN

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Revisión

Vitamina B12, ácidos grasos EPA y DHA durante el embarazo y la lactancia en mujeres con alimentación basada en plantas

Vitamin B12, fatty acids EPA and DHA during pregnancy and lactation in women with a plant-based diet

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Resumen

El embarazo y la lactancia representan una etapa compleja desde el punto de vista nutricional ya que durante estas etapas aumentan las necesidades de energía, proteínas y micronutrientes. La literatura describe que una alimentación basada en plantas, bien planificada, puede ser suficiente en el aporte de energía, proteínas y micronutrientes, a excepción del aporte de vitamina B12 y posiblemente de ácidos grasos poliinsaturados de la serie n3, principalmente EPA y DHA. Durante los últimos años la adherencia a esta dieta ha aumentado rápidamente en la población, por lo que el objetivo principal de este artículo es revisar la evidencia actual sobre el consumo y concentraciones de vitamina B12, EPA y DHA durante el periodo de embarazo y la lactancia en mujeres que siguen una alimentación basada en plantas. Se realizó una búsqueda bibliográfica en PubMed, Scopus, Web of Science y Ovid MedLine utilizando términos libres y MESH. Se seleccionaron 11 artículos en esta revisión. Las dietas vegetarianas y veganas bien planificadas, y con la suplementación adecuada de vitamina B12, EPA y DHA, son compatibles durante el periodo de embarazo y lactancia, logrando ser un predictor positivo en el contenido de estos en la leche materna. Situación similar fue observada en niveles plasmáticos en mujeres suplementadas con B12. Sin embargo, es importante continuar con investigaciones en este ámbito que consideren una adecuada anamnesis dietética, evaluación integral del estado nutricional, la estimación de requerimientos nutricionales y un plan nutricional individualizado.

Palabras clave:

Dieta vegetariana/vegana. Embarazo. Lactancia. Ácido eicosapentaenoico (EPA). Ácido docosahexaenoico (DHA). Vitamina B12.

Abstract

Pregnancy and lactation represent a complex stage from a nutritional point of view, since energy, protein and micronutrient requirements increase during these stages. The literature describes that a well-planned plant-based diet can be sufficient in energy, macronutrients and micronutrients, with the exception of vitamin B12 and possibly n3 polyunsaturated fatty acids, mainly EPA and DHA. During the last few years, adherence to this diet has increased rapidly in the population, so the main objective of this article is to review the current evidence on the intake and concentrations of vitamin B12, EPA and DHA during pregnancy and lactation in women following a plant-based diet. A literature search was performed in PubMed, Scopus, Web of Science and Ovid MedLine using free terms and MESH. Eleven articles were selected in this review. Well-planned vegetarian and vegan diets, with adequate supplementation of vitamin B12, EPA and DHA, are compatible during pregnancy and lactation, being a positive predictor of their content in breast milk. A similar situation was observed in plasma levels in women supplemented with B12. However, it is important to continue with research in this area that considers an adequate dietary anamnesis, integral evaluation of nutritional status, estimation of nutritional requirements and an individualized nutritional plan.

Keywords:

Vegetarian/vegan diet. Pregnancy. Lactation. Eicosapentaenoic acid (EPA). Docosahexaenoic acid (DHA). Vitamin B12.

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INTRODUCCIÓN

Durante los últimos años, la tendencia hacia una alimentación vegetariana y vegana ha ido en aumento a nivel mundial (1). Se han evidenciado múltiples beneficios asociados a estas dietas durante el periodo perinatal, como protección contra el desarrollo de preeclampsia y diabetes gestacional, reducción de la exposición a agentes genotóxicos, prevención de la ganancia excesiva de peso y prevención de enfermedades pediátricas como sibilancias, diabetes, defectos del tubo neural, fisuras orofaciales e incluso algunos tumores (2-4).

Una alimentación basada en plantas consiste en el consumo abundante y regular de todo tipo de frutas, verduras, granos integrales, legumbres, semillas, hierbas y especias, mínimamente procesadas, excluyendo todos los productos de origen animal tales como carnes, aves, pescados, huevos y productos lácteos (5).

El embarazo y la lactancia se consideran períodos críticos desde el punto de vista nutricional debido al incremento de las necesidades energéticas, proteicas y de algunos micronutrientes (6,7). Se ha observado que posibles deficiencias pueden estar mediadas por el estado nutricional, la calidad de la dieta y la ingesta materna, y el nivel socioeconómico (8).

Se ha descrito que una dieta vegetariana, especialmente la vegana, puede ser insuficiente en la ingesta de nutrientes como la vitamina B12 y los ácidos grasos EPA y DHA (2,9,10). Sin embargo, en la actualidad, estas dietas han demostrado satisfacer los requerimientos nutricionales en las distintas etapas, cubriendo las necesidades energéticas y las de macro y micronutrientes a través de una adecuada planificación alimentaria (11,12).

La vitamina B12 y los ácidos grasos poliinsaturados EPA y DHA cobran mayor importancia durante el embarazo y la lactancia en las mujeres que siguen una alimentación basada en plantas y principalmente en las veganas, ya que las principales fuentes alimentarias de estos nutrientes son de origen animal. La vitamina B12 participa en el metabolismo energético, la síntesis de glóbulos rojos y el desarrollo cognitivo. Su déficit en los lactantes se asocia a un mayor riesgo de bajo peso al nacer, daños cognitivos y manifestaciones hematológicas (13). Los ácidos grasos EPA y DHA participan en el desarrollo del cerebro y la función cognitiva y en la formación de la retina, además de asociarse a una menor probabilidad de parto prematuro y de bajo peso de nacimiento (13,14).

El objetivo principal de este artículo es revisar la evidencia actual sobre el consumo y las concentraciones de vitamina B12, EPA y DHA durante el periodo de embarazo y lactancia en mujeres que siguen una alimentación basada en plantas.

METODOLOGÍA

Se realizó una búsqueda bibliográfica en PubMed, Scopus, Web of Science y Ovid MedLine siguiendo el diagrama PRISMA (Fig. 1). Para la búsqueda se utilizó una combinación de los términos: "VEGAN DIET", "VEGETARIAN DIET", PREGNANCY, BREASTFEEDING, "VITAMIN B12", "FATTY ACIDS", EPA y DHA. Se consideraron estudios en seres humanos de tipo observacional, de casos-controles, retrospectivo y de acceso abierto sin restricción de idioma y que se hubieran publicado en los últimos 10 años.

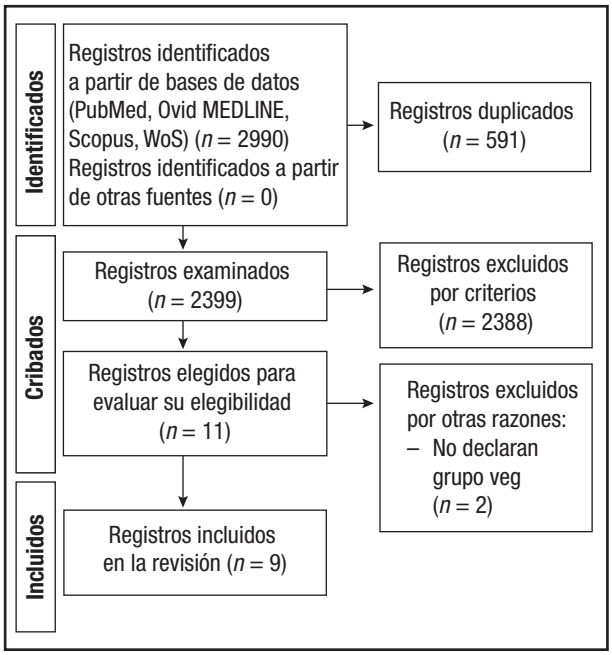

Figura 1.

Proceso de selección de estudios: diagrama de flujo Prisma.

Se consideró como criterio de inclusión el que los artículos se hubieran realizado en madres y/o lactantes durante el periodo de embarazo y/o lactancia, con o sin suplementación de B12, EPA y DHA. Se excluyeron aquellos realizados en madres gestantes con enfermedades como diabetes *mellitus*, diabetes gestacional y desnutrición, y/o con hijos prematuros con patologías como alergias alimentarias, cardiopatías, enfermedades digestivas u otras.

Se realizó además un análisis crítico de los estudios seleccionados mediante el instrumento de evaluación de la calidad *Strengthening the Reporting of Observational Studies in Epidemiology* (STROBE).

RESULTADOS Y DISCUSIÓN

Se incluyeron un total de 9 estudios: 6 evaluaron las concentraciones de vitamina B12 y 4 evaluaron los niveles de EPA y DHA.

Los principales resultados se encuentran en la tabla resumen de la búsqueda (Tabla I).

VITAMINA B12

Cinco estudios evaluaron los niveles plasmáticos de B12 en embarazadas; 1 evaluó la concentración en el cordón umbilical, 1 los evaluó en lactantes y 1 evaluó la concentración de B12 en la leche materna.

Tabla I. Tabla resumen de resultados de búsqueda

Autor (año, país)	Objetivo	Metodología	Principales resultados
Knight B., 2015 UK (15)	Investigar esta relación entre IMC materno y vitamina B12 y ácido fólico séricos en una cohorte de embarazos	Estudio transversal *n* = 995 embarazadas. < 15 SG Grupo vegetarianas (*n* = 85) Grupo omnívoras (*n* = 910) Ambos grupos mantienen el uso de suplementos de B12 previos. No informa de dosis	Sin diferencias significativas en la concentración de B12 según el patrón dietético. Baja concentración (< 150 pmol/L) de B12 en 20 % de las embarazadas. Mayor concentración de B12 en las mujeres que tomaron suplemento vitamínico durante el embarazo ($p < 0,001$)
Mittal M., 2017 India (16)	Evaluar el estado de la vitamina B12 en lactantes indios sanos alimentados exclusivamente con leche materna de 1 a 6 meses y en sus madres	Estudio transversal *n* = 100 embarazadas y sus hijos (lactantes de término) Grupo vegetarianas (*n* = 46) Grupo omnívoras (*n* = 54) Sin uso de suplementos de B12	Anemia en el 58 % de las madres y 69 % de sus hijos. Deficiencia de B12 (< 200 pg/mL) en el 46 % de las madres y en el 57 % de los lactantes. Sin diferencias significativas entre los grupos. La dieta materna fue el único factor con influencia significativa en los niveles de B12 en las madres ($p < 0,01$), pero sin diferencias significativas en los lactantes. Correlación positiva entre los niveles de B12 de los lactantes y sus madres ($p = 0,021$)
Pawlak R., 2018 EEUU (17)	Analizar la concentración de vitamina B12 en la leche materna y el patrón de suplementación de vitamina B12 en madres con diferentes patrones dietéticos: vegetarianas, veganas y no vegetarianas	Estudio transversal *n* = 74 madres Grupo vegetarianas (*n* = 26) Grupo veganas (*n* = 22) Grupo omnívoras (*n* = 26) Mantienen el uso de suplementos previos (B12, complejo B y vitaminas prenatales). No especifica dosis	Bajos niveles de B12 (< 310 pmol/L) en las muestras de leche materna del 19,2 % de las vegetarianas, 18,2 % de las veganas y 15,4 % de las omnívoras, sin diferencias significativas según el patrón dietético. El uso de suplementos de B12 fue un predictor positivo significativo de su concentración en la leche materna ($p = 0,024$), no así el uso de complejo B o prenatales. El 78,4 % usaron suplementos de B12, todos superiores a la dosis recomendada (2,8 µg/d)
Denissen K., 2019 Holanda (18)	Examinar la asociación de la ingesta de vitamina B12 en los alimentos con las concentraciones circulantes de B12 y la presencia de deficiencia de B12 en embarazadas	Estudio transversal *n* = 1266 embarazadas Grupo pescetarianas (*n* = 45) Grupo ovolactovegetarianas (*n* = 27) Grupo vegetarianas (*n* = 75) Grupo omnívoras (*n* = 1119) Mantiene uso de suplementos previos de B12. No especifica dosis	Vegetarianas y ovolactovegetarianas tienen menor ingesta total de B12 y biomarcadores de B12 considerablemente más bajos que las omnívoras y pescetarianas ($p < 0,001$). El 46 % usaron suplementos de B12, donde el 74,1 % usaron dosis orales diarias de 1,0 µg/d. Relación significativa entre la dosis y la respuesta de la vitamina B12 total en la dieta ($p < 0,001$)
Avnon T., 2020 EE. UU. (19)	Determinar la influencia de la dieta materna en los niveles de B12 en sangre materna y cordón umbilical	Estudio observacional *n* = 273 embarazadas Grupo vegetarianas (*n* = 60) Grupo veganas (*n* = 64) Grupo pescetarianas (*n* = 37) Grupo omnívoras (*n* = 112) Mantienen uso de suplementos previos (B12, multivitamínicos y hierro). No informa de dosis	Sin diferencias significativas en los niveles séricos de B12 según el patrón dietético, ni en el cordón umbilical. 18 % de veganas presentan déficit de B12 (< 200 pg/ml). Diferencia significativa entre veganas con y sin suplementación de B12 en los niveles de vitamina en el cordón umbilical ($p < 0,001$) y sangre materna ($p = 0,003$). Sin diferencias significativas en la tasa de anemia materna y anemia neonatal, ni en los niveles bajos de B12 umbilical según el patrón dietético
Perrin M., 2019 EE. UU. (20)	Evaluar los patrones de utilización de suplementos y las concentraciones de ácidos grasos en la leche materna de mujeres que siguen patrones de dieta vegana, vegetariana y omnívora	Estudio observacional *n* = 74 madres lactantes Grupo vegetarianas (*n* = 26) Grupo veganas (*n* = 22) Grupo omnívoras (*n* = 26) Mantiene uso de suplementos previos (B12, complejo B y vitaminas prenatales, EPA y DHA). No informa de dosis	Sin diferencias significativas de la baja concentración de DHA en la leche materna según el patrón dietético ($p = 0,555$) El uso de suplemento de EPA/DHA fue un predictor positivo significativo del contenido de la leche materna de ALA, DHA y omega 3 totales ($p = 0,002$; $p = 0,017$; $p < 0,001$). Las mujeres vegetarianas poseían concentraciones significativamente mayores de omega 3 totales y menores concentraciones de grasas saturadas y grasas trans en comparación con los otros grupos ($p \leq 0.001$)

(Continúa en página siguiente)

Tabla I (Cont.). Tabla resumen de resultados de búsqueda

Autor (año, país)	Objetivo	Metodología	Principales resultados
Crozier S., 2019 UK (21)	Investigar el vegetarianismo durante el embarazo y su asociación con el estado nutricional materno y la concentración de B12 y EPA + DHA	Estudio observacional *n* = 2643 madres embarazadas a término Grupo vegetarianas (*n* = 91) Grupo omnívoras (*n* = 2552) Mantienen uso de suplementos previos. No se informa de suplementos ni dosis	Menor concentración de B12 en las vegetarianas ($p < 0,0001$), sin diferencias en homocisteína. La concentración sérica materna de EPA y DHA considerablemente más baja en el grupo vegetariano ($p < 0,001$). La dieta vegetariana durante el embarazo se asoció con concentraciones maternas más bajas de cobalamina y algunos PUFA, DHA y ARA
Khandelwal S., 2020 India (22)	Examinar los efectos de la suplementación materna con DHA desde la mitad del embarazo hasta los seis meses posparto sobre el desarrollo neurológico posnatal.	Ensayo clínico *n* = 957 embarazadas ≤ 20 SG Grupo con DHA (*n* = 478; 73 VEG): 400 mg/d DHA de algas Grupo con placebo: (*n* = 479; 87 VEG): 400 mg/d aceite de soya/maíz	Sin diferencias significativas de DHA en glóbulos rojos maternos al inicio del estudio ($p = 0,77$), Aumento significativo de los niveles de DHA al momento del parto ($p < 0,001$). Aumento significativo de los niveles de DHA en los lactantes a los 6 ($p < 0,001$) y 12 meses ($p < 0,001$)
Joshi K., 2019 India (23)	Determinar si el patrón dietético de las mujeres embarazadas tiene algún efecto compensatorio sobre la expresión del FADS, mejorando así la conversión de precursores en LCPUFA para ahorrar LCPUFA general	*n* = 75 embarazadas ≥ 37 SG Grupo vegetarianas (*n* = 25) Grupo omnívoras (*n* = 50) No informa de suplementos	Sin diferencias significativas de DHA según el patrón dietético ($p > 0,05$). Sin diferencias significativas de AA + DHA según el patrón dietético ($p \geq 0,05$). ALA significativamente mayor en el grupo de las omnívoras ($p < 0,05$), al igual que LA + ALA ($p \leq 0,05$). No hubo diferencias significativas entre los niveles plasmáticos de LA, AA y DHA de los grupos vegetariano y no vegetariano

LA: ácido linoleico; ALA: ácido alfa linolénico; AA: ácido araquidónico; DHA: ácido docosahexaenoico; EPA: ácido eicosapentaenoico; CU: cordón umbilical. FADS: gen de la ácido graso-desaturasa; SG: semanas de gestación; tHcy: homocisteína total; Hto: hematocrito.

Knight y cols. evidenciaron que un 20 % de las embarazadas presentaba bajos niveles de B12 sin diferencias significativas entre los patrones dietarios, resultados similares a los obtenidos por Avnon y cols., que tampoco encontraron diferencias en la tasa de anemia materna entre los grupos que seguían un patrón alimentario basado en plantas y los omnívoros. Ambos estudios consideraban la suplementación de B12 pero ninguno incluyó información sobre las dosis de suplementación (15,19). Resultados contrarios obtuvieron Crozier y cols., en donde las embarazadas vegetarianas tuvieron menores concentraciones de B12 plasmático; el estudio considera la suplementación previa pero no entrega información de la dosis diaria ni de quiénes se suplementan con B12 (21). Resultados similares fueron los de Denissen y cols., que señalan que el grupo de las embarazadas vegetarianas tenía un consumo menor y biomarcadores de B12 más bajos que el de las omnívoras y las pescetarianas; el estudio mantuvo suplementación previa, con un promedio de consumo de 1 µg diario (18), lo cual está por debajo de la recomendación diaria en el periodo de embarazo y de lactancia, que es de 50 µg diarios en el periodo de mantención (25).

En el estudio de Mittal y cols. no se consideró el uso de suplementos de B12. Un 58 % de las madres presentaban anemia y un 46 % déficit de B12, sin diferencias significativas entre los grupos. Es importante mencionar que la dieta materna influyó significativamente en los niveles de B12 de las madres, por lo que también es un factor importante a considerar en las estrategias de planificación nutricional (16).

La vitamina B12 es esencial para los seres humanos y se ha visto una alta prevalencia del déficit en muchos grupos de la población, no solo en las personas que son vegetarianas. Entre sus funciones destaca la síntesis de glóbulos rojos, así como su función cognitiva y neurológica (13).

El estudio de Avnon y cols. evaluó las concentraciones en muestras de cordón umbilical, sin diferencias significativas entre los patrones alimentarios. Además se observó que la suplementación de B12 se había asociado a mejores niveles de esta vitamina en el cordón umbilical y la sangre materna de las madres veganas suplementadas, al compararlas con las no suplementadas (19).

En el estudio de Pawlak y cols. se evaluaron los niveles de B12 en la leche materna y estos se encontraron bajos en un 52,8 % de la muestra, sin diferencias significativas por tipo de dieta. Este estudio también evidenció que el uso de suplementos de B12 era mayor en veganas y que este influye positivamente en la concentración de B12 en la leche materna (17). La evidencia menciona el uso de suplementos individuales de B12 como predictor positivo de las concentraciones de B12 en la leche materna, por lo que su suplementación es de relevancia (27).

Se recomienda el uso de suplementos de B12 tanto para la madre como para su hijo/a en el periodo de lactancia (Tabla II),

considerando el grado de deficiencia de acuerdo con los resultados de los niveles plasmáticos (25).

La suplementación mejora las concentraciones de B12 en el plasma materno, la leche materna y el cordón umbilical (15,17,18,28).

La dieta materna también es un factor positivo en las concentraciones de B12, lo cual repercute directamente en el lactante (16,17,25). La alimentación vegetariana bien planificada y suplementada con B12 logra cubrir todas las necesidades nutricionales de la madre, tanto en el embarazo como en la lactancia (25,26). Se recomienda el consumo de alimentos fortificados, sin descuidar la suplementación diaria de B12 y la asesoría de un profesional especialista en nutrición (25,28).

ÁCIDOS GRASOS EPA Y DHA

Cuatro estudios revisaron el efecto de la dieta basada en plantas sobre la concentración de ácidos grasos, tres en la sangre materna (21-23) y uno en la leche materna (20).

De acuerdo a los resultados de Perrin y cols., en la leche materna no hubo diferencias significativas entre las bajas concentraciones de DHA según el patrón alimentario. Sin embargo, las vegetarianas poseían mayores concentraciones de omega 3 totales y menores concentraciones de grasas saturadas y grasas trans en comparación con las mujeres omnívoras ($p \leq 0{,}001$), lo cual podría deberse a la calidad de los alimentos consumidos en este patrón alimentario. Sin embargo, los autores no entregan detalles de la variabilidad ni de la calidad de la dieta materna, tampoco de las dosis de suplementación o de quiénes las recibían. La suplementación resultó ser un predictor positivo de la concentración de DHA y PUFA-n3 en la leche materna (20).

La evidencia señala que la composición de macronutrientes de la leche materna se mantiene estable independientemente del patrón alimentario a corto y mediano plazo, siempre que las reservas maternas sean suficientes (29). No obstante, los lípidos se encuentran entre los nutrientes con mayor susceptibilidad a los cambios de composición de la leche materna, destacándose el aporte exógeno de ácidos grasos PUFA-n3, EPA y DHA debido a la incapacidad del organismo de poder sintetizar PUFA-n3, siendo importante que el aporte de estos provenga de la dieta materna, mejorando así el aporte al lactante a través de la leche materna (30,31).

Los PUFA-n3, principalmente EPA y DHA, son importantes en el desarrollo cognitivo y visual en la temprana edad (3,14). Por otro lado, estudios recientes muestran que la concentración de ácidos grasos en la leche materna podría estar relacionada positivamente con el peso corporal ($p < 0{,}05$) y el índice de masa corporal (IMC) ($p = 0{,}048$) (32,33).

Joshi y cols. tampoco encontraron diferencias significativas entre las concentraciones de DHA según el patrón alimentario; sin embargo, los niveles de ALA fueron significativamente más altos en las omnívoras, al igual que las concentraciones de LA + ALA. Cabe destacar que este estudio no describe el uso de suplementos de EPA y/o DHA (23). A diferencia de los resultados encontrados por Crozier y cols., que observaron que las madres vegetarianas poseían menores concentraciones plasmáticas de ácidos grasos en general y concentraciones significativamente más bajas de EPA y DHA con respecto a las madres omnívoras, estas eran, sin embargo, las que mayormente se suplementaban. Este estudio no especifica ni dosis ni tipo de ácido graso suplementado, información relevante para evaluar los resultados (21). Estos resultados podrían también deberse a que las dietas vegetarianas se asocian con un menor consumo de grasas totales y grasas saturadas, y con un mejor perfil de ingesta de ácidos grasos (34).

Khandelwal y cols. incluyeron el uso de suplementación (400 mg de DHA marino) en su estudio; observaron niveles significativamente más altos en las concentraciones de DHA, tanto en las muestras sanguíneas de las madres como en las de cordón umbilical, y en los hijos/as a los 6 y 12 meses de edad de las mujeres que fueron suplementadas con DHA en base a algas (22). Cada vez existen más suplementos de EPA y DHA disponibles en el mercado aptos para veganos, los cuales son principalmente de origen microbiano o de microalgas. Ryan y cols., buscado evaluar la viabilidad y la bioequivalencia de un suplemento de DHA (200 mg) de aceite de algas (*Schizochytrium*), observaron que se logró aumentar el %DHA, así como su concentración plasmática, en los vegetarianos y veganos de forma significativa (35).

La evidencia sugiere que en una dieta basada en plantas se debe consumir suficiente ácido α-linolénico y limitar la ingesta de ácido linoleico, esto, debido a la baja tasa de conversión de ALA a EPA y DHA. Además, se debe considerar la suplementación de DHA marino (27,36).

Tabla II. Recomendación de la suplementación de B12 en el embarazo y la lactancia

Grupo etario	En mantención			En déficit			
	Dosis única diaria	Dosis diaria simple	Dosis semanal	Vit. B12 sérica (< 101 pg/mL)	Vit. B12 sérica (101-203 pg/mL)	Vit. B12 sérica (203-298 pg/mL)	Vit. B12 sérica (298-406 pg/mL)
Embarazadas y lactantes	50 µg	2 µg x 3	1000 µg x 2	1000 µg/d por 4 meses	1000 µg/d por 3 meses	1000 µg/d por 2 meses	1000 µg/d por 1 mes
Niños de 6 meses a 3 años	5 µg	1 µg x 2	–	1 dosis de 250 µg/d o 3 dosis de 10 µg/d por 4 meses	1 dosis de 250 µg/d o 3 dosis de 10 µg/d por 3 meses	1 dosis de 250 µg/d o 3 dosis de 10 µg/d por 2 meses	1 dosis de 250 µg/d o 3 dosis de 10 µg/d por 1 mes

Adaptada de Baroni L, Goggi S, Battaglino R, Berveglieri M, Fasan I, Filippin D, et al. Vegan nutrition for mothers and children: Practical tools for healthcare providers. Nutrients 2018;11(1):5. DOI: 10.3390/nu11010005.

Para lograr obtener suficientes niveles de EPA y DHA en aquellos que sigan un patrón alimentario basado en plantas, se recomienda el consumo de alimentos ricos en ALA, como nueces, semillas, aceite de lino y chía, además de una adecuada proporción de ALA y w6, para favorecer la conversión (27). Su suplementación se aconseja de acuerdo con la etapa del ciclo de la vida (25) (Tabla III).

Tabla III. Recomendación de la suplementación de DHA preformado en el embarazo y la lactancia

Grupo etario	Dosis diaria
Embarazadas	100-200 mg DHA
Lactantes (6 meses a 3 años)	100 mg DHA

Adaptada de Baroni L, Goggi S, Battaglino R, Berveglieri M, Fasan I, Filippin D, et al. Vegan nutrition for mothers and children: Practical tools for healthcare providers. Nutrients 2018;11(1):5. DOI: 10.3390/nu11010005.

CONCLUSIÓN

La nutrición materna variada y equilibrada es fundamental para un buen desarrollo del embarazo y del feto. Una alimentación basada en plantas puede llevarse a cabo durante todo el ciclo vital, incluidos el embarazo y el periodo de lactancia, considerando la suplementación individualizada de B12, EPA y DHA para lograr cubrir las recomendaciones en estos periodos.

Si bien en la actualidad varias organizaciones de nutrición avalan las dietas basadas en plantas en todo el ciclo vital, la evidencia actualizada en torno a la ingesta y las concentraciones de B12, EPA y DHA en los periodos de embarazo y lactancia aún es escasa. Sin embargo, a la fecha, las dietas vegetarianas no han demostrado tener un mayor riesgo de daños a la salud sino, más bien, se ha observado que son más compatibles y beneficiosas en todo el ciclo vital.

La mayoría de los estudios analizados incluyeron participantes vegetarianos, veganos y no vegetarianos sin una definición estandarizada del patrón alimentario, sin información detallada referente a la dosis y tipo de suplementación utilizada, según el patrón alimentario. Además, el tamaño de los grupos de estudio y de control fue muy variado y en ciertos casos presentaron escasa cantidad de información respecto a la suplementación utilizada, la ingesta materna detallada, los niveles previos al embarazo de estos nutrientes, el estado nutricional y/o la composición corporal materna, entre otros. Es por esto que es importante continuar con la investigación en torno a la suplementación de B12, EPA y DHA en la alimentación vegetariana y vegana durante el embarazo y la lactancia, para así contribuir a la evidencia actual, considerando el número importante de madres que cada vez más adoptan este patrón alimentario.

Para una adecuada intervención nutricional es necesario considerar, por parte del profesional del área de nutrición, la recopilación detallada de información nutricional a través de una anamnesis alimentaria, una evaluación integral del estado nutricional, una estimación de requerimientos nutricionales y un plan nutricional individualizado, a fin de apoyar y guiar a las usuarias, tanto en los periodos de embarazo y lactancia como en todo el ciclo vital.

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Revisión

Correlation and comparison between different measurement sites of waist circumference and cardiovascular risk in children: a systematic review and meta-analysis

Correlación y comparación entre diferentes lugares de medición de la circunferencia de la cintura y el riesgo cardiovascular en niños: revisión sistemática y metaanálisis

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Abstract

Background: waist circumference (WC) is a component of metabolic syndrome (MetS) and an excellent marker for the risk of cardiovascular disease (CVD) in children. This study aimed to provide information on the anatomical measurement sites of WC and their comparative correlation with MetS and its components in children.

Methods: the literature search included papers published between January 2005 and September 2023 that met the following criteria: pediatric patients (2-18 years), WC measurement at different anatomical sites (≥ 2), and CVD risk by MetS. The quality of each study was determined using the STROBE and modified GRADE scales. The meta-analysis evaluated the $WC_{iliac\text{-}crest}$ and WC_{middle}.

Results: five observational studies (total population: 1,224) were included. WC was measured at 2-4 anatomical sites. In all studies, the correlations between different WC measurement sites and CVD risk were similar. The STROBE assessment ranged from 12-20/22 and the GRADE was A for all the articles. The meta-analysis showed that the heterogeneity (I^2 test) of the $WC_{iliac\text{-}crest}$ and WC_{middle} with CVD variables was substantial.

Conclusion: All WC measurement sites showed adequate correlation with CVD risk, with some small individual differences. WC_{narrow} and $WC_{umbilucus}$ have adequate consistency and could be excellent alternatives in daily clinical practice because of their ease of measurement. Further studies are needed to evaluate the correlation between different WC measurement sites and CVD risk in children stratified according to pubertal stage and sex.

Keywords:

Waist circumference.
Pediatric obesity.
Cardiovascular risk.
Metabolic syndrome.

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Resumen

Antecedentes: la circunferencia de la cintura (CC) es un componente del síndrome metabólico (SM) y un excelente marcador de riesgo cardiovascular (RCV). El objetivo de este estudio fue proporcionar información sobre los sitios de medición anatómica de la CC en niños y su correlación comparativa con el SM y sus componentes.

Métodos: búsqueda bibliográfica incluyó artículos entre enero 2005 y septiembre 2023 con los siguientes criterios: niños (2-18 años), CC medida en ≥ 2 sitios anatómicos y SM. La calidad de cada estudio se evaluó con las escalas STROBE y GRADE modificada. El metaanálisis evaluó la CC cresta iliaca y CC media.

Resultados: se incluyó cinco estudios observacionales (población total: 1224). Todos los estudios mostraron similares correlaciones entre los diferentes sitios de medición de CC y el RCV. La evaluación STROBE fue de 12-20/22 y GRADE fue A en todos los artículos. El metaanálisis mostró que la heterogeneidad (prueba I^2) de la CC cresta ilíaca y la CC media con las variables de RCV fue significativa.

Conclusión: todos los sitios de medición de la CC mostraron una correlación adecuada con el RCV, con algunas pequeñas diferencias. CC estrecha y CC umbilical tienen una consistencia adecuada y podrían ser excelentes alternativas en la práctica clínica diaria debido a la facilidad de medición. Se necesitan más estudios para evaluar la correlación entre diferentes sitios de medición de la CC y el riesgo de RCV en niños estratificados según la etapa puberal y el sexo.

Palabras clave:

Circunferencia de la cintura. Obesidad pediátrica. Riesgo cardiovascular. Síndrome metabólico.

INTRODUCTION

Waist circumference (WC) is the main indicator of abdominal adiposity and reflects the amount of visceral adipose tissue (VAT). Therefore, it is considered the best measurement for detecting patients at risk of cardiovascular disease (CVD) (1). CVD risk assessment in children with obesity has gained relevance because it may predict increased mortality in adulthood owing to coronary heart disease and stroke (2). Obesity in children is associated with type 2 diabetes *mellitus* (T2DM), dyslipidemia, arterial hypertension, non-alcoholic fatty liver disease, genu valgum, and obstructive sleep apnea (3). The pathophysiological mechanisms that lead to an increased risk of developing CVD with early atherosclerosis in patients with obesity (4) are related to increased insulin resistance (IR) (5) and activation of chronic inflammation (6). The CVD risk in children is assessed based on the presence of metabolic syndrome (MetS). The "Third Report of the National Cholesterol Education Program (NCEP) in Adults Panel of Treatment III" (7) defined MetS when a patient has three of the following components: abdominal obesity measured by WC, increased triglyceride (TG), decreased high-density cholesterol (HDL), hypertension, and fasting hyperglycemia or T2DM (8).

The detection of CVD risk factors is perform with WC measurement in the routine physical exam. Although this evaluation is practical and simple; several recommendations should be made for each anatomical measurement site (Fig. 1). The WC at the narrowest visual abdominal part (WC_{narrow}) was initially described by Lohman et al. (9) and later by the International Society for the Advancement of Kinanthropometry (ISAK) (10), the WC at the midpoint between the lower rib and the top of the iliac crest (WC_{middle}) by the World Health Organization (WHO) (11), and the WC above the border of the iliac crest ($WC_{iliac\text{-}crest}$) by the National Health and Nutrition Examination Survey (NHANES) (12). WC at the level of the umbilicus ($WC_{umbilicus}$) was described by Croft et al. (13) and Eisenmann et al. (14). WC_4 was unusual and described by Rudolf et al. (15).

Interestingly, the anatomical WC measurement site was not based on comparative correlation studies between different WC measurement sites and cardiovascular risk. The objective of this review is to evaluate anatomical WC measurement sites and their comparative correlation with other MetS components in children.

METHODS

The study protocol was registered in the Prospero ID CRD42023454847.

SEARCH STRATEGY

The literature search was conducted by AMBT, without language restriction in Lilacs, MEDLINE/PubMed, Web of Science, and Scopus databases on October 2023. Papers published between January 2005 and August 2023 were included. The PICO framework was used to develop search strategies and ensure comprehensive and bias-free searches: Population: Patients between 2-18 years. Intervention: WC measurement. Comparison: WC measurement at different anatomical sites (≥ 2). Diagnostic outcomes: CVD risk or other MetS components.

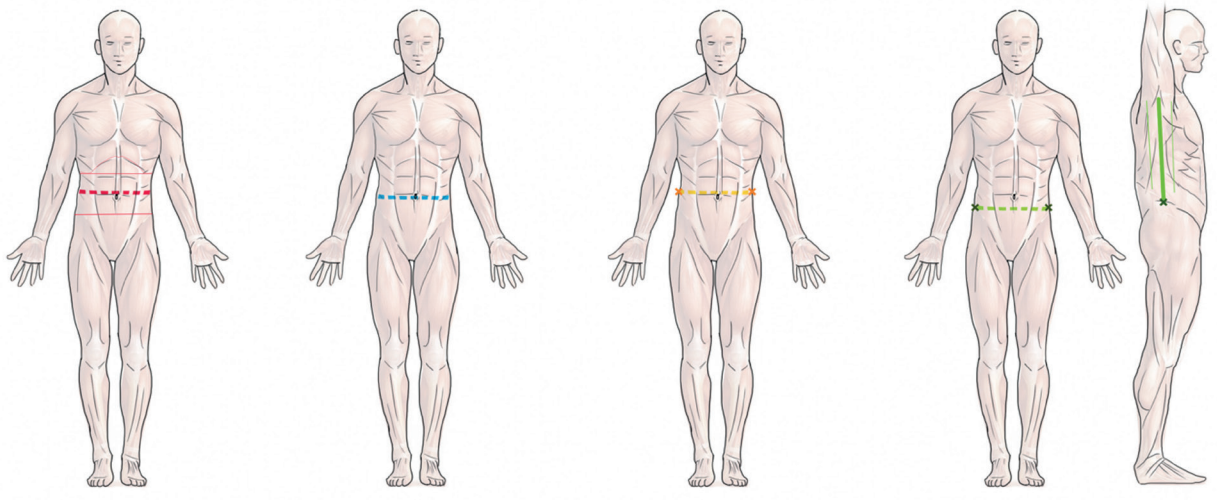
The combination of the boolean descriptors were: "Waist circumference" AND ("measurement anatomical sites" OR "Waist circumference AND pediatric OR cardiometabolic risk factor"). "Waist circumference" AND ("measurement anatomical sites" OR "Waist circumference AND pediatric OR metabolic syndrome"). "Waist circumference measurement sites" and "metabolic syndrome."

ELIGIBILITY CRITERIA

Observational studies that had ≥ 2 anatomical sites of WC and their correlation with MetS or other components of MetS.

STUDY QUALITY AND RISK OF BIAS ASSESSMENT

Eligible studies were assessed by two investigators independently (RGM and DBML). Any divergence was resolved by a third evaluator (LFMR). The quality of each study was determined using the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist (22 items) (16). The modified



WC_{middle}	$WC_{umbilicus}$	WC_{narrow}	$WC_{iliac\ crest}$
WHO (37,38)	Croft et al. (13)	ISAK (10)	NHANES (12)
Stand with arms relaxed on the sides. Measurement at the level of the mid-axillary line and the midpoint between the lower border of the last rib and the upper border of the iliac crest.	Standing. Tape measurement at navel level.	Standing with arms crossed over the chest. The examiner faces him and takes measurements at the narrowest level between the 10th rib and iliac crest. If it is not evident, the midpoint is taken.	Stand with arms crossed and hands on opposite shoulders. The examiner should be on the patient's right side. Measurement at the intersection of the mid-axillary line with the upper border of the iliac crest.

Figure 1.

WC measurement recommendations (WHO: World Health Organization; ISAK: International Standards for Anthropometric Assessment, United Kingdom; NHANES: National Health and Nutrition Examination Survey).

Grading of Recommendations Assessment, Development, and Evaluation (GRADE) scale (Table I) was applied, considering A (good), B (moderate), and C (low) when the paper characteristics were complete, partial, or non-specific, respectively.

THE STRATEGY OF DATA SYNTHESIS

The methodology of the systematic review followed the Cochrane Manual guidelines (17), and was adjusted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines (18).

STATISTICAL ANALYSES

Meta-analysis was performed with Jamovi 2.2.5 version (by EELH and MLEV) using WC coefficients of correlation with components of MetS included in 4/5 articles. Bosy-Westphal et al. (19) were excluded because they included both children and adults. The WC measurements included in the meta-analysis were the $WC_{iliac\text{-}crest}$ and WC_{middle}. Other WC measurements were

Table I. GRADE evaluation of the of the scientific articles

GRADE score for the characteristics of the paper: A. Completely described B. Partially described C. Not described
Characteristics described in the paper:
Inclusion and exclusion criteria
Methods of sample selection
Stratified by sex, social group, or lifestyle
Baseline valued described
WC measurement method description
Definition of cardiovascular risk or MetS and its components
Bias or confounders taken in account
Statistical analysis applied

GRADE: Grading of Recommendations, Assessment, Development and Evaluation; WC: waist circumference; MetS: metabolic syndrome.

excluded because there were only two publications of each one. A random effects model was used to fit the data. Analysis was performed using the Fisher r-to Z-transformed correlation coefficient. Heterogeneity was estimated using the Cochran Q test and I^2 statistic. If $I^2 > 50$ % or $p < 0.1$, heterogeneity of the results was considered. Studentized residuals and Cook distances were used to determine whether the studies were outliers or influential in the model context. Studies with a studentized residual larger than the $100 \times (1 - 0.05 / [2 \times k])$ th percentile of a standard normal distribution were considered potential outliers. Studies with Cook's distance greater than the median and six times the interquartile range of Cook´s distance were considered influential. The Begg and Muzumbar rank correlation test and Egge's regression test, using the standard error of the observed outcomes as a predictor, were used to verify the funnel plot asymmetry.

RESULTS

From 3,680 non-duplicate records, ten studies were selected because they evaluated ≥ 2 WC anatomical sites. After the full texts were reviewed, five studies were excluded because they did not include MetS components (Fig. 2). Finally, we included five studies with 1,224 children (5-18 years old) of both sexes: Hitze et al. (20) and Bosy-Westphal et al. (19) (both in the German group), Johnson et al. (21), Harrington et al. (22), and López et al. (23). Table II presents the characteristics of the studies. Bosy-Westphal et al. studied prepubertal and pubertal children and adults. Except for the study by López et al. (23), all other studies divided their results by sex. Harrington et al. (22) assessed children according to ethnicities(21). Each article measured WC at to 2-4 anatomical sites, which showed adequate reproducibility. WC of the inferior margin of the ribs (WC_{rib}) was measured in the German group (19,20). The WC at the level of the umbilicus ($WC_{umbilicus}$) and WC_{narrow} was measured by Johnson et al. (21) and Harrigton et al. (22). WC was measured four centimeters (cm) above the umbilical scar (WC_4) and was evaluated by Hitze et al. (20). The $WC_{iliac\text{-}crest}$ and WC_{middle} were measured in all studies included in this review.

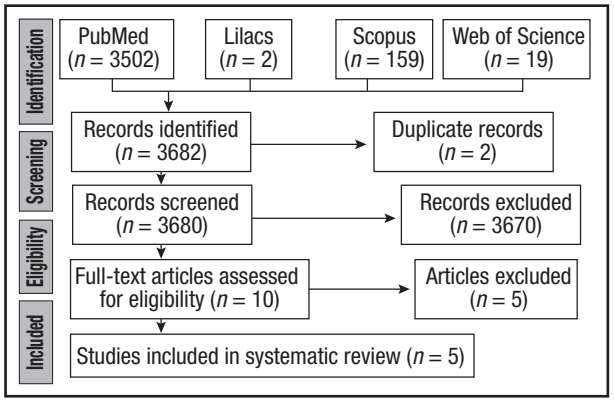


Figure 2.
Flow diagram of search results.

All studies evaluated WC while standing but with different arm positions: hanging freely (19,20) or crossing over the chest (21).

STATISTICAL EVALUATION IN THE INCLUDED STUDIES

Pearson's correlation was performed between each WC measurement site and MetS components in all articles. In some cases, adjustments for age (19,22), ethnicity (21), or logarithmic transformation of variables are necessary (19-23). The prevalence of obesity and MetS differed between these studies (21-23). Johnson et al. (21) described a different prevalence of MetS according to each definition criterion: the modified National Cholesterol Education Program (NCEP) (24), International Diabetes Federation (IDF) (25), and Cook et al. (26). López et al. (23) described MetS according to the IDF (Table II).

DIFFERENCES BETWEEN WC MEASUREMENT SITES

The studies showed that the magnitude of WC (cm) was different in measurement sites and that there were inherent to sex, ethnicity and puberal stage (20). The correlation between the magnitude of all WCs was strong (r = 0.93-0.99).

WC MEASUREMENT SITES AND METS

In Hitze et al. (20), in the female (F) group, all WC measurements showed positive correlations with systolic blood pressure (SBP), diastolic blood pressure (DBP), TG, glucose, and Homeostatic Model Assessment for Insulin Resistance (HOMA-IR), but they did not show any correlation with total cholesterol (TC) and low-density cholesterol (LDL). In the male (M) group, all WC measurements were positively correlated with DBP, LDL, and HOMA-IR. They did not show any correlation with the SBP, TG, TC, or glucose levels.

Bosy-Westphal et at. (19) showed that the WC measurement correlation at all anatomical measurement sites was adequate with abdominal fat, but it was better with subcutaneous adipose tissue (SAT) than with VAT. In prepubertal M, the relationship between the $WC_{iliac\text{-}crest}$ with VAT and HOMA-IR was lower than that in the other WC.

In Johnson et al. (21) the correlation coefficient showed a significant positive association between all WC measurement sites and the SBP, DBP, and HOMA-IR. The TG levels were positively correlated with WC_{narrow} and $WC_{middle.}$ Correlation between CVD risk variables and WC_{narrow} or WC_{middle} was slightly higher. The correlation between MetS and CVD risk was similar for all WC measurements, with only differences. According to the IDF definition of MetS, WC_{narrow} and WC_{middle} were significantly associated with MetS, and the number of MetS components. According to Cook's

definition of MetS, there was no association between MetS and all WC; however, WC_{narrow} and WC_{middle} showed significant odds ratios (OR) with the number of MetS components. For the definition of MetS according to the NCEP, an association was observed between MetS and WC_{narrow} or WC_{middle} but not with $WC_{iliac\text{-}crest}$ or $WC_{umbilicus}$.

Harrington et al. (22) evaluated the age-controlled correlation between WC and logVAT was significant in all the groups. The correlation between all anatomical measurement sites and MetS components was good, except for the glucose levels in the white-M and AA-F groups. There was no correlation between any WC measurement site and DBP in the white-M.

López et al. (23) reported a statistically significant correlation between WC_{middle} and $WC_{iliac\text{-}crest}$ and SBP, DBP, TG, and HDL levels. Glucose levels showed a low correlation with all WCs measurements.

The STROBE scale yielded a result between 12 and 20 points for 22 items. The modified GRADE scale results for all included articles were A (good evidence) (Table II).

META-ANALYSIS

Figure 3 shows the results of the meta-analysis. The random-effects model showed that the correlation of $WC_{iliac\text{-}crest}$ and WC_{middle} with the average variables of MetS differed significantly from 0. The $WC_{iliac\text{-}crest}$ and WC_{middle} I^2 test in all evaluations with the CVD risk variables showed heterogeneity: HDL (66.4 %, $p = 0.028$ and 69.12 %, $p = 0.019$), TG (77.96 %, $p = 0.006$ and 68.78 %, $p = 0.028$), SBP (94.68 %, $p < 0.001$ and 95.7 %, $p < 0.001$), and DBP (90.09 %, $p < 0.001$ and 90.56 %, $p < 0.001$). Glucose presented low heterogeneity in both WC (0 %, $p < 0.634$; 0 %, $p < 0.722$). In the studentized analysis, López et al. (23) presented atypical values for HDL, SBP, and DBP for WC_{middle} and $WC_{iliac\text{-}crest}$. Glucose analysis in both WC and TG in WC_{middle} showed no outliers. Hitze et al. (20) showed the possibility of an outlier in the correlation between WC_{middle} and TG levels. Cook's evaluation showed that none of the studies could be considered influential on any of the variables studied. Egge's regression analysis and Begg's rank correlation tests did not indicate asymmetry in the components of MetS evaluated; therefore, the construction of the funnel graph (Fig. 3) with a few studies generated the possibility of bias.

DISCUSSION

This review shows that the studies included had adecuate comparative correlation between all WC measurement sites and other MetS components except glucose which shows a low correlation. It provides an advantage because measurements are easier at certain anatomical points depending on the characteristics of each patient.

The correlation coefficient evaluation in this meta-analysis shows no difference in the correlation between WC_{middle} or $WC_{iliac\text{-}crest}$ and other MetS components. Studies carried out in different countries have shown that measuring WC_{middle} can predict the presence of MetS in pediatric patients (27,28). WC is considered a good predictor of MetS because it is positively correlated with MetS (29). A review in adult patients reported that there was no substantial difference in the WC measurement site protocols in terms of cardiovascular morbidity, and mortality (30).

We were not able to perform stratified analyses by sex, age, pubertal stage or ethnicity, because data were insufficient. Children are in constant development: this modifies the correlation between WC measurements at different anatomical sites and other MetS components. Fat distribution is very similar between girls and boys in their first childhood years, and then changes at puberty, the beginning of sexual development (31,32). Other studies have already shown these differences by sex in abdominal fat distribution, and some indicate that the presence of obesity does not seem to modify this distribution; that is, the WC_{narrow} is the smallest and the $WC_{umbilicus}$ is the largest (33). Furthermore, it is possible that the fat deposits distribution by ethnic group may contribute to different cardio-metabolic risk (34).

Some studies included in this review defined the overwaist at all anatomical sites using percentiles created for WC_{middle}. This may have modified their results because each WC anatomical measurement site should have specific percentile value. This is important when evaluating a clinical measurement that constitutes a diagnostic tool for MetS, and to avoid bias. We did not find percentile values for WC_{rib} in the literature, and there are only few population studies for the $WC_{umbilicus}$ (14) and WC_{narrow} (35,36).

In children and adolescents, all definitions of MetS (IDF, Cook, and ATP III) consider the same components, but there is great variability due to lack of standardization of the cut-off points. Similary, the frecuency of WC $\geq 90^{th}$ percentile varies according to the WC measurement site and the MetS definition used, modifying therapeutic decisions. The lack of consensus on the WC measurement site in children underestimates or overestimates the CVD risk, as reported in research studies on MetS.

All studies reviewed followed appropriate measurement techniques and standardization, although each author differed in the arms position. The subject's position standing upright with arms relaxed on both sides was described by Lohman et al. (9) to measure WC_{narrow} and by the WHO to measure WC_{middle} (37,38). Patients standing with arms crossed over their chest and hands on their shoulders were described by NHANES (12) to measure the $WC_{iliac\text{-}crest}$ and by ISAK (10) to measure WC_{narrow} (20-22). Thus, Lennie et al. (39) found significant differences in WC measurements performed at different positions in adults. There have been no studies on this topic in the pediatric population. In the smallest or very restless children, arms crossed on the chest and hands on the shoulders are more comfortable and provide more stability.

Technical difficulties in locating bony anatomical references in children with obesity are uncomfortable for patients (15); therefore, WC_{narrow} and $WC_{umbilicus}$ facilitate waist measurement. Some children with significant abdominal subcutaneous tissue have a hanging position at the umbilicus, which modifies the umbilical scar position.

Table II. Structured summary of the results of the included studies

Author, year		Hitze et al., 2008	Bosy-Westphal et al., 2009	Johnson et al., 2010	Harrington et al., 2013	López et al., 2016
Journal name (JRI)		*Obes Facts* (3.9)	*J Nutr* (4.2)	*J. Pediat* (3.7)	*Pediatr Obes* (3.42)	*Endoc Pract* (3.86)
Country-City		Germany-Kiel	Germany-Kiel	Canada-Edmonton	USA-Louisiana	Mexico-CDMX
n		180	234 (prepuberal 74, puberal 160)	73	371 (White 178, AA 193)	366
Inclusion criteria	Age (median or range)	13.2 ± 3.7 years	11.97 years (prepuberal, 9.05 years; puberal, 14.9 years)	8 to 17 years	5 to 18 years	10 to 18 years
	% Female	50.5	50.5	56.2	52.83	48.9
Exclusion criteria		Use of drugs that influence the results	Use of drugs that influence the results	Not indicated	Race other than white or AA	Genetic or endocrine obesity and drugs that influence the results
Measurement sites of WC	WC_{rib}	✓	✓			
	WC_{middle}	✓	✓	✓	✓	✓
	$WC_{iliac\ crest}$	✓	✓	✓	✓	✓
	WC_{narow}			✓	✓	
	$WC_{umbilicus}$			✓	✓	
	WC_4	✓				
WC measurement	Anthropometric tape	Nonelastic (no brand indicated)	Nonelastic (no brand indicated)	Spring-loaded (FitSystems) (Calgary, Alberta, Canada)	Not indicated	Nonstretchable fiberglass (no brand indicated)
	Position of the patient	Stand with arms hanging freely	Standing	Standing with arms crossed over the chest. Mirror to see that the tape measure did not slip down the back	Standing with arms relaxed at their sides	WHO and NHANES measuring method
	Precision and accuracy of their measurements	4 trained observers. Each observer simultaneously performed the measurements of the 4 sites. Intraobserver CV: WC_{narrow} 0.6 %, WC_4 1.5 %, WC_{middle} 1.1 %, $WC_{iliac\ crest}$ 0.7 %. Inter-observer CV: WC_{narrow} 1 %, WC4 1.9 %, WC_{middle} 1.9 %, $WC_{iliac\ crest}$ 3.1 %	4 trained nutritionists. CV intra observer e interobserver: WCnarrow 0.59 y 1.29 %; WCiliac crest 1.43 y 2.64 % y WCmiddle 1.19 y 2.52 %	The same clinical performed all measurements of WC sequentially 2 times. If they differed > 0.5 cm, a third sequence was taken	3 trained technicians. Interobserver and intraobserver CV: 0.98 and 0.99	Measurements were performed by a pediatric obesity specialist and a pediatric endocrinologist. Interobserver CV ±0.41 cm with kappa 0.95-0.98 at the different WC sites

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Table II (Cont.). Structured summary of the results of the included studies

Author, year		Hitze et al., 2008	Bosy-Westphal et al., 2009	Johnson et al., 2010	Harrington et al., 2013	López et al., 2016
Definition WC > 90th		WC_{middle} (31)	Not considered	*Fernández et al.* (32) ($WC_{iliac\ crest}$)	*Fernández et al.* (32) ($WC_{iliac\ crest}$)	*Fernández et al.* (32) ($WC_{iliac\ crest}$), *Klünder et al.* (33) (W_{middle})
Definition of MetS		Not assessed	Not assessed	MetS and its components were evaluated without WC with the definitions of IDF, NCEP and by Cook et al.	MetS components: HDL ≤ 45 mg/dL, TG ≥ 75 mg/dL (5-9 years) or ≥ 90 mg/dL (10-18 years). Fasting hyperglycemia ≥ 100 mmol/L). Hypertension = SBP or DBP ≥ 90th for age, sex, and height. Defined MetS when they had ≥ 2 components except WC	MetS according to IDF if they had 3 components (except WC): TG ≥ 150 mg/dL), HDL < 40 mg/dL) (M and F) and in ≥ 16 years in M < 40 mg/dL and in F < 50 mg/dL, glucose ≥ 100 mg/dL, arterial hypertension if SBP and/or DBP ≥ 130/85 mmHg
Study design		Cross-sectional, observational	Cross-sectional observational. Children and adults analyzed comparatively and separately	Cross-sectional observational in children with obesity (BMI ≥ 85th)	Cross-sectional, observational	Cross-sectional, observational in children with and without obesity
Sample size calculation		Not indicated	Not indicated	Not indicated	400	Not indicated
Statistical analysis	Correlation of each WC with components of MetS	Pearson correlation. Comparison between correlations was performed with the Meng et al. test	The strength of the correlation coefficients was compared with Meng's method. For the correlation between WC and CVD risk, the data were adjusted for age	Pearson correlation. Evaluated the association between BMI and MetS components. Both controlled for age, sex, and ethnicity	Pearson correlation, controlled for age	Pearson correlation
	Others	Variables with a non-normal distribution (SBP, DBP, TG, HDL, and glucose) were adjusted	TG, HOMA-IR levels were normalized by logarithmic transformation	Logistic regression to calculate the OR of MetS and increase in its components related to WC and BMI Z. All variables were adjusted for age and ethnicity	The difference between WC in cm was compared by repeated-measures ANOVA and Turkey post-hoc tests. VAT was adjusted	We determined the ROC curve to see the WC ≥ P 90th of both measurements and the waist-to-height ratio > 0.5 with the CVD risk variables
Prevalence of overweight/obesity		12.2 % with overweight (F:11 %, M:13.5 %)	Puberty: F: 26.1 %, M: 26.3 %. Prepuberty: F: 0 %, M:7.7 %	All with BMI > 85th, 95 % of children with BMI > 95th)	Obesity according: IOTF: 28 %, CDC: 33.4 %	Overweight: 24 %. Obesity: 55 %
Prevalence of MetS		Not evaluated	Not evaluated	NCEP: F: 39 %, M: 34 %. IDF: F: 43.9 %, M: 50 %. Cook: F: 39 %, M: 56.8 %	13.8 % (M White: 19 %, M AA: 10 %, F White: 16.9 % a F AA: 9.7 %)	IDF: 32.80 %

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Table II (Cont.). Structured summary of the results of the included studies

Author, year		Hitze et al., 2008	Bosy-Westphal et al., 2009	Johnson et al., 2010	Harrington et al., 2013	López et al., 2016
Differences between WC measurement sites		$WC_{rib} < WC_4 < WC_{middle} < WC_{iliac-crest}$ ($r > 0.93$, $p < 0.01$). WC_{rib} and WC_4 (cm) were lower in F. WC_{middle} and $WC_{iliac-crest}$ did not show differences between sexes. Prevalence WC ≥ 90th F and M was: WC_{rib}: 13.2 % and 15.7 %, WC_4: 14.3 % and 19.1 %, WC_{middle}: 18.7 % and 22.5 % and $WC_{iliac-crest}$: 37.4 % and 30.3 %	WC (cm) in prepuberty and puberty was: $WC_{rib} > WC_{middle} > WC_{iliac-crest}$ ($p < 0.001$)	WC (cm) by sex: M: $WC_{umbilicus} > WC_{iliac-crest} > WC_{middle} > WC_{narrow}$. WC_{narrow} *vs* $WC_{iliac-crest}$ ($p < 0.01$), or *vs* WCumbilicus ($p < 0.08$) and not significant *vs* WC_{middle}. F: $WC_{umbilicus} > WC_{iliac-crest} > WC_{middle} > WC_{narrow}$. WC_{narrow} was significantly different from all WC. Correlation between all WC: r = 0.93-1, $p < 0.0001$	WC (cm): White F $WC_{umbilicus} > WC_{iliac-crest} > WC_{middle} > WC_{narrow}$ ($p < 0.05$). White M and AA F no significant difference between $WC_{iliac-crest}$, and $WC_{umbilicus}$ AA M WC_{narrow} was statistically smaller. WC ≥ 90th = WC_{narrow}: 20.7 %, WC_{middle}: 29.6 %, $WC_{iliac\,crest}$: 31.5 %, and $WC_{umbilicus}$: 31.1 % (evaluated with percentile values of $WC_{iliac-crest}$)	All group: High SBP 7.7 %, fasting hyperglycemia 10.7 %, high TG 37.4 %., low HDL 56.4 %
Correlation of each WC with MetS components		F: All WC had positive correlation with SBP, DBP, TG, glucose, HOMA-IR and negative correlation with HDL. Not correlated: TC y LDL. M: All WC had positive correlation with DBP, LDL, HDL and HOMA-IR. Not correlation: SBP, TG, TC and glucose. The difference between correlation coefficients was significant ($p < 0.05$) in: F: $WC_{iliac-crest}$ *vs* WC_{rib} with the variable TG. M: $WC_{iliac-crest}$ *vs* WC_{rib}, WC_4 and WC_{middle} with LDL showed positive correlation ($p < 0.01$)	In all groups the correlation between all WC with SAT (r = 0.65-0.76) showed better correlation than VAT (r = 0.75 to 0.89). Correlation in prepubertal and pubertal between all WC with VAT was 0.73-0.87, with SBP 0.73-0.93 and similar with cardiovascular risk (numerical data not shown in the paper). Prepubertal M: correlation between $WC_{iliac-crest}$ with VAT (r = 0.65) and HOMA-IR (r = 0.13, $p < 0.05$); were lower than the other WC (WC_{middle} with VAT r = 0.76, and WC_{middle} with HOMA-IR r = 0.45, WC_{rib} and VAT r = 0.76 and WC_{rib} with HOMA-IR r = 0.33	Correlation between all WC with: SBP (r = 0.40-0.48), DBP (r = 0.37-0.46), Insulin (r = 0.43-0.63), HOMA-IR (r = 0.43-0.62). TG had positive correlation with WC_{narrow} and WC_{middle}. Correlation among WC_{narrow} and WC_{middle} was slightly stronger with CVD risk variables. Association of MetS for IDF: WC_{narrow} (OR 2.18; IC 1.23-3.85; $p = 0.007$) and WC_{middle} (OR 1.81; IC 1.06-3.09; $p = 0.03$); showed higher risk of MetS and number of MetS components. MetS - Cook definition: MetS was not associated with any WC; but it was associated with the number of components in WC_{narrow} (OR 2.10; IC 1.28-3.44; $p = 0.003$), WC_{middle} (OR 1.83; CI 1.13-2.98; $p = 0.01$). MetS-NCEP: was associated in WC_{narrow} (OR 3.80; CI 1.28-11.33; $p = 0.02$), and WC_{middle} (OR 3.24; CI 1.08-9.72; $p = 0.04$)	Correlation between all WC measurement sites: 0.97 to 0.99 (between all groups and by race and sex). Age-controlled correlation beatween WC and log VAT was significant in all groups: white and black M = 0.81-0.86, white F and AA = 0.87-0.89. Correlation of all WC with MetS components was strong except glucose for white M and AA-F. In AA-M the correlation between glucose with WC_{narrow} was lower but not with other WC. There was no correlation between all WC with DBP in white-M	Correlation between WC_{middle} was significant with SBP 0.72, DBP 0.63, glucose 0.13, TG 0.42 and HDL -0.46. Correlation between $WC_{iliac-crest}$ with: SBP 0.71, DBP 0.61, glucose 0.12, HDL -0.455. Sensitivity WC > 90th for WC_{middle} and $WC_{iliac-crest}$: Hypertension 88.9 and 81.5, hyperglycemia 64.1 and 59, hypertriglyceridemia 64.4 and 64.4, low HDL 63.1 and 65.1 and to identify ≥ 2 components of MetS was 67.9 and 68.8, respectively. The AUC for $WC_{middle} > 90^{th}$ and $WC_{iliac-crest} > 90^{th}$: hypertension (0.69 and 0.64), low HDL (0.62 and 0.62) and ≥ 2 components of MetS (0.617 and 0.608)
	STROBE	16	16	From 12 to 18	20	From 16 to 19
Evaluations of the quality of evidence	GRADE	A	A	A	A	A

JRI: journal rank indicator; AA: African American; WHO: World Health Organization; NCHS: National Center of Health Statistics; CV: coefficient of variation; MetS: metabolic syndrome; IDF: International Diabetes Federation; NCEP: National Cholesterol Education Program; HDL: high density lipoprotein cholesterol; TG: triglycerides; SBP: systolic blood pressure; DBP: diastolic blood pressure; M: male(s); F: female(s); BMI: body mass index; CVD: cardiovascular disease; HOMA-IR: Homeostatic Model Assessment for Insulin Resistance; OR: odds ratio; VAT: visceral adipose tissue; NPV: negative predictive value; PPV: positive predictive value. BMI: body mass index; IOTF: International Obesity Task Force; CDC: Centers for Disease Control and Prevention; NHANES: National Health and Nutrition Examination Survey; TC: total cholesterol; LDL: low-density lipoprotein cholesterol; SAT: subcutaneous adipose tissue; CI: confidence interval; AUC: area under the curve; STROBE: Strengthening the Reporting of Observational studies in Epidemiology; GRADE: Grading of Recommendations; Assessment; Development and Evaluation.

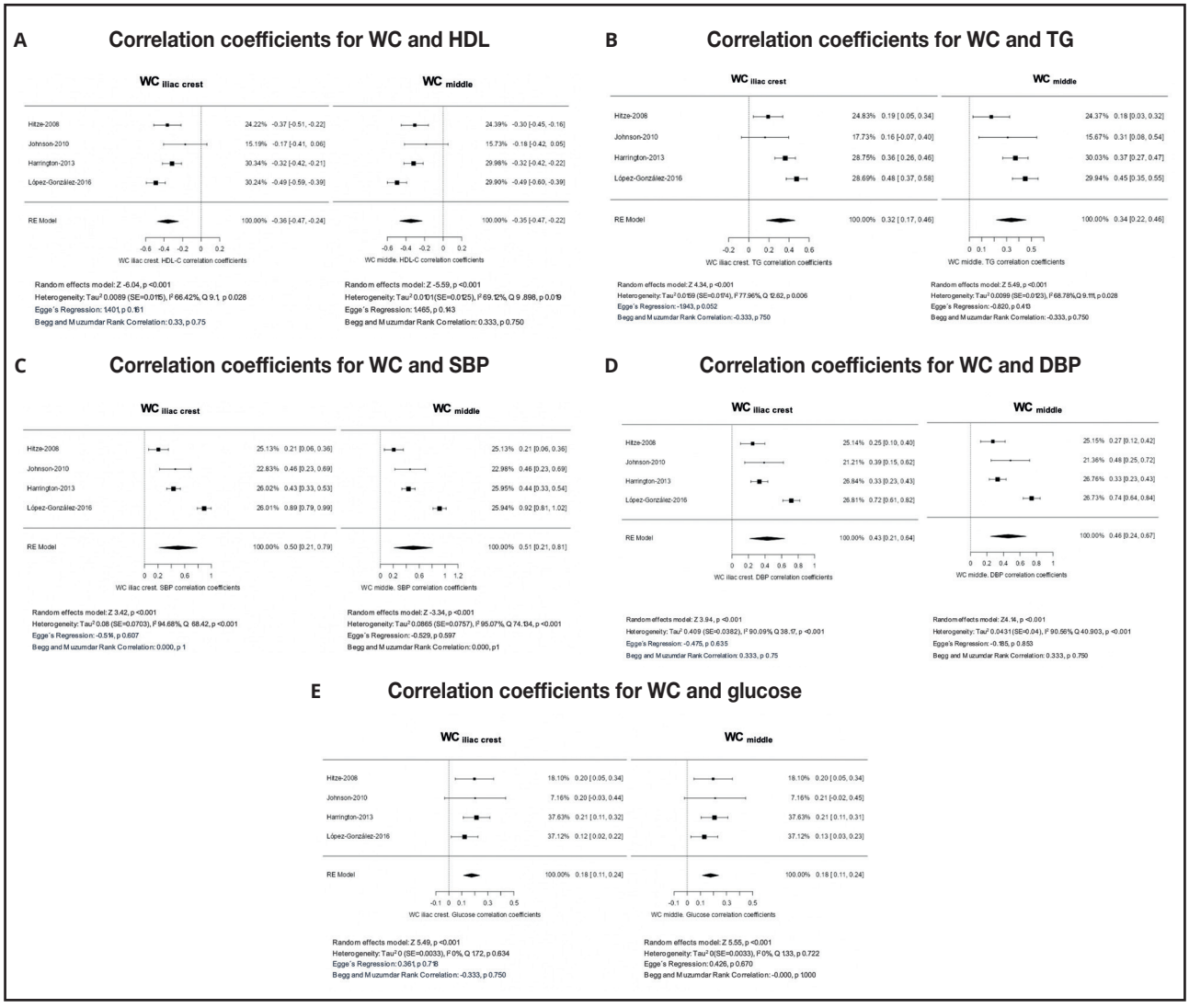

Figure 3.

Meta-analysis of correlation coefficients for $WC_{iliac\text{-}crest}$, WC_{middle}, and MetS components (WC: waist circumference; $WC_{iliac\text{-}crest}$: waist circumference measured above the iliac crest; WC_{middle}: waist circumference measured between the floating rib and the iliac crest; MetS: metabolic syndrome; HDL: high-density lipoprotein cholesterol; TG: triglycerides; SBP: systolic blood pressure; DBP: diastolic blood pressure) (Supplementary material: https://www.nutricionhospitalaria.org/anexos/05144-01.pdf).

However, this measurement may still be significant due to the prominence of the abdomen. In daily pediatric practice, WC is measured by physicians, nutritionists, pediatricians, and nurses. Work team training is essential to ensure precision in the technique and the anatomical site of measurement.

In table III, we summarize the strengths and weaknesses of each WC measurement site in children that can be better adapted to daily clinical practice according to training in measurement techniques and the characteristics of children.

A major limitation of our results is related to the fact that only few studies have assessed the correlation between different anatomical WC measurement sites and MetS in children and adolescents. This draws attention, considering that WC is the most relevant point for CVD risk exploration in clinical practice. Therefore, this systematic review should be the starting point for future studies on the specific characteristics of CVD risk according to age and sex at different measurement sites. It is essential to create specific percentiles for each WC measurement site for each ethnic group or population.

CONCLUSIONS

There is similar and adequate correlation between all WC measurement sites and other MetS components in the included studies, regardless the anatomical site of measurement. However, there are differences by age, pubertal development, and

Table III. Strengths and weaknesses of WC measurement sites

Measurement site	Strengths	Weaknesses
WC_{middle}	Established measurement protocol. Percentile tables in different ethnic populations. Good correlation with MetS	Difficulty in locating the anatomical point. Measurement can be uncomfortable and requires more time
$WC_{iliac\text{-}crest}$	Established measurement protocol. Percentile tables in different ethnic populations. Good correlation with MetS	Difficulty in locating the anatomical point. Difficult to stabilize the tape measure on a curved skin surface
WC_{rib}	Anatomical site location can be easy to locate and measure	No established measurement protocol. Not commonly used. May underestimate WC measurement
WC_{4}	Less comfortable and easier to locate in overweight or obese patients	No established measurement protocol. Not commonly used. The point of measurement can be at different sites on the abdomen, which can give a lot of variability
$WC_{umbilicus}$	Description of measurement protocol. Tables of percentiles in different ethnic population	Modification of umbilical scar location by adipose tissue descent in patients with obesity
WC_{narrow}	Established measurement protocol. Percentile tables in different ethnic populations. Good correlation with MetS	It is an anatomical site that may be difficult to visualize in some patients

ethnicity that have not yet been clearly defined.

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ARÁN

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Artículo Especial

Niveles máximos de vitaminas y minerales en alimentos enriquecidos y complementos alimenticios en la Unión Europea

Maximum levels of vitamins and minerals in fortified food and food supplements in the European Union

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Resumen

Introducción: la Comisión Europea y un grupo de trabajo de 7 Estados miembros de la UE, liderado por Alemania y con la participación de Bélgica, España, Francia, Grecia, Irlanda y Países Bajos, han estado tratando de fijar niveles máximos para la suplementación de vitaminas y minerales en alimentos enriquecidos y complementos alimenticios. Después de someterlo a la consideración de todos los Estados miembros, la Comisión consultará a las partes interesadas.

Objetivos: analizar la evolución y la situación actual de diversas cuestiones relacionadas con este fin.

Métodos: evaluación y comentarios sobre legislación de la UE aplicable, evolución de los valores de referencia de nutrientes en la UE y sugerencias para su posible actualización, recopilación de los niveles máximos de ingesta tolerable en la UE y de sus recientes actualizaciones, alternativas posibles cuando no hay niveles máximos de ingesta tolerable en la UE y encuestas de ingesta alimentaria efectuadas en algunos países de la UE.

Resultados: análisis de dos modelos dispares de establecimiento de niveles máximos de suplementación en la UE y comparación entre ambos modelos.

Conclusiones: sobre los dos objetivos a conseguir en la fijación de las cantidades máximas para esta suplementación, es decir, evitar que se sobrepasen los niveles máximos de ingesta tolerable de ciertos nutrientes y, al mismo tiempo, corregir déficits de ingesta de otros nutrientes, a fin de prevenir riesgos para la salud de grupos poblacionales; además, se sugiere la actualización de los valores de referencia de nutrientes y su ampliación con valores específicos para niños menores de 3 años.

Palabras clave:

Niveles máximos de vitaminas y minerales. Alimentos enriquecidos. Complementos alimenticios. Legislación de la Unión Europea. Valores de referencia de nutrientes. Niveles máximos de ingesta tolerable.

Abstract

Introduction: the European Commission and a Task Force of 7 EU member States, led by Germany and involving Belgium, Spain, France, Greece, Ireland and the Netherlands, have been trying to set maximum levels for vitamin and mineral supplementation in fortified foods and food supplements. After submitting it to all member States for consideration, the Commission will consult the stakeholders.

Objectives: to analyze the evolution and current situation on various issues related to this purpose.

Methods: evaluation and comments on the applicable EU legislation, evolution of the nutrient reference values in the EU and suggestions for their possible update, compilation on the tolerable upper intake levels in the EU and their recent updates, possible alternatives when there are no tolerable upper intake levels in the EU, and dietary intake surveys carried out in some countries of the EU.

Results: analysis of two different models for establishing maximum levels on supplementation in the EU and comparison between both models.

Conclusions: are formulated on the two objectives to be achieved in setting the maximum amounts for this supplementation, that is to say, to avoid that the tolerable upper intake levels of some nutrients are exceeded and, at the same time, to correct intake deficits in other nutrients, in order to prevent health risks on population groups; in addition, the updating of the nutrient reference values and their expansion with specific values for children under 3 years old are suggested.

Keywords:

Maximum levels of vitamins and minerals. Fortified foods. Food supplements. European Union legislation. Nutrient reference values. Tolerable upper intake levels.

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LEGISLACIÓN DE LA UE APLICABLE

En un artículo anterior (1) explicábamos la situación de no fijación a nivel comunitario de unos máximos armonizados para la adición de vitaminas y minerales en los complementos alimenticios. Han transcurrido más de 22 años desde la publicación de la Directiva 2002/46/CE que los regulaba parcialmente. Ante esta falta de armonización, mencionábamos cómo algunos países de la UE y otros países europeos habían establecido unos máximos diarios de esos micronutrientes en complementos alimenticios, mientras que otros, entre los que se incluye España, no lo habían hecho. Entre los países que han fijado niveles máximos, algunos de ellos, como es el caso de Hungría y Turquía, han establecido unos máximos iguales o próximos a los "niveles máximos de ingesta tolerable" (UL) (2,3), mientras que Alemania está en el extremo opuesto con máximos cercanos o incluso bastante inferiores a los *"valores de referencia de nutrientes"* (VRN). Entre ambos extremos se mueven los restantes países que los han fijado.

En dicho artículo nos focalizábamos en los niveles máximos recomendados por Francia en 2019 en complementos alimenticios. Advierten que la suplementación en niños < 3 años, embarazo y lactancia solo debe hacerse bajo supervisión de un profesional de la salud y aconsejan no ingerirlos en ciertas situaciones, en función del nutriente: mujeres que buscan quedar encintas, fumadores y los que toman algunas medicaciones o padecen ciertas enfermedades. Según sea el riesgo de los distintos nutrientes, los clasifican en 3 grupos:

- *Riesgo bajo:* sin fijación de máximos.
- *Riesgo moderado:* máximos (salvo para el magnesio) basados en la mitad del UL en adultos, reduciéndolo en 50 % en niños > 10 años y en 80 % en niños de 3-10 años (para la vitamina D son la mitad sus UL).
- *Riego elevado:* máximos basados en 25-80 % del UL en adultos, reduciéndolo (salvo para el beta-caroteno y el calcio) en 50 % en niños > 10 años y en 80 % en niños de 3-10 años.

En ese mismo artículo, comentábamos que el Reglamento (CE) 1925/2006, sobre la adición de vitaminas, minerales y otras sustancias determinadas a los alimentos, publicado 4 años más tarde, seguía los mismos criterios que la Directiva 2002/46/CE, al prever la consideración conjunta de tres factores para la determinación de los niveles máximos:

1. Los niveles máximos de seguridad de vitaminas y minerales (UL), tal como se hayan establecido mediante la evaluación científica del riesgo a partir de datos científicos reconocidos, teniendo en cuenta, según proceda, los diferentes grados de sensibilidad de las distintas categorías de consumidores (p. ej. niños, embarazo y lactancia).
2. La ingesta de vitaminas y minerales a partir de otras fuentes de alimentación (generalmente se toma el percentil 95 de ingesta de las encuestas alimentarias).
3. Las aportaciones de referencia de vitaminas y minerales (VRN).

En cuanto a las cantidades mínimas de vitaminas y minerales, cuando se añadan a los complementos alimenticios, el artículo 5.3 de la Directiva 2002/46/CE especifica que "con objeto de garantizar que los complementos alimenticios contengan cantidades suficientes de vitaminas y minerales, se establecerán, según proceda, cantidades mínimas por dosis diaria recomendada por el fabricante". No se ha fijado hasta ahora un criterio armonizado en la UE para este mínimo. Bélgica e Italia lo han fijado en un 15 % del VRN, opción que parece razonable y que podría ser adoptada a nivel de la UE e identificada como *"cantidad significativa"* a efectos de la aplicación del artículo 5.1.b.i) del Reglamento (CE) 1924/2006, relativo a las declaraciones nutricionales y de propiedades saludables en los alimentos.

En el caso de los alimentos enriquecidos, el artículo 6.6 del Reglamento (CE) 1925/2006 especifica que "la adición de una vitamina o un mineral en un alimento tendrá como resultado la presencia de dicha vitamina o mineral en el alimento en al menos una cantidad significativa…". La interpretación de qué es una "cantidad significativa" nos la da el Anexo XIII, parte A, punto 2 del Reglamento (UE) 1169/2011 sobre información alimentaria facilitada al consumidor:

- 15 % del VRN por 100 g o 100 ml, excepto en bebidas,
- 7,5 % del VRN por 100 ml, en bebidas, o
- 15 % del VRN por porción, si el envase solo contiene una porción.

No parece que tenga sentido condicionar la aplicación del 15 % del VRN por porción a que el envase contenga una sola porción, ya que si contuviera varias porciones también sería lógica su aplicación, tal como hace la Norma Codex (4) en las "Directrices para el uso de declaraciones nutricionales y saludables". Esta Norma considera también una "cantidad significativa" cuando se alcanza el 5 % del VRN por 100 kcal, teniendo en cuenta que con una ingesta de 2000 kcal se alcanzaría el 100 % del VRN:

- 15 % del VRN por 100 g en sólidos,
- 7,5 % del VRN por 100 ml en líquidos o
- 5 % del VRN por 100 kcal o
- 15 % del VRN por porción.

En algunos alimentos con una finalidad nutricional concreta, como es el caso de las soluciones electrolíticas con hidratos de carbono dirigidas a reponer las pérdidas de agua y electrolitos producidas por una sudoración intensa, se debería permitir que no se alcanzase el 7,5 % del VRN por 100 ml para algunos electrolitos (p. ej. potasio, calcio y magnesio) ya que sus pérdidas por transpiración resultan mucho menores. Para los sustitutivos de comidas para el control de peso, el Reglamento (UE) 2016/1413 fija unos mínimos por comida para las vitaminas y la mayoría de los minerales.

Los alimentos para lactantes y niños de corta edad (preparados para lactantes y preparados de continuación, alimentos a base de cereales y otros alimentos infantiles), los alimentos para usos médicos especiales y los sustitutivos de la dieta completa para el control de peso, están regulados por el Reglamento (UE) 609/2013 y sus actos delegados (5), los cuales establecen para vitaminas y minerales unos mínimos y máximos por 100 kcal o para la dieta diaria, no siéndoles de aplicación el Reglamento (CE) 1925/2006.

Nuevas fuentes de vitaminas y minerales han sido autorizadas en la UE para su empleo en complementos alimenticios y también, para la mayoría de estas fuentes, en alimentos enriquecidos. Se establecen, por lo general, unas cantidades máximas diarias o por 100 g o 100 ml y, siempre, la obligación de indicar la fuente adicionada en la lista de ingredientes del etiquetado de los alimentos. Hasta finales de junio del año 2024, han sido 19 las nuevas fuentes autorizadas (8 para 4 vitaminas y 11 para 7 minerales), las cuales están recogidas en el Reglamento (UE) 2017/2470, que establece la lista de nuevos alimentos de conformidad con el Reglamento (UE) 2015/2283, relativo a nuevos alimentos:

- *Vitaminas:* D (2 - calcidiol y con D_2), K (1 - K_2), niacina (2 - con nicotinamida) y folato (3 - metilado).
- *Minerales:* magnesio (1), hierro (4), zinc (1), selenio (1), cromo (2), boro (1) y silicio (1).

VALORES DE REFERENCIA DE NUTRIENTES (VRN) EN LA UE

Los VRN fueron introducidos en 1990 mediante la Directiva 90/496/CEE para el etiquetado nutricional de los alimentos y abarcaban 12 vitaminas y 6 minerales. La Directiva 2008/100/CE, que modificó la anterior, incorporó el VRN de la vitamina K y amplió el número de minerales con VRN: potasio, cloruro, cobre, manganeso, fluoruro, selenio, cromo y molibdeno. Al mismo tiempo, elevó los VRN de algunos micronutrientes (vitaminas E, C, B_{12} y magnesio) y disminuyó los de otros (tiamina, riboflavina, niacina, vitamina B_6, fósforo y zinc), manteniendo los del resto (vitaminas A, D, ácido pantoténico, calcio, hierro y yodo). Como ya denunciamos en otro artículo (6), en la Directiva 2008/100/CE se hubieran tenido que aumentar también los VRN de calcio (de 800 mg a 1000 mg) y de vitamina D (de 5 µg a 15 µg) pero, en el primer caso, la presión de la industria láctea europea y, en el segundo, la desidia de los responsables de impulsar la Directiva, lo frustraron. La publicación del Reglamento (UE) 1169/2011 hubiera sido un buen momento para corregir ambos errores, especialmente el del calcio, pues en 2011 la leche pasó de ser "fuente de calcio" (cantidad significativa al alcanzar el 15 % del VRN en 100 ml) a "alto contenido de calcio" (ya que el Reglamento la disminuyó al 7,5 % del VRN en 100 ml), propiciando así que las leches no enriquecidas en calcio se igualaran con las enriquecidas, al poder ambas utilizar la declaración nutricional "alto contenido de calcio". Los VRN actuales están diseñados a partir de los requerimientos nutricionales de la población adulta y no de los menores de edad. Otra cuestión que también denunciábamos en ese artículo es que para los alimentos, no incluidos en el Reglamento (UE) 609/2013, dirigidos exclusivamente a niños menores de 3 años, no se deberían aplicar los VRN de adultos sino los que establece el Anexo VII del Reglamento (UE) 2016/127 sobre preparados para lactantes y preparados de continuación. En el periodo 2013-2019 la EFSA publicó los *"valores de referencia de la dieta"* (DRV) de vitaminas y minerales (6,7), excepto para el cromo, boro y silicio. Los DRV se presentan en forma de *"ingesta de referencia para la población"* (PRI) o, en su defecto, de *"ingesta adecuada"* (AI). Han pasado 16 años desde la última actualización de los VRN y éstos merecerían una nueva revisión a fin de ajustarlos a los DRV de los adultos. Sugerimos en la tabla I la posibilidad de efectuar unos cambios en los VRN actuales:

- *Aumentarlos:* en vitaminas D, E, C, riboflavina, B_6, B_{12}, potasio, cloruro, calcio, hierro, zinc, cobre, manganeso, molibdeno y selenio.
- *Disminuirlos:* en vitaminas A, K, ácido pantoténico, fósforo y magnesio.

NIVELES MÁXIMOS DE INGESTA TOLERABLE (UL) EN LA UE

Los UL han sido definidos por la EFSA (8) como "el nivel máximo de ingesta diaria crónica total de un nutriente (de todas las fuentes) que no se espera que represente un riesgo de efectos adversos para la salud de los seres humanos". Los UL se obtienen a partir del *"nivel inferior de observación de efectos adversos"* (LOAEL) o del *"nivel de no observación de efectos adversos"* (NOAEL), dividiendo dichos niveles por un *"factor de incertidumbre"* (UF) igual o superior a 1. En el periodo comprendido entre los años 2000 y 2005, primero el Comité Científico para la Alimentación Humana (SCF) y luego la Autoridad Europea para la Seguridad Alimentaria (EFSA), emitieron dictámenes de UL para todas las vitaminas y minerales, los cuales fueron recopilados en 2006 por la EFSA (8). Fijaron un UL para:

- *Vitaminas:* A preformada, D, E, niacina (niveles muy desiguales entre ácido nicotínico y nicotinamida), B_6 y folato (añadido).
- *Minerales:* calcio, magnesio (añadido), zinc, cobre, yodo, selenio, molibdeno, fluoruro y boro (añadido).

Para otros micronutrientes no les fue posible establecer un NOAEL, ni tampoco un LOAEL, por insuficiencia de datos experimentales o de observación y, en consecuencia, no pudieron fijar un UL:

- *Vitaminas:* beta-caroteno, K, C, tiamina, riboflavina, ácido pantoténico, biotina y B_{12}.
- *Minerales:* sodio, potasio, cloruro, fósforo, hierro, manganeso, cromo y silicio.

En 2012 la EFSA (6) revisó los UL de calcio y vitamina D. Para el calcio mantuvo el UL de 2500 mg/d para los adultos, sin fijar UL para < 18 años. Para la vitamina D dobló los UL anteriores, pasando de 25 a 50 µg/d en niños de 1-10 años y de 50 a 100 µg/d en personas > 10 años, y mantuvo el UL de 25 µg/d para los lactantes.

En 2020-2021 la Comisión Europea encargó a la EFSA la revisión de algunos UL y la fijación de nuevos UL. La EFSA, tras establecer en 2022 una guía para su fijación y aplicación (9), ha emitido los correspondientes dictámenes en 2023 y 2024:

- *Revisión UL:* vitaminas A preformada, D, E, B6, folato (añadido) y selenio. Además, la EFSA ha reevaluado los UL del cobre.
- *Nuevos UL:* beta-caroteno, hierro y manganeso.

Tabla I. Propuesta de nuevos valores de referencia de vitaminas y minerales para adultos

Micronutrientes	Unidad	VRN (valor referencia nutriente)	PRI o AI fijados por la EFSA	Nuevo VRN propuesto
Vitaminas				
A (equivalentes de retinol)	µg	800	650-750	750
D (colecalciferol)	µg	5	15	15
E (equivalentes α-tocoferol)	mg	12	11-13	13
K (fitomenadiona)	µg	75	70	70
C (ácido ascórbico)	mg	80	95-110	110
B_1 (tiamina)	mg	1,1	0,84-1,05	1,1
B_2 (riboflavina)	mg	1,4	1,6	1,6
B_3 (niacina)	mg	16	13,4 – 16,8 EN	16
B_5 (ácido pantoténico)	mg	6	5	5
B_6 (piridoxina)	mg	1,4	1,6-1,7	1,7
B_8 (biotina)	µg	50	40	40
B_9 (folato)	µg	200	330 EFD	200
B_{12} (cianocobalamina)	µg	2,5	4	4
Minerales				
Calcio (Ca)	mg	800	950-1000	1000
Fósforo (P)	mg	700	550	550
Magnesio (Mg)	mg	375	300-350	350
Hierro (Fe)	mg	14	11-16	16
Zinc (Zn)	mg	10	10-13	13
Yodo (I)	µg	150	150	150
Cobre (Cu)	mg	1	1,3-1,6	1,6
Manganeso (Mn)	mg	2	3	3
Molibdeno (Mo)	µg	50	65	65
Selenio (Se)	µg	55	70	70
Cromo (Cr)	µg	40	NE	40
Sodio (Na)	mg	NE	2000	
Potasio (K)	mg	2000	3500	3500
Cloruro (Cl)	mg	800	3100	3100
Fluoruro (F)	mg	3,5	2,9-3,4	3,5
Boro (B)	mg	NE	NE	
Silicio (Si)	mg	NE	NE	

PRI: Population Reference Intake (ingesta de referencia para la población).
AI: Adequate Intake (ingesta adecuada).
NE: no establecido
Vitamina B1: PRI = 0,1 mg x (8,4 – 10,5 MJ) = 0,84 – 1,05 mg.
Niacina: 1 mg equivalente de niacina (EN) = 1 mg niacina preformada = 60 mg triptófano de la dieta. PRI = 1.6 mg EN/MJ = 1,6 mg x (8,4 – 10,5 MJ) = 13,4 – 16,8 mg EN.
Folato: 1 µg equivalente de folato en la dieta (EDF) = 1 µg folato de fuente natural + 1,7 x µg folato añadido si es <400 µg (o 2 si es ≥400 µg)
Zinc: los PRI de zinc aumentan con la cantidad de fitato de la dieta (300 y 1200 mg/d, respectivamente, para ambos extremos de las horquillas), debido a su efecto inhibitorio sobre la absorción de zinc. Mujeres 7,5-12,7 mg y Hombres 9,4-16,3 mg, según la cantidad de fitatos en la dieta.

VITAMINA A PREFORMADA Y BETA-CAROTENO

Para la *vitamina A preformada,* la EFSA (10) ha mantenido los UL anteriores, excepto para las mujeres a partir de la menopausia para las cuales el SCF fijó un UL de 1500 µg/d y la EFSA lo ha igualado a los 3000 µg/d aplicables a toda la población adulta, ya que no ha apreciado en estas mujeres una salud ósea disminuida con ingestas ≤ 3000 µg/d. En cuanto al *beta-caroteno,* la EFSA (10) no ha podido establecer un UL, al no observar efectos adversos, excepto en fumadores a los cuales desaconseja su consumo, y ha indicado que su ingesta como nutriente debe limitarse al objetivo de alcanzar los requerimientos de vitamina A. Aplicando el factor de conversión de beta-caroteno/retinol de 6:1, el PRI de 750 µg/d de retinol para los hombres adultos y el de 650 µg/d para las mujeres adultas equivalen a 4,5 y 3,9 mg/d de beta-caroteno, respectivamente.

VITAMINA D

La EFSA (11) ha mantenido los UL que fijó en 2012, excepto para los lactantes de 6 a 12 meses para los cuales lo aumentó en 2018 de 25 a 35 µg/d.

VITAMINA E

La EFSA (12) ha mantenido los UL establecidos en 2003 por el SCF, siendo de 300 mg/d para los adultos. En determinados tipos de pacientes no se deben aplicar estos UL y su suplementación debe ser bajo supervisión médica: medicación anticoagulante o antiplaquetaria, prevención secundaria de enfermedades cardiovasculares, síndromes de malabsorción de vitamina K o condiciones causantes de deficiencia de vitamina E.

VITAMINA B_6

La EFSA (13) ha considerado adecuado el LOAEL de 50 mg/d aplicado por el SCF en el año 2000 pero ha doblado el UF, aumentándolo de 2 a 4, debido a la limitación de datos disponibles. Por ello, los UL han disminuido a la mitad, pasando en la población adulta de 25 a 12 mg/d.

FOLATO

El SCF no fijó un UL para el folato presente en los alimentos de forma natural, al no haber observado efectos adversos. Para el folato añadido a los alimentos, los UL que estableció el SCF en el año 2000 han sido mantenidos por la EFSA (14), siendo de 1000 µg/d para los adultos.

HIERRO

La EFSA (15) no ha podido establecer unos UL. En su lugar, ha establecido unos *"niveles de ingesta segura",* que en el caso de la población adulta es de 40 mg/d, incluyendo embarazo y lactancia. Para niños de 1-17 años, la EFSA ha fijado estos niveles mediante una escala alométrica (peso corporal) a partir del UL de los adultos. En el caso de los lactantes de 4-11 meses, estos niveles se aplican solo al hierro añadido a los alimentos enriquecidos y complementos alimenticios. No se aplican a las personas que reciben hierro bajo supervisión médica.

COBRE

La EFSA (16) ha considerado que el UL de 5 mg/d para adultos que estableció el SCF en 2003 es suficientemente prudente y, en consecuencia, ha mantenido los UL del SCF.

SELENIO

La EFSA (17) se ha basado en el NOAEL de 330 µg/d de extensos ensayos aleatorizados en humanos, que dividido por un UF de 1,3 da un UL de 255 µg en adultos, inferior al de 300 µg definido previamente por el SCF. Basándose en ese nuevo UL para los adultos, mediante una escala alométrica (peso corporal^{0,75}), ha establecido unos UL para < 18 años.

MANGANESO

Dado que la EFSA (18) no ha podido fijar unos UL, a partir de los datos de ingesta del percentil 95 de cuatro países ha establecido unos "niveles de ingesta segura", que es de 8 mg/d en el caso de los adultos.

UL ACTUALES

- *Vitaminas:* en la tabla II se recogen, para las distintas edades, embarazo y lactancia, los UL establecidos por el SCF y la EFSA.
- *Minerales:* en la tabla III se reflejan, para las distintas edades, embarazo y lactancia, los UL fijados por el SCF y la EFSA o, en su lugar, los "niveles de ingesta segura" de la EFSA.

ALTERNATIVAS CUANDO NO HAY UL EN LA UE

Quedan algunas vitaminas y minerales sin UL o sin "nivel de ingesta segura". Ante su ausencia, se podrían emplear las alternativas que proponemos.

Tabla II. Nivel máximo de ingesta tolerable (UL) para 6 vitaminas. EFSA 2006-2024

Edad, sexo y situación	A preformada µg ER/d	D (EVD) µg/d	E (α-T) mg/d	Niacina Ácido nicotínico mg/d	Niacina Nicotinamida mg/d	B6 mg/d	Folato añadido µg/d
4-6 meses	600	25	50	NE	NE	2,2	200
7-11 meses	600	35	60	NE	NE	2,5	200
1-3 años	800	50	100	2	150	3,2	200
4-6 años	1100	50	120	3	220	4,5	300
7-10 años	1500	50	160	4	350	6,1	400
11-14 años	2000	100	220	6	500	8,6	600
15-17 años	2600	100	260	8	700	10,7	800
≥ 18 años	3000	100	300	10	900	12	1000
Embarazo	3000	100	300	NE	NE	12	1000
Lactancia	3000	100	300	NE	NE	12	1000

NE: no establecido. Vitamina A: *1 µg equivalentes de retinol (ER) = 1 µg de retinol (vitamina A preformada) = 6 µg de beta-caroteno. Vitamina D: 1 µg equivalentes de vitamina D (EVD) = 1 µg colecalciferol (D_3) = 1 µg ergocalciferol (D_2) = 0,4 µg monohidrato de calcidiol = 40 UI. Vitamina E: α-tocoferol (α-T). Se aplica a todas las formas estero-isoméricas de α-T.* Vitaminas sin UL establecido: *beta-caroteno, K, C, tiamina, riboflavina, ácido pantoténico, biotina y B_{12}.*

Tabla III. Nivel máximo de ingesta tolerable (UL) para 11 minerales. EFSA 2006-2024

Edad, sexo y situación	Ca mg/d	Mg añadido mg/d	Fe mg/d	Zn mg/d	Cu mg/d	I µg/d	Se µg/d	Mn mg/d	Mo µg/d	F mg/d	B añadido mg/d
4-6 meses	NE	NE	5	NE	NE	NE	45	2	NE	NE	NE
7-11 meses	NE	NE	5	NE	NE	NE	55	2	NE	NE	NE
1-3 años	NE	NE	10	7	1	200	70	4	100	1,5	3
4-6 años	NE	250	15	10	2	250	95	5	200	2,5	4
7-10 años	NE	250	20	13	3	300	130	6	250	2,5-5	5
11-14 años	NE	250	30	18	4	450	180	6	400	5	7
15-17 años	NE	250	35	22	4	500	230	7	500	7	9
≥ 18 años	2500	250	40	25	5	600	255	8	600	7	10
Embarazo	2500	250	40	25	NE	600	255	8	600	7	10
Lactancia	2500	250	40	25	NE	600	255	8	600	7	10

NE: no establecido. Magnesio: añadido mediante sales rápidamente disociables (p. ej. cloruro, sulfato, aspartato, lactato) y compuestos (p. ej. óxido). Hierro: son "niveles de ingesta seguros" pues no se ha podido fijar UL. En lactantes se refiere solo al hierro suplementario de alimentos enriquecidos y complementos alimenticios. Manganeso: son "niveles de ingesta seguros" pues no se ha podido fijar UL. Minerales sin UL establecido: sodio, cloruro, potasio, fósforo, cromo y silicio.

Aunque la EFSA no pudo establecer UL para estos nutrientes, en 2004 y 2005 emitió consideraciones útiles sobre algunos de ellos y en 2010 sobre el cromo:

- *Vitamina C (19):* dosis suplementarias de hasta 1 g diario no han sido asociadas con efectos gastrointestinales adversos.
- *Fósforo (20):* las personas sanas pueden tolerar ingestas ≤ 3000 *mg*/d, aunque en algunas de ellas una suplementación > 750 *mg*/d puede provocar síntomas gastrointestinales leves.
- *Sodio (21):* los elevados niveles de ingesta de sodio en Europa (3-5 g/d), en un 70-75 % provenientes de alimentos procesados, contribuyen a incrementar la presión sanguínea, lo que provoca enfermedades cardiovasculares y renales.
- *Potasio (22) y cloruro (23):* una ingesta de potasio de 5-6 g/d de fuentes alimentarias se considera segura para la población sana. La suplementación de 3 g/d de potasio en forma de cloruro potásico (2,72 g/d de cloruro) no causa efectos adversos.
- *Cromo (24):* admitió el nivel máximo de 250 µg/d de suplementación establecido por la OMS en 1996.

Podría utilizarse el UL que estableció el *Food and Nutrition Board* de los EUA en 1997:

- *Calcio para niños (25):* 0-6 meses 1000 mg, 6-12 meses 1500 mg, 1-8 años 2500 mg y 9-18 años 3000 mg.

La FAO/OMS (26) publicó en 2002 un informe sobre los requerimientos de vitaminas y minerales:

- *Vitamina B_{12}:* con la ingesta de 1000 µg no se han reportado efectos adversos.

Guía de valores máximos de suplementación en la población adulta (para un peso de 60 kg) del *Expert Group on Vitamins and Minerals* de 2003 del Reino Unido (27), con los cuales no se espera que se produzcan efectos adversos:

- *Vitamina K:* 200 µg/d. Según el SCF (8), en pacientes que reciben anticoagulantes cumarínicos *únicamente* se debería suplementar bajo supervisión médica.
- *Tiamina:* 100 mg/d.
- *Riboflavina:* 43 mg/d.
- *Ácido pantoténico:* 200 mg/d.
- *Biotina:* 900 µg/d.
- *Silicio:* 700 mg/d. Coincide con el máximo recomendado por Francia en complementos alimenticios para los adultos (1).

ENCUESTAS DE INGESTA ALIMENTARIA EN LA UE

A falta de una encuesta representativa del conjunto de la UE, se recogen en la tabla IV los datos de 8 países que las han realizado a nivel estatal. En España se han realizado 5 estudios a nivel estatal, 3 en niños y adolescentes (ANSALMA [28], ENALIA [29] y EsNuPi [30]) y 2 en niños mayores y adultos (ENIDE [31] y ANIBES [32]). Comentamos los resultados, en cuanto a vitaminas y minerales, de EsNuPi y ANIBES, por ser los más recientes y no solaparse las edades entre ambos.

Tabla IV. Encuestas de ingesta alimentaria realizadas en países de la UE

País	Edad (años)	Encuesta	Año
Alemania	< 1-4	VELS	2002-2003
	6-11	EsKiMo II Nationale	2015-2017
	14-80	Verzehrsstudie II	2008
España	0,5-3	ANSALMA	2013
	0,5-17	ENALIA	2012-2014
	1-9	EsNuPi	2019
	18- 64	ENIDE	2011
	9-75	ANIBES	2013
Finlandia	< 1-6	DIPP	2001-2009
	13-15	NWSSP	2007-2008
	25-74	FINDIET	2012-2017
Francia	3-79	INCA 2	2006-2007
Irlanda	5-12	NANS	2003-2004
	18-90	NCFS	2008-2010
Italia	< 1-98	INRAN SCAI	2005-2006
Países Bajos	7-69	DNFCS	2007-2010
Suecia	18-80	RIKSMATEN	2010

El estudio EsNuPi (1-9 años) permitió detectar que los niños que recibían leches adaptadas (enriquecidas) tenían, en general, un patrón de consumo *más saludable.* Nutrientes que condicionan la salud ósea:

- *Calcio:* el 26 % de los niños ≥ 4 años que recibían leches no adaptadas tenían una ingesta media inferior al *requerimiento medio* (AR, 680 mg/d), siendo el 15 % en los que recibían leches adaptadas. En los niños de 1 a < 4 años < 1 % tenían una ingesta inferior al AR (390 mg/d).
- *Fósforo:* el 100 % de los niños excedían las AI (250-440 mg/d), lo que también sucede en individuos de 10-75 años (31,32).
- *Magnesio:* la media y la mediana de las ingestas están próximas a las AI (170-230 mg/d).
- *Vitamina D:* el 100 % de los niños tenían una ingesta inferior a la AI (15 µg/d), con una media de 3 µg/d los que recibían leches no adaptadas y de 7,3 µg/d los que recibían leches adaptadas.

El estudio ANIBES (9-75 años) comparó las ingestas reportadas de forma plausible con el 80 % del DRV de la EFSA y detectó que un alto porcentaje de esta población tenía una ingesta de algunos micronutrientes inferior al 80 % del DRV:

– *Vitaminas:* D 89 %, folato 88 %, E 59 %, C 42 % y A 39 %.
– *Minerales:* zinc 65 %, calcio 44 % y magnesio 40 %, así como hierro 49 % de las mujeres.

MODELOS PARA ESTABLECER NIVELES MÁXIMOS DE SUPLEMENTACIÓN EN LA UE

En artículos anteriores (1,2) ya nos referimos a algunos modelos propuestos para fijar los máximos de vitaminas y minerales en alimentos enriquecidos y complementos alimenticios en la UE. Nos centramos en dos modelos publicados más recientemente: Flynn (33) (2017) y BfR (34) (2021).

MODELO FLYNN IRLANDÉS

Este modelo, promovido por un grupo de investigadores de la *School of Food and Nutritional Sciences, University College* de Cork liderado por Albert Flynn, se basa en los datos de ingesta de la población irlandesa (Tabla IV). Fija unos *"niveles máximos seguros"* (SML) de vitaminas y minerales en complementos alimenticios y alimentos enriquecidos. Con los datos procedentes de 1274 adultos de 18-64 años y 298 niños de 7-10 años de la ingesta de 7 nutrientes (retinol, vitaminas D, E, B_6, ácido fólico añadido, calcio y hierro) de alimentos convencionales (C), alimentos enriquecidos (F o FF) y complementos alimenticios (S), establece un modelo que calcula de forma separada, para restarla del UL, la ingesta (I) del percentil 95 de (C + FF), en el caso de los complementos alimenticios, y la ingesta del percentil 95 de (C + S), en el caso de los alimentos enriquecidos. En la tabla V se detallan los parámetros de este modelo:

– *Complementos alimenticios:* SML_S (por cantidad diaria) = UL - $(CI + FFI)_{95}$.
– *Alimentos enriquecidos:* SML_F (por cantidad diaria) = UL - $(CI + SI)_{95}$.

Resultados: los SML_s en complementos alimenticos fueron menores en niños que en adultos, excepto para el calcio y hierro. La ingesta energética diaria de alimentos enriquecidos de consumidores con altas ingestas de dichos 7 nutrientes (percentil 95) osciló entre 138-342 kcal en adultos y 50-309 kcal en niños, y sus SML_F por 100 kcal fueron menores en niños que en adultos para las vitaminas B_6 y D, mayores para la vitamina E y con pequeñas diferencias para los demás nutrientes. La inclusión de una sobredosificación del 25 % para dichos nutrientes en alimentos enriquecidos y complementos alimenticios tuvo poca repercusión en los SML. Cantidades significativas de estos nutrientes pueden ser añadidas a ambos tipos de alimentos para los dos grupos poblacionales y ambos SML pueden considerarse seguros a largo plazo.

Respecto a los alimentos enriquecidos, menciona que la falta de datos sobre su contribución específica en las ingestas de vitaminas y minerales y, en particular, en la ingesta energética total, ha conllevado a hipótesis excesivamente conservadoras y a la aplicación de UF adicionales a fin de minimizar el riesgo de exceso de ingesta en subgrupos poblacionales, lo que ha derivado en una subestimación de los SML_F.

Tabla V. Parámetros del modelo irlandés de Flynn y colaboradores

Niveles máximos seguros (SML) En complementos alimenticios y alimentos enriquecidos son los que aseguran que no se excede el UL en consumidores con altas ingestas (percentil 95) de nutrientes (vitaminas y minerales) a partir de otras fuentes dietéticas
Complementos alimenticios (S) Los SML_S de nutrientes fueron estimados mediante la diferencia del UL y el percentil 95 de la ingesta conjunta de nutrientes de alimentos convencionales (CI) no enriquecidos (excepto cuando su adición sea obligatoria) y de alimentos enriquecidos (FFI). Se expresa por dosis diaria en un complemento alimenticio: SML_S (por dosis diaria) = UL – $(CI + FFI)_{95}$
Alimentos enriquecidos (F o FF) Los SML_F de nutrientes fueron estimados mediante la diferencia entre el UL y el percentil 95 de la ingesta conjunta de nutrientes de alimentos convencionales (CI) no enriquecidos (excepto cuando su adición sea obligatoria) y de complementos alimenticios (SI). Expresado por cantidad diaria en un alimento enriquecido: SML_F (por cantidad diaria) = UL - $(CI + SI)_{95}$ También se expresa por 100 kcal de la ingesta usual diaria de energía de alimentos enriquecidos con el nutriente específico para grandes consumidores (percentil 95) de energía de estos alimentos (EFF_{95}): SML_F (por 100 kcal) = [UL - $(CI + SI)_{95}$]/[EFF_{95}/100] = SML_F (por cantidad diaria)/(EFF_{95}/100)

MODELO BfR ALEMÁN

El modelo del Instituto Federal Alemán para la evaluación de riesgos (BfR) es mucho más restrictivo que el de Flynn, pues está basado fundamentalmente en evitar cualquier posible exceso de ingesta total de vitaminas y minerales por encima de los UL. Afirma que los complementos alimenticos pueden resultar aconsejables en casos aislados y que no son necesarios para la mayoría de la población, la cual tiene un buen estado nutricional. Añade que los suplementos son más utilizados por personas que tienen buenos estilos de vida y dietas equilibradas. También que los estudios científicos internacionales han demostrado que no se esperan beneficios para la salud de ingestas de micronutrientes por encima de los requerimientos y que el uso de complementos alimenticios con altas dosis y el consumo adicional de alimentos enriquecidos comportan unos niveles de ingesta elevados e incrementan el riesgo de ingesta excesiva.

Este modelo diseña unos máximos diarios para las 13 vitaminas y los 17 minerales. Para muchos nutrientes toma como base el UL y le resta el percentil 95 de ingesta de alimentos convencionales (excluyendo los enriquecidos y los complementos alimenticios) para el grupo de edad de ingesta más elevada (adultos y adolescentes de 15-17 años). El margen resultante lo divide entre 2, dejando un 50 % para su uso en complementos alimenticios y el otro 50 % para su uso en alimentos enriquecidos, es decir, considerándolos de forma conjunta y no de forma

separada como el modelo de Flynn. Ello conduce a unos niveles máximos más reducidos. Para algunos micronutrientes vuelve a dividir por 2 el margen que queda para su adición en complementos alimenticios a fin de compensar el riesgo de consumo de más de un complemento con el mismo nutriente. En estos casos una opción más razonable sería no dividir ese margen por 2 sino advertir al consumidor, en el etiquetado de los complementos con un alto contenido en ese nutriente, que no debería tomar más de un complemento que lo contenga. Y para los alimentos enriquecidos, antes de convertir los máximos por 100 kcal en máximos por 100 g o 100 ml (en función de la densidad energética de los distintos alimentos y bebidas), utiliza la hipótesis de que su ingesta representa el 15 % o el 30 % de la energía total consumida, porcentajes totalmente exagerados para un micronutriente en particular, incluso si lo referimos a la presencia de cualquier vitamina o mineral añadidos a los alimentos enriquecidos, en lugar de referirnos al micronutriente que se trate en particular. En efecto, un estudio encomendado a Euromonitor (35) confirmó que, aunque el enriquecimiento es relevante en muchas categorías de alimentos, el mercado global de alimentos y bebidas enriquecidas es bastante pequeño dentro del mercado total de alimentos preenvasados. Según este estudio, el valor de este segmento de mercado en la UE en 2020 representaba solo el 3,6 % del mercado total de alimentos preenvasados. Este porcentaje sería todavía menor si lo referimos al mercado total de alimentos, incluyendo en ellos los no preenvasados.

COMPARACIÓN ENTRE AMBOS MODELOS: LA VITAMINA D COMO EJEMPLO

El modelo de Flynn propone para la suplementación de vitamina D los siguientes "valores máximos seguros": en complementos alimenticios 92 µg/d en adultos y 46 µg/d en niños, así como en alimentos enriquecidos 90 µg/d en adultos (56 µg/100 kcal) y 44 µg/d en niños (33 µg/100 kcal). Según el BfR, en Alemania solo el 44 % de los adultos de 18-79 años y el 54 % de los niños de 0-17 años tienen un nivel sérico de 25-OH-D3 ≥ 50 nmol/l (adecuado para la salud ósea), el 15 % y el 12,5 %, respectivamente, un nivel < 30 nmol/l (riesgo aumentado de osteomalacia y raquitismo), mientras que los restantes 41 % y 33,5 %, respectivamente, tienen un nivel de 30 a < 50 nmol/l (riesgo aumentado de salud ósea inadecuada). Pese a ello, el modelo alemán limita la suplementación con vitamina D a un máximo de 20 µg/d (800 UI) en complementos alimenticios y la restringe a unas pocas categorías de alimentos enriquecidos (lácteos, pan, cereales, grasas para extender y aceites) con un máximo de 1,5 µg/100 kcal, basado en la hipótesis de que un 30 % de la energía proceda de alimentos enriquecidos. Según datos de extensos ensayos clínicos aleatorizados (36), la suplementación diaria de 50 µg (2000 UI) de vitamina D_3 es una forma simple, efectiva y segura para prevenir y tratar su deficiencia en la población general adulta, elevando y manteniendo su nivel sérico por encima de 50 nmol/l (20 ng/ml) y 75 nmol/l (30 ng/ml, óptimo por presentar el menor riesgo de mortalidad) en > 99 % y > 90 % de la misma, respectivamente, sin que existan motivos significativos de preocupación por su seguridad al suplementar esta dosis durante varios años, incluso cuando el nivel sérico inicial es suficiente.

Mientras que el máximo de 90 µg/d en el modelo de Flynn debe ser interpretado para el total de complementos alimenticios que tome un adulto, en el modelo del BfR el máximo de 20 µg/d se aplica a cada complemento alimenticio, pudiendo ocurrir que un individuo consuma más de un complemento con vitamina D. Por ello, sugerimos un máximo de 50 µg/d para cada complemento en las personas > 10 años. En el caso de los niños de 3-10 años, dado que su UL es la mitad del de las personas > 10 años y que la AI de ambos grupos poblacionales es idéntica (15 µg), sugerimos un máximo de 25 µg/d para cada complemento, en lugar de los 46 µg/d para el total de complementos en el modelo de Flynn. Ambos máximos de vitamina D, que sugerimos para los complementos alimenticios, coinciden con los recomendados en 2019 por Francia (1).

CONCLUSIONES

Resulta urgente y necesario, tras dos décadas de espera, que se definan unos niveles máximos para la suplementación en vitaminas y minerales en alimentos enriquecidos y complementos alimenticios, de aplicación armonizada en todos los países de la UE. Junto a unos máximos para adultos, se deberían establecer unos máximos para niños mayores de 3 años y, si procede, también para menores de 3 años. La tremenda disparidad de niveles máximos autorizados para su suplementación en los distintos países europeos rompe la unidad de mercado y comporta perjuicios para los consumidores, la industria alimentaria y las autoridades locales. Además del objetivo de no superar de forma notoria los UL de algunos nutrientes en una parte significativa de la población, que podría poner en riesgo su salud, nos debe interesar también que dicha suplementación pueda ayudar a corregir déficits de nutrientes. Para algunos nutrientes este déficit se presenta de forma generalizada en la población, como es el caso de la vitamina D en muchos países europeos que no tienen una política de suplementación para esta vitamina, entre ellos Alemania y España, mientras que, en otros, como Irlanda y Finlandia, se recomienda su suplementación.

Sería conveniente la actualización de los VRN de acuerdo con los DRV fijados por la EFSA, pues llevan 16 años sin revisarse, y la aplicación de los VRN del Anexo VII del Reglamento (UE) 2016/127 a todos los alimentos dirigidos a menores de 3 años. La correspondiente modificación del Anexo XIII del Reglamento (UE) 1169/2011 podría aprovecharse para precisar, en su artículo 18.2, que la indicación de las vitaminas y minerales en la lista de ingredientes del etiquetado de los alimentos se haga con la fuente del micronutriente, en lugar de con su nombre (p. ej. vitamina A) como, de forma injustificada, sentenció el Tribunal de Justicia de la UE (37) en el año 2022, al contrario de lo que resulta obligatorio para las nuevas fuentes autorizadas. Otras razones de peso avalan la incoherencia de esta sentencia.

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REVISIÓN SISTEMÁTICA FRENTE A "SCOPING REVIEW": GUÍA PARA UNA ELECCIÓN INFORMADA EN LAS INVESTIGACIONES

Sr. Editor:

En el acelerado ámbito de la investigación científica, donde el volumen de publicaciones crece exponencialmente cada año, la capacidad de sintetizar eficazmente la evidencia existente se vuelve cada vez más crucial. A pesar de la disponibilidad de múltiples metodologías de revisión, persiste una confusión generalizada entre los investigadores sobre cuándo optar por una revisión sistemática (RS) y cuándo por una *scoping review* (ScR) (1). Este manuscrito busca clarificar estas diferencias y ofrecer una guía concisa para una elección informada, apoyándose en la literatura existente y en ejemplos prácticos.

Las RS son reconocidas por su rigurosidad metodológica, enfocándose en responder preguntas de investigación específicas mediante la evaluación crítica de la calidad y la certeza de la evidencia disponible (2-4). Por otro lado, las ScR, con su naturaleza exploratoria, son ideales para mapear la evidencia existente en un área de investigación amplia, clarificar conceptos e identificar brechas de conocimiento (1,5,6).

La elección entre estos métodos debe ser deliberada y basarse en criterios claros. Por ejemplo, un investigador que busca comprender el impacto del ácido docosahexaenoico en la salud mental materna podría optar por una ScR para explorar la diversidad de enfoques y resultados (7). En contraste, la evaluación de la efectividad del resveratrol sobre las funciones cognitivas en adultos mayores requeriría la precisión y el enfoque de una RS (8).

Es imperativo que los investigadores evalúen meticulosamente el objetivo de su estudio, la especificidad de su pregunta de investigación y el contexto actual del área temática antes de seleccionar el método más adecuado. Esta elección informada no solo incrementa la pertinencia y aplicabilidad de los resultados obtenidos, sino que también optimiza la utilización de los recursos disponibles para la investigación. La tabla I proporciona una guía de selección detallada para asistir en este proceso.

Tabla I. Guía de selección: revisión sistemática frente a "scoping review"

Tipo de Revisión	Indicaciones
Revisión sistemática	– Descubrir la evidencia internacional – Confirmar la práctica actual, abordar cualquier variación, identificar nuevas prácticas – Identificar e informar áreas para futuras investigaciones – Identificar e investigar resultados contradictorios – Producir declaraciones para guiar la toma de decisiones
"Scoping review"	– Identificar los tipos de evidencia disponibles en un campo dado – Aclarar conceptos clave/definiciones en la literatura – Examinar cómo se realiza la investigación sobre un tema o campo determinado – Identificar características o factores clave relacionados con un concepto – Como precursor de una revisión sistemática – Identificar y analizar brechas de conocimiento

Fuente: cita 1.

Conflicto de intereses: los autores no declaran tener conflictos de interés.

Declaración de uso de inteligencia artificial: los autores declaran que se utilizó ChatGPT para la corrección y edición del manuscrito.

La profundización en la comprensión de estas metodologías y una reflexión crítica sobre la elección del enfoque más adecuado son fundamentales para la comunidad investigadora. La claridad metodológica no solo mejora la calidad de nuestras síntesis de evidencia sino que también fortalece las bases sobre las que construimos nuestras recomendaciones prácticas y políticas.

Agradecemos la oportunidad de compartir estas reflexiones con sus lectores y esperamos que fomenten una discusión productiva sobre este tema crucial.

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IS CAROTID INTIMA-MEDIA THICKNESS ASSOCIATED WITH LOWER LEVELS OF VITAMIN D LEVELS IN CHILDREN AND ADOLESCENTS WITH OBESITY?

Dear Editor,

Liu et al. published in the July issue an article titled "Lower levels of vitamin D are associated with an increase in carotid intima-media thickness in children and adolescents with obesity" (1). The authors investigated in children and adolescents with obesity the correlation between vitamin D levels and carotid intima-media thickness (cIMT), a surrogate marker of pre-clinical atherosclerosis (1). Included were 440 children and adolescents aged 6-16 with obesity, divided into three groups: 119 patients had vitamin D deficiency (79 males and 40 females; median age, 11.68 years); 228 patients had vitamin D insufficiency (155 males and 73 females; median age, 11.34 years), and 93 patients had vitamin D sufficiency (70 males and 23 females; median age, 11.35 years) (1). All subjects had bilateral carotid ultrasound to assess cIMT (1). The study "showed a significant negative correlation between vitamin D levels and cIMT in the low vitamin D level group, even after adjusting for various confounding factors ($p < 0.05$)". The authors concluded "that vitamin D deficiency exacerbates the risk of CIMT abnormalities in children and adolescents with obesity" (1). Some comments are needed to evaluate the results of this study in a more balanced way.

The authors measured cIMT bilaterally at the common carotid artery (CCA) "at its thickest part 1 cm proximal to the bifurcation" (1). CIMT was expressed as the average value of the left and right cIMT (1). However, the authors failed to mention and to discuss that there is no agreement on the cIMT measurement protocol. It is important to recall that there are two main thoughts as to cIMT measurement protocols: one is to measure at one single site, namely the distal wall of the CCA in the proximity of the bifurcation (2) while another is to measure at multiple sites, involving all or a combination of different CA sections (proximal/distal walls) of the CCA, bifurcation and internal CA (3,4). A distal wall CCA measure is mostly based on the higher spatial resolution of the distal CCA wall (2), while a composite measure reflects the asymmetric manifestation of atherosclerosis more accurately, and arguably the actual cIMT (3,5). A further point that Liu et al. (1) failed to specify is whether measurements occurred, as recommended (2), synchronized with the cardiac end-diastolic phase. This is a critical aspect as cIMT values vary according to vessel-diameter changes during the cardiac cycle (6). Therefore, without synchronization, measurements in the three groups of the Liu et al. study (1) will have occurred randomly in both cardiac phases, rendering the cIMT values incomparable.

As sub-millimetric differences will categorize subjects into different cIMT categories, a meticulous measurement protocol and a detailed reporting of cIMT data acquisition are essential; only in this way the scientific community is able to

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Artificial intelligence: the author declares not to have used artificial intelligence (AI) or any AI-assisted technologies in the elaboration of the article.

evaluate the results. Given these methodological flaws, the cIMT results and the conclusion of this study "Vitamin D deficiency may be an independent risk factor for atherosclerosis in children and adolescents with obesity" (1) should be considered with caution.

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EL ALGORITMO DE "CLIQUEPERCOLATION" EN LOS ANÁLISIS DE REDES CON RELACIONES ESTADÍSTICAS

Sr. Editor:

En esta revista se ha publicado un artículo sobre un modelo multivariante de análisis de redes cuyas conexiones se basan en relaciones estadísticas parciales (1). Este método estadístico sistemático cuenta con algoritmos que detectan agrupaciones *(clusters)* entre los nodos (variables) de la red (2,3). Incluso, en los modelos de redes también se pueden reportar nodos superpuestos, es decir, que pueden pertenecer a más de una agrupación (4,5). Esto es recomendable en los sistemas de variables que se refieren a cogniciones, comportamientos y emociones debido a que tales medidas pueden estar asociadas condicionalmente con varias agrupaciones de la red (6). Para ello, uno de los algoritmos de superposición es el "Clique Percolation (CP)" (7,8) y, para contribuir a su ejecución de manera práctica, el objetivo de esta carta es describir el procedimiento del uso del CP mediante el paqueteR CliquePercolation (9) a partir de una red que incluía ítems de ansiedad, depresión y alimentación emocional (Fig. 1A) procedentes de un estudio previo de 400 adultos peruanos (10). Es recomendable tener previamente instalado el paquete qgraph:

```
install.packages ("qgraph")
library (qgraph)
install.packages ("CliquePercolation ")
library (CliquePercolation)
```

Luego de tener una red graficada (la instrucción será "plot1"), se consideran principalmente dos métricas para el uso del CP: la primera permite direccionar los k-cliques en base a la conexión de 3 o más nodos como mínimo (k.range). La segunda es el rango promedio de correlaciones de la red estimada (l.range; en la figura 1A se observan valores de relación entre 0.06 y 0.55), además de algoritmos como "entropy" para seleccionar el valor óptimo de "fuzzymod" que permita reconocer comunidades acordes con la literatura científica confirmada, como los modelos teórico-psicométricos. Los comandos R son:

```
threshold <-cpThreshold(plot1, method = "weighted",
k.range = c(3:4), l.range = seq(0.2, 0.06, - 0.01),threshold =
c("entropy","fuzzymod")
```

Este análisis permite obtener valores de "fuzzymod" según cada valor de correlación en la red. Se recomienda seleccionar el umbral de "fuzzymod" más alto (en este caso fue de 0.341), el cual se ajusta a k = 3 e l = 0.08. Por tanto, manualmente se introducen los valores de k e l según el resultado anterior mediante el siguiente comando:

```
values<- cpAlgorithm(plot1, k = 3, method = "weighted",
l = 0.08).
```

Luego, finalmente, para graficar la red con CP donde se incluyan las variables superpuestas, se procede con esta última indicación:

```
cpColoredGraph(plot1, list.of.communities = values$list.
of.communities.labels, theme = "colorblind", edge.labels = T,
layout= "spring")
```

En la red resultante (Fig. 1B) se denotan dos clústeres (color gris y morado) y el nodo AN1 (ansioso y nervioso) superpuesto entre

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Inteligencia artificial: los autores declaran no haber usado inteligencia artificial (IA) ni ninguna herramienta que use IA para la redacción del artículo.

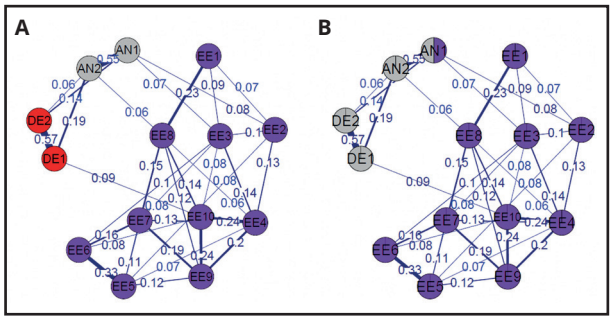

Figura 1.

Redes de depresión, ansiedad y alimentación emocional. A: Red sin algoritmo de CliquePercolation. B: Red utilizando CliquePercolation (DE: síntomas de depresión del Patient Health Questionnaire-2 [PHQ-2]; AN: síntomas de ansiedad del General Anxiety Disorder-2 [GAD-2]; EE: elementos del Emotional Eater Questionnaire [EEQ]).

ambas comunidades en la red, cuyos nodos de color gris pertenecen al grupo de angustia psicológica (ansiedad y depresión) y los nodos de color morado al dominio de alimentación emocional. Esto denota que la respuesta de nerviosismo y ansiedad puede considerarse de carácter transdiagnóstico entre ambos clústeres, esencial para la prevención de estas reacciones psicológicas vinculadas a la conducta alimentaria de mayor riesgo.

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PORTERAS ALIMENTARIAS: UNA REFLEXIÓN AL ROL DE GÉNERO EN LOS AMBIENTES DOMÉSTICOS

Sr. Editor:

En el número 4 del presente año, la revista *Nutrición Hospitalaria* publica un artículo que permite reflexionar sobre el rol que, en el imaginario colectivo y en el individual, presentan las mujeres en el contexto de los ambientes alimentarios domésticos.

La investigación, desarrollada por Franch y cols. (1), invita a transitar en diversas realidades de las mujeres chilenas, permitiendo al lector ser parte de la visión que las participantes interpretan del compromiso y también, en algunos casos, de la obligación que representa la alimentación del grupo familiar en sus hogares. Las reflexiones y resultados del artículo contribuyen en el estudio de la dietética y la nutrición, al concepto que proviene de las ciencias sociales y que responde a las "porteras alimentarias", un rol de género femenino de tareas domésticas referidas a la alimentación. En su análisis, develan que las dinámicas propias de la evolución de la alimentación a través del tiempo aún mantienen una estructura patriarcal clásica en donde las mujeres de los sectores socioeconómicos vulnerados presentan brechas en la distribución y las actividades domésticas que las confinan a utilizar gran cantidad de su tiempo en el hogar, en tareas asociadas a la alimentación propia y de la familia.

La estructura social e institucional masculinizada reconoce un rol de género con caracterizaciones femeninas y masculinas que se traducen en abusos cotidianos de quienes están alejados de los poderes sociales (2). Diversas culturas han estereotipado funciones según el género, profundizando en la concepción de que son las mujeres las encargadas de los cuidados en el interior de los hogares, situación que se ha perpetuado a través del tiempo y que, por ejemplo, desde el relato de las mujeres mayores, pareciera complejo (no imposible) de modificar (3,4).

A través del curso de la vida, las mujeres aprenden y traspasan sus saberes alimentarios de manera intergeneracional: hijas-madres-abuelas desarrollan un entretejido sociocultural que direcciona la mantención de la alimentación en sus hogares (5). En esta compleja trama, las mujeres adultas y también mayores mantienen un cometido de alimentación en sus ambientes domésticos, resignificando el ser porteras alimentarias.

Si bien en el tiempo se han flexibilizado los roles de género y, por lo mismo, los hombres están incorporándose, en ocasiones solo desde los discursos, a las labores domésticas como el cocinar, si disponen de habilidades personales para esta actividad, o el ser responsables de las compras de alimentos (6,7), adquiriendo habilidades gastronómicas que les facultan cocinar en los ambientes domésticos independientemente de la trayectoria de vida que estén cursando (8,9).

Las reflexiones finales del estudio de Franch y cols. (1) reflejan una realidad social del país de origen del estudio que no es ajena a los sucesos de otras comunidades: mujeres multifacéticas, encargadas de la alimentación familiar. ¿Se puede reconsiderar esta realidad? Solo el tiempo podrá responder a esta interrogante. Por el momento, el equipo sanitario que trabaja en la comunidad puede visualizar a las porteras alimentarias como un puntal que permite realizar acciones que contribuyen a la alimentación saludable y la salud de sus familias.

Conflictos de interés: las autoras declaran no presentar conflictos de interés en el artículo.

Uso de inteligencia artificial (IA): para su redacción, no se ha hecho uso de IA o de otras tecnologías que usen IA en el proceso de elaboración del artículo.

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Crítica de Libros

A COMER TAMBIÉN SE APRENDE

Autor: José Manuel Moreno
Ediciones Palabra. 2024. Madrid
Portada: pasta blanda
160 páginas

Actualmente existe mucha información sobre la alimentación de la población general. Sin embargo, es llamativo que el conocimiento de lo que debe ser la alimentación saludable para la población sana ha surgido después del conocimiento de lo que deberían comer personas enfermas o con riesgos nutricionales (embarazo, lactancia, vejez, etc.), ya que hasta mediados del siglo XX no se hacían estudios en la población sana. Esto ha ocurrido especialmente en la población infantil: los libros de texto pediátricos antiguos no abordaban la alimentación del niño sano en general y menos aun englobándola en un contexto en el que se incluyeran particularidades como las diferentes edades, contexto familiar y escolar, etc.

Afortunadamente en los últimos decenios ya han aparecido numerosos libros que abordan la alimentación infantil prácticamente desde todos los puntos de vista. Esta proliferación de textos ocurre por estar escritos por muy diferentes profesionales de la salud (pediatras, nutricionistas, dietistas, epidemiólogos, etc.) y están destinados a diferentes profesionales de la salud, a padres, maestros, responsables de comedores escolares, etc. Por ello se hace difícil escoger qué libros pueden ser más prácticos destinados a los padres que son los primeros responsables de la alimentación de sus hijos sanos.

En este contexto sociológico se publica el libro *A comer también se aprende* del Dr. J. M. Moreno que ofrece una visión muy original de cómo explicar a los padres la alimentación de sus hijos. El autor, experto nutricionista pediátrico con amplia experiencia asistencial, expone de manera clara la alimentación infantil, especialmente del niño pequeño. El libro tiene 13 capítulos, los 5 primeros versan sobre los aspectos más básicos de la alimentación del niño pequeño (alimentación periconcepcional y del embarazo, importancia de los primeros mil días, lactancia materna, alimentación complementaria, etc.); el resto de capítulos tienen como objetivo aspectos menos estudiados en otros textos, como son la influencia de los padres en las comidas de sus hijos, comer en familia, importancia del desayuno y de los

comedores escolares, enfoque frente a situaciones en las que la alimentación puede tener relación con determinados síntomas (regurgitaciones, cólicos, estreñimiento, etc.), repercusiones de las diferencias culturales, la importancia de una alimentación sostenible desde el punto de vista medioambiental, la repercusión del juego y la actividad física en el contexto de vida sana. Cada capítulo tiene una introducción teórica básica muy comprensible a la que siguen una serie de preguntas extraídas de las que hacen los padres en una consulta habitual y sus correspondientes respuestas, las cuales, en ningún caso, son categóricas y sí muy explicativas. Para hacer una más amena lectura en todos los capítulos se exponen curiosidades bajo el epígrafe "Sabías que", así como tablas y figuras que facilitan la lectura.

Quizás lo más destacable de este libro es el material elaborado por el equipo de dietistas y nutricionistas de la Clínica de la Universidad de Navarra en Madrid presentado como códigos QR en los que se muestran vídeos con recetas, trucos culinarios, consejos, etc. Todo ello muy bien explicado. Quizás en una próxima edición de este libro este apartado debería ampliarse porque es sumamente útil.

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