Nutrición Hospitalaria

Nutr Hosp. 2015;31(3):1352-1358
ISSN 0212-1611 • CODEN NUHOEQ
S.V.R. 318

Original/*Valoración nutricional*

Assessment of the reliability and consistency of the "Malnutrition Inflammation Score" (MIS) in Mexican adults with chronic kidney disease for diagnosis of protein-energy wasting syndrome (PEW)

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Abstract

Background: **The protein-energy wasting syndrome (PEW) is a condition of malnutrition, inflammation, anorexia and wasting of body reserves resulting from inflammatory and non-inflammatory conditions in patients with chronic kidney disease (CKD).One way of assessing PEW, extensively described in the literature, is using the Malnutrition Inflammation Score (MIS).**

Objective: **To assess the reliability and consistency of MIS for diagnosis of PEW in Mexican adults with CKD on hemodialysis (HD).**

Methods: **Study of diagnostic tests. A sample of 45 adults with CKD on HD were analyzed during the period June-July 2014.The instrument was applied on 2 occasions; the test-retest reliability was calculated using the Intraclass Correlation Coefficient (ICC); the internal consistency of the questionnaire was analyzed using Cronbach's α coefficient. A weighted Kappa test was used to estimate the validity of the instrument; the result was subsequently compared with the Bilbrey nutritional index (BNI).**

Results: **The reliability of the questionnaires, evaluated in the patient sample, was ICC=0.829.The agreement between MIS observations was considered adequate, $\kappa = 0.585$ ($p < 0.001$); when comparing it with BNI, a value of $\kappa = 0.114$ was obtained ($p < 0.001$).In order to estimate the tendency, a correlation test was performed. The r^2 correlation coefficient was 0.488 ($P < 0.001$).**

Conclusion: **MIS has adequate reliability and validity for diagnosing PEW in the population with chronic kidney disease on HD.**

(*Nutr Hosp*. 2015;31:1352-1358)

DOI:10.3305/nh.2015.31.3.8173

Key words: *Protein energy wasting. Nutritional assessment. Dialysis. Validation. Reliability.*

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Recibido: 1-X-2014.
Aceptado: 4-XI-2014.

EVALUACIÓN DE FIABILIDAD Y CONSISTENCIA DE LA HERRAMIENTA "MALNUTRITION INFLAMMATION SCORE (MIS)" EN ADULTOS MEXICANOS CON ENFERMEDAD RENAL CRÓNICA PARA DIAGNÓSTICO DEL SINDROME DE DESGASTE PROTEÍNICO ENERGÉTICO (DPE)

Resumen

Antecedentes: **El síndrome de desgaste proteínico-energético (DPE) se refiere a una condición de desnutrición, inflamación, anorexia, y emaciación de reservas corporales resultante de las condiciones inflamatorias y no inflamatorias que prevalecen en pacientes con enfermedad renal crónica (ERC).Una forma ampliamente descrita en la literatura para evaluar el DPE es el Malnutrition Inflamation Score (MIS).**

Objetivo: **Valorar la fiabilidad y consistencia del MIS en adultos mexicanos con ERC en Hemodiálisis (HD) para Diagnóstico de DPE.**

Métodos: **Estudio de pruebas diagnósticas. Se analizó una muestra de 45 adultos con ERC en HD, Durante el periodo Junio-Julio 2014. El instrumento se aplicó en 2 ocasiones, la fiabilidad test-retest se calculó mediante el Coeficiente de correlación Intraclase (CCI), la consistencia interna del cuestionario se analizó mediante el Coeficiente α de Cronbach. Se calculó una prueba de Kappa ponderada para estimar la validez del instrumento, posteriormente se comparó con el índice nutricional de Bilbrey (IB).**

Resultados: **La fiabilidad entre cuestionarios valorada en la muestra de pacientes fue de CCI = 0.829. La concordancia entre observaciones MIS es considerada como adecuada $\kappa = 0.585$ ($p<0.001$), al compararlo con IB se obtuvo un valor de $\kappa = 0.114$ ($p<0.001$). Para conocer la tendencia se realizó una correlación $r^2=0.488$ ($P < 0.001$).**

Conclusión: **El MIS presenta una adecuada fiabilidad y validez para diagnosticar DPE en la población con enfermedad renal crónica en HD.**

(*Nutr Hosp*. 2015;31:1352-1358)

DOI:10.3305/nh.2015.31.3.8173

Palabras clave: *Desgaste proteínico energético. Evaluación nutricional. Diálisis. Validación. Fiabilidad.*

Abbreviations

PEW: Protein-energy wasting.
CKD: Chronic kidney disease.
MIS: Malnutrition Inflammation Score.
HD: Hemodialysis.
ICC: Intraclass Correlation Coefficient.
BNI: Bilbrey nutritional index.
ISRNM: International Society of Renal Nutrition and Metabolism.
SGA: Subjective Global Assessment.
BMI: Body Mass Index.
TIBC: Total iron binding capacity.
GI: Gastrointestinal symptoms.

Introduction

Protein-energy malnutrition has been identified as a common problem in patients with chronic kidney disease (CKD), with a current prevalence of 18 to 70%[1–5]. In 2010, Espinosa *et al*. found that the prevalence of nutritional status in hemodialysis patients was as follows: 35.5% were within the normal range; 40.8% had mild malnutrition; 13.2% had moderate malnutrition; and 10.5% had severe malnutrition, meaning that 64.5% of the hemodialysis population had some degree of malnutrition[6] as diagnosed by a composite nutritional index called Bilbrey Nutritional Index (BNI)[7]. Other values have been reported in other parts of the world using different diagnostic methods. Considering the different terminologies and the confusion that arose after the creation of theese diagnostic systems, the International Society of Renal Nutrition and Metabolism (ISRNM) convened an expert panel to review and develop standard terminology and definitions related to cachexia, malnutrition and inflammation in patients with chronic kidney disease[8–10], giving rise to the concept of PEW"protein-energy wasting"[11–16], which has been associated with increased mortality in this population[8,12,17–19].

It is suggested that a better way to assess the nutritional status of these patients is by using composite nutritional indices[20], since the diagnosis of nutritional status becomes more understandable when including several indicators. Since the introduction of Subjective Global Assessment (SGA) in 1987, we have witnessed many nutritional assessment tools. In 1999, Kalantar *et al*. proposed a modified and quantitative SGA called "Dialysis Malnutrition Score" that included seven components: weight changes, changes in dietary intake, gastrointestinal symptoms, functional capacity, comorbidities, analysis of subcutaneous fat and presence of muscle wasting. With the recognition of the role of inflammation in PEW, and in an attempt to create a more complete and quantitative scoring system, the same group proposed adding three new components to the "Dialysis Malnutrition Score": Body Mass Index (BMI), concentration of serum albumin, and total iron binding capacity (TIBC), changing the name to "Malnutrition Inflammation Score" (MIS)[8,15,21–23]. Another proposed way for assessing theese patients was established by the ISRNM, which recommends diagnosing PEW using four readily available categories: 1. Biochemical Parameters (serum albumin, prealbumin and cholesterol). 2. Anthropometric Parameters (BMI, total unintentional loss of weight and body fat). 3. Measurements of Muscle Mass (average arm circumference, muscle circumference, creatinine). 4. Dietary intake (daily caloric and protein intake)[8]. That is why the use of MIS is proposed as a tool for the diagnosis of PEW in CKD patients, as it is generally practical and easy to apply[14,21,24], given that all the variables analyzed by it are usually found in patient records or can be obtained directly from the patient by means of a brief nutritional screening, without any additional treatment cost. In addition, it has been reported that the predicting power of MIS equals that of the serum concentration of IL-6 and is somewhat higher than PCR. This finding implies that the concentrations of PCR and IL-6 can be easily replaced by MIS in daily clinical practice as a way to determine the nutritional and inflammatory status of the patient[8,11,14,22,25].

Besides being a predictor of mortality, it has been shown that MIS captures most of the main criteria suggested by ISRNM for the diagnosis of PEW. Considering the relationship between MIS, inflammatory markers, diagnostic markers of PEW and mortality, one could speculate that MIS has a wide range of clinical utility, from the assessment of nutritional status to the diagnosis of inflammation in patients with CKD, besides being an specific tool that can be used in both inpatient and outpatient settings; however, there is little evidence of its use in the Mexican population. Therefore, the aim of this study is to assess the reliability and consistency of MIS for the diagnosis of PEW in Mexican adults with CKD on HD.

Material and methods

Overview of the instrument

MIS specifies the choice responses for each variable (Fig. 1):

Medical History: 1. Changes in dry weight after dialysis (3-6 months): No change in dry weight or loss <0.5kg; minor loss; loss of more than 1 kg but <5%; loss greater than 5%.2. Dietary intake: good or unchanged appetite; suboptimal diet; moderate intake; hypocaloric diet. 3. Gastrointestinal symptoms: no symptoms and a good appetite; few symptoms, poor appetite and occasional nausea; occasional vomiting and occasional GI symptoms; diarrhea or vomiting; severe anorexia.4. Functional capacity: good functional capacity, the patient feels well; occasional difficulty to walk, the patient feels tired often; difficulty with independent activities (going to the toilet); patient in bed or wheelchair, with little physical activity. 5. *Comorbidity according to time on dialysis:

Evaluación de Desnutrición Inflamación			
(A) Historia medica			
1. Cambios en el peso seco despues de dialisis (3-6 meses)			
0 Sin cambios en el peso seco o pérdida <0.5Kg	**1** pérdida menor 0.5 – 1.0Kg	**2** pérdida de más 1kg pero <5%	**3** pérdida >5%
2. Ingesta dietética:			
0 Buen apetito o sin cambios en la ingesta	**1** Dieta sub optima dieta solida	**2** Ingesta moderada dieta de liquidos completa	**3** Dieta liquidos hipocaloricos
3. Sintomas gastrointestinales:			
0 No hay sintomas buen apetito	**1** Pocos sintomas, poco apetito y nauseas ocasionalmente	**2** Vómito ocasional y sintomas GI ocasionales	**3** Diarrea ó vómito. Anorexia grave.
4. Capacidad funcional			
0 Buena capcidad funcional. El paciente se siente bien.	**1** Dificultad ocasional para deambular. Se siente cansado frecuentemente.	**2** Dificultad con actividades independientes. (Ir al baño)	**3** Paciente en cama, o silla de ruedas. Con poca o sin AF.
5. Comorbilidad según el tiempo en dialisis. *			
0 Menos de 1 año en dialisis. Sin comorbilidades	**1** Dializado de 1 a 4 años. Baja comorbilidad	**2** Dializado por más de 4 años. moderada comorbilidad	**3** Cualquier comorbilidad severa o múltiples comorbilidades que tenga.
(B) Examen fisico			
6. Pérdida de los depositos de grasa o perdida de grasa subcutanea; debajo del ojo, biceps, triceps.			
0 Normal (s/cambios)	**1** Leve	**2** Moderado	**3** Grave
7. Signos de pérdida de masa magra; clavivula, escapula, hombros, cuadriceps.			
0 Normal (s/Cambios)	**1** Leve	**2** Moderado	**3** Grave
(C) Índice de Masa corporal			
8. IMC (Kg/m^2)			
0 >20kg/m^2	**1** 18 – 19.9Kg/m^2	**2** 16 – 17.9Kg/m^2	**3** <16 Kg/m^2
(D) parametros bioquimicos:			
9. Albumina			
0 >4.0g/dl	**1** 3.5 – 3.9g/dl	**2** 3.0 – 3.4g/dl	**3** <3.0g/dl
(E) Capacidad total de fijación de Hierro (CTFH) o Transferrina			
0 CTFH >250mg/dl o Transferrina >200 mg/dL	**1** CTFH 200-249mg/dl o Tranferrina 170 – 200	**2** CTFH 150 – 199mg/dl o Tranferrina 140 – 170	**3** CTFH <150mg/dl o Tranferrina <140 mg/dL

Puntaje total: (0-30Pts) Normal = <3 Leve= 3 – 5 Moderado= 6 – 8 Grave = >8

Fig. 1.—Components of the comprehensive MIS.

less than one year on dialysis without comorbidities; dialyzed from 1 to 4 years; low comorbidity; dialyzed for more than 4 years with moderate comorbidity; any severe comorbidity or multiple comorbidities presented by the patient. The following legend is also included: (*Greater comorbid conditions: congestive heart failure class III or IV; AIDS; coronary artery disease; moderate to severe chronic obstructive pulmonary disease; severe neurological sequelae; neoplasias; undergoing chemotherapy or having come out of it recently).

The physical exam consists of 2 items, loss of fat stores or subcutaneous fat below the eye, in biceps and triceps, and signs of loss of lean mass in clavicle, scapula, shoulders and quadriceps. The body mass index and

biochemical parameters such as albumin and TIBC or transferrin are estimated from the results of the various evaluations.

Interpretation of MIS

The results are obtained from the simple sum of each of the items, finally expressing them into the following categories:

Normal Nutritional Status: 0,1 and 2 points; Mild Malnutrition: 3-5; Moderate Malnutrition: 6-8; Severe Malnutrition: from 9 points in the simple sum of the items.

Population and Methods

To validate the instrument, we selected 49 adults with CKD on HD, all belonging to the chronic hemodialysis unit of the National Institute of Medical Sciences and Nutrition. The data were collected during the months of June-July 2014.Those patients who were hospitalized when the measurements were taken underwent evaluation upon return. Of the original sample, it was not possible to perform a complete evaluation in 4 patients, 3 of them because they did not show up at the unit on the day of sampling and another patient because he remained hospitalized throughout the study period, leaving for analysis a total of 45 patients.

Anthropometric measurements were taken (height, weight, arm circumference and skinfold circumference of biceps, triceps, subscapular and suprailiac muscles) and the data were used to estimate body mass index, percentage of total body fat and muscle arm circumference, in order to calculate BNI. In addition, the most recent laboratory results were recorded: concentration of albumin, transferrin or TIBC, and total count of lymphocytes within the last month.

The measure of reliability is based on internal consistency and reproducibility, on the agreement between observers and/or observations. This instrument was applied on two occasions by two nutritionists from the Nutritional area of the Nephrology Department, with a lapse of three weeks between each application. The first application lasted a week and included all patients from each round of hemodialysis sessions. Only in the first round, the evaluation was applied at the end of the session; in the second and third rounds, the evaluation was applied before the sessions started. The next measurement was taken 3 weeks afterwards, at the same times, in order to achieve consistency between the diagnoses of both observers.

Data analysis

The descriptive statistics of the study are shown as mean ± standard deviation. The test-retest reliability was calculated using the Intraclass Correlation Coefficient (ICC); the internal consistency of the questionnaire for assessing homogeneity was analyzed using Cronbach's α coefficient. The item-total correlation was also calculated; it measures the degree of association between the diagnosis and the total scale.

Regarding the reproducibility between observers and the validity of the instrument, a weighted Kappa test was used to compare the four diagnoses of MIS with each other. Subsequently, the result of the Kappa test was compared with BNI, which is currently used as a routine diagnostic tool in the Nutrition area of the Nephrology Department and which has the same diagnostic output (normal nutritional status, mild, moderate and severe malnutrition).

All analyzes were performed using SPSS version 16 for Windows.

Results

We studied 47 patients (19 men and 26 women), table I shows the characteristics of the population, the test-retest reliability of the questionnaires, assessed in the patients sample, was ICC=0.829, indicating proper homogeneity between the items. The internal consistency results of MIS are shown in table II. A consistency of α=0.669 was obtained in the first application (test). When considering the correlation of each item with respect to the test, the variable "comorbidities and time on dialysis" was found to have the lowest value, showing little association with the final score, followed by TIBC, however, when these variables were excluded from the test, the result showed no significant change (α 0669-0698 for comorbidities and α 0.669-0.71 for TIBC). On the other hand, the best correlation was found for the variable "loss of muscle" (r^2=0.534), meaning that when this variable is excluded from the test, its reliability decreases (α 0.669- 0.611). A consistency of α=0.642 was obtained in the second application (re-test). This time the variable "gastrointestinal symptoms" showed the lowest correlation (r^2=0.095), meaning that when this variable is excluded from the test, its reliability improves, but the change is mini-

Table I
Anthropometric and demographic characteristics

	Men n= 19	*Women n=26*	*P Value*
Gender (%)	42.2	57.8	0.297
Age (years)	45.3 ± 20.3	38.2 ± 18.6	0.235
Time on dialysis (months)	8.3 ± 7.2	10.0 ± 8.2	0.471
Weight (kg)	67.9 ± 15.3	53.4 ± 10.0	0.000
Height (meters)	1.6 ± 0.1	1.5 ± 0.1	0.000
BMI (kg/m^2)	23.8 ± 4.8	21.7 ± 3.6	0.119

Table II
Internal Consistency of Malnutrition Inflammation Score

Cronbach`s α Coefficient	*Observer 1 0.669*		*Observer 2 0.642*	
	Correlation ítem-total	Cronbach`s α upon excluding the ítem	Correlation ítem-total	Cronbach`s α upon excluding the ítem
Body weight history				
Body weight change	.317	.661	.284	.643
Food Intake	.414	.635	.366	.612
Gastrointestinal Symptoms	.441	.637	.095	.650
Functional capacity	.482	.617	.503	.581
Comorbidities, time on dyalisis	-.096	.698	-.170	.682
Physical exam				
Fat	.439	.629	.551	.576
Muscle mass	.534	.611	.464	.590
Body mass index	.439	.624	.253	.629
Albumin	.299	.658	.419	.590
TIBC	.216	.671	.371	.603

mal (α=0.642-0.650). "Comorbidities" and "time on hemodialysis" showed negative correlation, meaning, likewise, that excluding them from the test improves its reliability (α=0.642-0.682).

Considering the reproducibility of the tool, we evaluated the agreement between two observers using a weighted Kappa test, which gave a value of K=0.585 (p <0.001) (Table III). This indicates that the agreement between observers for this tool is adequate and can be used to obtain a diagnosis. Given that BNI produces the same results than MIS, a comparison was made between their diagnoses (Table IV); we found a value of K=0.114 (p <0.001), meaning that the agreement between diagnoses was inadequate. However, in order

Table III
Agreement interobserver

		Measurement 2 MIS				*Total*
		Normal	Mild	Moderate	Severe	
Measurement MIS	Normal	9	3	0	0	12
	Mild	2	7	5	0	14
	Moderate	0	1	5	2	8
	Severe	0	0	1	10	11
Total		11	11	11	12	45

Table IV
Agreement interdiagnoses second measurement MIS and BNI

		BILBREY				*Total*
		Normal	Mild	Moderate	Severe	
MIS	Normal	4	7	0	0	11
	Mild	4	5	2	0	11
	Moderate	2	5	2	2	11
	Severe	1	2	5	4	12
Total		11	19	9	6	45

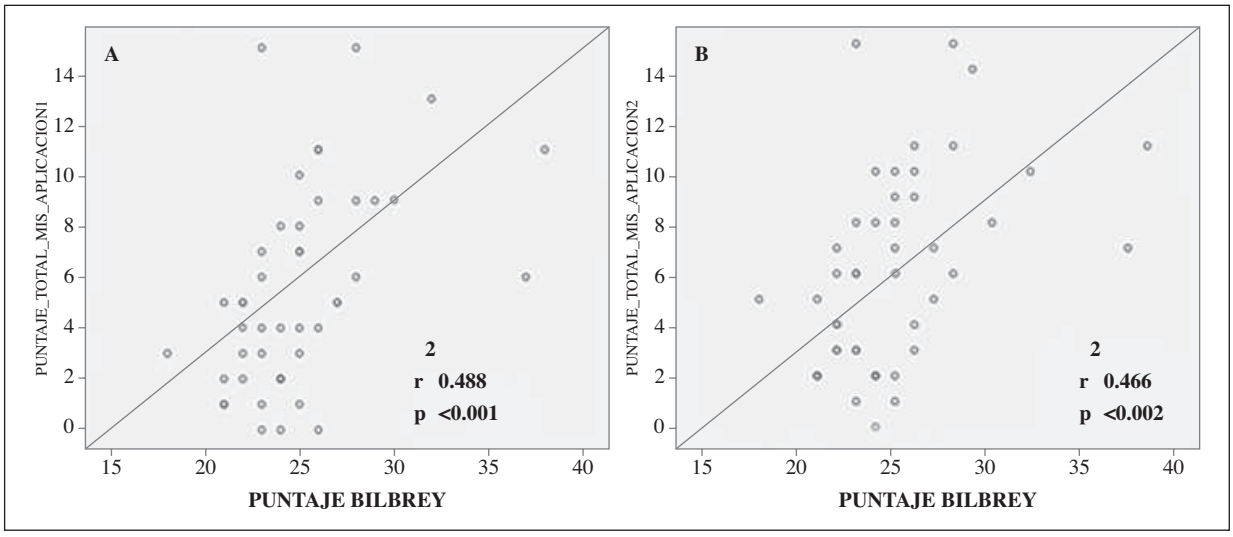

Fig. 2.—Correlation between total score of BNI to the total sum of MIS (Simple sum of ítems). A First measurement, B Second measurement.

to know if both tests show the same tendency, we carried out tests of concordance between the score of the two evaluations, obtaining a correlation of r^2=0.488, p<0.001 (Fig. 2), which indicates that the scores are consistent, but do not yield the same diagnosis. While MIS found 11 patients had normal nutritional status, 11 had mild malnutrition, 11 were moderately malnourished and 12 were severely malnourished, for BNI the numbers were 11, 19, 9 and 6, respectively, agreeing 100% only in those patients who had a good nutritional status; when the patients had some degree of malnutrition, the diagnoses did not agree.

Discussion

MIS was first used in 2001 as a complete and quantitative tool; it was used to assess malnutrition and inflammation in patients on Renal Replacement Therapy (RRT).Today, it is used to assess the nutritional status of at least 100000 patients per year. MIS has been associated with quality of life and mortality, as the risk of 1-year mortality increases significantly for patients with a score ≥4; however, there is little evidence of its use or validity in the Mexican population[14,22,26].

This study concerns a cultural adaptation of the instrument to the Mexican population, with a comparison between the diagnosis output of MIS and that of BNI, a tool now used routinely in our circle. The relevance of this study is that it presents results that can contribute to practice and clinical research aimed at assessing the nutritional status of patients with CKD.

The present study shows that MIS has proper internal consistency, with an ICC=0.82, which is completely acceptable, showing good accuracy and reproducibility. Its internal consistency is almost equal to that found by Fetter *et al*. when adapting it to the Portuguese language[27] (ICC=0.88). Furthermore, when analyzing the correlations of the items and their association with diagnosis, it was found that all correlated significantly, with the exception of "comorbidities" and "time on dialysis", which, besides presenting low correlation, produced a negative result. This contrasts with the results obtained in the Brazilian population, for which the lowest correlation was found in food intake[27].

Regarding interobserver reproducibility, a moderate reproducibility was found (K=0.585, p<0.001), similar to results found by Beberashvili (Kappa test=0.68, p <0.001)[28]; however, a recently published study by Fetter showed high reproducibility (Kappa test=0.78, p <0.001)[27]. One of the main strengths of this study is that it compared MIS with BNI, finding a good agreement between assessments, which means that the tendency in both instruments was significantly correlated, although they did not yield the same diagnosis when malnutrition was present.

Therefore, we can conclude that MIS has good reliability and validity for diagnosing PEW in patients with CKD on HD. It is a quick and easy tool to use and its usefulness in clinical practice is even better than that of the Bilbrey nutritional index, which requires certain mathematical formulas in order to be applied. It is also important to note that MIS takes into account all the criteria set by the International Society of Renal Nutrition and Metabolism (ISNRM) for the diagnosis of protein-energy wasting.

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