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Trabajo Original

Obesidad y síndrome metabólico

Medical supervised duodenal-enteral feeding for the treatment of overweight and obesity: MESUDEFT

Nutrición duodenoenteral médicamente supervisada para el tratamiento del sobrepeso y la obesidad: MESUDEFT

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Abstract

Background: the development of specialised nutritional support techniques allows the maintenance of an adequate supply of nutrients in those patients in whom oral feeding is not possible or is insufficient in relation to their requirements, trying to improve the quality of life, especially in those with chronic diseases.

Methods: single-center clinical study carried out in a clinical-nutritional center consisting of a medically supervised nasogastric-duodenal tube feeding treatment for overweight, obesity and increased body fat percentage in patients requiring it by means of duodeno-enteral feeding, expecting losses of more than 10 %.

Results: twenty-nine patients completed the protocol (20.4 % male and 79.6 % female) with a mean age of 38 years (SD: 12.4); 87.2 kg (SD: 18.5) mean weight; 37.9 kg (SD: 4.8) mean iFat%; 32.4 (SD: 5.4) iMean body mass index (BMI); 100 cm (SD: 16.0) iMean waist; 113.6 cm (SD: 10.4) iMean hip; 33.8 cm (SD: 3.9) iMean upper arm circumference; 65.5 cm (SD: 7.5) iMean thigh circumference; 9.7 (SD: 4.8) iVisceral fat index; and 22.9 days (SD: 13.9) mean treatment. A mean of 22.9 (SD: 13.9) days of MESUDEFT influences weight loss, fat loss, visceral fat loss and decreased arm, hip and thigh circumferences ($p < 0.05$) (i: initial).

Conclusions: MESUDEFT is shown to be an effective alternative as a sole treatment or as an adjunct prior to bariatric surgery for obesity or overweight treatment with a minimum of 10 % loss of BMI and fat mass at completion and 3-6 months follow-up.

Keywords:

Obesity. Overweight. Enteral nutrition.

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Video: Evolution Changes. Download video at: https://figshare.com/articles/media/MESUDEFT_Evolution_Changes/20377683

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Resumen

Antecedentes: el desarrollo de técnicas especializadas de soporte nutricional permite mantener un aporte adecuado de nutrientes en aquellos pacientes en los que la alimentación oral no es posible o es insuficiente en relación a sus requerimientos, intentando mejorar la calidad de vida, especialmente de aquellos con enfermedades crónicas.

Métodos: estudio clínico unicéntrico prospectivo realizado en un centro clínico-nutricional consistente en un tratamiento con alimentación por sonda nasogástrica-duodenal médicamente supervisado para el sobrepeso, la obesidad y el aumento del porcentaje de grasa corporal en pacientes que lo requieran mediante alimentación duodenoenteral, durante un mes aproximado, con previsión de pérdidas superiores al 10 % y con control posterior entre los tres y los seis meses siguientes.

Resultados: veintinueve pacientes completaron el protocolo (20,4 % varones y 79,6 % mujeres) con una edad media de 38 años (DE: 12,4); 87,2 kg (DE: 18,5) iPeso medio; 37,9 kg (DE: 4,8) iGrasa% media; 32,4 (DE: 5,4) iIMC medio; 100 cm (DE: 16,0) iCintura media; 113,6 cm (DE: 10,4) iCadera media; 33,8 cm (DE: 3,9) iCircunferencia braquial media; 65,5 cm (DE: 7,5) circunferencia muslo media; 9,7 (DE: 4,8) iÍndice de grasa visceral; y 22,9 días (DE: 13,9) de tratamiento medio. Una media de 22,9 (DE: 13,9) días de MESUDEFT influye en la pérdida de peso, la pérdida de grasa, la pérdida de grasa visceral y la disminución de las circunferencias del brazo, la cadera y el muslo ($p < 0,05$) (i: inicial).

Conclusiones: MESUDEFT se muestra como una alternativa eficaz como tratamiento único o como coadyuvante previo a la cirugía bariátrica de la obesidad o tratamiento del sobrepeso con una pérdida mínima del 10 % del índice de masa corporal (IMC) y de la masa grasa al finalizar y con control durante los siguientes 3-6 meses.

Palabras clave:

Obesidad. Sobrepeso. Nutrición enteral.

INTRODUCTION

Overweight and obesity have been proven to be major concerns in global health, affecting both countries with medium and low economic power as well as those with higher economic power, regardless of age, sex, or socioeconomic position (1,2). Obesity increases the risk of metabolic disorders, cardiovascular diseases, musculoskeletal diseases, Alzheimer's disease, depression, and some malignancies, as well as lowering one's quality of life, unemployment, productivity, and social disadvantage (3). The majority of obesity appears to be multifactorial, meaning that it is a consequence of complicated interactions between multiple genes and environmental variables (1-3).

As a result, a variety of treatments have been offered, including pharmaceutical treatments, diet, lifestyle modifications, and surgical interventions (4). The latter option is reserved for morbidly obese patients (body mass index [BMI] > 40) or obese (BMI > 35) patients with associated diseases (coxarthrosis, gonarthrosis, moderate or severe respiratory diseases, and patients who need to lose weight quickly due to scheduled vascular or orthopedic surgery but are ineligible for bariatric surgery due to esthetic or pneumological risk) who do not respond to other available options (5). Morbidly obese patients scheduled for bariatric surgery are advised to lose 10 % of their preoperative weight to reduce surgical issues such as extended operating time, suboptimal surgery, and a higher rate of conversion to open surgery (6).

Castaldo et al. have shown that in 112 patients, a carbohydrate-free diet administered via enteral nutrition (EN) for two weeks, followed by a nearly equivalent oral diet administered for another two weeks, resulted in a significant reduction in BMI and waist circumference as well as improvements in blood pressure and insulin resistance values with no major complications (7). Weight loss-based enteral feeding regimens have shown promising outcomes in the treatment of obesity (8). Tube feeding can produce outstanding results under proper medical care and may favor appetite management because there is evidence to support the anorexigenic effect induced by nasogastric tube feeding (8).

Sukkar et al. demonstrated that ten days of EN treatment (with protein intake 0.8-1 g/kg per day without carbohydrate intake [lower than 1 %] and an adequate intake of vitamins, electrolytes and fiber) followed by 20 days of a low-calorie diet was safe and effective at reducing total body weight and abdominal circumference, as well as improving patients' respiratory capacity, without major complications or side effects when assessing the feasibility of a protein-sparing modified diet delivered by a nasogastric tube enterally (with continuous feeding) in obesity treatment (6).

Healthcare professionals around the world are increasingly concerned about the nutritional status of patients and have developed specialized nutritional support techniques to maintain adequate nutrient intake in patients for whom oral feeding is not possible, or is insufficient in relation to their needs, in an attempt to improve the quality of life of patients, especially those with chronic diseases (9). EN is one of the most developed disciplines in modern medicine and provides nutritional support by administering nutrients directly to the gastrointestinal tract through chemically defined formulas orally or through nasoenteric tubes or ostomies (10) with the aim of correcting or improving nutritional status, or preventing nutritional deterioration by supplying the nutritional requirements of the digestive tract covering the total or partial nutritional needs of patients (11,12).

As a result, enteral nutrition strategies may be a viable option to other methods, particularly when it is indicated to enhance patient adherence to the specified diet prior to bariatric surgery. However, to our knowledge, there is no evidence on the use of the enteral feeding method in overweight or obese patients or on the dietary regimes to be supplied, nor on how long to administer it before surgery.

This study aims to evaluate the efficacy of duodenal enteral nutrition for pathogenesis and treatment of overweight and obesity and to provide an alternative that can be applied worldwide by clinicians without the complications of surgery and at a lower cost to healthcare systems.

METHODS

STUDY DESIGN

This prospective single-center clinical trial study conducted at an official accredited clinical nutrition center was designed to compare changes with enteral feeding in obesity-related parameters among overweight and obese patients (body mass index [BMI], calculated as weight in kilograms divided by height in meters squared] ≥ 25 or BMI ≥ 30). This study was approved by the BiomediKcal - Advanced Medical Nutrition & Lifestyle Center of Barranquilla, Colombia, under ClinicalTrials.gov identifier NCT03542864. The study was conducted in accordance with the Helsinki guidelines and written informed consent was obtained from every participant.

PARTICIPANTS

Patients aged 18-65 years of both sexes without considering patients who attempted a weight loss diet in the previous month or earlier, as this aspect is not necessary to analyze resistance/adherence to current treatment. Inclusion criteria were: > 18 years, BMI ≥ 25, desire for weight loss, desire to improve body image, voluntariness, and signing of informed consent. Exclusion criteria were: swallowing or esophageal impairment, unwillingness to sign the informed consent, and active acute illness.

SAMPLE SIZE

Based on the number of participants from previous obesity treatment studies by Baltasar et al. (13) and Roa et al. (14), sample size was calculated according to the formula:

$$\text{Necessary sample size} = \frac{(Zscore)^2 \times \text{StdDev} \times (1\text{-StdDev})}{(\text{margin of error})^2}$$

- Confidence level: 95 %.
- Population size: 31.
- Margin of error: 5 %.
- Ideal sample size: 29.

Feeding was by naso-duodenal tube and the duration was 12-29 days, depending on the desired fat and/or weight loss in relation to basal metabolism. Then, a personalized nutritional treatment was continued for two weeks: it consisted of a hypocaloric diet personalized to the patient's food preferences (after filling out a questionnaire on food exclusions) using Dietowin 8.0 nutritional expert software, explaining to the patient the daily meals in quantity and quality that he/she should eat, as well as the preparation of each meal. Physical activity was recommended during the protocol. A weight and/or fat loss of more than 10 % was expected. Follow-up was done during the following three to six months.

MEDICAL PROCEDURE

In the first phase, and after initial medical-nutritional assessment and approval, a nasogastric-duodenal tube was placed and connected to a portable nutritional infusion pump for the supply of hypocaloric food (a mixture of carbohydrates, lipids, proteins, vitamins and trace elements) at the indicated time.

Materials used in the protocol are shown in figure 1:

- Nasogastric-duodenal feeding tube Levin FR 20. Size: 125 cm. Brand: Sherleg (Sherleg Laboratories SAS; https://www.sherleg.com/siliconcaths).
- Kangaroo™ Joey Enteral Feeding Pump (Cardinal Health; https://www.cardinalhealth.com/en.html
- Covidien Kangaroo™ ePump Set Anti-Free Flow 1000 ml.

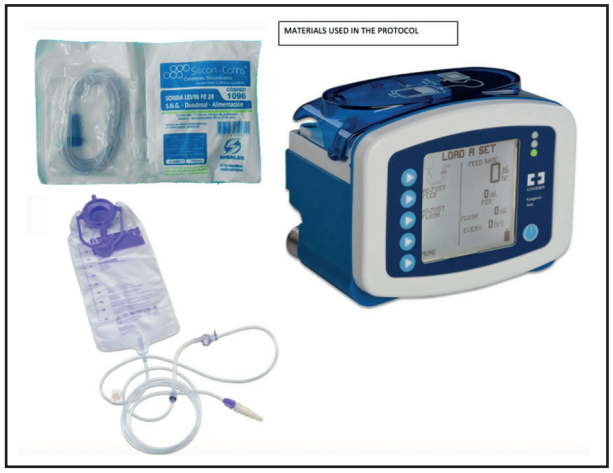

Figure 1.
Materials.

PRE-PROCEDURE

1. Complete medical health assessment: physical examination of systems; vital signs; review of analytical results (complete blood count, complete lipid profile, glycated hemoglobin [HbA1c], uric acid and urine test); determination of height, weight, waist, hip, arm and thigh circumference; body composition analysis with impedance measurement variables (by bioimpedance, Tanita MC 780 MA; Tanita, Tokyo, Japan); taking initial photographs for patient motivation (15).
2. Interpretation of the results of the medical examination.
3. Statement of expected goals.
4. Explanation of the procedure for signing the informed consent form.
5. Prescription of medicines: prokinetics and gastric protectors: bisacodyl 5 mg orally daily every night before the procedure. Omeprazole capsule 20 mg daily every day orally during the whole treatment.
6. Fasting recommendations.
7. Scheduling of the procedure for the following day.

PROCEDURE DAY

1. New medical assessment: assessment of enteral nutrition treatment (ENT) and cardiovascular health.
2. Application of local anesthesia for the pharynx.
3. Measurement of the length of the duodenal nasogastric tube.
4. Placement of nasogastric duodenal nasogastric tube (Fig. 2).
5. Confirmation of correct placement of the duodenal nasogastric tube: at the beginning of the protocol, the initial location in the gastric chamber was checked by introducing air through the tube and auscultation of air bubbles through a stethoscope.
6. Preparation of duodenal enteral feeding.
7. Initiation of enteral infusion pump feeding: 12 hours per day.
8. Appointment for new medical control.

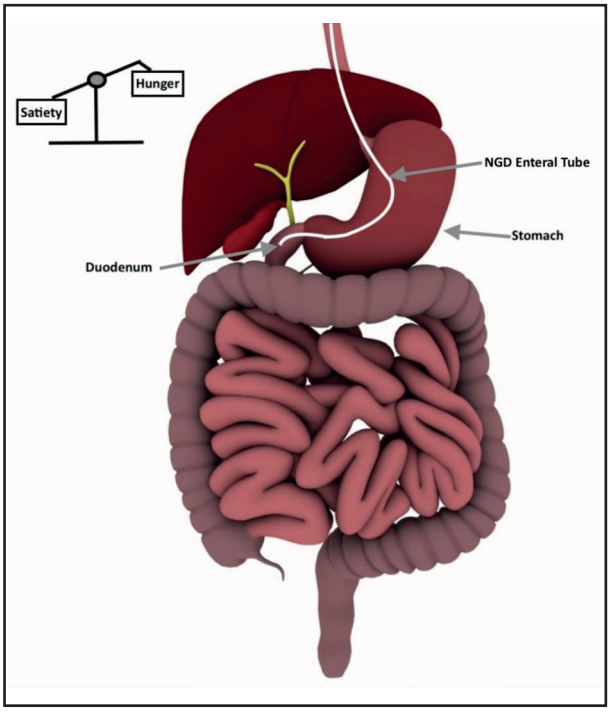

Figure 2.
Enteral tube correct placement.

The nutritional formula is based on 20 % protein (whey, soy protein isolate, egg albumin); 20 % fat (with these two fatty acids: alpha linoleic acid and linoleic acid); 60 % carbohydrates; enriched with vitamins, omega 3-6-9, glutamine with minerals and with trace elements. Ingredients: calcium caseinate, soy protein isolate, whey protein concentrate, canola oil, corn oil, sucrose, maltodextrin, vitamins (A, D3, E, C, B1, B2, B6, niacin, B12, K1, calcium pantothenate, folic acid, biotin), minerals (potassium citrate, sodium citrate, tricalcium phosphate, ferrous sulfate, zinc sulfate, copper sulfate, sodium molybdate, sodium selenite, potassium iodide, sodium sulfate manganese and magnesium oxide). Each scoop contains approximately 320 kilocalories; the indicated dose is determined by 45-60 % of the patient's basal metabolic rate (BMR) diluted in 1,000 ml of water. During treatment, the patient may drink water or tea on demand. Physical activity (walking) is recommended. Weekly checks of weight, perimeters and body composition are made to adjust nutritional requirements.

FINAL DAY

Withdrawal of the nasogastric duodenal tube: at the end of the treatment (after removal of the tube), the correct position was checked when we saw the bile content inside, followed by personalized nutritional treatment.

STATISTICS

With the data obtained, the initial and final BMI were calculated according to the World Health Organization (WHO) (1) criteria, as well as the percentages of weight loss and waist, arms, hips and segmental body composition. Data were analyzed with IBM SPSS Statistics version 26.0 software and all variables were included by performing the Shapiro-Wilk W-test to test the assumption of normality. A significance level of $p < 0.05$ was considered. With the tabulated data, the means of the variables were compared using the t-test for independent samples (Levene's test for equality of variances) with gender (male and female) as the grouping variable; 95 % confidence interval of the difference.

RESULTS

Thirty-one patients (19.4 % male and 80.6 % female) started the protocol with a mean age of 38 years (SD: 12.0), 86.7 kg (SD: 18.4) mean iWeight, 37.5 kg (SD: 5.2) mean iFat% and 32.4 (SD: 5.5) mean iBMI. When exclusion criteria were applied, the total number of patients included in the study was 29 (20.4 % male and 79.6 % female), with a mean age of 38 years (SD: 12.4); 87.2 kg (SD: 18.5) mean iWeight; 37.9 (SD: 4.8) mean iFat%; 32.4 (SD: 5.4) mean iIMC; 100 cm (SD: 16.0) mean iWaist circumference; 113.6 cm (SD: 10.4) mean iHip circumference; 33.8 cm (SD: 3.9) mean iArm circumference; 65.5 cm (SD: 7.5) mean thigh circumference; 9.7 (SD: 4.8) iVisceral fat index; and mean 22.9 days (SD 13.9) treatment (Table I).

After 26.0 (SD: 22.3) days of MESUDEFT and expecting a 10 % variation from baseline values in males, there are significant changes in body weight, waist circumference, hip circumference, arm circumference, thigh circumference, % fat and visceral fat index ($p < 0.05$); and after 22.1 (SD: 11.3) days in females there is a significant variation of 10 % of the initial values changes in body weight, hip circumference, arm circumference, thigh circumference, % fat and visceral fat index ($p < 0.05$) despite no change in waist circumference (Table II).

Table I. Descriptive statistics

Initial patients (*n* = 31) **19.4 % male** **80.6 % female**	**Minimum**		**Maximum**		**Mean**	**SD**
Age	18		62		38	12.0
Weight kg	58.0		130.0		86.7	18.4
Fat%	26.0		45.0		37.7	5.2
BMI	23.0		48.0		32.4	5.5
Total patients (*n* = 29)	**Male 20.7 %**		**Female 79.3 %**		**Mean**	**SD**
	Mean	**SD**	**Mean**	**SD**		
Age (years)	36.3	17.8	38.3	11.1	38	12.4
iWeight (kg)	107.3	22.2	82.0	13.6	87.2	18.5
Ibmi	37.0	7.5	31.4	4.2	32.5	5.4
iBMR (Kcal)	2138	329.0	1,530.5	192.1	1,656.2	333.2
iWaist (cm)	117.7	13.9	95.4	13.2	100.0	16.0
iHip (cm)	116.2	16.3	113.0	8.6	113.6	10.4
iArm (cm)	36.7	4.7	33.1	3.4	33.8	3.9
iThigh (cm)	66.2	9.3	65.3	7.2	65.5	7.5
iFat mass (kg)	37.3	13.8	32.2	8.1	33.3	9.5
iFat%	33.7	5.9	39.0	3.8	37.9	4.8
iVisceral fat (index)	16.8	5.4	7.8	2.3	9.7	4.8
iTotal muscle mass (kg)	66.3	8.7	46.8	5.8	50.9	10.2
NGDP *(days)*	26.0	22.3	22.1	11.3	22.9	13.9

BMI: body mass index; BMR: basal metabolic rate; SD: standard deviation.

An average of 22.9 (SD: 13.9) days of MESUDEFT influences weight loss, fat loss, visceral fat loss and decrease in arm, hip and thigh circumferences ($p < 0.05$), with no influence on decrease in waist circumference and muscle mass loss ($p > 0.05$) (Table III).

Increased visceral fat loss is related to sex with no change over a sustained period of time ($p < 0.05$), but no relationship with overall fat loss ($p > 0.05$). Fat mass loss is significantly related to weight loss, waist circumference loss, hip circumference loss, arm circumference loss, thigh circumference loss and visceral fat loss ($p < 0.05$). After removal of MESUDEFT, muscle weight is not affected ($p < 0.05$), but there are changes in long-term control ($p > 0.05$) (Table III).

Gastritis is observed in 15 % of all patients.

DISCUSSION

Our results clearly show a loss of BMI and fat mass at the end of the protocol and at the 3-6 months follow-up, and can be compared to those of other successful obesity treatments. A minimum loss of 10 % was achieved in all variables studied.

Duodenal nutrition is routinely performed in hospital settings and in those patients who for medical reasons require post-pyloric feeding, e.g., emergency and elective abdominal surgery protocols that allow oral feeding after repair of perforated duodenal ulcer or intestinal anastomosis and that allow the repair site to heal and normal intestinal peristalsis to resume, so that the chances of leakage at the repair site are minimized (16).

Table II. Medical supervised duodenal-enteral feeding treatment changes

Variable	Male *n* = 6 (20.7 %) Mean ± SD				Female *n* = 23 (79.3 %) Mean ± SD			
	Initial (i)	Final (f) 3 to 6 months	10i % expected loss (%Achievement)	*p*-value	Initial (i)	Final (f) 3 to 6 months	10i % expected loss (%Achievement)	*p*-value
Weight (kg)	107.3 ± 22.2	96.2 ± 18.3 69.1 ± 0.0	96.5 ± 20.0 (100.3 % ± 6.9)	0.01	82.0 ± 13.6	75.3 ± 12.4 78.2 ± 10.6	73.6 ± 12.3 (97.8 % ± 63.1)	0.00
BMI	37.0 ± 7.5	33.3 ± 5.3 26.8 ± 0.0	33.3 ± 6.6 (100.1 % ± 7.1)	0.01	31.4 ± 4.2	28.9 ± 3.7 29.8 ± 3.5	28.3 ± 3.8 (97.9 % ± 3.1)	0.00
BMR (Kcal)	2138 ± 329	1,975 ± 279 1,541 ± 0.0	1,924 ± 296 (97.3 % ± 4.7)	0.00	1,531 ± 192	1,450 ± 177 1,497 ± 152.6	1,377 ± 173 (94.9 % ± 1.8)	0.00
Waist (cm)	117.7 ± 13.9	107.3 ± 10.9 88.2 ± 0.0	105.9 ± 12.7 (98.8 % ± 6.5)	0.05	95.4 ± 13.2	85.1 ± 11.0 87.6 ± 9.2	85.8 ± 11.8 (100.8 % ± 5.4)	0.47
Hip (cm)	116.2 ± 16.3	111.7 ± 12.7 92.1 ± 0.0	104.7 ± 14.6 (93.7 % ± 3.5)	0.00	113.0 ± 8.6	108.7 ± 8.4 110.16 ± 7.6	101.7 ± 7.7 (93.6 % ± 1.8)	0.00
Arm (cm)	36.7 ± 4.7	33.7 ± 2.8 29.8 ± 0.0	32.8 ± 4.4 (97.3 % ± 6.3)	0.02	33.1 ± 3.4	30.9 ± 3.0 31.3 ± 2.4	29.9 ± 3.0 (96.4 % ± 3.7)	0.00
Thigh (cm)	66.2 ± 9.3	61.3 ± 7.2 51.2 ± 0.0	59.7.3 ± 8.5 (97.1 % ± 3.1)	0.00	65.3 ± 7.2	60.8 ± 6.1 62.2 ± 6.8	58.7.3 ± 6.5 (96.6 % ± 4.4)	0.00
Fat mass (kg)	37.3 ± 13.8	31.2 ± 10.6 15.6 ± 0.0	33.6 ± 12.5 (107.6 % ± 11.7)	0.01	32.2 ± 8.1	28.1 ± 7.1 46.6 ± 4.6	29.0 ± 7.3 (103.6 % ± 7.6)	0.03
Fat %	33.7 ± 5.9	31.5 ± 5.2 22.6 ± 0.0	30.4 ± 5.5 (96.6 % ± 3.9)	0.00	39.0 ± 3.8	36.7 ± 3.9 36.8 ± 4.0	35.1 ± 3.4 (96.0 % ± 4.0)	0.00
Visceral fat (index)	16.8 ± 5.4	14.0 ± 3.4 12 ± 0.0	15.1 ± 4.9 (107.3 % ± 17)	0.03	7.8 ± 2.3	6.6 ± 2.3 7.2 ± 2.1	7.0 ± 2.1 (108.3 % ± 12.6)	0.01
Total muscle mass (kg)	66.3 ± 8.7	62.0 ± 7.4 50.8 ± 0.0	± 6.5i % loss	0.00	46.8 ± 5.8	44.8 ± 5.4 44.9 ± 5.3	± 3.9i % loss	0.00
NGDP (days)	26.0 ± 22.3				22.1 ± 11.3			
Age (years)	36.3 ± 17.8				38.3 ± 11.1			

Levene's test for equality of variances.

Table III. Paired samples correlations

Paired samples correlations						
t-test						**Sig. $p < 0.05$**
Days 22.9 (SD 13.9)	Age					0.18
	Gender	MESUDEFT removal	M	6	29	0.55
			F	23		
		3 to 6 months control	M	1	15	
			F	14		
	Weight loss	MESUDEFT removal				0.02
		3 to 6 months control				0.18
	BMI loss	MESUDEFT removal				0.00
		3 to 6 months control				0.04
	Fat loss	MESUDEFT removal				0.00
		3 to 6 months control				0.02
	Visceral fat loss	MESUDEFT removal				0.00
		3 to 6 months control				0.28
	Waist perimeter loss	MESUDEFT removal				0.07
		3 to 6 months control				0.15
	Hip perimeter loss	MESUDEFT removal				0.00
		3 to 6 months control				0.11
	Arm perimeter loss	MESUDEFT removal				0.05
		3 to 6 months control				0.37
	Thigh perimeter loss	MESUDEFT removal				0.01
		3 to 6 months control				0.20
	Muscle weight	MESUDEFT removal				0.20
		3 to 6 months control				0.70
Gender	Visceral fat loss	MESUDEFT Removal				0.00
		3 to 6 months control				0.05
Fat mass loss	Gender	MESUDEFT removal				0.40
		3 to 6 months control				0.08
	Weight loss	MESUDEFT removal				0.00
		3 to 6 months control				0.00
	Waist perimeter loss	MESUDEFT removal				0.00
		3 to 6 months control				0.00
	Hip perimeter loss	MESUDEFT removal				0.00
		3 to 6 months control				0.00

(Continues on next page)

Table III (cont.). Paired samples correlations

Paired samples correlations			
t-test			Sig. $p < 0.05$
Fat mass loss	Arm perimeter loss	MESUDEFT removal	0.00
		3 to 6 months control	0.00
	Thigh perimeter loss	MESUDEFT Removal	0.00
		3 to 6 months control	0.00
	Visceral fat loss	MESUDEFT removal	0.00
		3 to 6 months control	0.35
Muscle weight	Weight loss	MESUDEFT removal	0.01
		3 to 6 months control	0.54

Given the evolution of the knowledge of physiopathology and the constant research on overweight and obesity and the increase in the number of patients worldwide (1-3), physicians and/or health personnel have a scientific and moral obligation to help with the discovery of new alternatives for treatment or the discovery of new ways to treat (17).

The indications for bariatric surgery have been evolving since the first National Institute of Health (NIH) consensus meeting in 1991. Currently, in Europe, most scientific associations assume the indications formulated in the clinical guidelines of the Interdisciplinary European Guidelines on Metabolic and Bariatric Surgery (18), but overall complications (19) as dyslipidemia, hypertension, deficiency of iron (52 %), calcium, vitamin B12 (70 %), thiamine, folic acid (35 %) and protein malnutrition (20). Alopecia is of great concern to patients and occurs more frequently in women than in men, associated with marked weight loss, zinc and iron deficiency and hormonal changes; it appears between the third and sixth postoperative month, recovering spontaneously after the sixth month, but supplementation is often necessary to accelerate the recovery process (21,22). Due to nutritional and metabolic complications such as short bowel syndrome, severe hypoglycemia refractory to medical management and chronic diarrhea, several patients required further surgery to restore the continuity of the gastrointestinal tract in order to control the complications (23). Therefore, our study attempts to present a new alternative for the medical treatment of obesity either as a sole treatment or as an adjunct to bariatric surgery.

Duodenal nutrition guidelines (23) indicate that it is not necessary to give prokinetic medication for the placement of the duodenal tube, as gastric emptying does the job. However, in our protocol we have given the indication to take bisacodyl 5 mg as pre-medication (the night before the procedure), as a gastrointestinal prokinetic to accelerate the motility of the digestive tract after the placement of the naso-duodenal tube with good results.

At hospital level, X-ray control is required to confirm placement, but in our study it was not indicated for the comfort of the patients; we confirmed that the tube was correctly placed when the biliary content was visible in the distal part of the tube when it was removed (Fig. 3). This method has the limitation that the correct position of the probe is not checked at the beginning of the treatment, only at the end.

The placement of the naso-duodenal tube is a simple, uncomplicated procedure, but in our study we acknowledge that two patients abandoned the MESUDEFT protocol after ten minutes and the following day due to discomfort in the nose and seeing themselves in the mirror as a "sick person"; however, the rest resisted the duration of the treatment without complications and were very motivated by the weekly photographic records and body composition assessment (Fig. 4). A video showing the evolution changes is available from: https://figshare.com/articles/media/MESUDEFT_Evolution_Changes/20377683

During the MESUDEFT protocol, complete (low-very low caloric content) and balanced nutrition was given by tube for approximately 12 hours per day. It should be noted that patients were not restricted to oral intake; in fact, due to the small caliber of the tube, liquid intake (water or tea) was allowed at a rate of approximately 35 ml per kg of body weight per day when nutrition was disconnected. Due to the motivation and good results, several

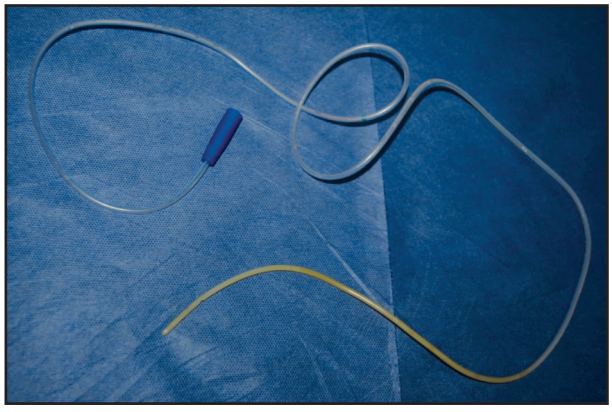

Figure 3.
Naso-duodenal tube removed (post-protocol).

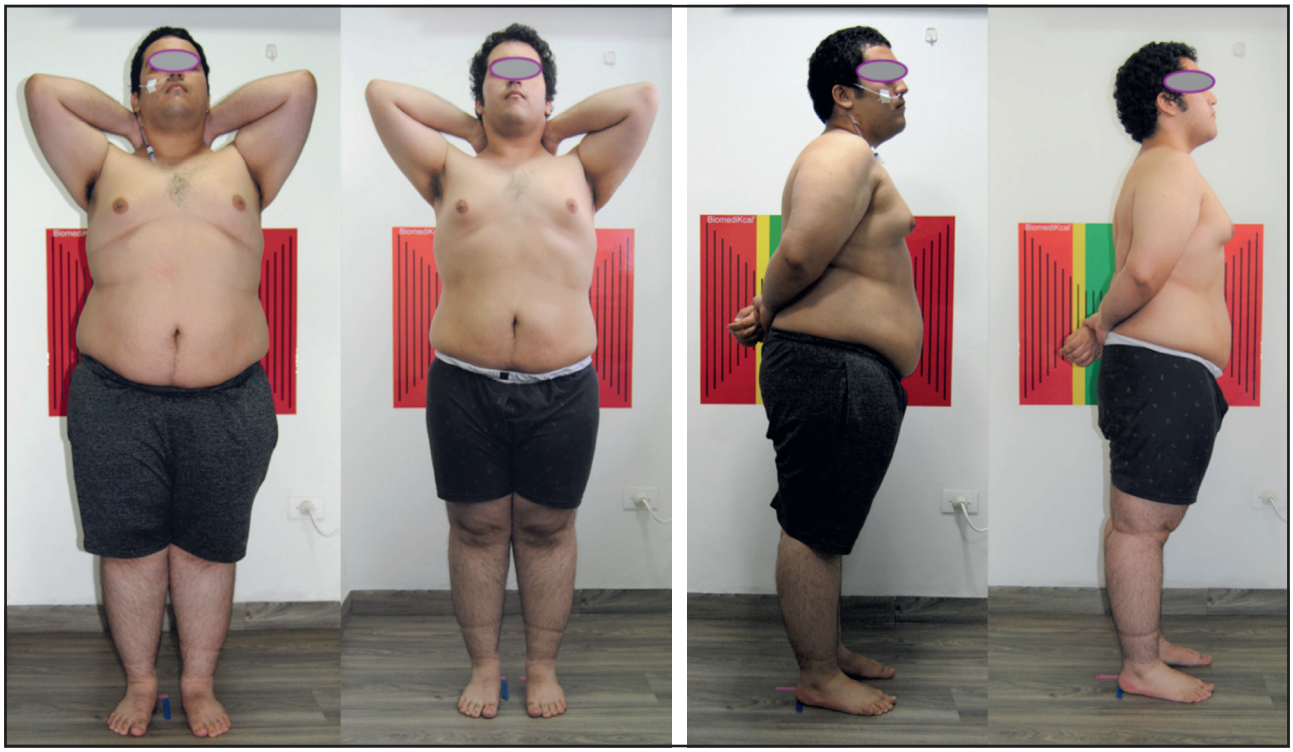

Figure 4.

Observable changes. Start day (1st) and end of protocol (29th).

patients reported at the end of the protocol that, without medical permission, they also drank soups or chicken broth.

Some patients had gastritis which was easily treated with omeprazole 20 mg/day. The majority of patients reported that they were not hungry during the protocol. In our opinion, this may be due to the fact that by providing complete and constant food for 12 hours through the duodenal tube, ghrelin levels decreased, causing the patient to report a feeling of satiety. It is necessary to do a new study and measure ghrelin levels to confirm or deny this. Obesity treatments should always be associated with physical activity (24) and, in our study, all patients were instructed to do physical activity such as walking, jogging or going to the gym if they were used to it. Likewise, the treatment does not cause disability, therefore, they could continue working normally from the hour after the duodenal tube was placed.

It is widely demonstrated that a hypocaloric or very low calorie diet gives good results for the treatment of overweight and obesity (25). The disadvantage is that the control over the patient and the desired or expected results are often not easy to achieve for the treating professional (25). A question that may arise for other professionals is what happens if the complete nutrition (hypocaloric or very low calorie) is given without the tube; will the same results be obtained orally? The answer is no. The indication for feeding directly into the duodenum is to give a break and try to decrease the total gastric emptying capacity, where, it seems, the hormones ghrelin and leptin play an important role (26). The MESUDEFT protocol cannot be performed on patients with Roux-en-Y gastric bypass surgery (RYGB) as the duodenum is needed for the tube to deliver full nutrition; however, the protocol can be performed on patients with laparoscopic sleeve gastrectomy. We assume that the results can be the same or better in patients who have undergone surgery. Further studies are needed to confirm this.

These novel results are encouraging, but we have some limitations: the number of participants, the number of patients in the control group decreased from three to six months, the follow-up time was brief, and the method of checking for appropriate tube installation was performed at the end of treatment. This is why we invite researchers to replicate our study in their home centers in order to compare results.

CONCLUSION

MESUDEFT is shown to be an effective alternative as a sole treatment or as an adjuvant prior to bariatric surgery for obesity or overweight treatment with a minimum 10 % loss in BMI and fat mass at completion and at 3-6 months follow-up.

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