Percutaneous Gastric Embolisation in Obese Patients: A Prospective Study of Mid-Term Outcomes

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Abstract

Introduction

Obesity represents one of the most pressing public health challenges that needs to be solved globally, with serious health implications. Percutaneous gastric embolisation has emerged as a promising technique in the management of obesity.

Objective

This study aims to evaluate the relationship between endovascular procedure and weight loss in obese patients. In addition, to determine the complications related to percutaneous gastric embolisation in these patients.

Design:

Prospective longitudinal cohort study during the period from 1 January to 31 December 2022 and received treatment with percutaneous gastric embolisation

Setting:

This study includes patients admitted to the Haemodynamics Service of the Cardiovascular Health Institute during the year 2022.

Participants:

This study includes 15 patients diagnosed with grade III obesity who met the following criteria: patients ≥ 18 years with a diagnosis of obesity as determined by a body mass index greater than 30 kg/m2 and less than 40 kg/m 2, admitted between January to December 2022, and patients with a diagnosis of obesity with BMI > 40 kg/m2 with contraindication or refusal of bariatric.

Main Outcome(s) and Measure(s):

This is one of the largest studies in percutaneous gastric embolisation an obese population, while assessing the sustainability of weight loss outcomes. The main findings of the study can be summarised as follows: a) The procedure is safe without major complications, ulcers or gastric ischaemia, b) These technique achieves significant weight loss that is maintained over time.

Results

86.7% were successful. Treated patients experienced significant weight loss when comparing baseline weight (101.2 ± 23.0 SE = 5.9) with weight at 6 months after the interventional procedure (91.5 ± 19.8, SE = 5.1) $t(14) = 5.3$, $p < 0.001$, $d = 0.45$. Especially males (106.7 ± 18.4, $p = 0.01$). No major vascular complications, gastric ulcer or ischaemia, or abdominal symptoms were documented in any of the

patients included in the study. Only 6 patients (40%) presented with epigastralgia, 9 (60%) with nausea and 3 (20%) with vomiting.

Conclusions

Percutaneous gastric embolisation is an effective and safe procedure to reduce body mass index with a high success rate, well tolerated by obese patients, without major complications, whose results are maintained over time.

INTRODUCTION

Obesity represents one of the most pressing public health challenges that needs to be addressed. According to the World Health Organisation, its prevalence has tripled since 1975, reaching 6–8% of the world's population in 2016, with a significant impact on the quality of life of individuals and a substantial risk for the development of chronic diseases. [1–3] In Europe, prevalence rates increased from 8.4% in 1980 to 20% in 2019, with the highest rates of 23.2% in the United States. [4]

This comes at an approximate cost of nearly $150 billion a year in the United States. [5] Despite sustained efforts to promote healthy lifestyles and implement various therapeutic strategies, the prevalence of obesity continues to increase globally. [6,7] In this context, a constant search for innovative and effective approaches to the treatment of obesity is required.

Percutaneous gastric embolisation (PGE) has emerged as a promising technique in the management of obesity, offering a less invasive approach than traditional surgical procedures such as gastric bypass surgery and vertical gastrectomy. PGE is based on inducing ischaemia in the gastric fundus by embolising the arteries that supply it, which reduces ghrelin production, thereby reducing the sensation of hunger and food intake. [8,9] As this technique evolves and is refined, its potential to be a safe and effective option for patients with severe obesity or those who are not candidates for bariatric surgery becomes increasingly evident. [10] However, studies evaluating these short- and long-term outcomes as well as assessing the occurrence of procedure-related complications are very limited. Therefore, further research in this area is essential to better understand this technique in order to provide a solid evidence base to guide clinical decision-making and improve the care of these patients.

This study aims to evaluate the relationship between endovascular procedure and weight loss in obese patients. In addition, to determine the complications related to percutaneous gastric embolisation (PGE) in these patients.

MATERIAL and METHOD

Prospective longitudinal cohort study involving 15 patients diagnosed with grade III obesity. These patients were admitted to the Haemodynamics Service of the “Instituto de Salud Cardiovascular ISACMed” during the period from 1 January to 31 December 2022 and received treatment with PGE. The

study population was constituted from all consecutive patients admitted to the ISACMed Cardiovascular Health Institute referred by the endocrinology service who met the inclusion criteria and none of the exclusion criteria.

Inclusion criteria:

- Patients ≥ 18 years with a diagnosis of obesity as determined by a body mass index (BMI) greater than 30 kg/m2 and less than 40 kg/m 2, admitted between January to December 2022.
- Patients with a diagnosis of obesity with BMI > 40 kg/m2 with contraindication or refusal of bariatric abdominal surgery.

Exclusion criteria:

- Patients with chronic kidney disease or glomerular filtration rate less than 60ml/min/1.73m2.
- Chronic treatment with non-steroidal anti-inflammatory drugs (NSAIDs).
- History of peptic ulcers, duodenal ulcer and others in the last 12 months.
- Active Helicobacter Pylori infection or treated within the last 3 months.
- Autoimmune diseases such as rheumatoid arthritis, systemic lupus erythematosus, Crohn's disease, multiple sclerosis.
- Active cancer or cancer under treatment within the last 5 years.
- Pregnant or breastfeeding women.

The modified 8-question Council of Nutrition appetite questionnaire was used to assess appetite loss. [(11)] Responses were scored using a 5-point Likert-type scale (A to E), labelled verbally. The total score was the sum of the scores for the 8 questions, with lower scores indicating impaired appetite (28 points or less).

For the diagnosis of obesity, the BMI was determined for each patient based on their weight and height, according to the WHO [(12)] definition based on a standardised measurement carried out by the healthcare staff of the Institute of Cardiovascular Health. Ultrasound-guided arterial punctures (transfemoral and transradial) were performed under local anaesthesia with lidocaine, using a 5F introducer with a 0.035 X 180 mm hydrophilic guide on a 100 cm radial and 60 cm femoral Cobra 5F catheter. The celiac trunk was cannulated and when possible the left gastric artery with the Cobra catheter. Arterial angiography was performed to delineate the celiac trunk and its branches: left gastric artery (LGA), hepatic artery, splenic artery, gastroduodenal artery and gastroepiploic artery. Once the Cobra catheter was positioned, a Progreat TM (Terumo) microcatheter (Terumo) was introduced, cannulating at least the middle third of the LGA. The branches of the gastric fundus were then embolised with 355–500 micron Polyvinyl alcohol (PVA) microspheres or microparticles, The other proximal branches of the left gastric artery were then embolised with 500–710 micron microparticles (Merit Medical*). (Merit Medical*). After embolisation, Perclose or Angioseal 6Fr arterial closure devices were placed randomly.

Statistical analysis

Continuous variables were expressed as mean with standard deviation (SD) or median (interquartile range (IQR), according to normal or asymmetric data distribution, which was assessed by the Shapiro Wilk test. Categorical variables are presented as numbers and percentages.

The χ 2 test was used for comparisons between qualitative variables, using the relative risk (RR) to define the intensity of this association, as well as Student's t-test for the comparison of means between quantitative variables. We worked for a confidence level of 95% and a critical or rejection zone (alpha) of 0.05, associated with the probability value p. The statistical programme SPSS version 25 was used for data analysis.

Data collection and definition of variables

For this study, the data were extracted from the register of patients admitted to ISACMedl and the medical records, disaggregated from any personal data.

Demographic and clinical variables: age (chronological age at hospital admission); gender (determined from biological sex); personal pathological history: arterial hypertension (considered as a history of arterial blood pressure figures higher than 140 mmHg systolic blood pressure and 90 mmHg diastolic blood pressure obtained in a medical consultation), diabetes mellitus (considered as a history of previous diagnosis recorded in the clinical history or the use of hypoglycaemic medication), obesity.

Laboratory variables were obtained per blood sample within standard clinical practice: glucose (mg/dl), glycosylated haemoglobin, creatinine (mmol/L), gamma-glutamyl transferase (U/L), glutamic oxaloacetic transaminase (U/L), glutamic pyruvic transaminase (U/L), triglycerides (mg/dl), high-density lipoproteins (mg/dl), low-density lipoproteins (mg/dl).

Procedural success was defined as occlusion of all distal branches of the LGA with patency of its trunk and all surrounding branches. Adverse events were categorised according to the Society of Interventional Radiology Classification [13] including any serious vascular adverse events (major haematoma, bleeding requiring medical intervention, arterial thrombosis or vessel dissection), superficial or deep mucosal ulcers, gastric ischaemia or perforation, and digestive symptoms (nausea, vomiting and epigastralgia). While assessment of procedure-related bleeding was performed using the Bleeding Academic Research Consortium (BARC) scale. [14]

RESULTS

In our study, 15 patients with a body mass index (BMI) greater than 30 kg/m², all undergoing PGE treatment, were included. Within this cohort, 26.7% of patients were found to have a history of hypertension and diabetes mellitus, and one patient had previously undergone a bariatric procedure, specifically Gastric Sleeve surgery. It is relevant to highlight that in this population, the female gender predominated, representing 60.0% of the participants. The mean initial weight of the patients was 101.2

± 23.0 kg, with an average waist circumference of 109.1 ± 23.0 cm and a BMI of 36.6 ± 6.1 kg/m², the remaining values are shown in Table 1.

Table 1
General characteristics of the population.

Variables	N (15)
Age *	41,2 ± 10,7
Gender Female, n (%)	9 (60,0%)
Hypertension, n (%)	4 (26,7%)
Diabetes Mellitus, n (%)	4 (26,7%)
Insulin use, n (%)	2 (13,3%)
Previous bariatric procedure, n (%)	1 (6,7%)
Waist circumference *	109,1 ± 16,4
Baseline weight *	101,2 ± 23,0
BMI * BMI	36,6 ± 6,1
Creatinina (mmol/L) *	10,1 ± 5,6
TGO (U/L) **	16,3 (14,0–36,0)
TGP (U/L) **	21,0 (15,0–51,0)
Glycaemia *	95,5 ± 11,5
glycosylated haemoglobin *	5,5 ± 0,6
Triglycerides *	158,5 ± 79,5
HDL * HDL	55,4 ± 18,5
LDL *	121,9 ± 33,9
*: mean, standard deviation, **: median interquartile range, BMI: body mass index, GOT: glutamic oxaloacetic transaminase, GPT: glutamic pyruvic transaminase, HDL: high-density lipoprotein, LDL: low-density lipoprotein, HDL: high-density lipoprotein, LDL: low-density lipoprotein	

Table 2
Variables related to the endovascular procedure.

Variables		N (15)
Microparticles	355–500	11 (73,3%)
	500–710	4 (26,%)
Access	Radial	4 (26,7%)
	Femoral	8 (53,5%9
	Conversion	3 (20,0%)
Embolised Artery	Left gastric artery	12 (80,0%)
	Right gastric artery	2 (13,3%)
	Both	1 (6,7%)
Result	Successful	13 (86,7%)
	Failed	2 (13,3%)
Procedure time (minutes) *		60 (50–90)
Radiation time (minutes) *		30,9 ± 10,1
Radiation dose (milligrays) *		3722,4 ± 1659,6
Waist diameter *		109,1 ± 16,4
Weight at 3 months *		95,7 ± 21,1
Weight at 6 months *		91,5 ± 19,8
Percent weight loss (3 months) *		5,3 ± 2,4
Percent weight loss (6th month) *		8,6 ± 3,3
Percentage of BMI lost ** Percentage of BMI lost **		5,9 (4, 8–9, 5)
Loss of apetite		13 (86,7%)

*: Mean, standard deviation, **: Median, interquartile range, Conversion: Changes in vascular access during the procedure due to technical aspects, generally from radial to femoral.

Regarding the percutaneous procedure, the most commonly used vascular access was the femoral access in 53.5%. During these procedures, LGA was embolised in 12 (80%) of the cases, and a median procedure duration of 60 minutes (RIC 50–90) was recorded. The mean hospital stay was 8 ± 8 hours.

Regarding the efficacy of the procedure, 86.7% of the procedures were found to be successful, with a mean weight loss of 8.6% ± 3.3 at month 6 and a median BMI loss of 5.9 (RIC 4.8–9.5). In addition, a significant reduction in appetite was observed in 13 (86.7%) patients, when applying a validated 8-

question visual scale. The main causes of procedural failure were related to anatomical variants, which prevented complete embolisation of the arteries responsible for perfusion of the gastric fundus. One patient developed collateral circulation after successful embolisation of the LGA.

Regarding adverse events, 6 patients (40%) experienced epigastralgia, 9 (60%) experienced nausea and 3 (20%) experienced vomiting. No major vascular complications, gastric ulcer or ischaemia, or abdominal symptoms were documented in any of the patients included in the study.

Obese patients treated with PGE experienced significant weight loss when comparing mean baseline weight (101.2 ± 23.0 SE = 5.9) with calculated weight at 6 months post procedure (91.5 ± 19.8, SE = 5.1) $t(14) = 5.3$, $p < 0.001$. Similar significance was shown in the percentage of weight loss in their measurements three months after the procedure (5.3 ± 2.4 SE = 0.6) compared to the results at the sixth month (8.6 ± 3.3) $t(14) = -6.8$, $p < 0.001$, $d = 1.14$ (Table 3). In relation to sex, male patients were associated with a greater weight loss in their evaluation at the third and sixth month respectively (112.2 ± 18.5; $p < 0.001$ and 106.7 ± 18.4; $p = 0.01$). In most cases, a decrease in BMI was observed at 6 months after percutaneous treatment. Figure 1.

Table 3
Comparison of weight and percentage weight loss after GPE.

Variables			**p valor**
	Initial Weight Mean (SD)	Weight 6th month Mean (SD)	
Weight loss (kg)	101,2 ± 23,0	91,5 ± 19,8	< 0,001
	1st month, Mean (SD)	6th month Mean (SD)	
Percentage weight loss (Kg)	5,3 ± 2,4	8,6 ± 3,3	< 0,001

DISCUSSION

This is one of the largest studies on PGE in an obese population, while assessing the sustainability of weight loss outcomes and percentage weight loss at 3 and 6 months after the interventional procedure. The main findings of the study can be summarised as follows: a) The procedure is safe without major complications, ulcers or gastric ischaemia, b) The PGE achieves significant weight loss that is maintained over time c) Weight loss is greater in male patients.

Our study has shown a high success rate of the procedure, which is in line with recent studies. [15,16] The characteristics of this minimally invasive percutaneous procedure, with a short intervention time, without hospitalisation, as well as the training of haemodynamicists, have contributed to these results. From the first investigations on PGE to the most current ones, success has been achieved in the majority of

patients. [17–19] Despite being a developing technique, anatomical variants and the presence of non-responders, the success rate of PGE is high compared to other techniques.

Despite being a developing technique, anatomical variants and the presence of non-responders, the success rate of PGE is high compared to other techniques. Among much larger populations, 2–13% of patients undergoing bariatric surgery require re-interventions due to procedural failure [20] while for the gastric balloon it is about 10%. [21] However, further studies with larger sample sizes are needed to assess the impact of these situations on weight loss in patients receiving PGE.

The weight loss and percentage weight loss of obese patients in our study population corresponds with the results of current research on the subject. [22,23] From the early research evaluating the efficacy of arterial embolisation in the treatment of acute gastrointestinal bleeding to the aculates in the treatment of obesity, there has been evidence of a loss of body mass after LGA embolisation. [24,25] In the GET LEAN pilot study, patients who received LGA embolisation had a decrease in average body weight at the six-month assessment. [26]

A similar result was obtained in the BEAT-Obesity study in severely obese patients, with a loss of excess weight at one month that was maintained up to 12 months. [19] Similarly, the first randomised clinical trial of LGA vs. sham procedure included 68 patients with BMI between 33 and 55 kg/m2, [15] mean absolute and percentage total weight loss were significant in the group receiving PGE when compared to the control group at 6 and 12 months.

When including a gender perspective in the analyses, we observed that male sex was associated with greater weight loss, which could be justified by a 100% success rate in the procedure among men and a higher percentage of appetite loss in relation to women. A meta-analysis including 6 non-randomised studies showed a greater weight loss in men as reported in our research. [27] Further studies are needed to investigate this difference.

Compared to bariatric surgery, PGE is safer, with a lower incidence of major complications. [8,9] Our study reports only minor manifestations related to the procedure such as nausea, vomiting and epigastralgia. Among the published studies, only one major complication has been documented which included: severe pancreatitis, splenic infarction and gastric perforation. [27] The other most frequent complications are superficial ulcers of the gastric mucosa, epigastric pain, nausea and vomiting. [26,28] The results of the first prospective study of PGE in 5 patients demonstrated that it is a safe procedure with only minor complications in treated patients. The study by Weiss CR et al. evaluating the safety of PGE in severely obese patients with a 12-month follow-up documented 11 minor adverse events. [19] Consistent with the results of our research, most adverse reactions resolve early and do not cause sequelae in patients.

This novel procedure compared to approved drugs for the treatment of obesity guarantees a higher percentage of weight loss. [29,30] Although it could be used as an adjuvant therapy to lifestyle modification and pharmacological treatment.

Limitations

The main limitations of this research lie in the characteristics of the study itself, the absence of a control group, as well as the small number of participants, even though it is one of the published works with the largest sample size. The fact that our study was conducted in a single centre makes it difficult to generalise the results. The absence of an endoscopic study of the patients treated makes it impossible to evaluate adverse reactions in the gastric mucosa.

CONCLUSIONS

The PGE is a useful procedure to reduce BMI with a high success rate, well tolerated by obese patients without major complications and maintained over time. It is a novel intervention that can undoubtedly contribute to body weight loss, helping to reduce this global public health problem. This will help to reduce its impact on diseases such as diabetes, hypertension, cardiovascular and endocrine-metabolic diseases.

Declarations

Ethical Approval and Consent to participate

The researchers participating in this study followed the applicable ethical and legal standards, in particular the Declaration of Helsinki and current legislation. Informed consent was obtained from the patients and approval was obtained from the hospital's ethics committee with registration code 14660-A.

Consent for publication

No applicable.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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CISP: participated in the conceptualization, supervision and writing-review & editing.

RAC: participated in the formal analysis, validation and writing – original draft.

LMTF: participated in the investigation and writing – original draft.

SSAB: participated in the data curation and visualization.

FLC: software and visualization.

MEBF: project administration and validation.

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Figures

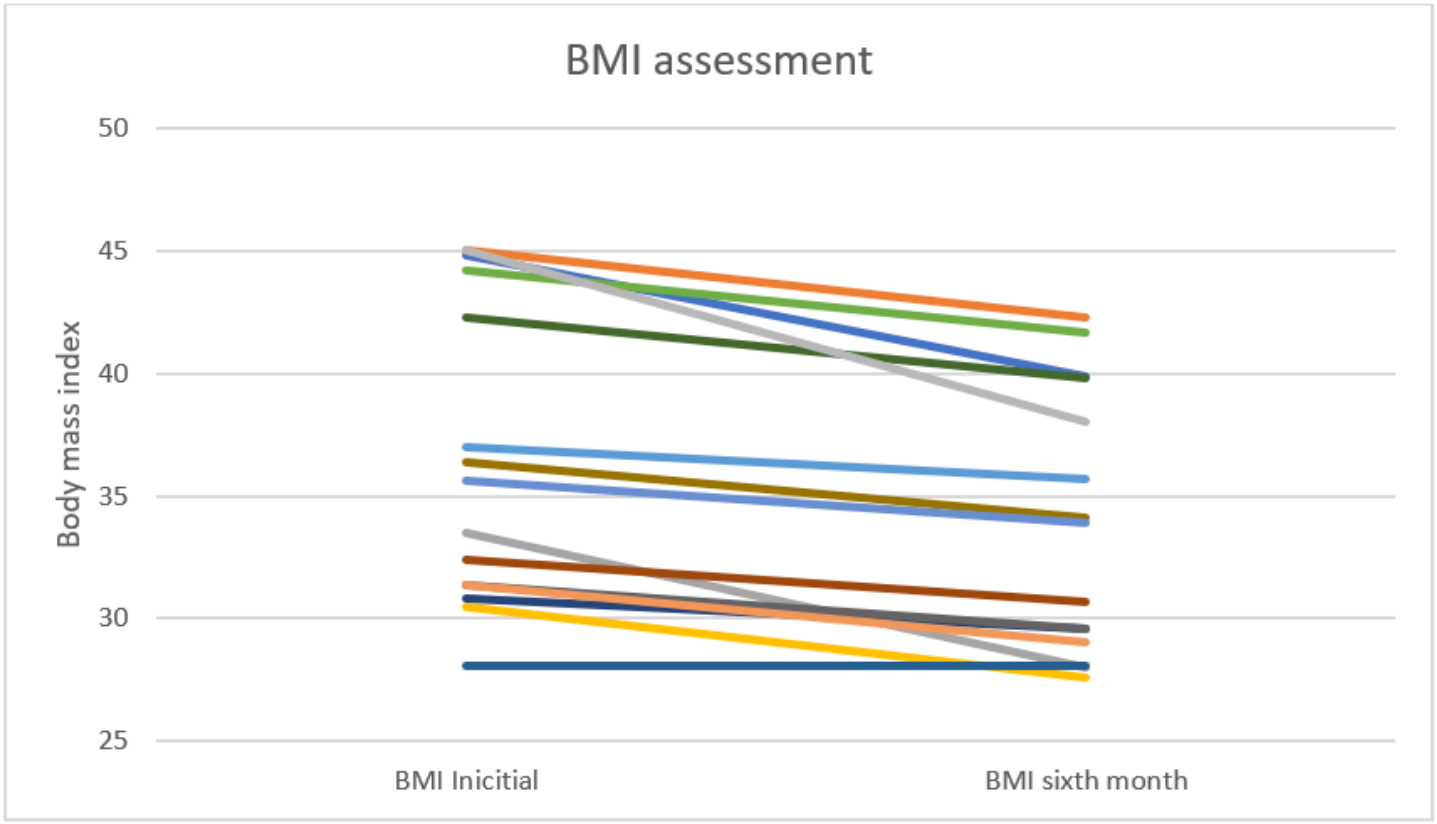

Figure 1

Change in body mass index 6 months after percutaneous gastric embolisation.