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Bariatric Embolization in the Treatment of Patients with a Body Mass Index Between 30 and 39.9 kg/m^2 (Obesity Class I and II) and Metabolic Syndrome, a Pilot Study

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Abstract

Introduction To evaluate the efficacy and clinical safety of bariatric arterial embolization (BAE) in adults with body mass index (BMI) between 30 and 39.9 kg/m^2 and metabolic syndrome (MS).

Materials and methods Between March and August 2018, ten female participants between 21 and 48-years-old, median BMI of 36.37 ± 2.58 kg/m^2 and MS were enrolled in this prospective trial. We embolized the fundal branches from the left gastric and other artery sources, which resulted in embolization of at least two arteries in 9 out 10 participants. Six months after bariatric embolization, efficacy was assessed by changes in total body weight (TBW), ghrelin and Homeostatic Model Assessment—Insulin Resistance (HOMA-IR) levels and by changes in quality of life (QOL) and in binge eating scale (BES) scores. Safety was assessed by the identification of any related complications, including gastric ulcers, screened by gastrointestinal endoscopy, performed before and one week and one month after BAE.

Results Six months after embolization, TBW decreased by 6.8% (6.22 kg ± 3.6;p = .01), serum ghrelin dropped from 25.39 pg/ml ± 10.63 to 17.1 ± 8.07 (p = 0.01), and HOMA-IR decreased from 7.29 ± 5.66 to 3.73 ± 1.99 (p = 0.01). The QOL scores improved from 59.64 ± 5.59 to 69.02 ± 11.97 ($p < 0.05$) and in the BES from 21.50 ± 8.89 to 9.60 ± 4.40 (p = 0.01). Endoscopy revealed symptomatic gastric ulcers in two participants, which had healed without sequelae. In one participant, ultrasound revealed an asymptomatic focal arterial thrombus at the left distal radial artery puncture site.

Conclusion BAE is effective in reducing weight, insulin resistance and ghrelin levels and improving BES and QOL scores in patients with class I and II obesity and MS, with no major complications.

Keywords Bariatric embolization · Obesity · Ghrelin · Metabolic syndrome · Quality of life · Binge eating · Insulin resistance

Abbreviations

AH	Arterial hypertension
BAE	Bariatric arterial embolization
BES	Binge Eating Scale
BMI	Body mass index
CVD	Cardiovascular disease
Hba1c	Glycated hemoglobin
HDL	High-density lipoprotein
HOMA-IR	Homeostatic Model Assessment-Insulin Resistance
IDF	International Diabetes Federation

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MS	Metabolic Syndrome
PPI	Proton pump inhibitor
TBW	Total body weight
TC	Triglycerides
T2D	Type 2 diabetes
GI	Gastrointestinal
QOL	Quality of Life

Introduction

Obesity is a chronic disease, that currently is considered a serious public health issue whose prevalence has been increasing in most countries worldwide, especially in the last 25 years [1, 2], It is not different in Brazil, whose percentage of obese people has increased from 11.4% to 20.3% in the period between 2006 and 2019 [3]. Within the spectrum of obesity, there is frequently the coexistence of Metabolic Syndrome (MS), a cluster of conditions which includes increased blood pressure, high blood sugar, excess body fat and dyslipidemia. Up to 25% of the adult population in Latin America has MS, similar to those found in European countries [7, 8]. The risk of this group of patients presenting with cardiovascular disease (CVD) in 5–10 years is twice as high as that of people without MS, and the risk of developing type 2 diabetes (T2D) is increased by five times [4]. The treatment of obesity is complex and multidisciplinary, and it presents a great challenge in medical practice. Pharmacological and behavioral treatments are only modestly effective and of limited duration [5]. A 5% of total body weight (TBW) loss is defined by the Food and Drug Administration as clinical significant for low-risk drugs [6]. For patients with BMI above 40/kg/m^2 or above 35 kg/m^2 with comorbidities, bariatric surgery is indicated; it has scientific evidence of achieving long-lasting TBW loss and reducing CVD and mortality. Although effective and with mortality rates less than 2%, bariatric surgery has complication rates up to 25%, and up to 50% of patients develop chronic nutritional deficiencies [7, 8].

It is known that a large part of the beneficial effects of bariatric surgery is consequences of changes in plasma levels of hormones involved in the homeostasis of the body's hunger/satiety state [9, 10]. For instance, in sleeve gastrectomy surgery, the gastric fundus is removed; in that portion of the stomach is where nearly 90% of the hormone ghrelin, a potent appetite stimulator, secreted in response to fasting, is produced. An increase in plasma ghrelin levels results in increased growth hormone secretion, gastric secretion and mobility. The exogenous administration of the active form of ghrelin, known as acylated ghrelin, in humans, results in an increase in appetite, accumulation of adipose tissue, suppression of insulin secretion, induces peripheral insulin resistance and impairs glucose tolerance, demonstrating its clear role in the development of obesity [11], insulin resistance and T2D [12].

Bariatric arterial embolization (BAE) has recently been described as a minimally invasive alternative capable of causing weight loss by reducing serum levels of ghrelin through ischemia of the gastric fundus. Previous published studies were mainly focused on morbidity obese population (BMI $\geq$ 40), and none of them was aimed to evaluate the impact of this new method on metabolic syndrome and specifically on class I and II obese population (BMI between 30 and 39.9 kg/m^2) [13–19]. A systematic review and meta-analysis of the main results obtained so far [20] showed an average weight loss of 8.85 kg $\pm$ 1.24 kg in 12 months, which was equivalent to approximately 8.2% of the TBW in a population with mean BMI of 41.05 kg/m^2. There was only one study [19] that analyzed the action of bariatric embolization on glycated hemoglobin (HbA1c) levels in ten prediabetic patients. They found that this procedure was capable of lowering the HbA1c to normal levels after 6 months (6.1 $\pm$ 0.2 to 4.7 $\pm$ 0.6, $p < 0.0001$).

All those trials have mainly targeted the embolization of the left gastric artery (LGA), which is the dominant artery responsible for the nutrition of the gastric fundus in humans, but the distal portion of the gastroepiploic and the short gastric arteries are important feeders as well. So if only LGA is embolized, it should lead to an early revascularization and loss of efficacy. There is no clear definition so far about the safety and potential benefit in targeting more than one feeding vessels with this new procedure. Considering the modest TWL described so far with BAE, the lack of effective therapeutic options for class I and II obese population and the theoretical beneficial potential of this technique on glucose homeostasis and, therefore, on metabolic syndrome, we decided to study the safety and efficacy of a broader embolization of the gastric fundus (not only LGA) in pre-menopausal women with a BMI between 30 and 39.9 kg/m^2 and metabolic syndrome.

Materials and Methods

Study Design and Participant Selection

This was a prospective, single-arm study approved by the research ethics committee. Participants were recruited from a public university hospital's obesity clinic from March 23 to August 27, 2018. The inclusion criteria were as follows:

Table 1 Diagnostic criteria for metabolic syndrome by IDF

Waist above 80 cm for women* associated with at least 2 of the following:	
Triglycerides	Above 150 mg/dl**
HDL cholesterol	For women: below 50 mg/dl**
Fasting glucose	Above 100 mg/dl**
Blood pressure	Above 130/85 mmHg**

IDF: International Diabetes Federation; HDL: High-density lipoprotein

*If BMI is > 30 kg/m2, central obesity can be assumed

** Or presence of treatment for type 2 diabetes, hypertension or dyslipidemia

Table 2 Characteristics of the 10 participants

Patient	Age	Weight (kg)	BMI (kg/m^2)	Waist (cm)	AH	T2D/ Prediabetes*	Dyslipidemia
1	21	104.2	38.3	133	+		↓HDL
2	41	92.2	33.9	105	+	Prediabetes	
3	48	94.8	39.9	110	+	T2D	
4	32	87.9	34.3	102		Prediabetes	↓HDL
5	37	88	36.6	94		Prediabetes	↓HDL
6	38	92	35.5	106	+	Prediabetes	
7	37	82.3	32.1	97		T2D	↓HDL
8	40	91.5	35.3	110			↓HDL, ↓TG
9	44	96.1	39.5	110	+	T2D	↓TG
10	37	109.1	38.2	119	+	Prediabetes	↓DL

Clinical and laboratory data of the 10 patients. BMI: Body mass index; AH: Arterial hypertension; T2D: Type 2 diabetes; HDL: High-density lipoprotein; TG: Triglycerides

* Prediabetes definition: Fasting blood glucose >99 mg/dL and <126 mg/dL and/or HbA1c > 5.6% and < 6.5%

non-menopausal females (18–49-years old), BMI between 30 kg/m^2 and 39.9 kg/m^2 (obesity classes I and II) and MS according to the International Diabetes Federation (IDF) [22] (Table 1), who were unable to lose weight, despite diet and nutritional guidance, in the last 6 months. The mean age was 37.5 ± 7.26 years. Seven out of ten participants were not candidates for bariatric surgery, and the other three refused surgery. All of them provided written informed consent and were followed for six months after BAE, which was considered an adequate follow-up time for safety and efficacy evaluation in this pilot study.

Only young females were included in this trial because more than 90% of patients followed in the obesity clinic were women and also because there is another arm of this clinical trial that is focused on bone density and microarchitecture following this procedure, so we decided not to include male or postmenopausal women.

The exclusion criteria were pregnancy or the desire to become pregnant in the next year; previous gastric surgery; advanced heart, lung or liver diseases; severe coagulation disorders or a history of alcoholism or drug abuse. One week before embolization, all participants were submitted to a upper gastrointestinal (GI) endoscopy. Severe gastritis, active ulcer or positive test for H Pylori infection was also considered as exclusion criteria. Any subject with mild or moderate gastritis was not excluded and was treated with omeprazole 40 mg bid, for 7 days before the procedure. We did not perform computed tomography angiography before the procedure because we judged that this could count for unnecessary radiation exposure in a fertile population.

A summary of the characteristics of the participants is provided in Table 2.

Embolization Procedure

Bariatric embolization was performed in an angiography suite with an Innova Flat Panel device (GE, USA) by two interventional radiologists with 10 and 3 years of experience under local anesthesia and conscious sedation, by right femoral (n = 2), in subjects measuring over than 1.65 m in height, or left distal radial (n = 8) access, using a 5F AVANTI femoral sheath (Cordis, FL, USA) for femoral access or a 5F radial sheath (Scitech, GO, Brazil) for left distal radial access.

In order to map the main feeders of the gastric fundus, angiographic studies of LGA, gastroduodenal and splenic arteries were performed with Cobra 2 (Cordis, FL, USA) and Mikaelson catheters (Cook, IN, USA) when performed via femoral approach and with JR4 (Terumo, Tokyo, Japan), IM (Terumo, Tokyo, Japan) and Cobra 2 (Cordis, FL, USA) shapes when performed via radial approach. The LGA branches feeding the gastric fundus were superselectively embolized with Progreat 2.8F microcatheters (Terumo, Tokyo, Japan) and 300–500 μm spherical particles (Embospheres; Merit Medical, UT, USA) to its stasis in all participants. After that, superselective right gastroepiploic and distal splenic artery digital subtraction angiography (DSA) was performed in order to look for residual significant perfusion of the gastric fundus. If there was any visible branch feeding the gastric fundus coming from these vessels, it was then superselective embolized distally as possible (Fig. 1). By the time of this trial, 300-500 μm spheres was the smallest size considered safe by previous humans trials. Cone beam CT was not available in our department.

Follow-up

All participants were discharged within 20 h after accepting a liquid oral diet. The following protocol was prescribed: one week of bland diet, followed by an individual hypocaloric low fat and low carbohydrate diet. All patients received a food record to fill in before (T0) and 1 and 6 months after the procedure (T1 and T6). Gastric protection was initiated with 40 mg pantoprazole intravenously during anesthetic induction and maintained with

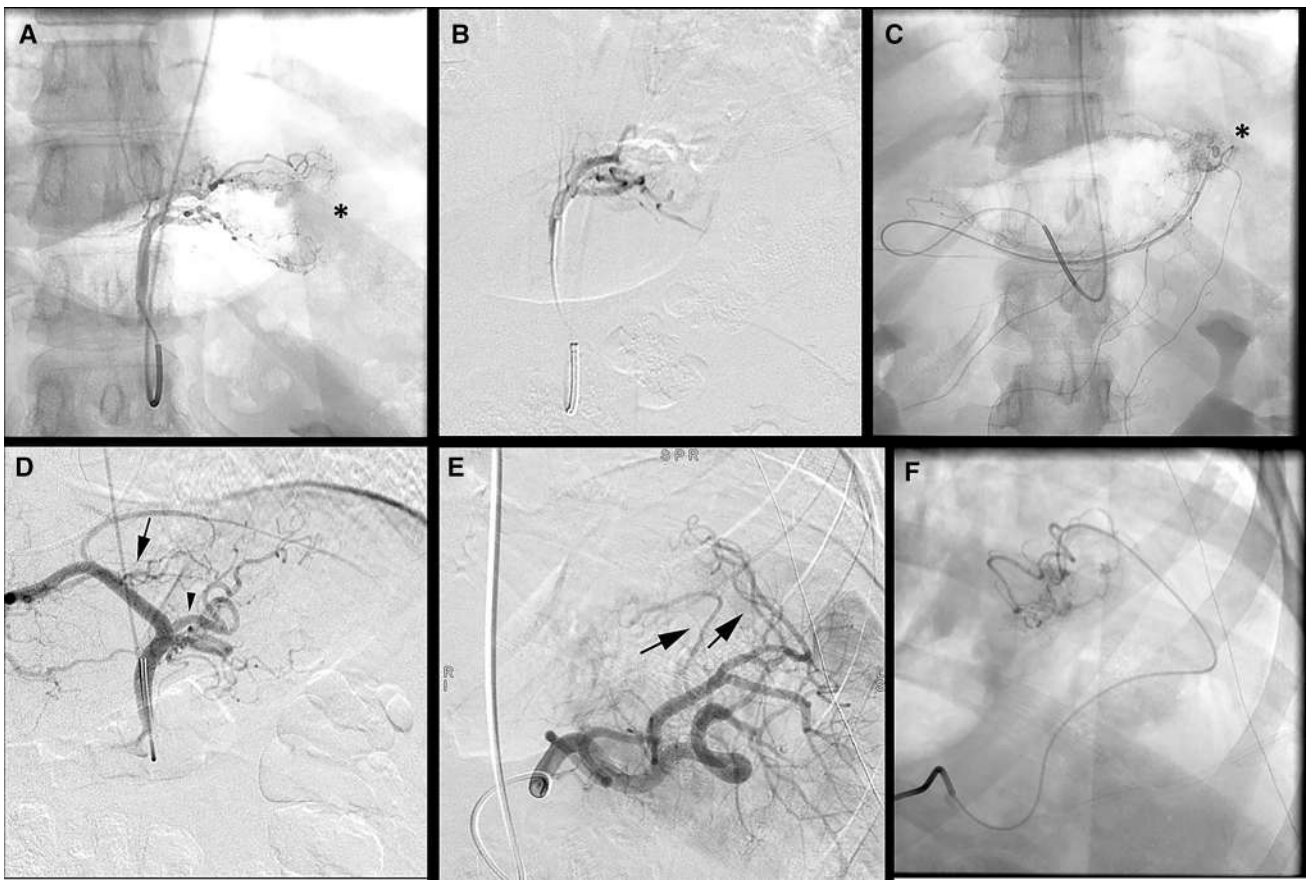

Fig. 1 **A** Left gastric digital arteriogram (non-subtracted) in the supine position from the left radial approach showing arterial branches to the gastric fundus (*) and proximal body. **B** Left gastric digital subtraction arteriogram after embolization with Embospheres showing occlusion of the distal branches of the left gastric artery. **C** Right gastroepiploic arteriogram (non-subtracted), after LGA embolization, showing faint opacification of distal branches of the right gastroepiploic artery supplying the gastric fundus (*). **D** Selective DSA in another patient showing an enlarged LGA, with an early bifurcation, an upper branch feeding the fundus (arrow head) and an accessory left gastric artery (arrow) arising from a replaced left hepatic artery which also is giving off branches to the fundus. **E** Selective DSA of the splenic artery in a different patient after embolization of fundus branches of the LGA showing enlarged short gastric arteries leading to revascularization of the gastric fundus (arrows). **F** Superselective embolization of short gastric arteries

Table 3 Timeline of interventions and evaluations

1 month before	Medical appointment with multidisciplinary team*, anthropometric measurements, blood samples, WHO-BREF and BES questionaries
1 week before	Gastrointestinal endoscopy
T0	Bariatric Embolization
1 week after	Gastrointestinal endoscopy
1 month (T1)	Gastrointestinal endoscopy, medical appointment with multidisciplinary team*, anthropometric measurements, blood samples, food record, WHO-BREF and BES questionaries
3 months (T3)	Medical appointment with multidisciplinary team*, anthropometric measurements, blood samples, WHO-BREF and BES questionaries
6 months (T6)	Medical appointment with multidisciplinary team*, anthropometric measurements, blood samples, food record, WHO-BREF and BES questionnaires

*Multidisciplinary team consisted with at least one professional of the following specialties: Interventional Radiology, Endocrinology and Nutrology

WHO-BREF abbreviated Word Health Organization Quality of Life

BES: Binge Eating Scale

omeprazole 40 mg orally bid for 30 days after the procedure or until the exclusion of any gastric lesions verified by the endoscopist. In one patient, the use of a proton pump inhibitor (PPI) was initiated one week before embolization due to the presence of moderate pangastritis observed on preintervention GI endoscopy.

The timeline of interventions and evaluations is provided in Table 3.

Outcome Measurements

Technical success was defined as embolization of all the major feeding vessels of the gastric fundus found on DSA.

Safety was evaluated through the identification of any related complications. For this, we adopted the updated Clavien-Dindo classification for surgical complications [21].

Upper GI endoscopy was performed one week and one month after embolization to identify early and late gastric procedure-related lesions.

The quantitative efficacy was assessed through reduction in TBW loss, BMI, Homeostatic Model Assessment-Insulin Resistance (HOMA-IR) and acylated ghrelin levels.

Weight, waist circumference and blood samples were assessed before (T0), at 1 month (T1), 3 months (T3) and 6 months (T6) after BAE. Excess body weight was defined as the weight above the value that corresponds to the BMI of 25 kg/m^2.

Acylated ghrelin was measured using the MILLIPLEX MAP Human Metabolic Hormone Magnetic Bead Panel—Metabolism Multiplex Assay kit.

Qualitative efficacy was assessed through evaluation of the binge eating scores using the Binge Eating Scale (BES) [22] and evaluation of quality of life through the abbreviated Word Health Organization Quality of Life (QOL) questionnaire, known as WHOQOL-BREF [23], which were filled out by the participants at T0, T1, T3 and T6.

Statistical Analysis

Descriptive statistics were used to summarize the participant characteristics, and the results are described as the mean ± standard deviation.

Wilcoxon tests were used to compare results at baseline and after follow- up. Statistical tests are based on a 2-sided significance level of 0.05. SPSS software, version 21.0 (IBM, New York, USA), was used for statistical analyses.

Results

No participant was excluded from this trial, and all of them completed the six-month follow-up. BAE was performed via the left gastric artery in all patients. In addition, the branches to the gastric fundus from the following arteries were embolized: the accessory left gastric artery (n = 1), gastroepiploic artery (n = 8) and short gastric artery (n = 1). A summary of the embolized arteries is described in Table 4.

Efficacy

The average weight at T0 was 94.30 kg ± 7.21, and at T6 it was 87.62 kg ± 7.13, with a TBW loss of 6.22 kg ± 3.6 (6.8% ± 3.8; p = 0.01). The excess weight loss of 21.95% ± 10.12% at T6 (Fig. 2A).

Table 4 Embolized arteries

Participants	Left Gastric	Accessory left gastric	Gastroepiploic	Short gastric
1	*	*	*	
2	*		*	
3	*		*	
4	*		*	
5	*		*	
6	*		*	
7	*		*	
8	*			*
9	*		*	
10	*			

Embolized vessels per patient. After embolization of the left gastric artery, we performed angiographic studies of the gastroduodenal and splenic arteries in search of important collateral nutrition of the gastric fundus, followed by superselective embolization of the feeding branches found, which resulted in the embolization of more than one vessel in 9 out of 10 participants

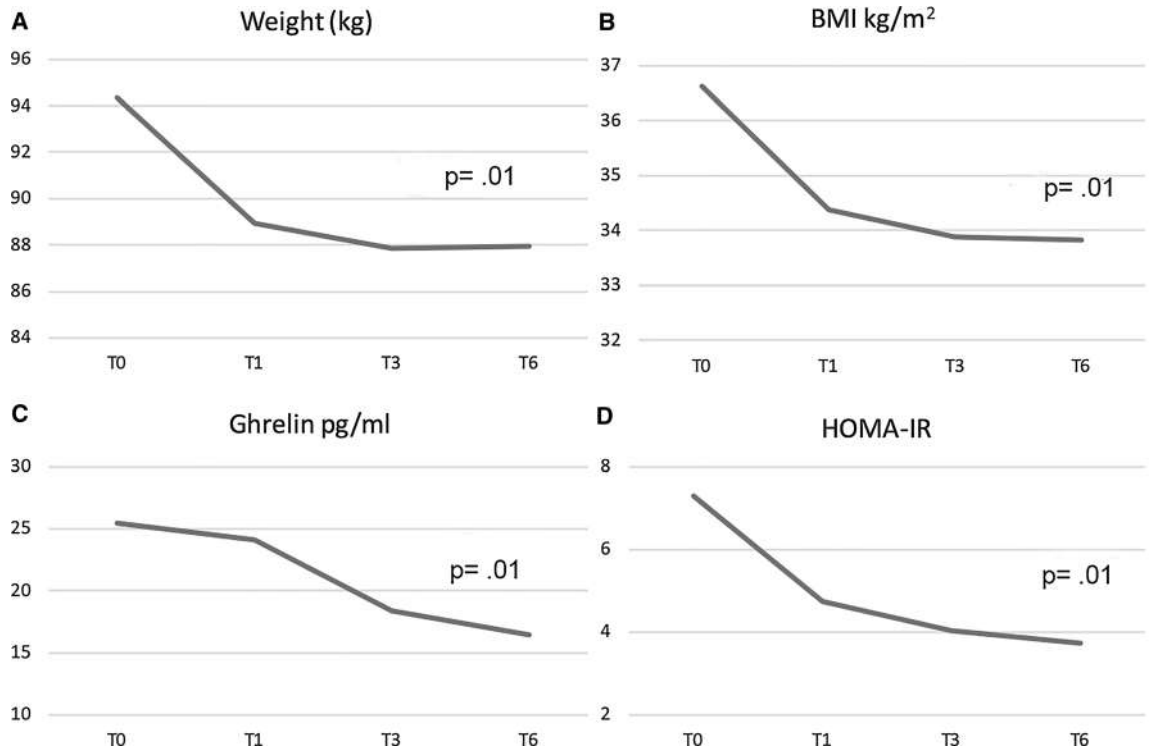

Fig. 2 The average changes in body weight (**A**), BMI (**B**), serum Acylated Ghrelin levels (**C**) and HOMA-IR (**D**) over the 6-month follow-up period after gastric artery embolization

The average BMI dropped from 36.37 kg/m^2 ± 2.58 to 33.82 kg/m^2 ± 2.65 with a mean reduction of 2.79 kg/m^2 ± 1.42 (p = 0.01) at T6 (Fig. 2B).

There was a reduction in waist circumference from 108.6 cm ± 11.16 at T0 to 102.67 cm ± 8.78 at T6 (p = 0.03).

Serum acylated ghrelin levels were 25.39 pg/ml ± 10.63 at T0 and 17.10 pg/ml ± 8.07 (p = 0.01) at T6. There was a sustained and continuous reduction of ghrelin levels over the six months period, reaching 32.7% at T6 (Fig. 2C).

Fasting glucose and insulin were reduced from 111.10 mg/dL ± 47.80 at T0 to 83.70 mg/dl ± 6.98 at T6 (p = 0.01) and from 26.24 µUI/ml ± 14.61 at T0 to 17.82 µUI/ml ± 8.70 at T6 (p = 0.01), respectively. There was a significant reduction in HOMA-IR (Fig. 2D) from 7.29 ± 5.66 at T0 to 3.73 ± 1.99 at T6 (p = 0.01).

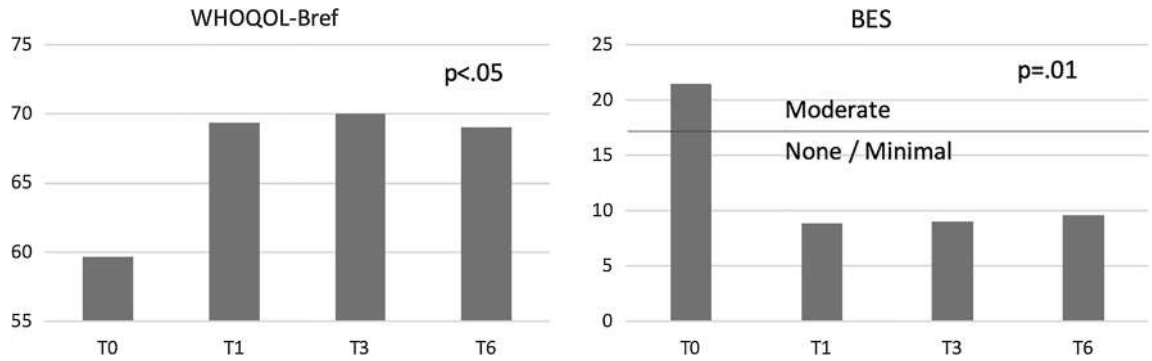

Fig. 3 The average changes of the patients' quality of life (QOL) and binge eating scale (BES) scores over the 6-month follow-up period after gastric artery embolization

HbA1c levels decrease from 6.58% ± 1.72 to 4.74% ± 2.58 ($p = 0.06$), improving in all three patients with T2D, without any change in their prior antidiabetic drugs (patient 1 = from 10.10% to 7.6%; patient 2 = 9.5% to 5.9%; and patient 3 = from 6.1% to 5.9%.).

There was no statistically significant improvement in serum triglyceride levels (110 mg/dL ± 43.68 to 96.80 mg/dL ± 50.19; $p = 0.07$); LDL levels (106.7 mg/dL ± 30.20 to 92.70 mg/dL ± 24.90; $p = 0.08$); or HDL levels (42.70 mg/dL ± 10.99 to 42.80 mg/dL ± 9.46; $p = 0.24$) during the trial period.

There was an increase in the WHOQOL-BREF scores from 59.64 ± 5.59 at T0 to 69.02 ± 11.97 at T6 ($p < 0.05$) and an important reduction in BES scores from 21.50 ± 8.89 at T0 to 9.60 ± 4.40 at T6 ($p = 0.01$), which reflects a rapid and sustained change from moderate binge eating to the absence of or minimal binge eating (Fig. 3).

It is worth mentioning that nine out of ten patients did not follow the proposed low-calorie diet after the first month following the procedure. On average, in the sixth-month food record, there was a consumption of 300 kilocalories more than the prescribed.

Safety

Two patients, one with moderate pangastritis on the GI endoscopy before the procedure, and the other who refused to use a PPI after the procedure, presented with a deep, symptomatic, gastric ulcer (1.5 and 4 cm in diameter, respectively) one week after the intervention. Both patients were managed on an outpatient basis with a full dose of omeprazole (80 mg bid) and liquid diet for 1 week. Eight patients had asymptomatic superficial ulcers on the 1-week GI endoscopy. All ulcers, including deep ulcers, were completely healed on the 1-month GI endoscopy (Fig. 4). Curiously, most ulcers, including deep ones, occurred in the transition from the lesser curvature into the gastric fundus, none of the ulcers were visualized in the gastric fundus.

There was a 5-cm segmental left distal radial artery thrombosis in one patient; it was refractory to full anticoagulation with rivaroxaban but without clinical sequelae.

In total, there were two Grade 1 (deep gastric ulcers) complications and one Grade 2 (puncture site thrombosis) complication according to the Clavien-Dindo scale.

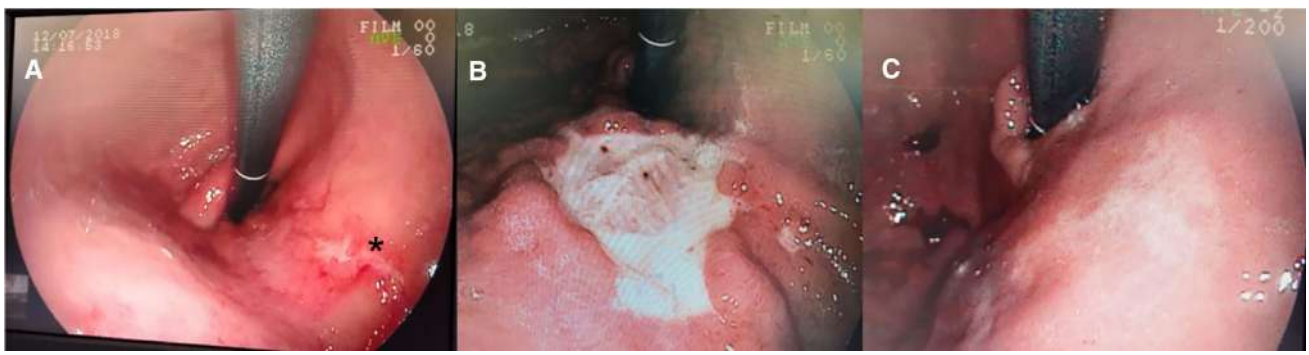

Fig. 4 Endoscopic photographs of gastric ulcers developed after gastric artery embolization. **A** superficial gastric ulcer (*); **B** deep gastric ulcer 1 week after the embolization; and **C** endoscopy at one month after the embolization showing complete ulcer healing

Discussion

This was the first trial to study the safety and efficacy of BAE in a female cohort with class I and II obesity and metabolic syndrome. In this trial, we also targeted other important feeders of the gastric fundus others than LGA, which resulted in embolization of more than one branch in nine out of the ten participants. This may have led to a significant reduction in ghrelin levels (32.7% in 6 months), which may be correlated to improvements in metabolic parameters, as well as in quality of life and binge eating scale scores, over the 6-month follow-up. This drop in ghrelin levels was approximately 49% higher than the average previous described [13–15, 17].

A significant impact on glucose metabolism was also shown, even without a great weight loss. There was normalization of fasting glucose and a 48.8% reduction in HOMA-IR levels after 6 months. These findings have not previously been described in the literature and may guide future investigations on this topic.

In our study, we observed a TBW loss slightly lower than described before in similar studies; 6.22 kg ± 3.6 in 6 months versus 8.85 kg ± 1.24 in 12 months [20]. Since we performed a more extensive embolization technique and achieved technical success, we believe that it was probably due to failure to follow the dietary guidelines, motivated by the lack of psychological counseling, long work and journey-to-work hours and low income of the participants. Another aspect to considerer is that we studied a female population, and, as described in the metanalysis conducted by Hafezi-Nejad et al. [20], the only variable positively associated with weight loss, was the male sex. Weight loss (6.8% of the total and 21.95% of the excess weight in 6 months), however, was greater than what is usually obtained with lifestyle changes alone (< 5% in 2 years) [24].

There was also an impressive rapid improvement in QOL and BES scales, that persisted for all the follow-up period.

We had two clinically significant deep ulcer cases that, despite not requiring hospitalization, reinforced the need for gastric protection with a PPI for at least 1 month after the procedure and that the procedure should be postponed in patients with gastric inflammatory findings found on the GI endoscopy performed before embolization. We consider that the presence small, superficial and asymptomatic ulcers at one week after embolization, is not a proper complication but an expected consequence of the local ischemia induced by the procedure. As we didn't have any ulcers in gastric fundus, we believe that those lesions were caused by reflux or by inadvertent injection of embolic material into branches of the lesser and greater curvature of the stomach, which boundaries with the fundus are very hard to determine in a collapsed stomach with the patient in a supine position. Gastric fundus seems to be a safe area to target but extreme caution should be taken regarding injection of embolic material to other sites.

The main limitations of this study were the small number of participants, short follow-up, the lack of a control group and the inclusion of only women in the menacme. The absence of psychological support may have impacted the adequate acceptance of the dietary recommendations.

Conclusion

In the present study, BAE was effective in reducing weight, waist circumference, serum ghrelin levels and insulin resistance, as well as improving binge eating and quality of life scores, in female pre-menopausal subjects with obesity class I and II and metabolic syndrome, with two Grade 1 and one Grade 2 complications according to the Clavien-Dindo scale. Further prospective, randomized studies are needed to confirm the safety, efficacy and ideal technique of this procedure.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Human and Animal Rights All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964.

Ethical Approval HELSINKI declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study. For this type of study, consent for publication is not required.

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