SCIENTIFIC PAPER JSLS

Analysis of Subcutaneous and Visceral Fat After Gastric Balloon Treatment

Luana C. Cabral, MD, MSc, Gustavo L. de Carvalho, MD, PhD, Rayssa A. B. de Melo, MD, Fernanda M. de Moura, MD, Ana Paula D. L. Leite, MD, MSc

ABSTRACT

Background and Objectives: This project is a continuation of a larger project entitled "Treatment with intragastric balloon (IGB) in patients with overweight and obesity in Recife" developed by Professor Dr. Gustavo Lopes de Carvalho. It is a project studying the effectiveness of treatment with IGB evaluating the loss of weight and body mass index and its impact on blood pressure, blood glucose, triglycerides, total cholesterol and fractions. It also assesses the lifestyle of patients studying whether treatment with IGB interferes in smoking, alcohol consumption, eating habits and physical exercises performed by patients.

The present study added a larger project, the separate evaluation of the different types of abdominal fat—visceral fat and subcutaneous cell tissue fat — and was conducted to discover which of the 2 types of fat undergoes the greater reduction after IGB treatment. To measure these 2 types of fat, we used the ultrasonography technique, because it has been shown to be accurate and noninvasive.

Methods: Twenty-five patients were evaluated before and after 6 months of IGB treatment.

Results: The patients' ages ranged from 20 to 61 years, with 60% being 40 years of age or older. The majority (72%) were women. All variables (weight, body mass index [BMI], VF, and SCTF) showed a significant reduction ($P < .05$) in mean values after treatment. The difference was highest in the SCTF (17.5%) and ranged from an 11.4% to an 11.6% reduction in all other variables. The average loss of SCTF was highest among the patients who had lost up to 10.0% of their initial weight (19.2% for the ≤10.0% group vs 15.9% for the >10.0% group); however, the difference was not significant ($P = .66$). The average loss of VF was higher in the subgroup of patients who had lost >10.0% of their initial weight (16.2% vs 6.3%; $P = .003$). The Pearson correlation between the reductions in SCTF vs VF was negative, low, and nonsignificant (−0.17; $P = .41$).

Conclusions: After 6 months of IGB treatment, there was no significant difference between the reduction in abdominal SCTF and VF, but the results signify a possible correlation between the percentage of body weight loss and the type of abdominal fat reduced, as the impact on the VF was higher when the patients lost >10.0% of their initial weight.

Key Words: Abdominal fat, Abdominal obesity, Abnominal ultrasonography, Intragastric balloon, Subcutaneous fat, Visceral fat.

INTRODUCTION

Obesity is a chronic, multifaceted disease that is difficult to treat and is characterized by the excessive accumulation of adipose tissue in the organism.[1] It is also associated with significant morbidity and mortality.[2] It is the second leading cause of death[3] and, at the end of the past millennium, reached epidemic proportions, becoming one of the major worldwide public health concerns in modern society.[4]

One of the less invasive treatments for obesity is the endoscopic insertion of an intragastric balloon (IGB). Balloon treatment is recommended for obese patients who are 40% above their ideal weight and who have had poor results in clinical obesity treatments, such as preoperative preparation of morbidly obese patients for bariatric operations[5] and nonbariatric procedures, such as gynecologic and orthopedic (vertebral column, joint replacement) operations and surgery for giant abdominal hernias. Recently, patients have been undergoing IGB treatment for cosmetic reasons, with good results.[1]

University of Pernambuco, Pernambuco, Brasil (Dr. Cabral, Dr. de Carvalho, Ms. de Melo, Dr. Leite).

Instituto de Medicina Integrado Professor Fernando Figueira, Pernambuco, Brasil (Ms. de Moura).

Disclosures: None reported.

Address correspondence to: Luana C. Cabral, UPE, Rua Presidente Delfim Moreira, No. 338, Apto 302, Bessa, João Pessoa, Paraíba, CEP 58035-260, Brasil. Telephone: (83)3021-5872/9972-5067, E-mail: luanaccabral@yahoo.com.br.

DOI: 10.4293/JSLS.2015.00023

IGB is mostly a treatment for obesity that has been developed as a temporary solution.[6] Some studies show moderate weight loss of 15 kg or more.[5] It is safe and presents a satisfactory rate of clinical success in the short term, with an improvement in such major comorbidities as hypertension and diabetes.[2]

Over the years, research has shown that an increase in body weight by itself is less important than the distribution of body fat, which causes metabolic changes.[7] In this context, central (visceral) obesity stands out, because it is considered harmful to health, as it is most commonly associated with cardiovascular morbidity and mortality, when compared to peripheral (subcutaneous) fat.[8]

Obesity is a complex disease that requires large-scale studies to detect the effects of genetic and environmental factors and their interactions. The addition of accurate measurements of fat deposits considerably increases the statistical power of these studies to evaluate the effectiveness of interventions in the treatment and prevention of obesity.[7]

The type of obesity can be determined by anthropometric measurements and by imaging tests, such as abdominal ultrasonography (US), computed tomography (CT), and magnetic resonance imaging (MRI).

The present study was a separate evaluation of the different types of abdominal fat—visceral fat (VF) and subcutaneous cell tissue fat (SCTF)—and was conducted to discover which of the 2 types of fat undergoes the greater reduction after IGB treatment. To measure these 2 types of fat, we used the US technique, because it has been shown to be accurate and noninvasive. Furthermore, it is low in cost, easily available, and of high reproductivity,[9] and it provides SCTF and VF content measurements without radiation exposure, increasing the safety profile. US is a technique that can be repeated whenever it is necessary, without harming the patient.[10]

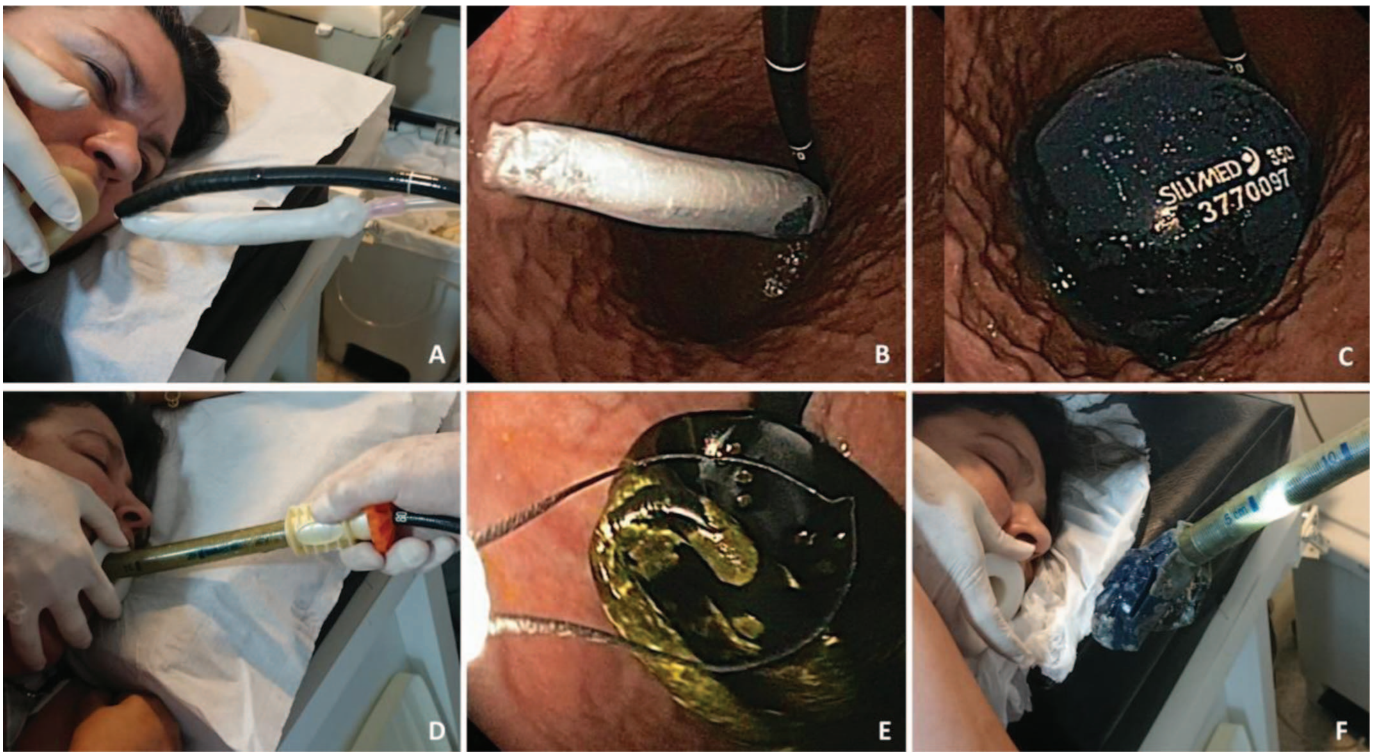

Figure 1. IGB placement and removal. A, A polipectomy snare is used to grasp the tip of the balloon cover, and the balloon is inserted together with the endoscope. B, Retrograde view of the endoscope (J-maneuver) showing the balloon completely inserted in the fundus of the stomach, just before it is filled. C, The filling is carefully monitored to achieve the best suitability for the individual stomach. D, A silicone double overtube (US–endoscopy esophageal overtube) is used to protect the airway during the removal procedure. E, After the balloon is completely deflated, a polypectomy snare is used to grasp the empty balloon on one corner. F, After a part of the balloon is gently brought inside the overtube (~20%), the balloon and the overtube are removed simultaneously, enhancing the protection of the airway and thus increasing the procedure's safety profile.

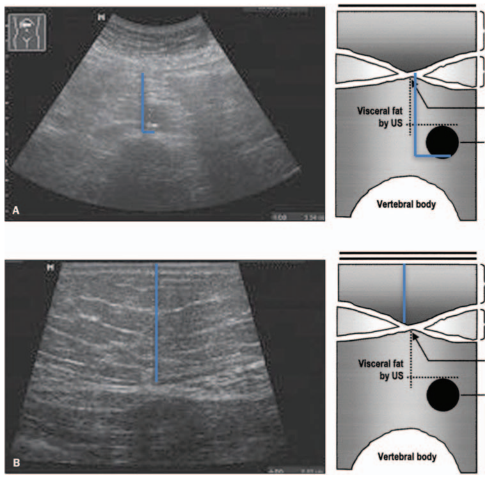

Figure 2. US images and measurements of (A) VF and (B) SCTF.

METHOD

Overweight or obese patients (age range, 18–70 years) who underwent the insertion of IGB in our obesity clinic from January 1, 2012, through August 31, 2013, were included in the study. This treatment for obesity consists of the endoscopic placement of an elastic, spherical, seamless balloon made of gastric acid–resistant silicone.[11]

The IGB was supplied empty and was delicately rolled up inside a thin silicone sheath, making placement and positioning in the gastric fundus possible by endoscope. The device consists of a smooth and transparent silicone shell that assumes a round shape when placed in the fundus and filled with 600–900 mL saline solution through direct visual examination. Fixed volumes of iopamidol contrast (20 mL; Iopamiron; Bracco Imaging, France SAS, Courcouronnes, France) and 2% methylene blue (10 mL) are added, with an approximate final proportion of 65:2:1.[12]

The filling procedure is continually monitored so that a better equivalent of the IGB volume to gastric fundus capacity is achieved, for a maximum of 900 mL (average, 640 mL). During the treatment, the balloon remains for 180 d, after which it is removed. Before the balloon is removed, the patient undergoes a second endoscopy with conscious sedation, and an esophageal overtube is placed to protect the airway. The balloon is deflated and safely removed with a polypectomy snare (**Figure 1**).[1]

The design of the study was quasi-experimental, with a before-and-after evaluation of the following variables: weight, height, body mass index (BMI), and the 2 types of abdominal fat: SCTF and VF.

Patients who did not complete the minimum required 6-month period with the IGB in place, either due to a balloon leak or withdrawal from the study, and those who did not attend the 2 required US evaluations were excluded from the study.

Data collection for the study was conducted in 2 stages, before and after the introduction of an IGB, by questionnaire, height and weight measurements to calculate BMI, and abdominal US.

The US examinations were performed by the lead investigator, a board-certified medical radiologist, who measured the VF with a 3.5-MHz convex transducer and the SCTF with a 7.5-MHz linear transducer, both transversely positioned 1 cm above the umbilicus, centrally, without exerting pressure on the abdomen.[7] The present study defined the thickness of the VF as the measurement between the inner face of the rectus abdominis muscle and the posterior wall of the aorta (**Figure 2A**), with the patient exhaling, and the thickness of the SCTF as the measurement between the skin and the outer face of the fascia of the rectus abdominis muscle (**Figure 2B**), both quantified in centimeters.[9] The measurements were repeated 3 times, and the largest of the 3 was recorded.

The patients were verbally informed about the study, and they read and signed an informed consent form confirming their willingness to participate in the research. The study was approved by the Brazilian Ethics Committee (Comitê de Éticaem Pesquisa; CEP) under CAAE 01328312.7.0000.5192, using the Brazil Platform (Plataforma Brasil).

For data analysis, absolute and percentage distributions were obtained, as well as the following statistical measures: average, SD, median, and correlation coefficient. Student *t* tests with equal or unequal variances, paired Student *t* tests, and the Wilcoxon test for paired data were used. The Shapiro-Wilk test was used to verify the normality hypothesis of the data. When the normality hypothesis was confirmed, the paired Student *t* test was chosen; and when it was rejected, the Wilcoxon test was used. The verification of the hypothesis of the equality of the variances was performed by the Levene *F* test.

The margin of error used in the statistical tests was 5% ($P < .05$). The results were entered in a spreadsheet (Excel; Microsoft, Redmond, Washington); the software used for data entry and retrieval of the statistical calculations was SPSS, version 21 (Cary, North Carolina).

RESULTS

Twenty-five patients were evaluated. The majority (72.0%) were woman of ages ranging from 20 to 61 years (average, 40.3 ± 11.7); 60.0% were ≥40 years of age, and the remaining 40.0%, <40 years.

Table 1 summarizes the variable data before and after IGB treatment, as well as the absolute and percentage differences between the 2 evaluations.

Table 1 shows a reduction in percentage and absolute values between the initial and the final data for all variables. For a fixed margin of error (5.0%) the differences in all the variables were significant ($P < .001$). The mean percentage difference was highest in the SCTF (17.5%) and ranged from 11.4% to 11.6% in the other 3 variables.

Table 2 shows the Pearson correlation between the decrease in SCTF and that in VF. VF had a negative correlation, with a value that was not significantly different from zero (−0.17; $P = .41$).

Table 3 provides the comparative results of the percentage reduction of SCTF and VF among those patients who had lost >10.0% (n = 13) of their body weight and those who had lost ≤10.0% (n = 12). The result that stands out in this table is that the average reduction in SCTF was highest among patients who had lost ≤10.0% of their body weight compared with those who had lost >10.0% (19.2% vs 15.9%); however, there is no significant difference ($P > .05$) between the 2 categories.

The mean percentage reduction in VF was highest among patients who had a weight loss >10.0% (16.2% vs 6.3%), showing significant differences between the 2 weight loss subgroups ($P = .003$). No significant differences were observed between the SCTF and VF variables in each of the weight loss subgroups ($P > .05$).

Table 2.
-Pearson Correlation Between the Reduction of SCTF and the Reduction of Visceral Fat

	VF
Variable	r (p)
SCTF	−0.174 (0.406)

DISCUSSION

In this study, we used the biometric measurements weight and height to calculate BMI and US as a tool to measure the thickness of abdominal VF and SCTF. All patients underwent obesity treatment with an IGB for 180 days (±15) and were evaluated before and after treatment.

Initial evaluations were performed on 51 patients, with the main difficulty of the study being the large number of withdrawals due to the need for 2 assessments, leading to the exclusion from the study of 26 patients (50.9%), of whom 2 (7.5%) did not complete the 6-month period of IGB treatment, and 24 (92.3%) did not return to participate in the required second US review, alleging scheduling conflicts and showing unwillingness to remain in the study once they already obtained a good weight loss result.

IGB treatment resulted in a reduction in weight and BMI in all of the evaluated patients, as well as a reduction in the thickness of the SCTF. Only 1 (4%) of the 25 patients showed an increase in the quantity of VF, and the same

Table 1.
Differences Between Initial and Final Measurements

	Evaluation		Difference		
Variable	Initial	Final	Absolute	Percentage	p*
	Mean ± SD (Median)	Mean ± SD (Median)	Mean	Mean	
Weight	95.09 ± 15.96 (91.30)	84.15 ± 15.48 (82.30)	10,94	11,60	<.001†
BMI	34.38 ± 4.01 (34.17)	30.38 ± 3.91 (29.57)	4,00	11,59	<.001†
SCTF	4.40 ± 1.19 (4,30)	3.60 ± 1.30 (3,60)	0,80	17,50	=.001‡
VF	8.13 ± 3.15 (8.00)	7.06 ± 2.36 (7.40)	1,07	11,41	<.001‡

* Significant difference at 5.0%.

† Wilcoxon test for paired data.

‡ Paired Student's t test.

Table 3.
Percentage of SCTF and VF Reduction According to the Percentage of Body Weight Loss

Body Weight Loss (%)	Precentage Reduction SCTF	VF	p*
	Mean ± DP (Median)	Mean ± DP (Median)	
>10%	15.91 ± 7.50 (12.28)	16.17 ± 9.22 (14.06)	=.935†
≤10%	19.22 ± 26.12 (11.32)	6.26 ± 4.90 (5.96)	=.144†
p*	=.666‡	=0.003§	

*Significant difference at 5.0%.
†Paired Student's t test.
‡Student's t test with equal variances.
§Student's t test with unequal variances.

patient showed the smallest decrease in body weight in both absolute and percentage values.

All the variables were reduced when compared to the initial value, and all differences were significant ($P < .001$).

In the work of Pontiroli et al,[8] US was performed on those patients who achieved a large reduction in BMI (from 44.3 to 36.4) and a greater reduction in VF dimensions (from 8.3 to 5.1 cm) relative to a smaller decrease in SCTF (from 4.9 to 3.9 cm), before and 1 year after bariatric surgery. Thus, we hypothesized that after IGB treatment patients would also lose more VF.

However, in our study, the mean percentage difference was highest in the SCTF (17.5%), although we emphasize that the reduction in SCTF (from 4.4 to 3.6 cm) and VF (from 8.1 to 7.0 cm) was not significant when calculated according to the Pearson correlation.

A comparison of the results in Pontiroli et al to those in our study shows that the BMI of our patients (range, 34.3–30.3) was much lower than that of Pontiroli's subjects (range, 44.3–36.4) and that their analysis took place after 1 year of treatment.

We divided our patients into 2 subgroups: a group that had lost >10% of their initial weight (n = 13) and a group that had lost ≤10% (n = 12), and we observed that there was a statistically significant difference ($P < .05$) in the reduction in thickness of the VF, indicating that the higher the percentage of the initial weight loss, the greater the reduction in VF. We did not analyze any differences in SCTF.

Therefore, a new question can be formulated: is there a correlation between the percentage of body weight loss and the type of abdominal fat that is reduced? A new hypothesis is also offered: the greater the weight loss, the greater the loss ratio (VF:SCTF). However, a larger study is needed to confirm this hypothesis.

We emphasize, however, that treatment with IGB should not be considered solely for aesthetic reasons.[12] For those patients who had lost >10% of their initial weight, we observed that there was a statistically significant difference in the reduction in the central obesity (VF) that is considered harmful to health because it is more commonly associated with cardiovascular morbidity and mortality.

CONCLUSIONS

After 6 months of IGB treatment, there was no significant difference between the reduction in abdominal SCTF or VF. However, the results indicate a possible correlation between the percentage of body weight loss and the type of abdominal fat reduced, as the impact on VF was higher when patients lost >10.0% of their initial weight.

References:

1. Carvalho GL, Barros CB, Okazaki M, et al. An improved balloon procedure using a new balloon: preliminary analysis of safety and efficiency. *Obes Surg*. 2009;19:237–242.

2. Bispo M, Silva MJF, Bana T, et al. O balão intra-gástrico no tratamento da obesidade: avaliação da sua eficacia, segurança e tolerabilidade. [The intragastric balloon in the treatment of obesity: evaluation of its effectiveness, safety, and tolerability] (in Portuguese). *J Port Gastrenterol*. 2008;15:103–109.

3. Zerrweck C, Maunoury V, Caiazzo R, et al. Preoperative weight loss with intragastric balloon decreases the risk of signif-

icant adverse outcomes of laparoscopic gastric bypass in super-super obese patients. *Obes Surg*. 2012;22:777–782.

4. Kotzampassi K, Grosomanidis V, Papakostas P, et al. 500 intragastric balloons: what happens 5 years thereafter? *Obes Surg*. 2012;22:896–903.

5. Mui WLM, Ng EKW, Tsung BYS, et al. Impact on obesity-related illnesses and quality of life following intragastric balloon. *Obes Surg*. 2010;20:1128–1132.

6. Fernandes M, Atallah AN, Soares BGO, et al. Intragastric balloon for obesity. *Cochrane Database Syst Rev*. 2007: CD004931.

7. Rolfe EDL, Sleigh A, Finucane FM, et al. Ultrasound measurements of visceral and subcutaneous abdominal thickness to predict abdominal adiposity among older men and women. *Obesity*. 2010;18:625–631.

8. Pontiroli AE, Frigè F, Paganelli M, Folli F. In morbid obesity, metabolic abnormalities and adhesion molecules correlate with visceral fat, not with subcutaneous fat: effect of weight loss through surgery. *Obes Surg*. 2009;19:745–750.

9. Diniz ALD, Tome RAF, Debs CL, et al. Avaliação da reprodutibilidade ultrassonográfica como método para medida da gordura abdominal e visceral. [Assessment of reproducibility of ultrasound as a method for the measurement of abdominal and visceral fat] (in Portuguese). *Radiol Bras*. 2009;42:353–357.

10. Ribeiro-Filho FF, Faria AN, Azjen S, et al. Methods of estimation of visceral fat: advantages of ultrasonography. *Obes Res*. 2003;11:1488–1494.

11. Stimac D, Majanovic SK, Turk T, et al. Intragastric balloon treatment for obesity: results of a large single center prospective study. *Obes Surg*. 2011;21:551–555.

12. Carvalho GL, Barros CB, Moraes CE, et al. The use of an improved intragastric balloon technique to reduce weight in pre-obese patients: preliminary results. *Obes Surg*. 2011;21:924–927.