



Changes in Body Adiposity, Dietary Intake, Physical Activity and Quality of Life of Obese Individuals Submitted to Intra-gastric Balloon Therapy for 6 Months

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Abstract

Background Obesity is an important risk factor for several chronic diseases and also is associated with worse quality of life. Intra-gastric balloon (IGB) is an effective method for weight loss. Although changes in lifestyle are critical to weight loss during and after IGB therapy, only a few studies evaluated dietary intake and none evaluated changes in physical activity with a validated questionnaire during the treatment. The aim of this study was to evaluate changes in total and central body adiposity, dietary intake, physical activity, and quality of life of patients with obesity submitted to IGB treatment for 6 months.

Methods Prospective observational study involving 42 patients with obesity using IGB for 6 months. The patients were evaluated, on the day of insertion and withdrawal or adjustment of IGB for total and central body adiposity (anthropometry and bioelectrical impedance), dietary intake, physical activity (Baecke questionnaire), and quality of life (SF-36 questionnaire).

Results There was a significant decrease in total and central body adiposity. The mean % total weight loss and % excess weight loss were 15.88 ± 1.42 and 56.04 ± 4.90 , respectively and waist circumference decreased 13.33 ± 1.39 cm. There was a reduction in energy intake, an increase in physical activity, and an improvement of quality of life during IGB treatment.

Conclusion The present study suggests that IGB treatment during 6 months in individuals with obesity is effective for decreasing total and central body adiposity being associated with reduction in energy intake, increase in physical activity, and improvement in quality of life.

Keywords Intra-gastric balloon · Obesity · Weight loss · Quality of life · Dietary intake

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Introduction

Obesity is a public health problem with high and increasing worldwide prevalence, being considered a pandemic [1, 2]. Excessive adiposity is an important risk factor for several chronic diseases such as type 2 diabetes mellitus, hypertension, dyslipidemia, osteoarthritis, obstructive sleep apnea, and some types of cancer, leading to a negative impact on morbidity and mortality [3–5], and to an increase in the costs of health care [6, 7]. Moreover, obesity may decrease the quality of life, interfering in physical, social and psychological components [8, 9].

Although a body mass index (BMI) ≥ 30 kg/m² is used to define obesity [10], this anthropometric parameter has important limitations as it does not distinguish between lean and fat mass and also does not evaluate body adiposity distribution. Total body adiposity can be evaluated by bioelectrical impedance (BIA) and central distribution of body adiposity

(associated with greater risk of morbidity and mortality) can be easily evaluated by waist circumference (WC) [11–13].

The treatment for excess weight is complex and a comprehensive program of lifestyle modification is considered the first option, including changes in dietary intake, increase in physical activity, and behavior therapy [14]. Other therapeutic approaches may also be used, such as pharmacological treatment, bariatric surgery, and intragastric balloon (IGB). The use of these approaches must consider the degree of obesity and co-morbidities [15].

The IGB is a temporary, safe, and effective method for weight loss [16, 17]. According to the Brazilian Intragastric Balloon Consensus Statement, IGB treatment may be indicated for individuals with a BMI ≥ 25.0 kg/m² and previous failure of clinical treatment to lose weight [18]. It acts as a space-occupying device, reducing stomach capacity and providing continuous satiety, improving adherence to hypocaloric diets [18–20].

Although lifestyle modifications (diet and increase in physical activity) are critical to achieve and maximize weight loss during and after IGB therapy [17], few studies evaluated dietary intake [21, 22] and none evaluated changes in physical activity with a validated questionnaire during IGB therapy. So until now, there is no consensus about changes in lifestyle during IGB treatment, which would be helpful for the improvement in the rate of success of this therapy. Similarly, only few studies evaluated the impact of IGB on quality of life [23–28]. Therefore, the aim of this study was to evaluate the changes in body weight, total and central body adiposity, dietary intake, habitual physical activity and quality of life, of patients with obesity submitted to IGB treatment for 6 months. A secondary aim was to evaluate the relationship between the decrease in energy intake and weight loss.

Patients and Methods

This prospective observational study was conducted with patients suffering from obesity that were submitted to IGB treatment for 6 months at a private clinic, between March 2016 and October 2017. Potential participants were recruited among patients who had already scheduled the placement of non-adjustable IGB (Orbera) or adjustable IGB (Spatz). The inclusion criteria were: adult patients (20–59 years) presenting BMI ≥ 30 and < 40 kg/m² that had failed to lose weight in well-conducted clinical treatments. The exclusion criteria were diagnosis of endocrine disorders (diabetes mellitus, hypothyroidism, polycystic ovary syndrome), AIDS, inflammatory conditions, malignant diseases, autoimmune diseases, chronic kidney disease, heart failure, or hepatic failure. Patients using any medication known to interfere with body weight were excluded. Individuals using pacemakers and defibrillators were not allowed in the study because current

guidelines do not recommend BIA in these patients [29]. Similarly, were excluded patients using orthopedic metal prosthesis as they may interfere in the results of BIA.

Patients who met the eligibility criteria and agreed to take part in the study were submitted to the evaluation of nutritional status, dietary intake, habitual physical activity, and quality of life at the day of balloon placement (baseline). The same evaluations were performed after 6 months at the day of balloon retrieval (for patients using non-adjustable IGB) or balloon adjustment (for patients using adjustable IGB). Half of the patients used the non-adjustable IGB and half the adjustable balloon. For patients using adjustable balloon, only one adjustment in balloon volume was scheduled at 6 months of treatment, while IGB withdrawal was scheduled at 1 year.

Balloon Placement

As described in a previous publication of our group [30], balloon insertion was performed after a diagnostic endoscopy to detect pathologies that might contraindicate balloon placement, such as active peptic ulcer, grade C-D esophagitis, large volume hiatal hernia, esophageal/fundus varices, esophageal strictures, and prior gastric surgery.

The endoscopy procedure was performed under deep sedation without endotracheal intubation, with continuous oxygen support of 5 l/min, under the supervision of an anesthesiologist. After implant of the balloon, correct positioning was checked endoscopically, with the balloon valve positioned 2 cm below the cardia. The balloon inflation was under direct vision with the endoscope in rear view position (U-turn maneuver). The balloon was filled with 3% saline solution and 10 ml of 4% methylene blue. The balloon volume ranged from 600 to 700 ml.

After filling, the balloon valve was closed with a syringe vacuum and the catheter disconnected by traction. Then, the balloon was visually inspected to detect possible deflation or valve malfunctions and to confirm correct positioning in the gastric fundus. If a leakage was detected, a prompt replacement of the defective balloon was conducted. After balloon placement, patients remained in the anesthesia recovery room until complete recovery from sedation had been confirmed and were then discharged.

Follow-up

In the first 3 days after balloon insertion, patients were instructed to use three antiemetic drugs (metoclopramide, ondansetron, and dimenhydrinate), an anti-foaming drug (dimethicone), and analgesics/antispasmodics (escopolamine plus dipyron, acetaminophen). All patients were put on a proton pump inhibitor (PPI; pantoprazole magnesium) throughout the treatment: a double dose in the first month (80 mg) and a full dose from the second month to the end (40 mg).

Table 1 Baseline characteristics of study participants

Characteristics	Total group (n = 42)
Age (years)	37.60 ± 1.28
Gender (male/female) (n; %)	10 (24%) / 32 (76%)
Smoking habit (n; %)	2 (5%)
Alcohol intake (n; %)	27 (64%)
Body mass index (kg/m ²)	35.15 ± 0.41
Hypertension (n; %)	6 (14%)
Dyslipidemia (n; %)	32 (76%)
Laboratory variables	
Glucose (mg/dL)	88.12 ± 1.51
Urea (mg/dL)	31.00 (26.00–36.00)
Creatinine (mg/dL)	0.80 (0.70–0.90)
Uric acid (mg/dL)	4.93 ± 0.20
Total cholesterol (mg/dL)	200.74 ± 6.24
HDL-cholesterol (mg/dL)	47.53 ± 1.99
LDL-cholesterol (mg/dL)	132.70 (100.20–158.90)
Triacylglycerols (mg/dL)	113.00 (83.00–157.00)

Values as mean ± error deviation for normal distribution or as median (interquartile interval) for not normal distribution or absolute values (%) HDL, high-density lipoprotein; LDL, low-density lipoprotein

Patients were also instructed to follow a 5-day liquid diet (with progressive increase in ingested volume). On the sixth day, a semi-solid diet was prescribed, and after the 13th day, solids were introduced. Thereafter, the patients were referred for personalized nutritional counseling, when an individualized low-calorie diet was prescribed. The total energy intake was determined as 12 kcal/kg actual body weight/day, varied from

900 to 1400 kcal/day and was similar to the recommended in previous studies with IGB [23, 31–34]. Additionally, vitamin and mineral supplementation were given to all patients during the entire treatment. Follow-up with multidisciplinary team including physician, nutritionist, and psychologist once a month was available for all participants.

Nutritional Assessment

Height was measured with a stadiometer accurate to ± 0.5 cm, and weight was obtained using a calibrated scale accurate to ± 0.1 kg (Welmy®) after participants, without shoes and wearing light clothing, attempted to empty their bladder. BMI was calculated using the standard equation (kg/m²) [10]. WC was measured in the standing position, midway between the lower margin of the last rib and the iliac crest, at mid exhalation. Hip circumference (HC) was measured at the widest point of the hip/buttocks area with the measuring tape parallel to the floor [35]. Waist-to-hip ratio was determined by dividing WC (cm) by HC (cm). Waist-to-height ratio was obtained by dividing WC (cm) by height (cm). Body adiposity index (BAI) estimates body fat (%) using two anthropometric measurements (HC and height) and was determined as described by Bergman et al. (2011) [36]. Neck circumference (NC) was measured at the standing position with the participants’ head positioned in the Frankfurt horizontal level following the description of Zhou et al. [37]. Percentage of body fat was estimated by BIA (Biodynamics® 450) according to manufacturer’s instructions, using specific predictive equations for obeses [38, 39].

Table 2 Parameters of body adiposity in obese individuals submitted to intragastric balloon (IGB) treatment during 6 months

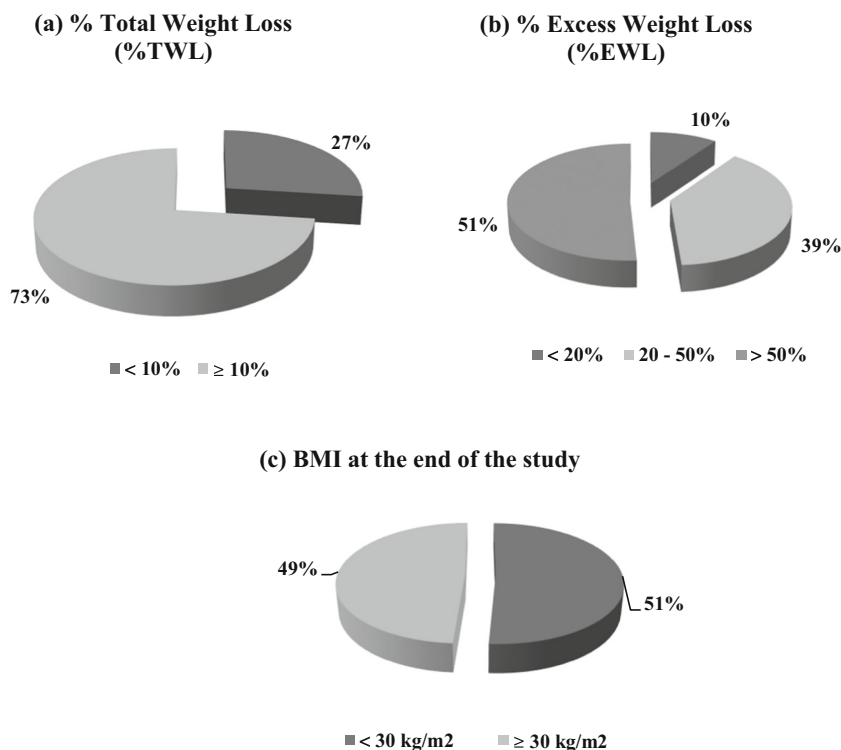
Variables	IGB treatment		Reduction	% reduction	p*
	Pre (n = 42)	Post (n = 42)			
Body weight (kg)	95.99 ± 1.94	80.57 ± 2.0	15.42 ± 1.48	15.88 ± 1.42	< 0.0001
Excess body weight (kg)	28.10 ± 1.25	11.26 ± 10.54	15.42 ± 1.48	56.04 ± 4.90	< 0.0001
Body mass index (kg/m ²)	35.15 ± 0.41	29.50 ± 0.54	5.65 ± 0.52	15.93 ± 1.42	< 0.0001
Body adiposity index (%)	39.03 ± 0.62	34.03 ± 0.70	5.00 ± 0.50	12.76 ± 1.24	< 0.0001
Waist circumference (cm)	108.42 ± 1.61	95.09 ± 1.59	13.33 ± 1.39	12.07 ± 1.18	< 0.0001
Hip circumference (cm)	120.54 ± 1.08	109.99 ± 1.36	10.55 ± 1.05	8.72 ± 0.85	< 0.0001
Neck circumference (cm)	38.08 ± 0.53	35.61 ± 0.50	2.47 ± 0.24	6.43 ± 0.89	< 0.0001
Waist-to-hip ratio	0.90 ± 0.01	0.87 ± 0.01	0.04 ± 0.01	3.74 ± 0.83	0.0001
Waist-to-height ratio	0.66 ± 0.01	0.58 ± 0.01	0.08 ± 0.01	12.03 ± 1.19	< 0.0001
Body fat mass (kg)	38.7 (36.2–46.3)	30.4 (27.0–35.7)	9.3 (4.9–13.6)	22.0(14.0–30.5)	< 0.0001
Body fat mass (%)	44.8 (40.9–46.6)	40.0 (35.1–43.2)	3.7 (2.3–5.4)	8.5 (2.5–11.6)	< 0.0001

Values as mean ± error deviation for normal distribution or as median (interquartile interval) for not normal distribution

Reduction = Pre IGB treatment – Post IGB treatment

*p value refers to differences between pre and post IGB treatment (repeated measures ANOVA)

Fig. 1 Success rates of intragastric balloon treatment according to (a) % total weight loss, (b) % excess weight loss, and (c) body mass index (BMI) < 30 kg/m² at the end of the study



The efficacy of IGB treatment was evaluated by using change in BMI (kg/m²), % total weight loss (%TWL), and % excess weight loss (%EWL), considering ideal body weight as the equivalent to a BMI of 25 kg/m². The success of the treatment was evaluated according to %TWL (≥ 10%) [18] and %EWL: patients divided into those who did not achieve the goal of the treatment (< 20%), those with successful treatment (20–50%), and those who had high success (> 50%).

Dietary Intake

The usual dietary intake was evaluated by a semiquantitative food frequency questionnaire (FFQ). This questionnaire contains 80 items and usual portions and was developed and validated for the Brazilian population [40]. Software SAS® and Brazilian Table of Food Consumption (*Universidade de Campinas*) were used to process data and to quantify the nutrients from FFQ.

Habitual Physical Activity

The habitual physical activity was evaluated by the Baecke questionnaire. This validated questionnaire assesses physical activity at three subscales: at work, sports during leisure time and other physical activities during leisure time [41, 42].

Quality of Life

To evaluate quality of life was used the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). This

validated questionnaire contains 36 items and assesses functional capacity, physical aspects, pain, general health status, vitality, social aspects, emotional aspects, and mental health [43].

Statistical Methods

Categorical variables were expressed as absolute numbers and percentage. The Shapiro-Wilk test was used to test the normality of the continuous variables and skewed data were log transformed to improve normality. Continuous variables with normal distribution were presented as mean ± standard errors and those without normal distribution were presented as median and interquartile range.

Repeated-measures *analysis of variance* (ANOVA) was used to evaluate changes in continuous variables obtained pre and post IGB treatment. The Pearson or Spearman linear correlation was used to test association between variables of interest, as appropriate.

Patients who (1) withdraw the IGB treatment before completing the 6 months of follow-up, (2) remained with Orbera balloon for more than 8 months, or (3) performed Spatz balloon adjustment before 6 months or after 8 months of follow-up were not included in final analyses. All statistical analyses were performed using STATA (v.12.0, Stata Corp, College Station, TX, USA) and a *p* value of < 0.05 was considered to be significant.

Table 3 Dietary intake of obese individuals submitted to intragastric balloon (IGB) treatment during 6 months

Variables	IGB treatment		Reduction	<i>p</i> *
	Pre (<i>n</i> = 42)	Post (<i>n</i> = 42)		
Energy (kcal/day)	1718 (1475–2283)	911 (713–1249)	892.8 (441.7–1140.0)	< 0.0001
Energy (kcal/kg/day)	20.1 (14.5–23.9)	11.5 (9.0–14.8)	6.4 (3.0–10.9)	< 0.0001
Protein (g/day)	86.0 (78.8–125.3)	61.1 (43.4–84.1)	31.3 (6.9–47.2)	< 0.0001
Protein (g/kg/day)	1.0 (0.8–1.2)	0.7 (0.6–1.1)	0.19 (0.01–0.36)	0.0005
Carbohydrates (g/day)	199.4 (144.6–291.0)	80.8 (66.1–129.8)	101.1 (64.4–186.2)	< 0.0001
Carbohydrates (g/kg/day)	2.0 (1.5–2.9)	1.1 (0.9–1.6)	0.83 (0.41–1.25)	< 0.0001
Lipids (g/day)	68.8 (49.3–85.1)	34.2 (24.3–48.2)	30.6 (13.7–48.4)	< 0.0001
Lipids (g/kg/day)	0.68 (0.53–0.93)	0.45 (0.32–0.56)	0.23 (0.08–0.42)	< 0.0001
Saturated FA (g/day)	27.1 (19.8–38.3)	14.6 (9.5–18.1)	12.6 (7.0–23.4)	< 0.0001
Polyunsaturated FA (g/day)	8.6 (5.9–12.4)	5.5 (3.5–6.8)	3.0 (1.5–4.6)	< 0.0001
Monounsaturated FA (g/day)	16.8 (12.4–21.5)	9.3 (6.7–12.1)	4.8 (1.9–10.6)	< 0.0001
Cholesterol (mg/day)	434.5 (347.0–532.0)	323.2 (195.4–472.4)	75.3 (–38.1–156.5)	0.007
Fiber (g/day)	14.5 (10.4–26.5)	10.0 (6.8–12.8)	5.5 (2.1–16.0)	< 0.0001
Calcium (mg/day)	879.0 (578.8–1046.3)	430.3 (337.2–543.0)	370.2 (188.5–612.9)	< 0.0001
Iron (mg/day)	8.6 (5.8–10.8)	4.8 (3.3–6.5)	3.2 (1.1–6.1)	< 0.0001
Vitamin A (μg/dia)	1112 (605–1857)	506 (305–905)	386.6 (125.7–1091.8)	< 0.0001
Vitamin C (mg/dia)	104.6 (32.4–235.4)	129.5 (57.9–188.2)	–7.0 (–58.7–61.70)	0.54

Values as mean ± error deviation for normal distribution or as median (interquartile interval) for not normal distribution

Reduction = Pre IGB treatment – Post IGB treatment

FA, fatty acids

**p* value refers to differences between pre and post IGB treatment (repeated measures ANOVA)

Results

A total of 173 subjects were interviewed, of whom 56 met the eligibility criteria and agreed to participate in the study. Forty-two patients completed all evaluations and were included in statistical analyses. The baseline characteristics of the participants are detailed in Table 1.

After 6 months of treatment, there was a significant reduction in all anthropometric variables, including those that evaluate central adiposity, and in body fat mass evaluated by BIA. The mean %TWL and %EWL were 15.88 ± 1.42 and 56.04 ± 4.90 , respectively (Table 2). Seventy-three percent of the patients achieved a %TWL $\geq 10\%$ and 90 a %EWL $\geq 20\%$, achieving success of treatment (Fig. 1). Additionally, more than half of the patients completed the study with a BMI < 30 kg/m² (Fig. 1).

During IGB treatment there was a significant decrease in the dietary intake of energy (52%), macronutrients, calcium, iron and vitamin A (Table 3). The reduction in energy intake presented a positive and significant correlation with the %TWL ($r = 0.37$; $p = 0.02$) (Fig. 2). Physical activity improved during IGB treatment, there was a significant increase in the total score

and in leisure-time index (Table 4). After IGB treatment there was an improvement in all variables evaluated in the questionnaire used to evaluate quality of life ($p < 0.05$) (Table 5). %TWL presented a positive correlation with the increase in functional capacity ($r = 0.49$; $p = 0.002$) and vitality ($r = 0.34$; $p = 0.04$).

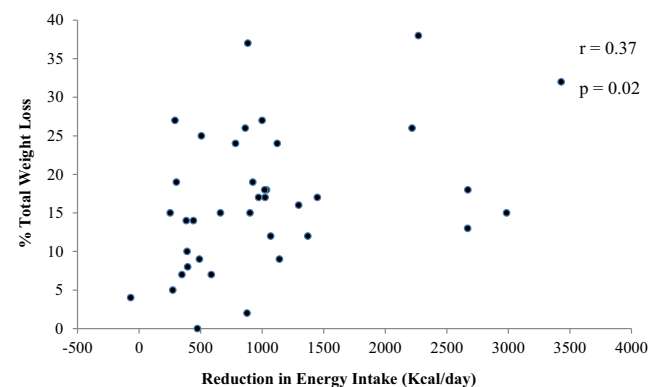


Fig. 2 Correlation between reduction in energy intake and % total weight loss in obese individuals submitted to intragastric balloon (IGB) treatment during 6 months

Table 4 Habitual physical activity of obese individuals submitted to intragastric balloon (IGB) treatment during 6 months

Variables	IGB treatment		Increase	<i>p</i> *
	Pre (<i>n</i> = 42)	Post (<i>n</i> = 42)		
Work index	2.43 ± 0.09	2.54 ± 0.09	0.11 ± 0.06	0.10
Sport index	2.13 ± 0.12	2.30 ± 0.10	0.17 ± 0.10	0.19
Leisure time index	2.17 ± 0.10	2.51 ± 0.09	0.34 ± 0.09	0.0005
Total Baecke score	6.69 ± 0.21	7.24 ± 0.20	0.55 ± 0.23	0.02

Values as mean ± error deviation

Increase = Post IGB treatment – pre IGB treatment

**p* value refers to differences between pre and post IGB treatment (repeated measures ANOVA)

Discussion

In the present study, there was a significant reduction in total body adiposity of individuals with obesity submitted to IGB treatment for 6 months. The mean weight loss was 15.42 kg, %TWL was 15.88, and BMI decreased 5.65 kg/m². These results are similar to those observed by Mitura e Garnysz (2015) [32]: a mean weight loss and BMI decrease of 15.9 kg and 5.8 kg/m², respectively, after 6 months of IGB treatment. However, other studies with the same length of follow-up found lower weight loss, %TWL and/or change in BMI. For example, Reimão et al. (2018) [28] observed a mean %TWL of 13.69 and mean BMI reduction of 3.4 kg/m²; Al-Sabah et al. (2015) [44] reported a mean weight loss of 10.9 kg and mean BMI decrease of 4.1 kg/m²; while Guedes et al. (2017) [27] found a mean weight loss and BMI reduction of 11.7 kg and 4.4 kg/m², respectively. A recent meta-analysis observed a mean weight loss of 12.86 kg and a BMI decrease of 5.21% [45]. Conversely, Nunes et al. (2017) [46] found a mean %TWL and BMI reduction of 18.9 and 6.76 kg/m², respectively. This study has

included patients with higher BMI (27 to ≥ 45 kg/m²), which may have contributed to the greater weight loss.

The decrease in central adiposity in the present study, according to the change in WC, was greater than that observed in other studies with a similar length of follow-up (6 months) [23, 27, 31, 47]. We can hypothesize that the greater decrease in total and central adiposity in the present study may be partially attributed to the nutritional counseling throughout the IGB therapy, with the prescription of a hypocaloric diet according to individual needs and preferences. The majority of the studies mentioned above do not inform if a hypocaloric diet was prescribed.

In our study, the energy intake decreased significantly during IGB treatment and at the end of the study was in agreement with the total energy intake that was prescribed (12 kcal/kg/day). There was a significant correlation between the %TWL and the decrease in energy intake, which reinforces our hypothesis that in the present study the prescription of a hypocaloric diet contributed to a greater weight loss. To date, only a few studies evaluated dietary intake during IGB treatment [21, 22, 28]. Donadio et al. (2009) [21] observed a decrease in energy intake and %TWL of 39.2% and 13.2, respectively both lower than that observed by our study.

There was a significant improvement in physical activity during IGB treatment in our study. Until now, none studies have assessed changes in physical activity using a validated questionnaire. It must be emphasized the importance to assess dietary intake and physical activity in these patients in order to evaluate changes in lifestyle, considered fundamental to weight loss and to prevent weight regain after IGB withdrawal [17, 48, 49].

In addition to increasing the risk of developing chronic diseases [4], obesity is associated with worse quality of life [9, 50]. On the other hand, weight loss in individuals with overweight or obesity is associated with improvement in quality of life [8]. The present study found an increase in the scores of all SF-36 domains after 6 months treatment with IGB, reflecting an improvement in quality of life. Similarly, Reimão et al. (2018) [28]

Table 5 Quality of life of obese individuals submitted to intragastric balloon (IGB) treatment during 6 months

Variables	IGB treatment		Increase	<i>p</i> *
	Pre (<i>n</i> = 42)	Post (<i>n</i> = 42)		
Functional capacity	60 (40–85)	90 (85–95)	20 (5–45)	0.0001
Physical aspects	75 (50–100)	100 (100–100)	25 (0–50)	0.001
Pain	61 (42–84)	84 (72–90)	11 (0–31)	0.001
General health status	72 (57–82)	82 (72–92)	8 (0–20)	0.0002
Vitality	35 (25–65)	65 (55–80)	25 (5–40)	< 0.0001
Social aspects	62.5 (37.5–87.5)	100 (62.5–100)	12.5 (0–37.5)	0.003
Emotional aspects	100 (33.3–100)	100 (100–100)	0 (0–66.6)	0.02
Mental health	52 (40–72)	76 (68–84)	16 (–4–36)	0.0003

Values expressed as median (interquartile interval)

Increase = Post IGB treatment – pre IGB treatment

**p* value refers to differences between pre and post IGB treatment (repeated measures ANOVA)

observed an increase in the scores of all SF-36 domains after 6 months of follow-up. While Mui et al. (2010) [23] observed improvement in almost all SF-36 domains, except for mental health. Using a different tool, Guedes et al. (2017) [27] observed a positive impact of weight loss during IGB treatment on specific domains of World Health Organization's Quality of Life (WHOQOL-BREF) questionnaire, except for the social domain. Courcoulas et al. (2017) [26] also found increase in the total score of another questionnaire (Impact Of Weight On Quality Of Life-Lite; IWQOL-Lite) and in 6 domains of SF-36 after 9-months of follow-up (6 months of IGB associated with lifestyle intervention and more 3 months only with lifestyle intervention after).

The present study has some limitations, as the absence of a control group and the lack of evaluation of the participants at least 6 months after IGB withdrawal.

Conclusion

The present study suggests that 6 months IGB treatment in individuals with obesity is effective for decreasing body weight, total and central body adiposity, being associated with reduction in energy intake, increase in physical activity, and improvement in quality of life. Additionally, the follow-up with a multidisciplinary team, including the prescription of a hypocaloric diet, may contribute to greater weight loss.

Compliance with Ethical Standards

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

Informed Consent Informed consent was obtained from all individual participants included in the study.

Human Rights The study was reviewed and approved by the Committee on Ethics and Research of Pedro Ernesto University Hospital/Rio de Janeiro State University.

All procedures performed in the study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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