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Efficacy and safety of intragastric balloon in the treatment of obesity in adolescent females

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Abstract

Background: The aims of this study are to evaluate the efficacy and safety of intragastric balloon (IB) to reduce the weight and body mass index (BMI) in severely obese adolescent females and to describe the changes in the liver enzymes and lipid and glucose metabolism biomarkers.

Methods: This study included 10 severely obese post-menarche adolescent females. We evaluated anthropometric data, lipid profile, glucose metabolism biomarkers, and liver enzymes before insertion and after removal of the IB.

Results: BMI and weight reduction were larger during the first month of intervention. Especially in the first week, there was a reduction of 1.74 ± 0.46 kg/m^2 ($p = 0.004$) and 6.46 ± 1.52 kg ($p = 0{,}002$), respectively. After 3 months, there was an average BMI reduction of 4.29 ± 1.04 kg/m ($p = 0.005$) and weight reduction of 12.9 ± 3.08 kg ($p = 0.004$). From the initial moment to study conclusion, there was a statistically significant reduction in insulin levels (9.0 ± 2.8 U/mL; $p = 0.012$) and in homeostatic model assessment-insulin resistance (2.0 ± 0.6; $p = 0.009$). Five patients reported, during the first week, epigastric pain; nausea and vomiting were observed in two patients. No adolescents presented dysphagia during IB use.

Conclusion: IB use in adolescent females with severe obesity in association with a conservative multidisciplinary treatment had a positive impact in BMI reduction, with few adverse effects. There was also an improvement in insulin resistance.

Keywords: Obesity, Adolescent, Child, Intragastric balloon

Background

Obesity in children and adolescents is a major public health problem; it continues in adulthood and may cause other chronic diseases [1]. In Brazil, during the last 30 years, overweight/obesity in male adolescents increased sixfold and in female, threefold [2]. Around 8.4% (IC 95% 7.6 to 9.2%) of adolescents are obese (z scores for body mass index (BMIZ) > + 2) [3].

Unfortunately, lifestyle interventions are often ineffective in the treatment of pediatric obesity. Studies show that this strategy causes an average weight reduction of only 10% in 12 months, but half of the weight lost is usually recovered in the first year, and, in 5 years, it returns to the initial condition [4].

The indications of bariatric surgery in children and adolescents are not clear as in adults. An American multicenter study involving 242 severely obese adolescents showed a significant reduction in associated morbidities and a reduction of 27% in weight, after a 3-year follow-up. The predominant adverse effects were micronutrient deficiencies, such as low ferritin levels, in 57% of individuals and the need of additional abdominal surgical procedures in 13%. The authors emphasized the need for more long-term studies evaluating the risks and benefits of surgery in this group [5].

Intragastric balloon (IB) is a minimally invasive, temporary, and completely reversible procedure, and its use as an adjunct in the obesity treatment is emphasized in

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some studies. The procedure is well accepted and safe, with satisfactory results in weight loss, as confirmed in adult population [6–8].

There are many types of IB. Usually, as in our study, IB is composed of a silicone elastomer which is implanted in the stomach endoscopically and then filled, under direct vision, with methylene blue and a saline solution (0.9% NaCl) [9, 10]. Subsequently, it is positioned in the gastric fundus, with reduction in stomach volume and promoting satiety.

In adults with a body mass index (BMI) greater than 27 kg/m^2, IB provides a percent excess weight loss ranging between 16 and 50.8%; blood glucose levels, insulin resistance, and liver enzymes are also reduced [11, 12]. Complications associated with IB occurred in about 2.8% of adults [13].

Publications analyzing the efficacy and risks of IB in adolescents are scarce. A pilot study of 10 severely obese children and adolescents (9–17 years old) found positive results in average weight loss (5.74 ± 1.46 kg) and BMI reduction after 3 months. There was also an improvement in biochemical parameters related to cardiometabolic risk [14].

Given the significant increase in obesity rates and the unsatisfactory results of the conventional treatment, this study aims to assess the efficacy and safety of IB in weight loss and BMI reduction in adolescent females with severe obesity and to describe the modifications in liver enzymes and lipid and glucose metabolism biomarkers.

Methods

Study design

Patients in our outpatient clinic who presented stability or an increase in BMI after 1 year of conventional interdisciplinary intervention consisting of medical, dietetic, and physical activity therapy [15] were included.

A longitudinal study was conducted involving 10 severely obese female adolescents (BMIZ > + 3), 12 to 18 years old at the ABC Medical School (Santo Andre, Brazil) outpatient pediatric obesity clinic. Menarche occurred at least 1 year before the beginning of the study. The girls underwent IB insertion at the Endoscopy Sector in the first week of November 2014 and removal in the last week of April 2015.

Patients were excluded from the study if they had any of the following: hormonal or genetic obesity, upper gastrointestinal tract disease (peptic ulcer, voluminous hiatal hernia, among others), type 1 or 2 diabetes mellitus, history of previous gastrointestinal surgery, corticosteroids, anti-inflammatory or anticoagulant therapies. The adolescents affirmed that they had no drinking or smoking habits.

All patients were followed and assessed by the multiprofessional team during the 6 months of IB use and conventional treatment. Nutritional and physical activity therapy were maintained. Blood samples were collected before the insertion (T0) and after the removal of the balloon (T1). Follow-up with the IB in place was performed weekly in the first 2 months, every 15 days in the 3rd and 4th months, and monthly in the 5th and 6th months. The protocol has been approved by the Research Ethics Committee (Faculdade de Medicina do ABC no. 723.830). Written informed consent was obtained from the parents and adolescents included in the study.

IB insertion

The balloons used in this study were manufactured by Medicone ®, Cachoeirinha, Rio Grande do Sul, Brazil. IB was implanted under sedation with midazolam (5–10 mg) and fentanyl (25–50 mcg) in the outpatient setting using standard techniques. First, diagnostic upper endoscopy was conducted to exclude any patient with contraindications. The IB was introduced through the cricopharyngeus under endoscopic vision and placed in the region of large gastric curvature and then filled with 400 mL of saline solution and methylene blue 1%. As there is no consensus in the literature about the volume to be injected into the IB for this population, it was decided to use 400 mL. In adults, the volume commonly used is 700 mL [11–13]; in the pediatric studies, the volume was 250 mL [14]. All patients were discharged on the same day of the procedure and received instructions to start liquid diet, 40 mg omeprazole daily for 6 months, and 8 mg sublingual ondansetron during the first 5 days if necessary. Use of ondansetron was rarely reported by the patients.

At the end of the treatment, about 6 months after first placement, balloon removal was performed by upper endoscopy under deep sedation (scopolamine intravenous). In the removal procedure, the IB was held with graspers, deflated by needle puncturing, and then carefully removed.

Collected data

We evaluated weight and height at 7, 14, 21, 90, and 180 days; the WHO Anthro Plus ® software was used to calculate body mass index (BMI, kg/m^2), BMIZ, and height/age (HAZ). Waist circumference was measured at the midpoint between the last rib and the iliac crest, and the measurement was used to calculate the waist/height ratio. Values of waist/height ratio > 0.5 were considered abnormal and are related to central obesity [16].

Blood pressure (BP) was measured and classified according to the Task Force recommendation's [17]. High blood pressure was considered when three measurements, performed at different times, were above the 95 percentile, according to gender, age, and height.

Blood tests were performed before insertion and after removal of the IB. After a 12-h fasting, 10 mL of blood was collected by peripheral venipuncture to analyze glucose level, insulin (chemiluminescence), glycated

Table 1 Characteristics of the obese adolescents before the intragastric balloon insertion

Variable	Unit	*N* = 10
Age	Years	15.1 ± 0.6
Menarche age	Years	12.2 ± 0.3
Time since menarche	Years	2.9 ± 0.5
Weight	kg	115.7 ± 4.0
Stature	m	1.66 ± 0.01
Waist circumference/height ratio	cm/cm	0.74 ± 0.02
Body mass index	kg/m^2	41.3 ± 1.4
Score *z* body mass index	BMIZ	3.9 ± 0.2
Score *z* height/age	HAZ	0.9 ± 0.2
Total cholesterol	mg/dL	199.0 ± 12.8
LDL-c	mg/dL	127.0 ± 7.9
HDL-c	mg/dL	47.0 ± 4.2
Triglycerides	mg/dL	126.4 ± 27.4
Non-HDL-cholesterol	mg/dL	152.4 ± 13.0
Glycemia	mg/dL	86.2 ± 3.8
Insulin	mg/dL	19.0 ± 3.3
HOMA-IR	mg/dL	4.2 ± 0.8
Glycated hemoglobin	%	5.3 ± 0.1

Mean ± standard error (SE)

hemoglobin, lipid profile (total cholesterol, LDL-C, HDL-C, and triglycerides), gamma-glutamyltransferase (GGT), and alanine aminotransferase (ALT). Insulin resistance was calculated according to homeostatic model assessment-insulin resistance (HOMA-IR).

The following values were considered inadequate: ALT > 40 U/L, blood glucose > 100 mg/dL; glycated hemoglobin > 5.7%; total cholesterol > 200 mg/dL, HDL-c < 40 mg/dL, LDL-c > 130 mg/dL, triglycerides > 130 mg/dL, and non-HDL cholesterol (total cholesterol – HDL-c) > 145 mg/dL [18].

Statistical analysis

The data were analyzed using SPSS 24.0 (IBM ®) statistical package. Categorical variables were presented as absolute and percentage numbers. Since all variables have normal distribution, they were presented as means and standard error (SE). A paired *t* test was used to compare the variables in the different phases of evaluation. The significance level was 5%.

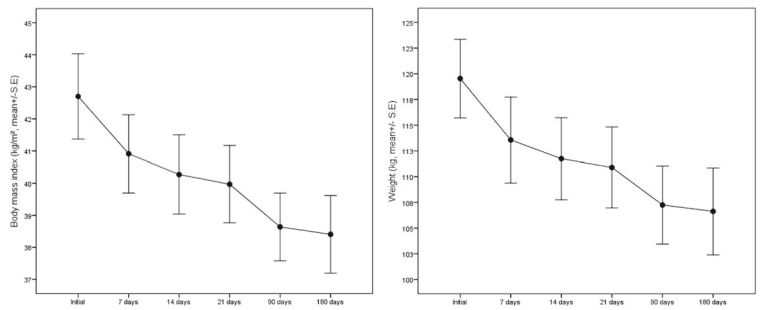
Results

The mean age was 15.1 ± 0.6 years (range 12 to 18 years), BMI 41.3 ± 1.4 kg/m^2 (range 34.6 to 49.9 kg/m^2), and BMIZ 3.9 ± 0.2 (range 3.0 to 5.2) (Table 1). All had waist/height ratio above 0.5 (0.74 ± 0.02, range 0.64 to 0.85).

All patients kept the IB inserted during the 6-month study period. There were no complications during placement of the IB; all attempts were successful. The main complaints occurred in the first week after the insertion. Five adolescents (50%) reported epigastric pain that disappeared with the use of scopolamine butylbromide. Five patients (50%) reported nausea, lasting from 1 to 4 days. Vomiting episodes were observed in two patients (20%), controlled with the use of ondansetron. No adolescents reported dysphagia during IB use.

Before placement of IB alterations in blood pressure, lipid profile and glucose metabolism were found in 20, 30, and 10% of the adolescents, respectively.

BMI and weight reductions were larger during the first week, with a reduction of 1.74 ± 0.46 kg/m^2 (p = 0.004) and 6.46 ± 1.52 kg (p = 0.002), respectively (Fig. 1). At the end of the 6-month period, we observed an average



	Paired Differences BMI (kg/m²)		Paired Differences Weight (kg)	
	Mean±S.E	* p-value	Mean±S.E	* p-value
Initial vs 7 days	-1.74±0.46	0.004	-6.46±1.52	0.002
7 days vs 14 days	-0.47±0.25	0.094	-1.35±0.70	0.097
14 days vs 21 days	-0.27±0.12	0.062	-0.75±0.35	0.063
21 days vs 90 days	-0.99±0.53	0.094	-2.72±4.50	0.089
90 days vs 180 days	-0.23±0.32	0.048	-0.62±2.50	0.503
Initial vs 180 days	-4.29±1.04	0.005	-12.9±3.08	0.004

* Paired-Samples T-Test

Fig. 1 Body mass index (kg/m^2) and weight follow-up during the intragastric balloon treatment. *Paired-sample *T* test

reduction of BMI, weight, and waist-to-height ratio of 4.29 ± 1.04 kg/m (p = 0.005), 12.9 ± 3.08 kg (p = 0.004), and 0.07 ± 0.01 (p < 0.001), respectively.

The average weight lost percentage after 7, 14, 21, 90, and 180 days was −7.6 ± 0.8%, −9.0 ± 0.9%, −9.7 ± 1.0%, −12.5 ± 1.9%, and −14.4 ± 2.7%, respectively. Figure 2 shows BMI reduction and weight loss during the observation period. At the end of the study, there was a statistically significant reduction in insulin concentration (9.0 ± 2.8 U/mL; p = 0.012) and in HOMA-IR (2.0 ± 0.6; p = 0.009) (Table 2).

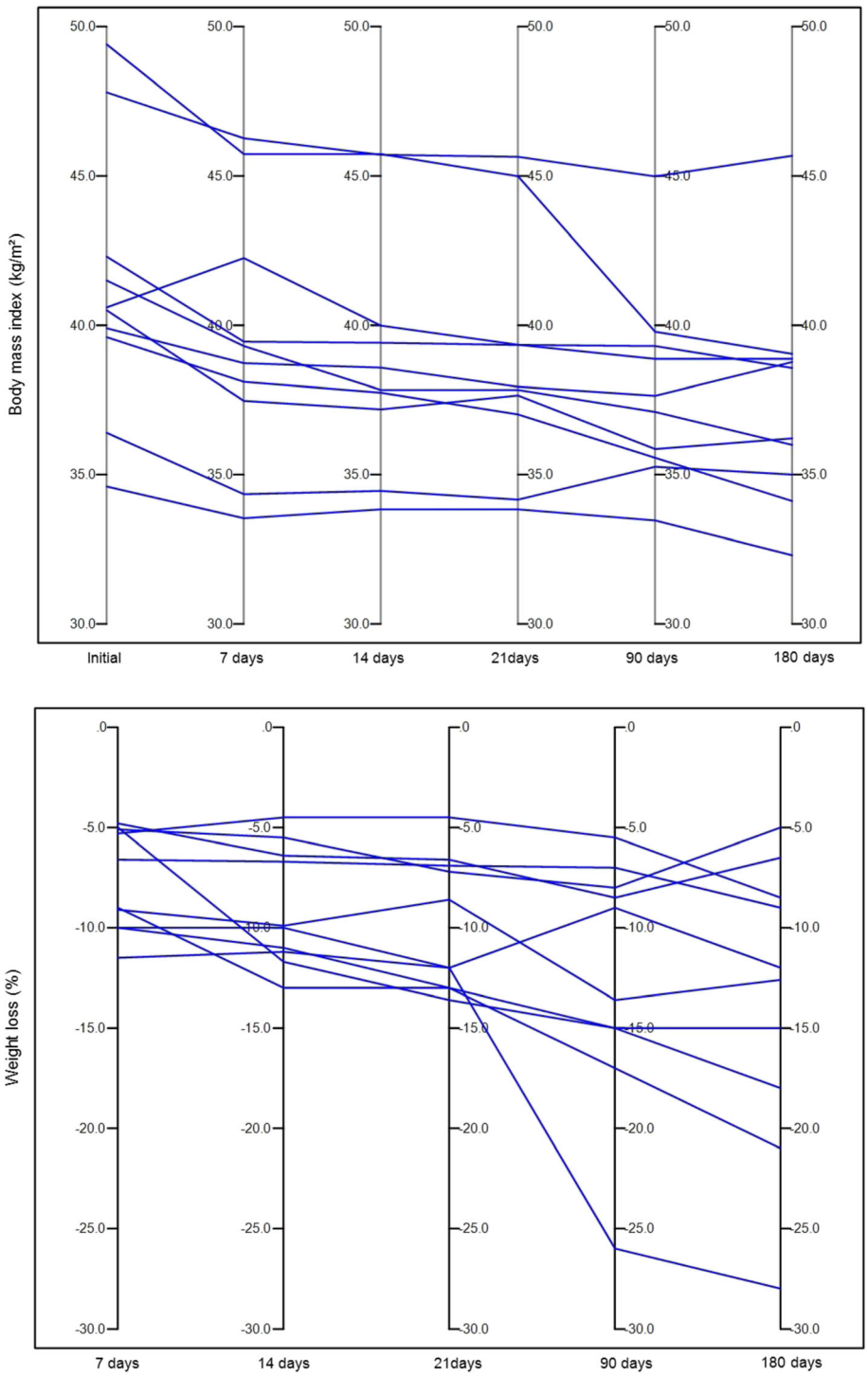


Fig. 2 Body mass index (kg/m^2) variation and weight loss percentage (%) in obese adolescents during intragastric balloon treatment

Table 2 Biochemical parameters before the intragastric balloon insertion and after balloon removal

Variable	Unit	Mean ± SE initial	Mean ± SE after 180 days	*p* value
Total cholesterol	mg/dL	199.4 ± 12.8	186.0 ± 11.8	0.229
HDL-c	mg/dL	47.0 ± 4.2	48.6 ± 3.9	0.593
LDL-c	mg/dL	127.0 ± 7.9	114.8 ± 9.0	0.112
Triglycerides	mg/dL	126.4 ± 27.4	114.1 ± 26.1	0.470
Non-HDL-cholesterol	mg/dL	152.4 ± 13.0	137.4 ± 13.5	0.119
Alanine aminotransferase	U/L	26.9 ± 5.0	23.0 ± 2.4	0.351
Gamma-glutamyltransferase	U/L	26.1 ± 6.0	46.2 ± 17.9	0.140
Glycemia	mg/dL	86.2 ± 3.7	78.8 ± 8.1	0.215
Insulin	U/mL	19.0 ± 3.3	10.0 ± 2.0	0.012
HOMA-IR		4.2 ± 0.8	2.2 ± 0.7	0.009
Glycated hemoglobin	%	5.35 ± 0.14	5.4 ± 0.17	0.571

Paired-sample *T* test

Discussion

This study demonstrated, in severely obese adolescent females, a positive effect of the use of IB associated with conventional treatment with an average reduction of 13 kg and 4 points in BMI after 6 months of insertion, with few adverse effects. There was also an improvement in insulin resistance with a considerable reduction of insulin levels and HOMA-IR.

IB combined with lifestyle programs has been suggested in the treatment of severe obesity because it is safe and minimally invasive [14, 19, 20]. In adults with IB treatment, the improvement of anthropometric parameters results, albeit temporarily, in cardiovascular risk reduction and better life quality [21]. Recent meta-analysis involving 11 studies showed that obese adults that had used IB had a superior weight loss, if compared to conventional treatment [8]. As observed by our study, another study conducted with 385 patients, aged between 13 and 41 years old, described a reduction of 5 points in BMI (13 kg) after 6 months. The weight loss was greater in patients who adhered to healthy eating habits and lifestyle guidance, emphasizing the importance of combing both methods [22].

Another important aspect concerns the maintenance of the positive effect on weight loss after balloon removal. Previously, the central aim of the statement was to reduce morbidity and mortality related to bariatric surgery [23]. A systematic review study in adults evaluating the kinetics of weight loss during treatment with IB and after its removal showed that more than half of the weight lost during treatment is maintained 1 year after the removal of the balloon [24].

In this study, some IB benefits were found regarding insulin concentrations and insulin resistance reduction measured by HOMA-IR. These findings were corroborated by studies in adults using IB treatment [12, 24, 25]. Improvement in insulin resistance and serum insulin concentrations are key points to positive changes in the metabolic profile during weight loss. The rapid decline in insulinemia can be explained by the reduction in adipose tissue, leptin, and proinflammatory cytokine concentrations, such as TNF-α and interleukin-6 [25].

Despite the satisfactory results with respect to insulin resistance, we did not find a significant impact on triglyceride blood levels and in the liver function tests. A previous study in obese adults with IB also found no changes in these biomarkers. However, evaluating dietary food intake, they observed a reduction in energy and carbohydrate and an increase in fat intake [26].

Regarding safety, it should be emphasized that no adolescent had serious complications during IB use. Epigastric pain and nausea were also reported by 50% of our patients, as described in literature [14]. About 20% of the adolescents did not use any medication, except omeprazol. A percentage of 44% has been described by Nobili et al. in obese children and adolescents in IB usage for 3 months [14].

There is variability in the efficiency of IB in reducing body weight [27], as observed in our study, since weight loss in the study group was heterogeneous, ranging from 5.7 to 19.5%. All patients showed weight reductions.

Limitations of our study included a small sample, no body composition or consumption and eating behavior assessments, and the absence of follow-up after the removal of IB.

This study is pioneer in evaluating the impact of IB after 6 months use, as part of a multiprofessional treatment for post-menarche obese adolescent females, in cases of conventional treatment failure. We found a heterogeneous weight and BMI reduction, an improvement in insulin resistance, and absence of serious complications. This data suggest that the procedure is effective and safe for this group of patients.

Conclusions

The results show that IB can be considered as adjuvant therapy for obesity in adolescents after menarche with associated morbidities where conventional treatment failed, considering the impact on weight reduction and improved insulin resistance. Future studies evaluating larger groups and long-term effects, with adjustments in the IB volume, are required.

Abbreviations

ALT: Alanine aminotransferase; BMI: Body mass index; BMIZ: Z scores for body mass index; GGT: Gamma-glutamyltransferase; HDL: High-density lipoprotein; HOMA-IR: Homeostatic model assessment-insulin resistance; IB: Intragastric balloon; LDL: Low-density lipoprotein

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Availability of data and materials

That data will not be shared, because the follow-up of this study has not yet ended.

Authors' contributions

CTP, TFS contributed to the preparation of the project, data collection, intragastric balloon insertion, analysis of results, and preparation of the manuscript, VF contributed to the data collection, nutritional counseling, and assessment and monitoring of nutritional status. FISS and EG contributed to the analysis of the results, preparation of the manuscript, and paper submission. ROSS contributed to the coordination and preparation of the project, data collection, analysis of the results, and preparation of the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

Research Ethics Committee of the Faculty of Medicine of ABC (no 723.830 on June 18, 2014).

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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