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Intragastric balloons in high-risk obese patients in a Brazilian center: initial experience

Balões intragástricos em obesos de alto risco em um centro brasileiro: experiência inicial

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A B S T R A C T

Objective: *to assess the short-term efficacy, tolerance and complications in high-risk morbidly obese patients treated with an intragastric balloon as a bridge for surgery.* **Methods**: *we conducted a post-hoc analysis study in a Brazilian teaching hospital from 2010 to 2014, with 23 adult patients with a BMI of 48kg/m², who received a single intragastric air or liquid balloon. We defined efficacy as 10% excess weight loss, and complications, as adverse events consequent to the intragastric balloon diagnosed after the initial accommodative period. We expressed the anthropometric results as means ± standard deviation, comparing the groups with paired T / Student's T tests, when appropriate, with p<0.05 considered statistically significant.* **Results**: *the balloons were effective in 91.3% of the patients, remained in situ for an average of 5.5 months and most of them (65.2%) were air-filled, with a mean excess weight loss of 23.7kg±9.7 (excess weight loss 21.7%±8.9) and mean BMI reduction of 8.3kg/m²±3.3. Complications (17.3%) included abdominal discomfort, balloon deflation and late intolerance, without severe cases. Most of the participants (82.7%) did not experience adverse effects. We removed the intragastric balloons in time, without intercurrences, and 52.2% of these patients underwent bariatric surgery within one month.* **Conclusion**: *in our center, intragastric balloons can be successfully used as an initial weight loss procedure, with good tolerance and acceptable complications rates.*

Keywords: *Gastric Balloon. Risk. Obesity, Morbid. Bariatric Surgery.*

INTRODUCTION

Obesity is an international health problem, with high morbidity and mortality[1]. Worldwide, more than two million people die annually due to obesity or overweight[2]. The higher the body mass index (BMI), the greater the risk of comorbidities[2]. Overall, mean BMI has increased by 0.4kg/m² per decade[3]. In Brazil, obesity affects 17.5% of the population and the prevalence of morbid obesity (BMI≥40kg/m²) increased by more than 255% since 1970s[4,5].

Health spending rises in direct proportion to the BMI as well. In 2011, Brazilian morbid obesity costs (US$ 64.2 million) corresponded to 23.8% of all expenses related to obesity (US$ 269.6 million)[2]. Theoretically, a decrease of only 1% in the mean BMI can potentially lead to a substantial reduction in the national economic burden imposed by obesity[6].

Extreme obesity is associated with a large decrease in life expectancy when compared to that of normal weight individuals, and the main causes of death are heart disease, cancer and diabetes. When calculating the years of life lost, the numbers are worrisome: in the BMI range of 40-45 kg/m², mean survival decreases by 6.5 years, of 50-55 kg/m², in 9.8 years, and in the range of 55-60 kg/m², in 13.7 years[7].

High-risk morbid obese individuals are usually defined by superobesity (SO), BMI=50kg/m², associated with males, age >45 years and presence of severe comorbidities. Such a population represents a challenge in bariatric surgery due to technical difficulties, high mortality rates, and perioperative morbidity, which reach

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12% and 40%, respectively, in the early postoperative period[8]. In fact, the 30-day mortality risk increases exponentially according to the number of comorbidities in these patients: 0-1 comorbidities: 0.03%; 2-3 comorbidities; 0,16%; and 4 comorbidities: 7,4 %[9].

To minimize this risk, a significant loss of preoperative weight is essential. Currently, the viable strategies to achieve it are hypocaloric diet, medications, hospitalization and Intragastric Balloon (IGB)[8,10]. However, the low calorie diet has a considerable circumvention rate, most anti-obesity drugs have been withdrawn from the market due to systemic side effects and hospitalization for an intensive program in a controlled environment is excessively onerous[10]. Thus, IGB have been widely used as a bridge for bariatric surgery in high-risk superobese patients. Generally, the established goal is 10% excess weight loss (10% EWL)[10], with positive effects on postoperative risk, technical complexity and shorter surgical times due to a decrease in the volume of the liver and adipose, subcutaneous and visceral tissues[11], and may improve the results of surgery after one year[12]. The degree of risk reduction seems to relate to the degree of weight loss, and patients with higher BMIs probably benefit more[13].

In six months, IGB generally reach the goal of 10% EWL or more, providing greater control of obesity-related diseases and improvement in metabolic profile, without compensatory increase of appetite hormones[10,14-16]. In fact, it is considered a safe procedure with few complications. Serious events are exceptional[17]. Perforation, the most feared, can occur in the stomach (0.2%) or more rarely in the esophagus, subsequent to implantation or endoscopic extraction[18-20]. Intestinal obstruction is estimated at 0.2%[18]. The main adverse effect is vomiting, especially in the first days post-procedure[21]. Additionally, there are reports of esophagitis and gastritis diagnosed after its removal[22].

Absolute contraindications to the use of IGB are previous gastric surgery, large hiatal hernias (≥5cm), pregnancy, potential hemorrhagic lesions in the upper gastrointestinal tract, coagulation disorders and severe liver diseases. Relative contraindications include previous abdominal surgery, esophagitis, Crohn's disease and psychiatric disorders[23].

In this study, our objective is to identify the short-term efficacy of IGB in the treatment of high-risk morbid obesity patients in a bridge-to-surgery strategy, assessing their tolerance and complications at our center.

METHODS

This is a *post-hoc* study-analysis from June 2010 to June 2014, at a public hospital in Fortaleza-CE. The institutional Ethics Committee approved the research protocol (Number 831,224), with written consent of the patients and the hospital for access to medical records. Participants included high-risk, morbidly obese adult patients who were refractory to conservative treatment, were involved in the weight loss program, and underwent IGB insertion as a bridge to bariatric surgery. We excluded individuals with BMI<48kg/m^2 or with balloon contraindications.

Each patient received a single balloon, which could be filled with 500cc of air or 500-700 cc of liquid. Until October 2012, we implanted air IGB, and liquid ones thereafter, due to changes in the availability of these devices in the hospital. The insertion of IGB occurred with conscious sedation assisted by an anesthesiologist and removal under general anesthesia under direct endoscopic control, using gastroscopes and standard accessories (needle catheter, grasping clamps and polypectomy loops). We performed a routine upper digestive endoscopy before IGB implantation.

The preoperative weight loss protocol consisted of multidisciplinary outpatient follow-up (with surgeons, internists, nutritionists, psychologists and psychiatrists), IGB implantation, hypocaloric diet (1000 cal/day) and physical activities. In addition, there were regular consultations with the bariatric endoscopist for assessment of efficacy and tolerance, weekly in the first month post-procedure, fortnightly in the second month, and monthly thereafter. We prescribed proton pump inhibitors during the IGB permanence, associated with antiemetics and analgesics during the first two weeks.

All patients had their weight monitored before IGB implantation, at each follow-up visit and at extraction. Using standard methods of weight loss quantification[24], such as Ideal weight corresponding to BMI 25kg/m^2 and % EWL, we defined the efficacy as at least 10% EWL.

We considered complications as adverse effects attributable to IGB diagnosed after two weeks of insertion, identified during the outpatient follow-up. In our experience, nausea, vomiting and abdominal pain are very common in such a period, consequent to gastric accommodation to the foreign body, and easily treated with oral medication. Therefore, we did not consider such complications in this study.

The studied variables included IGB type, length of stay, associated complications, % EWL, weight variation and BMI. We used used SPSS 20 to process the data, and expressed results as mean ± standard deviation. We used the paired T and Student's T tests, as appropriate, for comparison between groups. We set the statistical significance at $p<0.05$.

RESULTS

Twenty-three patients received IGB and their characteristics are shown in table 1. The main comorbidities at the beginning of treatment were hypertension, sleep apnea syndrome and diabetes.

Table 1. *Characteristics of high-risk patients with morbid obesity treated with IGB as bridge to bariatric surgery.*

	N	%	Mean±SD
Age (years)			
19-67	23	100	40.8±11.4
Gender			
Male	12	52.2	
Female	11	47.8	
Number of Comorbidities			
0	7	30.4	1.47
1	5	21.8	
2	4	17.4	
3	7	30.4	
Practice of physical activity			
Yes	8	34.8	
No	15	65.2	
IGB Type			
Air	15	65.2	
Liquid	8	34.8	

SD: standard deviation.

The IGB stayed for an average time of 5.5 months and most of them (65.2%) were air-filled, with a mean weight loss of 23.6kg (21.7% EWL), with maximum 41kg (35.8% EWL). BMI reduced on average 8.3kg/m^2. All anthropometric parameters, before and after IGB, displayed statistically significant differences, with $p<0.0001$. Table 2 shows such results.

Table 2. *Anthropometric parameters in high-risk, morbidly obese individuals before and after the use of the IGB.*

	Before	After	Weight loss results	*p*
Weight (kg) (mean±SD)	175.3±33.1 [122-238]	151.6±31.0 [97-214]		<0.0001
EW (kg) (mean±SD)	112.0±26.0 [73.6-168.4]	88.3±24.9 [48-136.1]		<0.0001
BMI (kg/m^2) (mean±SD)	61.7±7.5 [48-78.6]	53.4±7.8 [40.6-68.6]		<0.0001
BMI reduction (kg/m^2) (mean±SD)			8.3±3.3 [1.5-14.0]	
Weight loss (kg) (mean±SD)			23.7±9.7 [4.3-41]	
% EWL (mean±SD)			21.7±8.9 [3.5-35.8]	
IGB time (months) (mean±SD)		5.5±1.4 [1-7]		

SD: standard deviation; EW: excess weight; EWL: excess weight loss.

The effectiveness of the balloons in our center was 91.3%. All, except for two participants, were clinically successful, exceeding the 10% EWL target. The first failure occurred in a female patient who, despite a time with IGB of seven months, reached only 3.5% EWL (4.3kg) and a BMI variation of 1.5kg/m^2. She did not adhere to the prescription of physical activity, nor to the low-calorie diet. The other failure occurred in a man with satisfactory adherence to the combined treatment during the six months. However, he obtained 9% EWL (13.5kg) and a BMI reduction of 4.0kg/m^2.

Given our small sample, the comparison tests performed did not reach statistical significance. However, there was a tendency for better EWL results in older patients, in the 40-67 years age range (23.1% EWL vs. 20.3% EWL, p=0.465), who were physically active (22.3% EWL vs. 21.3% EWL, p=0.820) and with more comorbidities (24.6% EWL vs. 22.05% EWL, p=0.842). There was no difference between the two types of balloons in relation to the final weight parameters.

As described in table 3, our complication rate was 17.3%, including abdominal discomfort (8.7%), balloon deflation with migration (4.3%), and late intolerance with severe dehydration (4.3%).

Table 3. *Intragastric balloon complications in high-risk, morbidly obese patients.*

Complications	N	%
Abdominal discomfort	2	8.7
IGB deflation/obstruction	1	4.3
Late intolerance/dehydration	1	4.3
No complications	19	82.7
Total	23	100

Cases of abdominal discomfort were mild, patients were treated conservatively and experienced gradual symptom resolution. On the other hand, the patient with balloon deflation had migration to the small intestine and obstruction, being submitted to surgery for removal of the device. Interestingly, the IGB had remained in situ during the six-month period. One late intolerance occurred after one month of fluid IGB use and the patient developed intense and refractory vomiting, aggravated by dehydration and acute renal failure. Treatment included hospitalization and balloon extraction. Bariatric surgery was performed during the same admission, after normalization of clinical parameters. Nevertheless, 18.9% EWL (20kg) was achieved preoperatively.

In 82.7% of patients, there were no complications and their IGBs were extracted when

programmed, without any technical difficulties described by endoscopists. The majority of patients (52.2%) underwent bariatric surgery (Roux-en-Y gastric bypass) within one month after balloon extraction. The remainder were submitted to surgery after this interval, following the schedule of bariatric surgeons.

DISCUSSION

There are several studies of IGBs with heterogeneity in BMI the selection criteria. Most of them define the lower limit of BMI at 40kg/m^2, with weight losses ranging from 17 to 21kg[16,25-28]. Much of the published data refers to Orbera's IGB, while there is a relative paucity of articles on Heliosphere[29], a 30g silicone-coated polymer with two layers interconnected by a valve, unlike most liquid IGBs, which are also made of silicone but weigh 500-600 g[23,30]. The Medicone IGB, which used in this study, requires further investigation, with little clinical data so far.

Experiments with the Heliosphere (air IGB) report weight losses of around 17kg. Its tolerance, efficacy and final results are equivalent to those of Orbera in a small series of cases[30-35], a finding that was also demonstrated in two controlled studies comparing both IGB, where there was no significant difference in the weight loss final parameters[36,37]. Likewise, our cohort did not find statistical difference between the two balloons in the final anthropometric parameters. However, technical problems with air IGB are repeatedly emphasized in the studies: considerable rates of spontaneous deflation, difficult removal due to valve size, longer extraction times, patient discomfort, laborious passage through the cardia or lower pharynx, and occasional need for more complex procedures such as rigid esophagoscopy or surgery[30,31,33,36,37]. Unlike the international literature, our endoscopists did not describe any technical challenges in the withdrawal and we believe that the reason was the previous extensive experience of the team with the use of IGB.

Compared with previous data, we reported greater weight loss, with a mean of 23.6kg (21.7% EWL), a maximum of 41kg (35.8% EWL) and a mean BMI decrease of 8.3kg/m^2. We believe that the greater initial weight, our multidisciplinary program with regular follow-up and the motivation of the participants contributed to these results. In addition, correlating with a national multicenter study that described a mean BMI decrease of 8.5kg/m^2 and 26.1kg EWL (23.5% EWL) in the superobese sample[38]. Our numbers are quite similar.

The weight loss results were excellent in 21 of the 23 patients (91.3% efficacy), with an average treatment duration of 5.5 months. Recently, Gaur *et al*.[39] have shown that IGB appear to be more effective in the first trimester of therapy, with mean results corresponding to 80% of the total amount lost. Current research has not explored the monthly kinetics of weight loss. However, this may represent a justification for shifting the six-month treatment paradigm.

This study showed a trend towards greater weight loss in older patients, exercise practitioners and patients with more comorbidities. Physical activity plays an important role in bariatric patients' care, with recent evidence demonstrating that higher levels of pre and postoperative activity are associated with greater weight loss[40]. Elderly patients with severe comorbidities such as diabetes have a high probability of weight loss[41].

Our overall complication rate was 17.3%. The literature cites a range of possible complications: intolerance with early removal (up to 6.3%), deflation and migration (1.6-28.9%), abdominal pain (5.8-11.6%), nausea and vomiting (up to 18%), minor side effects (0.2-1.27%) and some rare reports of fatalities (0.07%)[23,30,39,42]. In our study, we observed a 4.3% rate (one participant) of late intolerance, resolved upon device removal. Many authors consider vomiting intrinsic to balloon use, especially in the early stages. Its appearance occurs within hours, persisting for a few days after placement, as a consequence of the natural adaptation of the stomach to the foreign body[43]. Thus, intolerance is characterized by vomiting that persists for longer periods, usually associated with abdominal discomfort. These unpleasant symptoms can lead to patient dissatisfaction or lack of motivation to continue therapy. At the same time, patients who do not experience these symptoms may refuse to follow dietary modifications, culminating in weight loss below the expected level[43]. However, when intense enough (hyperemesis), vomiting may trigger a dangerous sequence of electrolyte imbalance/ dehydration/ renal failure, characterizing the indication

for IGB withdrawal if refractory to conservative treatment[43,44]. This chain of events happened in our patient, leading the authors to opt for the early removal of IGB. On the other hand, our two participants (8.7%) with abdominal discomfort evolved successfully with conservative treatment.

We had one case (4.3%) of spontaneous IGB deflation, complicated by intestinal migration and obstruction. Deflation is a well-known phenomenon, common to all existing types of balloons. The only postulated risk factor is implant permanence exceeding the recommended withdrawal date, with greater susceptibility to device dysfunction and leakage[39]. The longer it remains in situ, the greater the likelihood of damage, such as erosions on the silicone surface[43]. Diagnosing a leakage of liquid IGB is relatively simple, given the urine of bluish coloration, because of the excretion of methylene blue. However, diagnosing the spontaneous rupture of an air IGB is a challenge, since it is usually an asymptomatic process. Frequently, one can only detect subsequent complications, such as mechanical ileus or perforations[45].

In conclusion, the current efficacy of intragastric balloons in high-risk obese patients at our center is 91.3%, with clinical success and satisfactory tolerance. Our complication profile is within published rates. Intragastric balloons can be used effectively, in association with diet, as a bridge to surgery in our center.

R E S U M O

Objetivo: identificar a eficácia em curto prazo, a tolerância e as complicações em obesos mórbidos de alto risco, tratados com balão intragástrico como ponte para cirurgia. **Método**s: estudo de análise *post-hoc* em um hospital acadêmico brasileiro durante o período de 2010 a 2014, de 23 pacientes adultos com IMC de 48kg/m² que receberam um único balão intragástrico de ar ou líquido. Eficácia foi definida como perda de excesso de peso de 10%, e complicações como eventos adversos consequentes ao balão intragástrico diagnosticados após o período acomodativo inicial. Expressaram-se os resultados antropométricos com média ± desvio padrão, comparando os grupos com testes T Pareado / T de Student, quando apropriado, com $p<0,05$ considerado estatisticamente significante. **Resultados**: os balões foram efetivos em 91,3% dos pacientes, permaneceram *in situ* por em média 5,5 meses e a maioria deles (65,2%) era de ar, com perda média de excesso peso de 23,7kg±9,7 (perda de excesso de peso de 21,7%±8,9) e redução média de IMC de 8,3kg/m²±3,3. As complicações (17,3%) compreenderam desconforto abdominal, deflação do balão e intolerância tardia, sem casos graves. A maioria dos participantes (82,7%) não experimentou efeitos adversos, seus balões intragástricos foram extraídos em tempo, sem intercorrências e 52,2% desses pacientes submeteram-se à cirurgia bariátrica no intervalo de um mês. **Conclusão**: no nosso centro, balões intragástricos podem ser usados com sucesso como procedimento inicial de perda ponderal, com boa tolerância e taxas aceitáveis de complicações.

Descritores: Balão Gástrico. Risco. Obesidade Mórbida. Cirurgia Bariátrica.

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