

ORIGINAL ARTICLE

Acute complications following endoscopic intragastric balloon insertion for treatment of morbid obesity in elderly patients. A single center experience

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ABSTRACT

BACKGROUND: Obesity is a serious disease, with an increasing incidence also among subjects over 60 years old; surgical management has proven to be the most effective in the production of significant and durable weight loss. Intragastric balloon (IGB) treatment promotes a reduction of five to nine Body Mass Index (BMI) units in 6 months with an impressive improvement of obesity-associated comorbidities.

METHODS: Two hundred and twenty-five patients, 106 men (47.1%) and 119 women (52.9%), were evaluated at our institution to be submitted to a IGB positioning. Of these, 12 patients (8 women and 4 men) were more than 60 years old. For all patients BMI, comorbidities, weight loss and complications were recorded. χ^2 test was used to evaluate differences in complications rate between elderly and other patients.

RESULTS: For the 12 elderly patients, we recorded a mean excess weight loss rate (EWL%) of 31.4. About complications, we recorded 2 severe esophagitis requiring IGB removal and 1 late gastric perforation. A higher complications rate was found in elderly population and the comparison with other patients revealed a significant difference ($P < 0.001$).

CONCLUSIONS: Our results underline that IGB treatment in elderly patients is safe and effective in terms of weight loss and improvement in comorbidities. IGB can cause complications which, sometimes, can be severe such as esophageal damage and gastric perforation. For the management of complications, we highly recommend a close follow-up in all patients and a deepened instrumental study in every suspect case.

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KEY WORDS: Complications; Gastric balloon; Endoscopy; Obesity, morbid.

Obesity is a serious disease, with substantial morbidity and mortality; weight reduction has been demonstrated to improve survival and obesity-related comorbid conditions. In the USA 35% of subjects over 60 years old suffer from obesity and in Italy the prevalence of obesity among the elderly has increased from 7.5% to 16%.¹ As opposed to lifestyle modification and dietary programs, surgical management has

proven to be the most effective in the production of significant and durable weight loss.²

Less invasive approach reached increasingly popularity; short hospitalization, lower postoperative pain and a better cosmetic resolution are the main advantages of these innovative technique.³

Intragastric balloon (IGB) treatment, promotes a reduction of five to nine Body Mass Index (BMI) units in 6 months with an impressive

improvement of obesity-associated comorbidities in all those patients not suitable for surgery due to different reasons. Furthermore, in our experience, IGB remains the most effective “bridge to surgery” option, allowing patients candidate to different bariatric procedures to approach surgery with a decreased operative risk.⁴

IGB complications include dislocation of the balloon causing intestinal obstruction, gastroesophageal (GE) reflux with severe esophagitis and upper gastro-intestinal bleeding, especially during balloon insertion or removal.⁵ Gastric perforation is one of the rare complications of IGB and the reported management in the literature is always surgical.⁶

Here we report our experience with 12 elderly obese patients treated with IGB.

Materials and methods

Starting from January 2005, 225 patients, 106 men (47.1%) and 119 women (52.9%) were evaluated at our institution by a multidisciplinary approach to receive a Bioenterics IntraGastric Balloon (BIB[®], Inamed Health-Allergan, Santa Barbara, CA, USA) positioning, following the Italian Society for Bariatric and Metabolic Surgery (SICOB) guidelines;⁷ of these, 12 patients (8 women and 4 men) were more than 60 years old, with a mean age of 62.8±1.5 years and a preoperative mean BMI of 53.8±3.3. Among elderly patients, 2 patients had type 2 diabetes mellitus (DM), 3 patients had hypertension, 1 had obstructive sleep apnea (OSA) and 3 suffered for arthrosis.

Regarding our standard operative technique, the balloon is usually introduced using an endoscopic camera following a scout examination of the stomach. Once the balloon is inside the gastric fundus, it is immediately filled with 400 to 600 mL sterile saline and 10 mL methylene blue. The procedure is usually performed with the aid of slight sedation (intravenous infusion of Midazolam 3 mg). Placement times takes 20-30 min. The patient is then monitored by the physician for a short time (4-6 h) before returning home. After treatment period (6 months), the intragastric balloon is removed. They are usually given proton pump inhibitor (PPI) for 7 days and antiemetic drugs if needed.

For all patients, information on demographics, preoperative and postoperative body mass index, and preoperative comorbidities were recorded at hospitalization while data regarding improvement or resolution of comorbidities, weight loss expressed as the percentage of excess weight loss (EWL%) and complications were recorded during 6-months follow-up.

Although an “ethical approval” statements does not apply to a retrospective study, it has to be remarked that all balloon procedures performed by authors were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. An informed consent to surgery was obtained from all patients who underwent a balloon placement performed by anyone of the authors of this study during these years.

Although information regarding patient identity was not given in this study, an informed consent to publication was obtained from all patients who underwent a balloon procedure performed by anyone of the authors of this study during these years.

Statistical analysis

χ^2 test was used to evaluate differences in complications rate between elderly and other patients; statistical analysis was performed with the Statistical Package for Social Sciences (Version 20.0 for Windows; SPSS Inc, Chicago, IL, USA) and a P value<0.05 was considered statistically significant.

Results

The IGB positioning promoted a mean excess weight loss rate (EWL%) of 31.4; moreover, at 6-months follow-up, we found a resolution rate of comorbidities of 50% for type 2 DM, 66% for hypertension, 100% for OSA and 66% for arthrosis.

Four complications (2.13%) were recorded in the total population, and of these 3/12 (25%) occurred in elderly patients: we documented 1 severe esophagitis in a 34-year-old patient (1/213, 0.4%) and 2 esophagitis requiring IGB removal and 1 late gastric perforation in elderly patients.

A higher complications rate was found in elderly population and the comparison with other patients revealed a statistically significant difference ($P < 0.001$).

For the two cases of esophagitis, both patients returned to our institute for acute epigastric pain; the endoscopic examination revealed signs of severe inflammation which required, for both, the BIB removal and an increase of PPI dosage. Further endoscopic controls were planned until complete resolution of signs of esophagitis.

About the case of gastric perforation, it occurred in a 64-year-old obese ($BMI = 36.3 \text{ kg/m}^2$) woman who had an endoscopic IGB insertion done in our Institute 30 days prior to emergency presentation and she lost 10 kg. Her past medical history was unremarkable except for joint impairment secondary to obesity; she had no history of previous surgery. She returned to our department because of diffuse abdominal pain of 12 h duration. Pain was severe with no other associated symptoms. No history of trauma or medication intake. Plan abdominal X-ray showed pneumoperitoneum. Intravenous fluids, antibiotics, pain killers, and PPI was administered and then she was shifted to the operating room. Under general anesthesia, a diagnostic laparoscopy was done and showed a small antral perforation with 700 mL of turbid fluid in the abdomen. A breach was made in the stomach to deflate and remove the balloon. The perforation was repaired with 2/0 PDS interrupted sutures. Peritoneal wash was done and a drain was kept. The patient had a good postoperative period, tolerated diet, and was discharged in a stable condition after 7 days.

Discussion

Obesity is a pandemic health problem in both developed and developing countries and the costs of care continue to grow in parallel with the prevalence of the disease. This morbid condition leads to a high incidence of complications and a decrease in life expectancy. In fact it is associated with development of comorbid conditions such as hypertension, diabetes mellitus, sleep apnea, congestive heart failure and certain tumor.^{8,9}

Obesity is notoriously difficult to manage. Diet, behavioral therapy, exercise, and pharma-

cologic intervention have traditionally been used but generally yield modest results, and weight regain is common. Despite potential risks, in cases of failed medical therapy, bariatric surgery should be considered the treatment of choice for severe obesity and related comorbidities.¹⁰⁻¹²

The physiologic concept of an IGB was first described by Nieben in 1982 with his idea of the placement of an artificial gastric bezoar, as a space-occupying device; this would induce a mechanical gastric distension with a decrease food intake.¹³

Endoscopic IGB approach to morbid obesity can be evaluated for particular indications: obese patients who reject bariatric surgery, morbidly obese ($BMI > 40$), superobese patients ($BMI > 50$) in preparation for bariatric operations and patients with BMI between 30 and 35 with other comorbidities.^{7, 14}

Intragastric balloon treatment is more drastic than medical treatment but less invasive than surgery. IGB could determinate a weight loss of 5-9 BMI units in 6 months with an impressive improvement of obesity-associated comorbidities; on the other hand, no response, intolerance, and weight regain have to be taken into account when this approach is chosen.¹⁵

Although most patients tolerate balloons well, IGBs can sometimes cause complications which are usually mild but, sometimes, can be severe. Mild complications include abdominal and back pain or discomfort, nausea, and vomiting which last only for a short period after balloon insertion and are usually self-limiting. Severe complications include dislocation of the balloon causing intestinal obstruction, severe esophagitis and upper gastro-intestinal bleeding and perforation, especially during balloon insertion or removal. The largest meta-analysis (12 studies, 3429 patients) found an obstruction rate of 0.8%, an inflammation or lesions in digestive lining (including esophagitis) rate of 2.1% and a gastric perforation rate of 0.1%.¹⁶

An increase in GE reflux diseases has been observed under basal conditions in patients who are obese, although the causes have not been clarified; insertion of an intragastric balloon can lead, at least, in the first few weeks of the treatment, to an increase in gastro-esophageal reflux.¹⁷ The

onset of severe esophagitis (classes C-D) after BIB placement, even in patients who were formerly totally asymptomatic, was demonstrated by Rossi *et al.* on 121 patients who underwent BIB insertion; they concluded that a probable explanation is an alteration in the tone of the lower esophageal sphincter (LES) due to modifications in intragastric pressure induced by the BIB.¹⁸

About gastric perforation, although the real mechanism of is not well known, the most likely hypothesis leads to the continuous contact of the balloon with the gastric wall that made possible the development of a gastric ulcer. The ulcer could perforate, particularly when patients have poor compliance to proton pump inhibitors, and the development of peritoneal complications could be lethal.¹⁹ In 2013, Giardiello *et al.*²⁰ found, as other risk factor that may increase the incidence of perforation, a previous gastric surgery; the authors concluded that gastric surgery should be an absolute contraindication to placing a BIB, because the compliance of the stomach wall has been modified.

For the management of this complication, the usual treatment is through a surgical approach, with removal of the balloon and repair of the gastric perforation.

Koutelidakis *et al.*²¹ reported gastric perforation in a 43-year-old man 2 days after the insertion of a BIB. The patient underwent laparotomy, and the balloon was deflated using a syringe through the gastric wall and was removed through the large linear perforation at the fundus of the stomach which was closed in 2 layers. Smigielski *et al.*²² reported the gastric perforation 9 days following a BIB insertion. The balloon was deflated and removed endoscopically, and the perforation was sutured laparoscopically. del Pozo *et al.*²³ were the first to report gastric perforation in a 65-year-old man after removal of a BIB, managed with laparotomy and a 2 layers perforation closure.

Our experience is focused on 12 IGBs insertion in elderly patients. It confirmed the results of several previous studies, suggesting that rates of perioperative morbidity and mortality might be higher.²⁴ The improvement in intraoperative and perioperative patient management have led to excellent results. While older patients have more

pre and postoperative comorbidities and lose less weight than younger patients, the results we described underline that weight loss and improvement in comorbidities are clinically significant.

About the complications found in the studied population, we reported two cases of esophagitis and one case of late IGB-induced gastric perforation which is a very rare complication, reported explicitly in few previous studies. All cases of esophageal damage requires BIB removal, PPI therapy and endoscopic follow-up until a complete resolution of signs of esophagitis. Treatment approach for perforation may vary from endoscopic IGB retrieval alone,²⁵ surgical IGB extraction and suture repair through laparotomy or laparoscopy,²²⁻²⁴ to a combined endoscopic IGB retrieval and laparoscopy perforation repair; the chosen technique generally depends on surgeon previous experience and technical availabilities in emergency conditions.

Conclusions

In conclusion, bariatric surgery is effective to reach obesity related comorbidities resolution among elderly obese patients and, according to our data, IGB approach is able to induce a documented improvement in quality of life for morbidly obese geriatric population.

Nevertheless, a significant increase of postoperative complications in elderly obese patients undergoing BIB placement must to be taken in account; to increase the safety of the IGB treatment, it is advisable to prescribe therapy with PPIs during the 6 months of balloon placement.²⁶

We highly recommend a close follow-up in all patients and a deepened instrumental study in every suspect case of gastro-intestinal injury.²⁷

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