

BioEnterics Intra-gastric Balloon: The Italian Experience with 2,515 Patients

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Background: The temporary use of the BioEnterics Intra-gastric Balloon (BIB) in morbidly obesity is increasing worldwide. The aim of this study is the evaluation of the efficacy of this device in a large population, in terms of weight loss and its influence on co-morbidities.

Methods: Data were retrospectively recruited from the data-base of the Italian Collaborative Study Group for Lap-Band and BIB (GILB). After diagnostic endoscopy, the BIB was positioned and was filled with saline (500-700 ml) and methylene blue (10 ml). Patients were discharged with diet counselling (~1000 Kcal) and medical therapy. The BIB was removed after 6 months. Positioning and removal were performed under conscious or unconscious sedation. Mortality, complications, BMI, %EWL, BMI loss and co-morbidities were evaluated.

Results: From May 2000 to September 2004, 2,515 patients underwent BIB (722M/1,793F; mean age 38.9 ± 14.7 , range 12-71; mean BMI 44.4 ± 7.8 kg/m²; range 28.0-79.1; and mean excess weight 59.5 ± 29.8 kg, range 16-210). BIB positioning was uncomplicated in all but two cases (0.08%) with acute gastric dilation treated conservatively. Overall complication rate was 70/2,515 (2.8%). Gastric perforation occurred in 5 patients (0.19%), 4 of whom had undergone previous gastric surgery: 2 died and 2 were successfully treated by laparoscopic repair after balloon removal. 19 gastric obstructions (0.76%) presented in the first week after positioning and were successfully treated by balloon removal. Balloon rupture (n=9; 0.36%) was not prevalent within any particular period of BIB treatment, and was also treated by BIB removal. Esophagitis (n=32; 1.27%) and gastric ulcer (n=5; 0.2%) presented in patients without a history of peptic disease and were treated conservatively by drugs.

Preoperative co-morbidities were diagnosed in 1,394/2,471 patients (56.4%); these resolved in 617/1,394 (44.3%), improved (less pharmacological dosage or shift to other therapies) in 625/1,394 (44.8%), and were unchanged in 152/1,394 (10.9%). After 6 months, mean BMI was 35.4 ± 11.8 kg/m² (range 24-73) and %EWL was 33.9 ± 18.7 (range 0-87). BMI loss was 4.9 ± 12.7 kg/m² (range 0-25).

Conclusions: BIB is an effective procedure with satisfactory weight loss and improvement in co-morbidities after 6 months. Previous gastric surgery is a contraindication to BIB placement.

Key words: Obesity, intra-gastric balloon, weight loss, complications, co-morbidity

Introduction

The BioEnterics Intra-gastric Balloon (BIB) is an endoscopic device for temporary treatment of obesity.^{1,2} Intra-gastric balloon positioning is potentially attractive to health-care practitioners who have experienced poor results with dietary programs, medications and behavioral therapy. Moreover, it has been recommended as a weight reduction adjunct before bariatric surgery and before all kinds of planned surgery in the morbidly obese, to reduce life-threatening co-morbidities and lessen surgical risk.²⁻⁴ The aim of this study is the retrospective evaluation in a large population of the efficacy of the BIB in terms of weight loss and its influence on co-morbidities.

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Patients and Methods

The BioEnterics IntraGastric Balloon (BIB, Inamed, Santa Barbara, CA, USA) was used in all patients who were selected according to NIH criteria and guidelines for bariatric surgery.⁵ They were independently evaluated by internists, dieticians and psychologists for preoperative selection. Exclusion criteria were: physical inability to maintain regular follow-up, problems precluding safe endoscopy; esophagitis (Grade 1); hiatal hernia (>5 cm); chronic therapy with steroids, non-steroidal anti-inflammatory drugs, or anticoagulants; active peptic ulcer or its previous complications; previous GI resections, structural abnormalities of the GI tract, lesions considered at risk for bleeding; pregnancy; and disorders of eating pattern. Specifically written informed consent was obtained from all the treated patients.

BIB placement was performed, after diagnostic endoscopy, under intravenous conscious or unconscious sedation (propofol 2 mg/kg) with the patient in lateral decubitus position. The BIB was inflated under direct vision with saline (500-700 ml) and methylene blue (10 ml) solution. After 6 months, endoscopy was performed and balloon removal was carried out using a dedicated instrument following complete deflation of the device.

On the first post-insertion day, intravenous saline (30-35 ml/kg/day) with omeprazole (20 mg/day), ondansetron (8 mg/day) and butylscopolamine bromide (20 mg 3x/day) were given to all patients. On the second post-insertion day, if the patients were

able to tolerate fluids, they were discharged with drug therapy: omeprazole (20 mg/day), anti-emetics (if required), and a 1,000 Kcal diet (carbohydrates 146 g, lipid 68 g, proteins 1 g/ kg ideal weight). Of the BIBs, 325 were placed as outpatients. Patients were followed weekly, and mortality, complications and their treatment, post-placement symptoms, comorbidities, BMI and %EWL were recorded. Comorbidities and their resolution are reported in Table 1. Data are expressed as mean \pm standard deviation, except as otherwise indicated.

Results

From May 2000 to Sept 2004, 2,515 patients underwent BIB placement (722M/1,793F; mean age 38.9 \pm 14.7, range 12-71; mean BMI 44.4 \pm 7.8 kg/m², range 28.0-79.1; mean excess weight 59.5 \pm 29.8 kg, range 16-210).

Complications

BIB positioning was uncomplicated in all but two cases (0.08%) with acute gastric dilatation treated conservatively. The balloon was removed between 24 hrs and 1 month after positioning in 11/2,515 patients (0.44%) due to psychological intolerance. Overall complication rate was 70/2,515 (2.8%). Gastric perforation presented in 5 patients (0.19%), 4 of whom had undergone previous gastric surgery: 2 died and 2 were treated successfully by laparoscopic gastric repair after BIB removal.

Table 1. Co-morbidities: definition and resolution criteria *

CO-MORBIDITY	DEFINITION	RESOLUTION CRITERIA**
Hypertension	Systolic >140/90 mmHg	120-130 mmHg
Diabetes	Fasting glycemia >120-130 mg/dl HbA1c >9%	Fasting glycemia <110 mg/dl HbA1c <6%
Respiratory disorders	Sleep apnea and / or tachypnea after little physical activity	Absence of symptoms
Osteoarthropathy	Subjective reduction of physical activity from joint pain	Absence of pain
Dyslipidemia	LDL cholesterol >250 mg/dl Tryglicerides >250 mg/dl	LDL cholesterol <200 mg/dl Tryglicerides <200 mg/dl

* = diagnosed in anamnesis or incidental finding during patient screening before BIB placement.

** = without pharmacological support.

The other perforation had had past thoracic and abdominal trauma, and was treated by balloon removal and laparotomic gastric suture. The postoperative mortality rate was thus 0.08% (2/2,515): these 2 patients had undergone previous gastric surgery (laparoscopic Nissen fundoplication) and died of untreatable peritonitis linked to the gastric perforation.

Gastric obstructions presented in 19 patients (0.76%) during the first week after positioning and were successfully treated by device removal. Balloon rupture (n=9, 0.36%) was not prevalent within any particular period of BIB treatment, but was also treated by BIB removal. Esophagitis (n=32, 1.27%) and gastric ulcer (n=5, 0.2%) presented in patients without a history of peptic disease and were treated conservatively by doubling drug doses.

Co-morbidities

One or more preoperative co-morbidities were diagnosed in 1,394/2,471 patients (56.4%): hypertension (509/1,394, 36.5%), diabetes (488/1,394, 35%), respiratory disorders (247/1,394, 17.7%), osteo-arthropathy (271/1,394, 19.4%), dyslipidemia (318/1,394, 22.8%), others (176/1,394, 12.6%) (Table 2). Co-morbidities were resolved in 617/1,394 (44.3%). Improvement of co-morbidities with less pharmacological dosage, or shift to other therapy, was observed in 625/1,394 patients (44.8%), while in 152/1,394 patients (10.9%), the weight loss has not been associated with changes in co-morbidities.

Weight Loss

After 6 months, mean BMI was 35.4 ± 11.8 kg/m² (range 24-73) and %EWL was 33.9 ± 18.7 (range 0-87). BMI loss was 4.9 ± 12.7 kg/m² (range 0-25).

Discussion

Several researchers over the years have tried different balloon devices, as they were thought to be promising and less invasive than surgery for the treatment of morbid obesity.⁶⁻¹¹ By the end of the '80s, several prospective, controlled studies reported that devices, such as Ballobes and Garren-Edwards gastric bubbles, had no significant adjuvant effects for weight reduction.⁶⁻¹¹ The reasons for this were considered to be the small volume of the balloon (220 ml for Garren-Edwards and 400 ml for Ballobes), the air filling having no weight effect on the stomach walls, and the cylinder shape. In addition, these devices had high rates of complications (gastric erosion 26%; gastric ulcer 14%; Mallory-Weiss tears 11%).⁷⁻¹¹

The more recently introduced BioEnterics Intra-gastric Balloon has a spherical shape, high volume capacity (500-700 ml), and uses saline for filling.¹² Studies have found that complication rates are very low.¹³⁻¹⁵ In the present study, BIB positioning was safe. Related hospital mortality occurred in 2 patients; both had previously undergone laparoscopic Nissen fundoplication, and gastric perforation with

Table 2. Co-morbidities at time of BIB removal (6 months)

CO-MORBIDITY	RESOLUTION	IMPROVEMENT†	NO CHANGE
Hypertension	228/509 (44.8%)	249/509 (48.9%)	32/509 (6.3%)
Diabetes	160/488 (32.8%)	264/488 (54.4%)	64/488 (13.1%)
Respiratory disorders	205/247 (83.0%)	42/247 (17.0%)*	—
Osteoarthropathy	111/271 (40.9%)§	125/271 (46.1%)	35/271 (12.9%)
Dyslipidemia	49/318 (15.4)#	116/318 (36.5)°	153/318 (48.1%)
Others	126/176 (71.6%)	15/176 (8.5%)	35/176 (19.8%)

† = lower drug dosage or shift to other therapy.

* = sleep apnea disappeared, but remain tachypneic after physical activity.

§ = patients without radiological evidence of arthritic modification.

= patients with hypertriglyceridemia.

° = the improvement was prevalently linked to normalization of tryglicerides while cholesterolemia has been less influenced by the weight loss after 6 months.

peritonitis was the cause of death. In the present series 6/2,515 patients had previously undergone gastric surgery and the perforation rate was 4/6 (66.6%). This indicates the absolute contraindication to placing the BIB in patients with previous gastric surgery in which stomach wall compliance is modified.

Gastric obstruction presented with abdominal pain and untreatable vomiting in 19 patients, and was diagnosed both in normally inflated (n=11) and in partially deflated (n=8) balloons. The reasons for gastric obstruction in the normally inflated balloons are unclear, while in patients with partially inflated or deflated balloons, the BIB was seen to have migrated into the pylorus, blocking food passage.

Past history of peptic ulcer, considered at risk for bleeding, is a contraindication to BIB use. Infrequently, gastric ulcer or esophagitis developed in patients with the BIB. In these patients, conservative treatment, with doubling omeprazole dosage, was successful.

Weight loss has traditionally been the main outcome measure in bariatric procedures. The mean BMI loss in the present series was 4.9 ± 12.7 kg/m². Obviously, this outcome is not comparable to results obtained from bariatric surgery, but noteworthy resolution of co-morbidities occurred. The risk of death from cardiovascular disease and other co-morbidities increases throughout the range of moderate and severe obesity.¹⁶ In our series, preoperative co-morbidities resolved or improved in 1,242/1,394 patients (89.1%). These results have been confirmed in studies that demonstrated the benefit of 10 kg weight loss in terms of co-morbidities (diabetes, blood-pressure, lipids, etc.) and related mortality.¹⁷⁻¹⁹

In this study, BIB was a safe and effective procedure for weight reduction, with low mortality and morbidity rates. The balloon can play a role in the preoperative treatment of morbidly obese patients who are to undergo bariatric or other elective surgeries, by lowering mortality and morbidity risk.^{19,20} Whether BIB is of benefit in the long-term treatment of morbidly obese patients remains to be determined.

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