The Intragastric Balloon – Smoothing the Path to Bariatric Surgery

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Background: Intragastric balloon placement in association with diet for weight reduction is steadily gaining popularity. However, long-term follow-up studies on the effect of this method in maintaining weight loss are lacking. This study evaluated the long-term outcome following balloon removal in morbidly obese patients who had selected this method for weight loss.

Methods: 140 morbidly obese patients who refused bariatric surgery because of fear of complications and mortality, underwent intragastric balloon placement and were followed over a 6- to 30-month period (mean 18.3 months) after balloon extraction. The 34 males and 106 females, with median age 38 years (range 16-62), median weight 122 kg (range 85-203), median BMI 42.3 kg/m² (range 35-61.3) and median excess weight (EW) 59 kg (range 29-132), received a Bioenterics Intragastric Balloon (BIB). Excess weight loss (EWL) ≥25% when the BIB was removed was considered a success. Weight fluctuations and any further interventional therapy requested by the patients after balloon removal were recorded.

Results: 100 patients (71.4%) lost ≥25% of their EW on balloon extraction and were categorized as successes, while 40 patients (28.6%) did not achieve that weight loss and were categorized as failures of the method. During the follow-up period, 44 of the originally successful patients (31.4%) regained weight and were categorized as recurrences, while the remaining 56 patients (40%) maintained their EWL of ≥25% and were considered long-term successes. During follow-up, 45 patients (32.1%) requested and underwent bariatric surgery for their morbid obesity (21 Adjustable Gastric Band, 11 Laparoscopic Sleeve Gastrectomy, 13 Laparoscopic Gastric Bypass). Of these, 13 (32.5%) were from the group of 40 patients categorized as failures on BIB removal, 28 (63.6%) were from the group of 44 patients whose obesity recurred, and 4 (7.1%) were from the 56 patients who although they maintained successful weight loss requested further weight reduction.

Conclusions: The BIB served as a first step and a smooth introduction to bariatric surgery for morbidly obese patients who initially refused surgical intervention. The incidence of surgical intervention was double in patients who initially experienced the benefits of weight loss and then had obesity recurrence, compared with patients in whom the method failed. Indeed, a significant number of patients were assisted in their efforts to lose and maintain an acceptable weight loss over a 6- to 30-month follow-up period.

Key words: Intragastric balloon, morbid obesity, bariatric surgery, weight loss

Introduction

Obesity is a common chronic disease that is affecting a gradually increasing portion of the population in industrialized countries.¹ ³ The relationship between severe obesity and serious medical conditions such as hypertension, type 2 diabetes, hyperlipidemia, low back pain, etc. is well documented.¹ ⁴ ⁷ Conservative management with diet, exercise and medications as well as interventional treatment of this disease with
various procedures aimed at reducing weight and therefore decreasing the risk of co-morbidities has been proposed.\textsuperscript{8-11} Among them, the temporary placement of an intragastric balloon in association with diet, is recently gaining popularity.\textsuperscript{12-14} Although the short-term beneficial effects of the intragastric balloon in reducing weight,\textsuperscript{15} ameliorating obesity co-morbidities,\textsuperscript{16} improving plasma antioxidant capacity,\textsuperscript{17} and reducing the risk of definitive surgical intervention\textsuperscript{18,19} is well documented, studies with long-term follow-up proving a possible permanent effect of this method on lowering patients’ weight are lacking. Additionally, the important question of whether this method may be used for treatment of morbidly obese patients, as opposed to of other invasive surgical techniques, remains unanswered.

This prospective study was designed to investigate the long-term outcome and effects of intragastric balloon placement on the weight of morbidly obese patients, who although potentially suitable candidates for bariatric surgery, had refused surgical intervention with conventional techniques.

**Patients and Methods**

**Patients**

From February 2003 through March 2006, the Bioenterics Intragastric Balloon (BIB – Inamed, Allergan, Santa Barbara, CA, USA) was implanted in 204 obese patients who had not undergone previous gastric surgery. We selected patients who satisfied the following categories:

A) Preoperative preparation of super-obese patients in an attempt to minimize weight and reduce operative risk (15 patients).

B) Contraindications to bariatric surgery, i.e. age >70 years (7 patients).

C) BMI 30-35 kg/m\textsuperscript{2} with severe obesity co-morbidities (18 patients).

D) Morbidly obese patients with BMI $\geq$35 refusing conventional surgical treatment because of fear of complications and/or mortality. In this category, the medical staff first suggested conventional surgical weight reduction methods. However, the patients decided to attempt weight loss with a simpler and non-invasive method, the BIB (164 patients).

**Balloon Placement and Extraction**

Under conscious or unconscious sedation or general anesthesia if required, the esophagus, stomach and duodenum were inspected with a flexible gastroscope to rule out any conditions such as severe esophagitis, large hiatal hernia, active peptic ulcer, pyloric stenosis, structural abnormalities of the GI tract or lesions considered at risk for bleeding. Then, the intragastric balloon was introduced. The device was advanced into the stomach and filled with 500 ml saline and 10 ml methylene blue solution. The patients were kept under observation in hospital for 24 hours and if able to tolerate oral fluids, were discharged, with specific dietary instructions (1,000 Kcal/day) and omeprazole 20 mg/day. Six months later (or as otherwise consented to by the patient; see results), under intravenous sedation or general anesthesia if required, endoscopy was performed and the BIB was removed using the balloon removal kit (Kobi Medizintechnik GmbH, Germany), following complete deflation of the device.

**Follow-up**

Complete follow-up was carried out in all patients entailing monthly visits to the out-patient departments from the time of BIB removal (first removal September 2003) until March 2006, or until the patients underwent bariatric surgery. We excluded category A, B and C patients as well as those patients from category D who had not completed at least a 6-month period after balloon removal from the long-term follow-up study. Three patients from category D, in whom the balloon was explanted early after BIB implantation because of discomfort or complications (continuous vomiting) were also excluded. A total of 140 morbidly obese patients from category D were thus available for analysis, with a follow-up period of at least 6 and up to 30 months after balloon extraction.

**Statistical Analysis**

Statistical analysis of data was performed using the SyStat v 10.0 program (SPSS Inc, Chicago, IL). Data is expressed as median and range, while all $P$-values are two-tailed. Between groups, results were assessed by Mann-Whitney U-tests and frequency analysis was