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Is Bariatric Surgery Necessary after Intragastric Balloon Treatment?

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Background: The use of the Bio-Enterics intra-gastric balloon (BIB) has been shown to be a safe and effective procedure for the temporary treatment of morbid obesity. We conducted a retrospective comparative analysis of the weight loss in patients that after BIB removal underwent bariatric surgery and those who did not wish surgery.

Methods: From January 2000 to March 2004, 182 BIBs were positioned in 175 patients (104 F / 71 M; mean age 37.1 ±11.6 years, range 16-67; mean BMI 54.4 ± 8.1 kg/m^2, range 39.8-79.5; mean %EW 160.8±32.9% range 89-264). Patients were excluded from this study who had emergency BIB removal for balloon rupture (n=2, 1.1%) and for psychological intolerance (n=7, 7.8%). All patients were scheduled for a bariatric operation, before BIB positioning. After BIB removal, a number of patients now declined surgery. Consequently, patients were allocated into 2 groups: Group A in whom BIB removal was followed by bariatric surgery (Lap-Band®, laparoscopic gastric bypass, duodenal switch) (n=86); Group B patients who after BIB removal refused any surgical procedure (n=82). Both groups were followed for a minimum of 12 months. Results were reported as mean BMI and %EWL ± SD. Statistical analysis was done by Student *t*-test or Fisher's exact test, with *P*<0.05 considered significant.

Results: Mean BMI and mean %EWL in the 166 patients at time of removal were 47.3 ± 8.1 kg/m^2 and 32.1±16.6%, respectively. At the same time, mean BMI was 47.6±6.9 and 48.1±6.5 kg/m^2 in group A and B (*P*=NS). At 12 months follow-up (100%), mean BMI was 35.1 kg/m^2 in Group A (BIB + surgery) and 51.7 kg/m^2 in Group B (BIB alone) (*P*<0.001).

Conclusions: After BIB removal, half (49.4%) of the patients scheduled for surgery refused a bariatric operation. These patients returned to their mean initial weight at 12 months follow-up. Therefore, bariatric surgery after BIB removal is highly recommended.

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Introduction

Morbid obesity is a chronic disease which requires long-lasting stable weight loss. The BioEnterics Intragastric Balloon (BIB, Inamed, Allergan) is a saline-filled, smooth, silicone sphere designed to remain in the stomach for 6 months. The use of the BIB has been found to be a safe and effective procedure for producing temporary weight loss.[1,2] Recently, with the widespread use of this device, some studies are reconsidering the limited use of this procedure, exploring the use of the BIB for more durable weight loss (1 year).[3] This study is a retrospective comparative analysis at 1-year follow-up of the weight loss results in patients who after BIB removal underwent bariatric surgery and those who now declined the surgery.

Patients and Methods

The BIB was positioned under conscious sedation with previous diagnostic endoscopy in all patients. The esophagus, stomach and duodenum were examined and *Helicobacter pylori* testing was performed. The balloon was inserted into the body of the stomach, and inflation was performed under direct vision with 500 ml saline and 10 ml of methylene blue.

After 6 months, the BIB® was removed per protocol by endoscopy, after complete deflation by a dedicated

instrument. Excluded from this study were patients with emergency BIB removal for balloon rupture (n=2, 1.1%) and those with early BIB removal for psychological intolerance (n=7, 7.8%). All patients had been clearly instructed regarding the necessity of a subsequent bariatric operation to increase or at least to maintain the weight loss eventually obtained. Thus, before BIB positioning, all patients were intended for a bariatric operation, but after BIB removal a number of patients declined both surgery and further dietetic counselling over time. For the study, patients were retrospectively allocated into two groups: Group A in whom BIB removal was followed by bariatric surgery (Lap-Band®, laparoscopic Roux-en-Y gastric bypass, duodenal switch) (n=86); Group B patients who after BIB® removal refused an operation or medical conservative treatment (n=82).

Both groups were followed for a minimum of 12 months. Results were reported as mean ± standard deviation. Statistical analysis utilized Student *t*-test or Fisher's exact test, with $P<0.05$ considered significant.

Results

From January 2000 to March 2004, 182 BIBs were positioned in 175 patients (104 F / 71 M; mean age 37.1 ± 11.6 years, range 16-67; mean BMI 54.4 ± 8.1 kg/m^2, range 39.8-79.5; mean %EW 160.8 ± 32.9%, range 89-264). At 6 months at time or removal, mean BMI and mean % excess weight loss (%EWL) in the 166 patients were 47.3 ± 8.1 kg/m^2 and 32.1±16.6%, respectively. At the same time, mean BMI was 47.6±6.9 and 48.1±6.5 kg/m^2 (*P*=NS) and mean %EWL was 31.8±17.9 and 32.9±15.8% (*P*=NS) in Groups A and B, respectively (Table 1). At 12 months follow-up (patient drop out 0), mean BMI was 35.1 kg/m^2 in Group A (BIB + surgery) and 51.7 kg/m^2 in Group B (BIB alone) ($P<0.001$).

Discussion

In our experience, BIB was originally placed for BMI reduction before bariatric surgery to reduce surgical and anesthesiological risks. In a previous study on 239 patients with BMI >50 kg/m^2 in a multicentric experience of the Italian Collaborative Study Group for the Lap-Band® System, the laparotomic conversion rate was significantly higher compared to operated patients with BMI <40.[4] Busetto et al,[5] in a case control study, demonstrated that preoperative treatment with the intragastric balloon reduced the risk of conversion to open surgery and the risk of intraoperative complications in super-obese patients treated with laparoscopic gastric banding.

Recently BIB placement has been proposed as definitive treatment. Herve et al,[3] in a study of 100 patients (mean BMI 34.0 kg/m^2, range 25.3-60.2) with the BIB left in place for a mean of 9.9 months, programmed a post-removal follow-up during which the patient was followed monthly. At time of BIB removal, mean weight loss was 12.0 kg, and mean %EWL was 39.6%. At 1 year after BIB removal, mean weight loss was 8.6 kg and mean %EWL was 26.8% (patient drop out 0). In that study at time of BIB removal, 26 patients were considered as having unsatisfactory results (%EWL <20%), 40 as good results (%EWL 20-50), and 34 as very good results (%EWL >50%). After 12 months, 56 patients continued with good (n=34) or very good (n=22) results.

Very recently, Melissas et al[6] reported a study of 140 patients who first refused bariatric surgery, and then underwent BIB positioning. Follow-up conducted at 6 and 30 months after balloon extraction found that 56 patients (40%) maintained an acceptable weight loss (%EWL >25). These patients are still under follow-up to evaluate their outcome at 5 years.

The present study does not find weight loss maintenance when patients refuse the dietetic and pharmacologic regimen and strict follow-up. This study indicates the need for a bariatric operation to main-

Table 1. Mean BMI and mean %EWL at time of BIB removal and 1 year after, in patients who underwent a following bariatric surgical operation (Group A) and patients who refused it (Group B)

	No. of Patients	BMI at BIB removal	BMI after 1 year	%EWL at BIB removal	%EWL after 1 year
Group A	86	47.6±6.9	31.8±17.9	35.1±6.9	69.6±28.2
Group B	82	48.1±6.5*	32.9±15.8*	51.7±16.3$^+$	27.1±9.7$^+$

*P=NS; ^+P=0.001.

tain the weight loss, and giving detailed information on this aspect to all patients. Surprisingly in the present study, half of the patients (49.4%) scheduled for surgery after BIB removal declined any bariatric operation and also declined continued visits and dietary counselling. These patients at 12 months follow-up regained to their initial weight. By this observation, bariatric surgery after BIB removal is highly recommended.

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