Intragastric Balloon for the Management of Super-Obese Patients

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Abstract

Background: Obesity is one of the major public health problem of modern society. Super-obese patients with many co-morbidities present a challenge in bariatric surgery because of the high perioperative morbidity and mortality. Previous attempts to manage obesity with the use of intra-gastric balloon prostheses in the 1980's achieved very disappointing results. The BioEnterics intragastric balloon (BIB) is an endoscopic device used preoperatively to induce weight loss to reduce the risk of surgery for morbid obesity. The present prospective study was done to assess the safety and effect of the use of Bioenterics® balloon model (Inamed) for obesity treatment.

Methods: From November 2004 to April 2006, the BIB was endoscopically placed in 38 high-risk super-obese patients with a mean body mass index of $55.3 \pm 9.8 \text{kg/m}^2$ and severe co-morbidities (mean $4.33 \pm 1.12$, range 3-7). Exclusion criteria included psychiatric disease, large hiatal hernia and peptic ulcer disease. The BIB was endoscopically removed 6 months later, at which time the patients were evaluated in terms of weight loss and improvement of co-morbid conditions.

Results: BIB placement was uneventful in all patients. The major side effect related to the procedure was occasional vomiting during the first 2 days (65%). The mean weight loss was $58.3 \pm 18.4$ kg and clinical re-evaluation revealed significant improvement in patient co-morbidity status (mean $2.23 \pm 0.7$, range 1-3; $p=0.024$). Thirty patients underwent a primary bariatric surgical procedure few days after BIB removal; 8 patients were rejected for surgery because of inadequate weight loss.

Conclusions: Intra-gastric balloon placement is a safe and effective first-stage treatment of high-risk super-obese patients in need of surgical intervention. Although not without risk, it is generally a simple procedure leading to satisfactory weight loss, improvement in co-morbidities and consequent reduction of the perioperative mortality and morbidity rates associated with surgery.

Key Words: Intragastric balloon – Morbid obesity – High-risk patients.

Introduction

OBESITY is a chronic incurable disease with considerable morbidity and mortality. Surgical treatment remains the only effective approach for long-term treatment of morbid obesity, because it provides reproducible, effective and sustained weight loss. A surgical approach is restricted to extremely obese patients (body mass index [BMI] $>40\text{kg/m}^2$).

The effectiveness of various surgical procedures in morbidly obese patients has been confirmed in several studies, with early mortality rates of 1-1% and early morbidity rates of 5-10% [1,2]. However, in morbidly obese patients with severe life-threatening comorbidities, the morbidity and mortality rates are significantly greater after surgery, reaching as high as 40% and 12%, respectively, in the early postoperative period [3]. Although controversy still exists regarding the exact definition of these high-risk patients, several criteria have been proposed. These include a BMI $>60\text{kg/m}^2$, male gender, age $>50$ years and the presence of serious medical conditions, such as hypoventilation syndrome, sleep apnea syndrome, severe hypertension, insulin-dependent diabetes mellitus type 2, deep vein thrombosis and severe venous stasis disease, all of which significantly increase the mortality and morbidity after bariatric procedures [4-8].

The major confronted risk when operating on these patients is the lack of a sufficient pulmonary and cardiovascular reserve necessary to survive the difficulty of the operation and in particular, any complications that might occur. To minimize this risk, it is essential that these patients lose a significant amount of weight before undergoing surgical intervention. During the past decade, the concept of a 2-stage operative approach has been introduced for high-risk obese patients, consisting of an initial sleeve gastrectomy followed 6-12 months later by a definitive procedure such as biliopancreatic diversion [9,10]. The first-stage procedure produces satisfactory initial weight loss.
and improvement in major co-morbidities, thereby reducing the risk of the primary procedure.

However, there is an intermediate group of patients who do not respond to medical therapy and who are not, or are not yet, surgical candidates. For this reason, nonoperative techniques, such as the endoscopically placed intragastric balloon, have been developed to provide an alternative first-stage approach for sufficient weight loss and improvement in co-morbid conditions (Table 1) [11,12]. The intragastric balloon appeared attractive for this group, but use of this device was abandoned in the 1980s because of a prohibitive number of complications and premature balloon deflation, mainly with the Garren-Edwards Gastric Bubble (GEB), which was approved by the Food and Drug Administration (FDA) in the United States.

During the past several years, the BioEnterics intragastric balloon (BIB, Inamed, Santa Barbara, CA) has been successfully used for preoperative weight reduction in morbidly obese patients with relatively low complication rates.

Years of research resulted in the development of a balloon that fulfilled the specified requirements: (1) The balloon should be smooth, seamless, and constructed of long-lasting material, with a low ulcerogenic and obstructive potential; (2) Incorporation of a radiopaque marker to allow appropriate follow-up in case of deflation and (3) The ability to adjust the balloon to a variety of sizes and to fill it with fluid instead of air. The BioEnterics Intragastric Balloon (BioEnterics Corp., Carpinteria, Calif.) meets these requirements. Based on data from animal and human studies, a minimal fill volume of 400 mL fluid was defined [5-10]. It is clear that use of an intragastric balloon must be integrated into a weight-care program that must be continued after balloon removal to maintain the weight reduction [2,3,11].

This study aims to investigate (as an integrated component of a weight-care program) the effectiveness of 6 months of BIB balloon treatment as a first stage procedure for morbid obese patients.

Material and Methods

From November 2004, when the Morbid Obesity Unit of the Department of Surgery was established at the Aseer Central Hospital, Abha, through August 2006, 200 morbidly obese patients underwent various bariatric procedures at our institution. From November 2004 to April 2006, after obtaining the institutional review board approval, the BIB was endoscopically placed in 38 super-obese patients (22 men and 16 women) who were considered to be at very high risk of initial surgical intervention. The goal in these patients was to achieve enough weight loss and corresponding improvement in co-morbidities to allow the primary bariatric surgical procedure to be performed with the minimal possible risk of perioperative complications.

The average age of these patients was 40.8 ± 8.1 years, with an average BMI of 60.1 ± 9.7 kg/m². The average body weight was 153.5 ± 28.2 kg and the average excess weight was 112.5 ± 24.4 kg.

The decision process used to select patients to receive the BIB was based on their BMI and the existence of specific risk factors (Table 1) known to increase perioperative morbidity and mortality [4-8]. A BMI of ≥ 50 kg/m² and the presence of ≥ 3 risk factors were our criteria for patient selection. All patients had at least 3 serious co-morbidities (4.33 ± 1.12, range 3-7; Table 2).

The patients took nothing by mouth the night before the procedure. BIB placement was conducted at the endoscopy unit, where an initial diagnostic gastroscopy was performed, a rapid urease test [Campylobacter-like organism (CLO)] was used to test for Helicobacter pylori infection and the balloon was directly placed without any sedation. The BIB was inflated under direct vision with 590 mL normal saline and 10 mL methylene blue solution for a total volume of 600-700 mL (Fig. 1). The duration of the procedure was 14-32 minutes (mean 19 ± 2.1).

This study aims to investigate (as an integrated component of a weight-care program) the effectiveness of 6 months of BIB balloon treatment as a first stage procedure for morbid obese patients.

All patients were hospitalized the day of BIB insertion and received intravenous fluids, gastrokinetics (metoclopramide 10 mg x 3 intravenously)
for 2 days, antiemetics (ondansetron hydrochloride 8 mg x 1 intravenously) for 3 days and proton pump inhibitors for the entire 6 months the balloon remained in place. If an H. pylori infection was confirmed by the CLO test, the patients began eradication therapy with amoxicillin 1000 mg x 2 and clarithromycin 500 mg x 2 for 10 days. On the first postinsertion day, all patients were started on clear liquids and if these were well-tolerated, a full liquid diet was introduced on day 2. Patients were also usually discharged on day 2 with specific dietary counseling, including a gradual progression during the first week to pureed and soft solid foods, as well as general instructions regarding meal size, eating slowly and what foods to avoid, such as caffeinated and carbonated beverages, fibrous foods, sweets and fatty foods. Additional instruction was provided on a patient-to-patient basis as necessary. Patients were evaluated monthly for 6 months, at which time, the balloon was removed endoscopically. Surgical intervention, which in all cases was a variant of the LAGB OR GBP [13], took place within the following few days.

Table (1): Risk factors associated with greater morbidity and mortality in super-obese patients.

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>No.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &gt;50 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypoventilation syndrome</td>
<td>19</td>
<td>50.0</td>
</tr>
<tr>
<td>Sleep apnea syndrome</td>
<td>31</td>
<td>81.6</td>
</tr>
<tr>
<td>Pickwick syndrome</td>
<td>5</td>
<td>13.2</td>
</tr>
<tr>
<td>Insulin-dependent type 2 diabetes mellitus</td>
<td>26</td>
<td>68.4</td>
</tr>
<tr>
<td>Hypertension requiring ≥2 different medications</td>
<td>11</td>
<td>28.9</td>
</tr>
<tr>
<td>Deep vein thrombosis/severe venous stasis disease</td>
<td>19</td>
<td>50.0</td>
</tr>
</tbody>
</table>

Table (2): Presence of co-morbidities (n=38).

<table>
<thead>
<tr>
<th>Co-morbidities</th>
<th>No.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypoventilation syndrome</td>
<td>19</td>
<td>50.0</td>
</tr>
<tr>
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<td>19</td>
<td>50.0</td>
</tr>
</tbody>
</table>

Table (3): Weight loss characteristics.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Before BIB insertion</th>
<th>After BIB removal</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (kg/m²)</td>
<td>55.3±9.8</td>
<td>44.3±9.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>153.5±29.2</td>
<td>138.3±30.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Excess weight (kg)</td>
<td>120.5±24.4</td>
<td>64.2±29.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Excess weight loss (%)</td>
<td>–</td>
<td>32.4±14.5</td>
<td>–</td>
</tr>
</tbody>
</table>

BIB: BioEnterics intragastric balloon.

Statistical analysis:

Statistical analysis was conducted using the Statistical Package for the Social Sciences, version 13.0 (SPSS, Chicago, IL). The differences between the initial and final values were assessed using parametric and nonparametric tests according to the normality distribution. p<0.05 was considered as statistically significant. Values are given as the mean ± standard deviation, unless otherwise defined.

Results

Balloon placement was uneventful in all patients. No side effects were attributed to the device, except for nausea and occasional vomiting in 65% of the patients that was usually mild and successfully treated by routine administration of gastrokinetics and antiemetics during the first 2 to 3 days. Only 2 patients experienced continuous vomiting after leaving the hospital, resulting in severe dehydration and readmission. They were treated conservatively with intravenous fluids and antiemetics and was discharged around 6 days later. The BIB remained successfully in place for the entire 6-month period and they underwent the definitive procedure without any further complications.

A positive CLO test was found in 12 patients (31.6%). Of these 12 patients, 10 (26.3%) had no gastric or duodenal ulcerations and the BIB was implanted with simultaneous initiation of eradication therapy. In 1 patient (2.6%), the initial diagnostic endoscopy revealed multiple gastric ulcers associated with the use of nonsteroidal anti-inflammatory drugs and BIB placement was postponed for 1 month until the ulcers had healed.

At the last follow-up examination, the BIB had been removed from 32 patients who had completed the predefined 6-month postinsertion period and 6 patients had had the BIB in place for 1 (in two patients), 3 (in two patients), and 4 months (in two patients). The mean initial BMI and excess weight, as well as the overall change in BMI and the percentage of excess weight loss, at BIB removal are presented in Table (3).
Corresponding with weight loss, significant improvement in patient co-morbidity status occurred, as determined by laboratory and clinical re-evaluation (mean 2.23 ± 0.7, p=0.024; Table 4). On the day after removal of the BIB, 8 patients were rejected for undergoing surgery because of insufficient weight loss and a lack of improvement in their co-morbid conditions that was attributed primarily to their inability to conform to dietary instructions. The remaining 30 patients underwent a variant of the gastric bypass or gastric banding [13], with no early postoperative complications. The mean operative times were 120.5 ± 42.3 minutes and 45.3 ± 15.2 minutes, respectively.

### Table (4): Co-morbidity status for 38 patients after BIB removal.

<table>
<thead>
<tr>
<th>Comorbidities</th>
<th>Before BIB insertion</th>
<th>After BIB removal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td></td>
<td>Res.</td>
<td>%</td>
</tr>
<tr>
<td>Hypoventilation syndrome</td>
<td>19</td>
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<td>26</td>
<td>68.0</td>
</tr>
<tr>
<td>Hyperetension</td>
<td>11</td>
<td>28.9</td>
</tr>
<tr>
<td>DVT/venous statis disease</td>
<td>19</td>
<td>50.0</td>
</tr>
<tr>
<td>No. of comorbidities* (Mean±SD)</td>
<td>4.33±1.12</td>
<td>2.23±0.7</td>
</tr>
</tbody>
</table>


### Discussion

The intragastric balloon was developed after many years of research in an effort to find less-invasive, nonoperative techniques for the treatment of morbid obesity. Several studies have shown that proper use of this device is associated with very low complication rates and substantial weight loss [14,15] resulting from decreased food intake and possible hormonal alterations [16].

In the present study, the BIB was used strictly as a first-stage, noninvasive procedure for weight loss in high risk super-obese patients with many severe co-morbidities. These patients are a unique and hard-to-define subgroup of the obese population in whom initial surgical intervention results in unacceptably high morbidity and mortality rates and prolonged postoperative hospital stays [4,6,17,18].

Conservative means for preoperative weight reduction have been applied successfully in super-obese patients before surgery, including short-term dietary programs, behavior modification and physical activity. This approach has been especially successful in decreasing the liver size before laparoscopic procedures in which an enlarged liver may cause technical problems [19]. Fris [20] reported a statistically significant reduction in liver size, percentage of body fat, BMI and weight after a 2-week preoperative low energy liquid diet in 50 morbidly obese patients that made laparoscopic surgery technically easier and more efficient. The study clearly stated, however, that patient compliance is essential for optimal results, a factor that often cannot be estimated or controlled. Furthermore, it is well known that prescribed caloric reduction and exercise programs, except in cases of in-hospital multidisciplinary dietary regimens, are generally unsuccessful for the vast majority of patients. For this reason, the combined use of the intragastric balloon with dietary instructions may be more effective in the initial treatment of high-risk morbidly obese patients [21].

The role of laparoscopic gastric banding (LAGB) in super-obese patients has also been examined in several studies [22,23]. The lower perioperative morbidity and mortality, ability to adjust the band and reversibility are the main advantages of this procedure. However, weight loss occurs more slowly and although LAGB has evolved considerably in the techniques of insertion, its role in the initial management of high-risk patients is controversial. Mittermair et al. [22] reported that LAGB is an effective technique in inducing weight loss, with an overall complication rate of ≤26.7%, mainly owing to the surgeons’ learning curve. Busetto et al. [11] performed a case-control study comparing the preoperative use of the intragastric balloon in superobese patients undergoing LAGB versus the use of LAGB alone. They concluded that LAGB alone is associated with slightly, but not significantly, greater rates of
intraoperative complications and confirmed the usefulness of preoperative treatment with the intragastric balloon in reducing the surgical risk, proposing this type of sequential therapy in super-obese patients.

The concept of a 2-stage surgical approach in high-risk obese patients was first introduced about 1 decade ago in an effort to minimize the surgical risk in this subgroup of obese patients. One such approach involved an initial sleeve gastrectomy followed 6-12 months later by a definitive bariatric procedure. The sleeve gastrectomy appears to be relatively simple and involves minimal risk in most patients. The placement of the intragastric balloon is usually safe, has been associated with minor, reversible complications, mainly gastroesophageal reflux, balloon deflation and gastro-duodenal ulcer formation [29]. In our series, most complications were also minor. The most frequent side effects were nausea and vomiting, which were mild in all cases, except for 4 cases of severe dehydration requiring administration of intravenous fluids. Furthermore, no patient required early BIB removal. The procedure itself lasted 18 minutes, no sedation was needed and no technical problems were encountered.

The weight loss results were excellent in 30 (78.9%) of the 38 patients, resulting in significant improvement of pre-existing co-morbidities, a finding that has also been demonstrated in other studies [15,30]. The 8 patients who did not achieve satisfactory weight loss did not follow the dietary instructions and were rejected for surgery. The remaining 30 patients underwent the primary bariatric surgical procedure of choice; LAGB or GBP [13], the day after BIB removal with an uncomplicated postoperative course.

Conclusions:

Super-obese patients with severe pre-existing co-morbidities present a challenge in the field of bariatric surgery because of the extremely high rate of perioperative morbidity and mortality associated with the surgery. To reduce the risk of surgery in these patients, it is essential that they achieve significant weight loss with consequent improvement in comorbid conditions before undergoing surgery. It would seem most prudent to achieve this by conservative means. Bioenteric Intragastric balloon (BIB) placement seems to be, in most cases, a safe and easily performed technique with low complication rates and excellent results in the early treatment of these patients. The procedure can play a role in weight reduction in super-obese patients in preoperative treatment of bariatric patients.

References
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