

The Bioenteric Intra-gastric Balloon (BIB) as a Management for Treatment-Resistant Obesity: The Lebanese Experience

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Received: 14 June 2019; Accepted: 01 July 2019

Citation: Hallal Mahmoud, Lakis Remi, Matar Rasha, et al. The Bioenteric Intra-gastric Balloon (BIB) as a management for Treatment-Resistant Obesity: The Lebanese Experience. J Med - Clin Res & Rev. 2019; 3(3): 1-4.

ABSTRACT

Introduction: Obesity is a major cause of mortality and morbidity worldwide. The endoscopic intra-gastric Balloon treatment is a non-surgical and viable method to help weight loss in obese or in morbidly obese patients. This study sought to assess the outcome of Bio enteric Intra-gastric Balloon (BIB) insertion in Al Zahraa Hospital University Medical Center (Zhumc), Beirut, Lebanon.

Methods: A prospective study that included 70 obese patients who failed medical management with no history of any bariatric surgery, Data was analyzed using SPSS software (Version 23.0)

Results: Most of the patients were females (57/70). The mean age and Body Mass Index (BMI) were 33.3 and 35.31 respectively. The tolerance rate was high with only one patient suffering from procedure intolerance. 51.4% of our patients had excess body weight loss (EBWL) more or equal to 40 % and 47.1% EBWL between 15-39 %. Weight loss was highest in overweight group (BMI 25-29.9) ($p < 0.05$).

Conclusion: BIB balloon endoscopy is a good and effective option for the treatment of obesity in the Lebanese population with an excellent tolerance rate and it is highly recommend for the overweight group.

Keywords

Bio-enteric Intra-gastric Balloon (BIB), Obesity, Excess Body Weight Loss (EBWL), Body Mass Index (BMI), Lebanon.

Obesity is one of the major public health problems in western countries. It is directly related to many diseases thus, causing an increase in general morbidity rates [1]. It is defined as an excess of total body fat (body mass index, BMI ≥ 30). Severe obesity relates to a BMI between 30 and 40, and morbid obesity to a BMI of more than 40. More than 1.4 billion adults worldwide suffer from this disease which usually progresses into diabetes, hypertension, and heart diseases. Weight loss is an effective way to prevent, reverse and delay this process [2].

Many approaches have been proposed for the management of obesity, medical and invasive ones. Medical management remains the first choice including dietary modifications and psychotherapeutic support, but it achieved only a mean weight

loss of about 5 kg. Multiple surgical modalities result in significant weight loss, but are associated with risk of serious perioperative complications, malabsorption and necessity of dietary supplementation. Furthermore, in 20% of cases, symptoms of GERD and vomiting were recorded and in more than 10% of patients, repeated bariatric surgery was required.

The use of Bio-enteric Intra-gastric Balloon (BIB) was debuted over 30 years ago. It promotes weight loss by increasing gastric emptying time and decreasing intragastric volume. It is reversible, minimally invasive, and less costly and may offer a potentially lower risk. The most common side effects are migration and gastric perforation, with an incidence of 1.4 and 0.1%, respectively [3].

Bio-enteric Intra-gastric Balloon (BIB) is indicated in patients with a body mass index (BMI) equal or greater than 27 kg/m² in Europe, or 30 kg/m² in the United States (US) after failure of medical treatment [4].

This study aims to determine the outcomes following BIB insertion in Al-Zahraa hospital university medical center in Beirut, Lebanon during 5 years.

Materials and Methods

This prospective study included patients who underwent BIB endoscopy for weight loss in Al-Zahraa hospital university medical center in Beirut, Lebanon. Patients between 18 and 65 years of age with a BMI greater than 27 who failed to achieve weight loss after adequate weight control program. Were included in this study. None of them had any of the following conditions: Severe esophagitis (grade 3–4), active peptic ulcer, pyloric stenosis or structural anomalies, hiatal hernia exceeding 5 cm, active psychiatric disorder, pregnancy and anticoagulant use.

Records of 70 patients who underwent intragastric balloon therapy for weight loss at Al-Zahraa hospital university medical center in Beirut, Lebanon, between 2014 and 2017 reviewed. The BIB positioned and filled with saline and methylene blue (600 ml). Patients were discharged with diet counseling (~1000 Kcal). The BIB was removed after 6 months.

Demographic information was gathered. Ideal BMI, and BMI, percentage EBWL were calculated and divided into different subgroups and patients' characteristics were compared between these subgroups.

The results were analyzed using SPSS software version 23. A P-value less than 0.05 were considered statistically significant. Results are expressed as mean as mean standard deviation.

Results

The mean age of patients was 30.3. Of all of them, 16 (22.85 %) patients were males while 54 (77.15%) were females with a higher mean of age in male patients (35.135 vs 28.8 years old).

Two patients had a known history of diabetes type 2, one patient had COPD, one had arthritis and the other was hypertensive (Table 1). All the patients mentioned had a history of failed trial of medical weight loss for at least 6 months and no history of bariatric surgery.

Patient number		70
Mean patient age (years)		30.3
Female: Male ratio		54/16
Mean patient weight (range) (kg)		94.8
Mean BMI (range) (kg/m ²)		35.31
Mean excess weight loss (using baseline BMI 23) (%)		45.551
Comorbidities	Diabetes	2
	Hypertension	1
	Arthritis	1
	COPD	1

Table 1: Summary of patients' characteristics.

According to their BMI our patient were grouped as follows: 13 were overweight, 22 belonged to class 1 obesity, 14 to class 2 and

21 to class 3. The mean preoperative BMI was 35.31. 92.3% of the overweight group lose more than 40% of their EBW in contrast with only 28.3% with similar results in class 3 obese patients, this effect was found to be statistically significant (p value = 0.019).

Two of our patients had complications, one had pancreatitis and another could not tolerate it and was removed 2 months after insertion.

The mean excess body weight loss was 44.96% and 51.4% of patients had an EBWL of 40% and more, while 47.1% other patient had an EBWL between 15-40 %. There was statistically significant reduction in weight and BMI at 6 months (p <0.05).

Males had more EBWL with 62.5% of them losing more than 40% of EBW, while most of women lost between 15-40 % of their EBW. But this effect between gender and weight loss was not statistically significant (p= 0.549).

Three out of five patients who had a history of comorbidities related to metabolic syndrome had a weight loss between 15-40 % while the other exceeded 40% but this effect was not statistically significant (p>0.05).

Discussion

After observing significant weight loss in multiple patient suffering from gastric bezoars, Neiban was first to suggest the use of intragastric device in 1982, as a modality for weight loss [5].

In the early 80's, cylinder shaped balloons such as allobes and Garren-Edwards gastric bubbles were used. These devices had high rates of complications (gastric erosion 26%; gastric ulcer 14%; Mallory-Weiss tears 11%). Later, many studies showed that these devices had no effect on weight reduction due to their very small volumes and because they were filled with air that could not compress the stomach. Therefore they were replaced by Bio-Enteric Intragastric Balloon(BIB) [6].

The Bio-enteric Intragastric Balloon is the most commonly used intragastric balloon worldwide. This Spherical shaped silicone balloon usually placed endoscopically in the stomach with a volume ranged between 400-800 ml and uses saline rather than air filling. Extensive clinical experience showed a lower complication rate with this balloon [7]. It should be removed endoscopically six month after its insertion . It is indicated in the treatment of obesity in adults who have a body mass index (BMI) between 30 to 40 kg / m² and who failed to achieve weight reduction after diet control.

In a study done in Sweden it was found that the Lebanese immigrants in Sweden had a high hazard ratio for choosing bariatric surgery for the treatment of obesity [8]. The use of endoscopic balloon in Lebanon is still limited and the data about it is poor.

Unlike the results found in the Asian population in Singapore in the study done by Ganesh et al, most of our patients tolerated the procedure with the BIB filled with 600cc of normal saline. Only

1 patient did not tolerate it. This could be explained by the fact that the Lebanese population share anatomical similarities with European Caucasians [7]. Most of our patient lost most of their EBW during the first few months after the insertion of the balloon and later the decrease in weight was minimal which was also observed in the study done by Ganesh et al. [7].

Many previous studies reported EBWL ranging from 28.63% to 41.2%. The Italian study included 2,515 patients who underwent BIB endoscopy between May 2000 and September 2004 (mean BMI 44.4 kg/m²) and a mean EBWL of 33.9% was reported at 6 months. While in a Turkish study that included 100 patients, a mean EBWL at 6 months was 28.63 ± 19.29% that was among the lowest levels mentioned in the literature and this may be because their study was in a non-experienced center and included their first group of patients undergoing this procedure. In our study, the mean excess body weight loss (EBWL) was 44.96%, which is higher than that found in the literature. These findings are comparable to those of the Herve et al. study (mean % EBWL 41.2%) but the only difference is that in their experience they removed the balloon one year later.

The mean BMI loss in our study was 5.84 kg/m² which is slightly more than that found in the Italian study (4.9 ± 12.7 kg/m²) [6]. In the Italian study done by Genco et al. A significant improvement in the comorbidities of their patients was noticed [6]. We observed similar results: two diabetic patients had normalization of their HbA1c, hypertensive patients showed less need of antihypertensive drugs and clinical improvement observed in the COPD and arthritis patients.

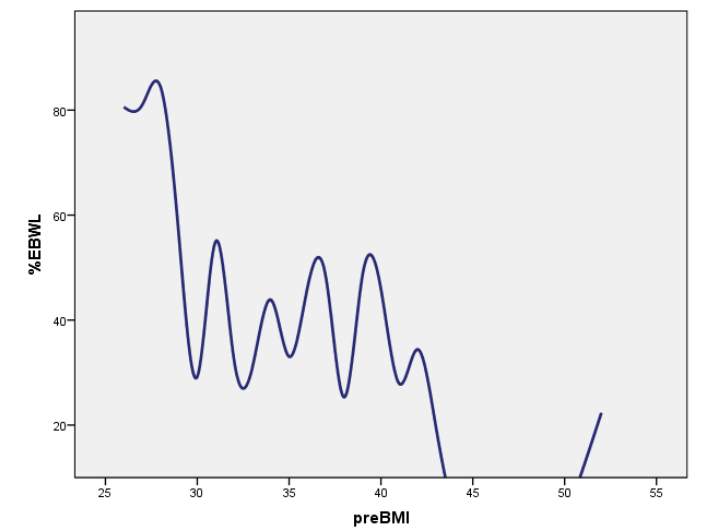


Figure 1: Interposition line showing the relationship between excess body weight loss after BIB insertion and pre-procedural BMI.

There are many complications associated with BIB insertion such as rupture or migration of the balloon, intestinal obstruction, peptic ulceration and injuries to the stomach or to the esophagus [6,9]. In our patients, we did not have any of these complications, but rather we had a case of acute pancreatitis that appeared 3 months after the insertion. Acute pancreatitis without BIB displacement of the

balloon is a very rare complication, one similar case reported in the literature. Our patient was treated medically after removal of the balloon and was fully recovered [10]. The indications for BIB procedure differs between the European and American guidelines and it is usually indicated in patients with BMI higher than 27 kg/m² in Europe while it is recommended for BMI greater than 30 kg/m² in the United States (US) [4].

In our study 92.3% of the overweight (BMI between 25-29.9) group lose more than 40% of their EBW, while the loss was of 28.3% of EBW only in class 3 obese patients, this effect was found to be statistically significant (p value = 0.019). In the class 1 obesity (30-34.9), 54.5% of patients lost between 15-40% of their excess body weight. The relationship between the classification of BMI and EBWL is summarized in both figure 1 and table 2, they both illustrate the association between lower initial BMI with higher EBWL with the overweight group having the most successful results post BIB insertion.

BMI classes		Excess body weight loss (%)			
		<15%	15-40%	>or = 40	Total
Overweight	Count	0	1	12	13
	% within BMI Group	0.0%	7.7%	92.3%	100.0%
	% within EBWL Group	0.0%	3.0%	33.3%	18.6%
	% of Total	0.0%	1.4%	17.1%	18.6%
Class 1	Count	0	12	10	22
	% within BMI Group	0.0%	54.5%	45.5%	100.0%
	% within EBWL Group	0.0%	36.4%	27.8%	31.4%
	% of Total	0.0%	17.1%	14.3%	31.4%
Class 2	Count	0	6	8	14
	% within BMI Group	0.0%	42.9%	57.1%	100.0%
	% within EBWL Group	0.0%	18.2%	22.2%	20.0%
	% of Total	0.0%	8.6%	11.4%	20.0%
Class 3	Count	1	14	6	21
	% within BMI Group	4.8%	66.7%	28.6%	100.0%
	% within EBWL Group	100.0%	42.4%	16.7%	30.0%
	% of Total	1.4%	20.0%	8.6%	30.0%
Total	Count	1		33	70
	% within BMI Group	1.4%		47.1%	100.0%
	% within EBWL Group	100.0%		100.0%	100.0%
	% of Total	1.4%		47.1%	100.0%

Table 2: Summary showing the variation of excess body weight loss after BIB insertion according to the BMI classes.

Conclusion

BIB is an effective non-surgical procedure for weight reduction, with low mortality and morbidity rates. We recommend it for overweight patient with lower BMI group (between 25-29.9) as a definitive means for weight loss but as for higher BMI it could be used as a bridge to bariatric surgery. BIB is a reversible procedure

with data lacking on its long term follow up after the removal of the device and therefore it is long term effects on weight loss should be reported in future studies.

Acknowledgment

We would like to acknowledge the invaluable support of the other members of the weight management and endoscopy teams at Al-Zahraa Hospital University Medical Center, Beirut, Lebanon.

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