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Post Intragastric Balloon Removal Complications in Patients with Morbid Obesity

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ABSTRACT

Background: If the obese patient is willing to take part in a weight loss program that is medically supervised, intragastric balloon implantation has been found to be a safe, well-tolerated, and moderately cost minimally invasive surgery for weight loss. The present research is a retrospective investigation that looks at previously reported cases to determine if the patient, the technology, or the practitioner is to blame for major visceral complications. **Aim:** The goal of this research was to document the difficulties experienced by morbidly obese patients following the removal of a bio-enteric intragastric balloon.

Patients and methods: Fifty morbidly obese patients (both sexes, ages 22-53 years) from the Suez Canal University Hospitals' Internal Medicine. **Results:** The patients' ages ranged from 22 to 53 years old, with a mean ±SD of 35.79 years. The average weight at the outset was 126.69±9.79 kilograms, or approximately 116.8±89.22 pounds. It was discovered that belching was the most often reported side effect, with 30 people (71.4% of the sample) reporting it. 18 patients (42.9%) reported feeling nauseous, 8 patients (19%) reported having bad breath, and 15 patients (35.7%) reported having reflux. **Conclusion:** Despite these concerns, hollow viscera complications are uncommon after a BIB or Orbera balloon implantation. By mandating training and accreditation programmes for bariatric endoscopic doctors and maintaining close supervision of obese patients undergoing balloon procedures, these complications can be avoided.

Keywords: Intragastric Balloon, Complications, Morbid Obesity.

INTRODUCTION

The use of intragastric balloons (IGBs) as a less intrusive treatment option for morbid obesity has a mixed track record of success and failure. Its use is restricted to a small set of strictly outlined scenarios [(1)]. The BIB (Bioenterics Intragastric Balloon) was introduced to Europe in 1991 and has since become the most popular and commonly used IGB. The identical balloon, marketed under the trade name ORBERA (Apollo Endosurgery Inc, Austin, Texas, USA), has been available for sale for several years after receiving FDA permission for usage in the US in the summer of 2015 [(2)]. When the FDA posted reports of adverse events, including four cases of "patient death not definitively attributed to the device or the insertion procedure" and one case of "potential complications associated with the balloon treatment," two psychiatrists surprisingly recommended that the device be discontinued. These argue that the ORBERA balloon and Re-Shape are not completely risk-free [(3)].

Since several published studies have shown with average reduction of among 55.6 & 32.1 % of extra body weight at six months following therapy or around 25 % at 1 year it looks to be potentially helpful. The bulk of the time, this loss was kept off for a short or medium amount of time, but in 23% of patients, along with diet, exercise, and lifestyle changes, the loss was kept off for up to 5 years. Hundreds of thousands of obese people who are at high risk of surgical problems or are just terrified of it choose to pursue this treatment option due to the ease of the process, the positive outcomes, and the relatively inexpensive cost of the device [(4)].The goal of this research was to describe complication after bio-enteric intragastric balloon removal patients with morbid obesity.

MATERIALS AND METHODS

A cross-sectional approach was used for this research. Between May 2017 and April 2018, researchers from the Internal Medicine and Gastrointestinal Endoscopy departments at Suez Canal University Hospitals in Ismailia, Egypt, conducted this study. Fifty patients with body mass indexes (BMIs) of 40 or more were included in the analysis. Patients' ages ranged from 22 to 53, with 12 (28.6%) men and 30 (71.4% women) making up the sample size. Participants met the following requirements to be included in the study: Participants were adults (over the age of 18) with BMI of 40 or higher, regardless of gender. Patients who have many medical issues or who refused to participate were not included.

An informed written consent was taken from all the participants before taking any data or doing any investigations.

All patients had thorough medical histories reviewed. The patients were told to adhere to a certain food plan before the research. Patients were instructed to keep a food journal, which was examined once a month. The participants underwent the BIB after a month of therapy that included a low-calorie diet (1500 kcal/d) and physical activity (a 45-minute walk five times a week). Endoscopically implanted in the stomach, the balloon (Inamed Health; Santa Barbara, CA) contained 500–600 cc of physiological saline containing methylene blue. The following appointments have been made during patient recruiting, 1 month after balloon insertion, 6 months after BIB removal, and 1 month after balloon removal.

The balloon was withdrawn from the patients six months after the BIB was implanted, along with an endoscopic examination of their esophagus, stomach,

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and duodenum to look for any potential side effects from the treatment. The study was approved by the local ethical committee of Suez Canal University. Each patient was given a written informed consent before admission to the study. All patients were assessed for complications.

Ethical Approval: Participants were provided with the necessary trial information and the study was authorized by the Ethics Board of Suez Canal University. Every person who took part in the research first gave their informed written consent. The Declaration of Helsinki, a global standard for the ethical conduct of medical research involving human participants, has been followed throughout this project.

Statistical Analysis: Microsoft Excel 2016 for Windows, part of Microsoft Office 2016 from Microsoft Corporation, in the USA, was used to compile the acquired data once it was coded and input by hand. Statistical analysis was performed utilizing IBM's SPSS (Statistical Package for the Social Sciences) software (IBM SPSS Statistics for Windows, Version 26.0, Armonk, NY: IBM Corp. Categorical information was displayed numerically and graphically as a percentage, while continuous information was summarized using measures such as mean, standard deviation, median, and interquartile range. The significance level was set at a p-value of 0.05. A P-value below 0.05 was determined to be statistically significant.

RESULTS

Patients' ages varied from 22 to 53 years, with a mean of 35.79 and a standard deviation of 8.63 years. Table 1 displays a male to female patient ratio of 0.46: 1, with 14male (28.6%) and 36 female (71.4%).

Table 1: Distribution of socio-demographic characteristics among the examined patients

Parameters		Studied patients (n=50)	
		N	%
Gender	Male	14	28.6%
	Female	36	71.4%
Age (years)	Mean± SD	35.79± 8.63	

SD: standard deviation.

Anthropometric data from the patients under study are displayed in Table 2. The average weight was 126.69 kg, the average height was 1.66 m, and the average BMI was 45.77 kg/m2. In the patients that were under study, the average waist size was 137.40 15.58 cm. The average healthy weight was 61.04 + 4.07 pounds. The mean excess weight (EW) was 65.65 kg with a mean excess weight percentage of 51.63 kg.

Table 2: Anthropometric measurements in the studied patients

	Mean	SD
Weight (Kg)	126.69	9.79
Height (m)	1.66	0.06
BMI (Kg/m^2)	45.77	3.71
Waist circumference (cm)	137.40	15.58
Ideal body weight (Kg)	61.04	4.07
EW	65.65	8.99
EW%	51.63	3.91

SD: standard deviation, EW: excess weight, BMI: body mass index.

The mean haemoglobin level was 13.00 1.05 g/dl and the mean WBCs were 5.01 1.31x103/ml, according to Table 3. The mean platelet count was 242.9072.29x103/ml as well. While the mean creatinine level was 0.970.17 mg/dl, the mean urea level was 1320.144.33 mg/dl. The mean ALT level was 28.24 U/L and the mean AST level was 26.62 U/L, respectively. The mean triglyceride level was 219.74 41.82 mg/dl and the mean total cholesterol was 214.94 29.86 mg/dl. While the mean HDL level was 47.43 7.33 mg/dl, the mean LDL level was 135.74 16.14 mg/dl.

Table 3: Laboratory findings in the studied patients

	Mean	SD
Hemoglobin (g/dl)	13.00	1.05
WBCs (x10^3/ml)	5.01	1.31
Platelets (x10^3/ml)	242.90	7.29
Serum Urea (mg/dl)	20.14	4.33
Serum creatinine (mg/dl)	0.97	0.17
AST (U/L)	26.62	4.89
ALT (U/L)	28.24	5.33
TC (mg/dl)	214.94	29.86
TGS (mg/dl)	219.74	41.82
LDL (mg/dl)	135.74	16.14
HDL (mg/dl)	47.43	7.33

SD: standard deviation, WBCs: white blood cells, TC:total cholesterol, TGS:triglycerides.

The mean EW at 1 month was 9.81 2.94, at 6 months it was 19.10 4.07, and at 1 year it was 21.14 4.49. Over the course of the follow-up period, EWL has significantly increased (p 0.001). The mean EWL% at one month was 14.944.06, at six months it was 29.064.68 and at one year it was 32.175.09. Table 4 demonstrates that the EWL% significantly increased throughout the course of the follow-up period (p 0.001). Belching was the most common consequence reported by 30 (71.4%) individuals, followed by nausea by 29 (69%) patients, it was found. 18 (42.9%) patients reported experiencing nausea, 8 (19%) patients reported having halitosis, and 15 (35.7%) patients reported experiencing reflux.

Table 4: EWL and EWL% changes at 1 months, 6 months and after 1 month of IGB removal in the studied patients

		Mean	SD	Test value	p- value
EWL (Kg)	**After 1 months**	9.81	2.94	79.605	**<0.001**
	After 6 months	19.10	4.07		
	1month After IGB removal	21.14	4.49		
EWL%	**After 1 months**	14.94	4.06	79.605	**<0.001**
	After 6 months	29.06	4.68		
	1month After IGB removal	32.17	5.09		

p≤0.05 is considered statistically significant, p≤0.01 is considered highly statistically significant Analysis done by Friedman's Two-Way ANOVA Test.

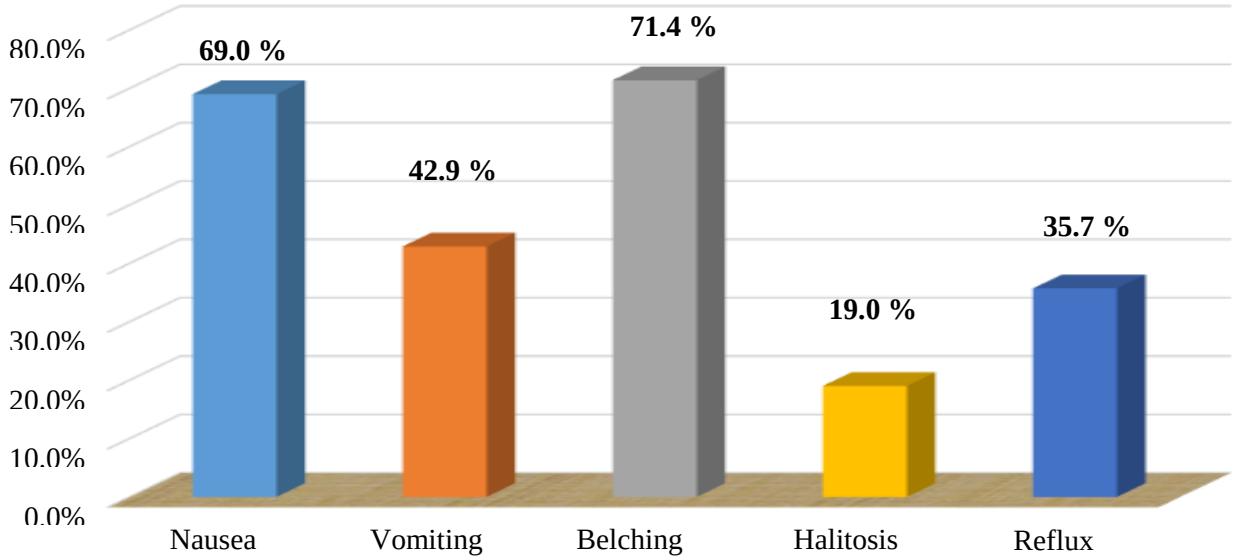

Figure 1: Distribution of studied patients regarding complications.

DISCUSSION

According to the opinions of doctors, the Bioenterics Intragastric Balloon (BIB) was the only intragastric balloon used for a long time, and similar goods have only lately entered the market. Preoperative intragastric balloon placement has been shown to reduce mortality and morbidity in extremely obese individuals undergoing bariatric or other elective surgery [(5)]. Patients' ages extended from 22 to 53, with a mean± SD of 35.79 ±8.63 years; we analysed data from 42 morbidly obese individuals. The male to female patient ratio was 0.4:1, with 30 females (71.4% of patients) to 12 males (28.6% of patients).

An IGB's goal is to promote weight loss and aid in the management of obesity-related complications without jeopardizing patient health. According to Brill [(6)], IGBs are appropriate for people with BMI between 30 and 40 kg/m^2 (class I and II obesity).

Patients with severe or morbid obesity (BMI >40 kg/m2 to >50 kg/m2, class III and IV obesity) may benefit from IGB placement in the lead-up to bariatric surgery because it reduces surgical risk, or it may allow for non-bariatric interventions that could not be safely performed due to weight limits (e.g., orthopaedic surgery, organ transplantation) [(7)].

The present study showed that mean baseline BMI was 45.77± 3.71Kg/m2 and the mean waist circumference in studied cases was 137.40± 15.58 cm. The mean EW loss after 1 month was 9.81± 2.94 Kg, 19.10± 4.07Kg after 6 months and 21.14± 4.49Kg one month after IGB removal. The mean EWL percentage after 1 months was 14.94 %, 29.06% and 32.17% after 1,6 months and one month after IGB removal respectively. The rapid loss of weight might be attributed to the significant nausea and vomiting and gastric upset. According **to Mohammed *et al.*** [(8)] After having the IGB implanted for 6 months, the subjects lost considerable amounts of weight and showed marked improvements in their EWL scores (5.543.15 and 14.3311.37 kg at 1 month and 6 months, correspondingly). After three months, there was less of a drop in body mass and a slower reduction in weight and other anthropometric measures. The difference remained statistically significant when measured against the initial levels, but lost its significance when compared against the values after BIB was removed.

In contrast, BIB treatment has a less favourable effect on body weight reduction in a trial conducted by **Ganesh *et al.*** [(9)], with weight loss of 5.9 kg after 6 months of therapy and 1.9 kg after a year. These outcomes, however, could be explained by a smaller baseline BM, a smaller balloon capacity (450 mL), and the absence of concurrent dietary and activity therapy.

The laboratory results for the current trial, including CBC, renal functions, and liver enzymes, were mostly within normal ranges, thus we removed participants who had additional comorbidities including diabetes and hypertension. IGB installation has been linked to considerable improvements in patient condition, as indicated by a reduction in the amount of medicine required or a mitigation of the techniques used to treat illnesses like diabetes mellitus, hypertension, and dyslipidemia [10,11]. The complex, multi-factorial induction of gastric satiety involves both endocrine and motor processes of the stomach, such as gastric distension, accommodation, and emptying. Ghrelin, leptin, and insulin, among other hormones, cooperate to control hunger, preserve energy balance, and govern a variety of metabolic processes [12].

IGB placement was safe and practical in the current investigation. It was only placed after anaesthesia in each case. There was no mortality or problems. The intragastric balloon used in conjunction with proton pump inhibitors (PPIs) and antiemetics was well tolerated and didn't cause any erosions or ulcers in the stomach or oesophagus. The most common adverse reaction was belching, which was experienced by 30 people (71.4%), followed by nausea in 29 people (69%) and vomiting in 18 people (42.9%). 15 (35.7%) patients experienced reflux, and 8 (19%) patients had bad breath.

According to **Genco *et al.*** [5], the primary adverse effect was heartburn, which was effectively managed by medical treatment for 53.12% of patients. Additionally, **Nikolic *et al.*** [13] shown that up to one-third of patients undergoing intragastric balloon therapy experienced moderate problems as a result of balloon adaptations. There were no significant problems, and the endoscopic complication incidence was minimal (5%).

IGBs seldom have severe adverse effects. In 1.4% of instances, migration, small bowel blockage, and stomach perforation have all been documented. Additionally, a few case reports have shown intestinal blockage brought on by balloon deflation and distal migration that required surgical removal [14–17].

CONCLUSION

The implantation of a BIB/Orbera balloon is still a safe technique with few hollow viscera-related problems. Such problems will be eliminated by requiring bariatric endoscopy doctors to complete training and accreditation programmes, as well as by strictly monitoring obese patients while they are using balloons.

DECLARATIONS

- **Consent for publication:** I attest that all authors have agreed to submit the work.
- **Availability of data and material:** Available
- **Competing interests:** None
- **Funding:** No fund
- **Conflicts of interest:** no conflicts of interest.

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