

Effectiveness of Intra-gastric Balloon Placement in Obese Patients

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ABSTRACT

Background: Intra-gastric balloon (IB) placement is gaining popularity for weight reduction.

Objective: To assess effectiveness, tolerability and safety of IB for management of obesity.

Methods and Materials: We retrospectively reviewed records of 196 obese patients who underwent IB placement at Ghassan Pharoan Hospital, Khamis Mushayt, Aseer Region, Saudi Arabia, during June 2011- June 2015. Weight loss, body mass index (BMI), and weight gain after removal of the IB were assessed. All included patients had >30 Kg/m² (i.e., obese or morbidly obese patients).

Results: 38 patients were male and 158 females within the age range of 16-60 with a mean age of 31.5±6.9 years. Patients' BMI was significantly less after removal of IB compared with that at placement (31.0±5.3 and 37.1±4.2 Kg/m², respectively, p<0.001). The mean duration of intra-gastric balloons placement in our patients was 5.1±1.6 months, with mean weight loss of was 15.4±10.4 kg. Experienced side effects associated with IB were mainly nausea (60.2%),

heartburn (12.2%), vomiting (1.5%) and epigastric pain (6.1%). Early removal of IB was performed for 10 patients (5.1%).

Conclusions: The IB for weight reduction of obese patients is effective and safe. It is well-tolerated by the majority of patients.

Key-words: Obesity, Weight Reduction, Intra-gastric Balloon.

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INTRODUCTION

Obesity is risk factor of several chronic diseases, e.g., cardiovascular diseases diabetes mellitus, osteoarthritis and some cancers. Overweight and obesity, as well as their related non-communicable diseases, are largely preventable by limiting food intake of fat and sugars in addition to regular physical exercise.¹

Some morbid obesity that cannot be reduced by diet and/or physical exercise are managed by the endoscopic intra-gastric balloon (IB). It is an endoscopic procedure to reduce weight by reducing stomach size and thus limiting the amount of food intake. The gastric balloon consists of soft, well-tolerated silicone that is filled with either sterile saline solution (salt water) or air. The filled gastric balloon creates a rapid sense of satiety. The balloon is generally removed either after six months² or after achieving target weight loss.³

Intra-gastric balloons are gaining popularity because of their effectiveness, safety, and easy technical. Its procedure is simple, repeatable, associated with low rate of complications, making leading to a mean weight loss of 16 kg during one course of treatment.⁴

The objective of this study is to assess the effectiveness, tolerability and safety of IB for management of obesity.

SUBJECTS AND METHODS

A retrospective review of clinical data from patients that underwent gastric balloon placement at Ghassan Naguib Pharoan Hospital (a private hospital) in Khamis Mushayt, Aseer Region, Saudi Arabia, between June 2011 till June 2015, was performed. A total of 196 patients were included in this study.

Inclusion criteria comprised obese patients with BMI ≥30 kg/m², after failure to achieve body reduction by lifestyle modification with or without pharmacological agents. On the other hand, patients with endocrinological causes for obesity, gastric lesions (e.g., peptic ulcer, hiatus hernia, previous gastric surgery) pregnancy, and those on anticoagulants, were excluded.

Hospital records of obese patients were retrieved by researchers. The collected data included personal characteristics, weight and BMI before placement and after removal and recorded side effects. Excess body weight and percentage of excess body

weight loss (EWL) were calculated. This was used to assess weight loss in these patients, and this was further analysed according to patient's age, gender, type of IB filling (water-filled or air-filled).

Calculations and Statistical Analysis

Ideal body weight was considered as weight corresponding to a BMI of 25 kg/m². Percent excess body weight loss (EWL%) for each participant was calculated according to the following equation:

$$(\text{weight before} - \text{weight after}) \times 100 / (\text{weight before} - \text{ideal body weight}).$$

Moreover, weight regain was defined as 50% of EWL within 6 months while the gastric balloon is in place.⁵

Data were collected initially in a special data collection form, then entered into a computer and analyzed using the Statistical Package for Social Sciences (SPSS, version 22.0, Chicago, IL, USA). Quantitative variables were expressed as mean ± standard deviation while categorical variables were presented as frequencies and percentages. Testing significance of differences was performed using t-test (paired or unpaired) and analysis of variance (ANOVA). All tests of significance were two-sided and p-values less than 0.05 were considered as statistically significant.

Table 1: Characteristics of studied patients at GNP hospital (n = 196)

Characteristics	No. (%)	
Age (years)	<30	78 (39.8)
	30-39	92 (46.9)
	≥40	26 (13.3)
	Mean±SD	31.5±6.9 years
Gender	Male	38 (19.4)
	Female	158 (80.4)
Type of balloon	Air-filled	17 (8.7)
	Water-filled	179 (91.3)
Side effects	Nausea	118 (60.2)
	Heartburn	24 (12.2)
	Epigastric pain	12 (6.1)
	Repeated vomiting	3 (1.5)
Duration (in Months)	<3	10 (5.1)
	3-4	24 (12.2)
	5-6	162 (82.7)
	Mean±SD	5.1±1.6 months

Table 2: Characteristics of weight loss among participant patients

Characteristics	Mean± SD
Height cm	160.7±11.7
Weight before balloon placement	96.6±14.3
Weight after balloon removal ⁽¹⁾	81.2±15.3
Weight loss	15.4±10.4
BMI before balloon placement	37.1±4.2
BMI after balloon removal ⁽¹⁾	31.0±5.3
EWL%	38.3±19.5

¹Difference between before placement and after removal are statistically significant (p<0.001) as assessed by paired t-test

Table 3: Percent excess body weight loss (EWL%) according to different characteristics of studied patients

Characteristics	Mean± SD	P-value	
Age (in years)	<30	42.9±24.1	0.172 ^a
	30-39	36.8±21.0	
	>40	43.6±23.9	
Gender	Male	42.5±23.6	0.56 ^b
	Female	39.7±22.6	
Type of Balloon	Air Filled	35.6±22.9	0.382 ^b
	Water Filled	40.7±22.8	
Duration (in months)	<3	17.8±18.1	<0.001 ^a
	3-4	41.2±25.0	
	5-6	45.4±20.0	

P-values were assessed based on ANOVA ^a or unpaired t- test ^b

RESULTS

Their mean age was 31.5 ± 6.9 years, 39.8% of patients aged less than 30 years, 46.9% aged 30-39 years and 13.3% were more than 40 years old. Most patients (80.4%) were females. The majority of participants (91.3%) underwent water-filled balloon ($n = 179$), while 8.7% selected air-filled balloon ($n = 17$). After IB placement, nausea was experienced by 118 patients (60.2%), while 3 patients (1.5%) experienced repeated vomiting. They were completely managed by gastrokinetics and antiemetics for 2-3 days. Moreover, 24 patients (12.2%) had heartburn and 12 patients (6.1%) had epigastric pain. They were treated by antacids and antispasmodics. However, the IB was removed early before 3 months in 10 patients. The mean duration of keeping the IB was 5.1 ± 1.6 months. Most participants kept their balloon for 5-6 months (82.7%) (Table 1).

Table (2) shows that before placement of the balloon, patients' mean weight (\pm SD) was 96.6 ± 14.3 kg. However, after removal of the IB, patients' mean weight (\pm SD) was 81.2 ± 15.3 kg. There was a mean weight loss of 15.4 ± 10.4 kg. With regard to BMI, the mean BMI among patients before placement was 37.1 ± 4.2 kg/m² and after balloon removal patients' BMI was 31.0 ± 5.3 kg/m². The patients experienced a mean EWL% of $38.3 \pm 19.5\%$. There were statistically significant reductions in weight and BMI after gastric balloon removal ($P < 0.001$).

Table (3) shows that duration of IB stay was a significant predictor for EWL%, while age, gender and type of balloon were not significant predictors.

DISCUSSION

Results of the present study showed that more than 85% of patients who underwent endoscopic IB placement aged less than 40 years and more than 80% were females.

These findings probably reflect the high incidence of obesity among younger Saudi population, especially among females, who also may express higher motives to achieve optimal or ideal body weight than males.

Alqarni⁶ noted that Saudi Arabia is now among the nations with the highest obesity and overweight prevalence rates, especially among females. In Hail, KSA, Ahmed et al⁷ reported that the overall prevalence of obesity was very high, being 71% among females and 56.2% males.

Moreover, several studies in Saudi Arabia emphasized that obese females, especially young ones, usually experience depression and marked social anxiety that frequently push them to seek weight loss treatment.^{8,9}

After IB removal in patients in the present study, there were statistically significant reductions in patients' body weight and BMI. Moreover, there was a mean EWL% of $38.3 \pm 19.5\%$. nevertheless, few side effects were experienced by participant patients, e.g., nausea (60.2%) and repeated vomiting (1.5%) which were transient and could be completely managed within 2-3 days, heartburn (12.2%) and epigastric pain (6.1%).

The present study indicated that the tolerability of IB is quite high. The duration of IB stay among most of our patients (82.7%) was 5-6 months. However, 10 patients (5.1%) underwent IB was removal within 3 months after its placement since their epigastric pain was persistent and could not be tolerated. Moreover, duration of IB stay was a significant predictor of EWL%. Therefore, patients who underwent early removal of their IB (before 3 months)

showed significantly less EWL% than those who underwent IB removal at 5-6 months ($17.8 \pm 18.1\%$ and 45.4 ± 20.0 , respectively, $p < 0.001$).

Mathus-Vliegen¹⁰ noted that, in general, IB placement is associated with minor, reversible complications, mainly gastroesophageal reflux, balloon deflation, and gastroduodenal ulcer formation.

In Abha, Saudi Arabia, Safty and Mater¹¹ reported that, after IB placement, 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. None of the patients required early IB removal.

Zafar et al.¹² reported that patients who underwent IB placement underwent transient nausea and vomiting. However, epigastric pain was a constant feature and a cause for early removal of the IB in 2 patients (6.6%).

Totte et al.¹³ and Alfalah et al.¹⁴ reported that proper use of IB is associated with substantial weight loss with very low rates of intolerable side effects.

In conclusion, in well-selected obese patients, IB is an effective device, with minimum side effects and high tolerability. It is associated with body weight loss and, therefore, can resolve several obesity-related morbidities among cooperative and dedicated obese patients. Thus, IB seems to be an effective method of significant weight reduction with little complications, making it a safe and effective approach in management of obesity.

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