

Intra-gastric balloon treatment of obesity: Long-term results and patient satisfaction

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ABSTRACT

Background/Aims: Intra-gastric balloon (IGB) treatment of obesity is a minimally invasive outpatient procedure that has been shown to help weight loss in some patients. The aim of this study is to analyze the long-term results regarding the effectiveness, tolerability, and patient satisfaction in a cohort of patients undergoing the IGB insertion.

Materials and Methods: Using a retrospective cohort study design, patients who had their IGB inserted/removed between the years 2009 and 2016 were contacted by phone and asked to answer a short questionnaire. The baseline characteristics, pre- and post- IGB weight, as well as their current weight were recorded. Different parameters of satisfaction were noted in addition to whether patients resorted to alternative weight-reduction measures.

Results: Ninety-nine eligible patients were contacted, and 65 consented to the study. The average weight loss achieved at the end of the treatment period (3 to 10 months) was approximately a 12% decrease from the baseline. Only 39% of patients were satisfied with the procedure, and less than 50% were satisfied with the weight loss achieved. When assessing the long-term follow-up, years after the IGB removal (3.3±1.76 years), the vast majority of patients (78.7%) regained weight or resorted to further bariatric measures.

Conclusion: IGB leads to weight loss among most patients, but it does not appear to fulfill patients' expectations. Further, the initial weight loss is not sustainable over time.

Keywords: Intra-gastric balloon treatment, patient satisfaction, results

INTRODUCTION

The latest World Health Organization reports identified obesity as a rising chronic condition with many devastating health consequences (1). In 2014, the number of overweight adults was estimated at 1.9 billion, while the number of obese adults was approximately 600 million (2). The conventional approach to diet and exercise usually leads to a modest weight loss over a prolonged period, with strict and rather tense conditions. This has led people who could not succeed or those who did not want to go through the burden of conventional methods to seek alternative measures to achieve the optimal weight. Alternative solutions for weight reduction ranged from pharmacotherapy (1-11) to surgical procedures, which have been gaining popularity in the recent years.

Intra-gastric balloon (IGB) is one of the non-surgical treatment options for obesity; it was first performed in 1982 by Nibben and was believed to have the potential benefit of a sustained 5%-10% weight loss to prevent obesity-related comorbidities and diseases (3). The endoscopic insertion of the IGB is a minimally invasive outpatient

procedure, requiring only local sedation, and a maximum of 2-hour hospital stay. It utilizes a water-filled intra-gastric-space-occupying device that induces early satiety and delays gastric emptying without having any effect on the gut's absorption.

The IGB insertion is usually considered to be an alternative therapy in overweight patients when diet and exercise alone fail (4). In addition, many patients who were not surgical candidates, or those who avoided the increased risks and costs of surgery, looked at the IGB implementation as a booster for weight reduction. They expected that this less invasive and far less risky procedure could motivate them to adjust into a healthier lifestyle with a bonus weight loss to start with (12-14).

The IGB can also be utilized as an effective first-stage treatment of high-risk, morbidly obese patients in need of surgical intervention. It was shown to cause satisfactory weight loss and improvement in comorbidities, consequently reducing the perioperative mortality and morbidity rates associated with bariatric surgery (5,6).

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However, per a 2007 meta-analysis by Fernandes et al. (7), there was no convincing evidence of significant long-term weight reduction from IGB when compared to conventional methods, and data regarding changes in metabolic parameters were still lacking.

Despite its long presence in the market, the IGB treatment for obesity just received the US Food & Drug Administration's approval in July 2015, while there is still no clear idea about its long-term benefits (8).

The aim of the present study is to present the experience from a tertiary care center in Lebanon with the IGB insertion, with a special emphasis on the effectiveness, tolerability, safety, and long-term patient satisfaction.

MATERIALS AND METHODS

Subjects

All consecutive patients that had their IGB inserted or removed during the 7-year period from 2009 to 2016 were included in the study population. Patients were identified by searching the endoscopy database, and the IGBs used were of the non-adjustable type: Orbera IGB (Allergan) filled with saline solution and methylene blue.

Medical records of all identified patients were reviewed; the demographic and clinical data were then abstracted from these records.

Patients who could not be reached by phone were excluded from further consideration.

The study was approved by our Institutional Review Board, and all subjects provided oral informed consent.

Study procedure

Patients included in this study completed a telephone interview and were asked to provide an oral consent to participate in our questionnaire research.

Questionnaire design

The baseline information collected from the medical records included the date of birth, gender, and the exact IGB insertion and removal date. The questionnaire covered additional patient's characteristics (age, body mass index [BMI], presence of diabetes mellitus, and hypertension), weight at 1 month, maximum weight loss and its duration, IGB removal time, and the corresponding weight, in addition to patient's current weight (at the time of phone call) at least 6 weeks after the IGB removal. Patients were

also asked about their inclination to get a second IGB and if they have had bariatric surgery after the IGB removal. Finally, we asked our patients to rate from 1 to 5 a series of questions that included their overall satisfaction, their initial satisfaction with the procedure, whether the results met their expectations, whether they would recommend the procedure to a friend, and finally whether they believe the procedure was cost effective.

We compared patient satisfaction in relation to age, gender, baseline BMI, and final weight lost after the therapeutic period with the IGB and divided the population per these parameters into the satisfied group and unsatisfied group.

Statistical analysis

Data were analyzed using the Statistical Package for Social Sciences version 23.0 software (IBM Corp.; Armonk, NY, USA). Continuous variables were presented as the mean±standard deviation, and categorical data were shown as numbers and percentages. The comparison of continuous data was performed by Student's t-test with normal distribution. The chi-squared test was used to compare groups with categorical variables, and a p-value less than 0.05 was considered significant.

RESULTS

From 2009 to 2016, we retrospectively reviewed the charts of 99 patients who had an IGB inserted/removed at the endoscopy unit of our institution. Thirty-four patients were excluded from our analysis because of failure to reach the patients or refusal to provide an informed consent. We evaluated the remaining 65 patients that consented to take part in our study and constituted the sample for statistical analysis. Of these patients, 14 were males (21.5%), and 51 were females (78.5%). The average age of patients was 39 years with a range between 16 and 68 years. The mean baseline weight and BMI were 93.6 kg and 32.9 kg/m², respectively. Among the 65 patients included, 4 patients had a premature (<2 weeks) IGB removal due to intolerability, 5 patients had an early (<3 months) IGB removal, and 27 patients kept their IGB in place for an acceptable period between 3 and 6 months, while the remaining 29 patients kept the IGB for longer than 6 months (ranging between 6 and 10 months).

Weight loss

The mean weight loss at 1 month from the IGB insertion was 5.1 kg (range 0-17 kg). The maximum mean weight lost during the treatment period was 11.1 kg on average (range 1-38 kg) requiring about 4.3 months to achieve.

The mean weight loss at the end of the treatment period (time of IGB removal) was 10.7 kg (range -7 to 37 kg) corresponding to a decrease of 11.9 % from the baseline weight. Results are shown in Table 1. One patient out of 56 had a weight increase of 7 kg at the IGB removal time.

Patient satisfaction

Less than half of our population (39.3%) were satisfied with the overall procedure, while 49.2% were satisfied with the weight lost at the end of the treatment period. The initial satisfaction with the procedure (endoscopic

balloon insertion) was reported as 46.1%. Only 35.5% of patients were satisfied enough to recommend the procedure to others. Finally, 57% of our population considered the IGB experience to be a cost-effective tool for weight reduction (Table 2).

Based on their impression of the overall IGB experience, the patients were divided into 2 groups: the satisfied and unsatisfied, as shown in Table 3. The mean age and baseline BMI of patients were similar for both groups; however, significant weight loss differences were found between them; the average weight lost in the satisfied group was 13.77±6.81 kg compared to 8.61±7.90 kg in the unsatisfied group (p<0.05)

Among males, 64.3% reported that they were dissatisfied with the overall experience of the IGB, while 58.0% of female patients shared the same dissatisfaction.

Overall, 7.7% of the patients reported that they have opted for a second IGB placement after the removal of the first balloon, and 30.8% ended up having a bariatric surgery.

Maintenance of weight loss

By comparing the patient’s current weight to that at the IGB removal time, we could determine the long-term effectiveness of the IGB as a weight-reduction method. We divided patients into 2 groups, the first group including those who could maintain their weight loss or who lost further weight without any additional medical interventions, and the second group including those who had gained weight or underwent further bariatric measures, such as a second IGB insertion or a sleeve gastrectomy. Excluding the 4 patients that removed the IGB prematurely (less than 2 weeks), only 13 out of 61 patients (21.3%) had a satisfactory long-term IGB results defined

Table 1. Descriptive statistics

	Minimum	Maximum	Mean
Weight loss 1 month after IGB (kg)	0	17	5.08 (±3.17)
Maximum weight loss after IGB (kg)	1	38	11.1 (±7.3)
Percentage of maximum weight loss after IGB	-6.4	30.8	11.47 (±7.7)
Time needed to maximal weight loss (days)	14	300	127.6 (±74.6)
Weight loss at removal time	-7.00	37.00	10.7 (±7.8)
Percentage of maximum weight loss during IGB	1.37	31.3	11.93 (±7.2)
IGB removal time (days)	1	300	173.95 (±72.1)
	Yes	No	
Patient had a second IGB inserted	5 (7.7%)	59 (92.5%)	
Patient had bariatric surgery	20 (31.5%)	44 (68.5%)	

IGB: intra-gastric balloon

Table 2. Satisfaction statistics

Impression	Overall	Weight Loss Met Expectations	Initial Procedure Satisfaction	Recommend to Friends or Family	Cost-Effectiveness of IGB
Strongly satisfied	7 (10%)	19 (29.2%)	11 (16.9%)	12 (18.5%)	18 (27.7%)
Satisfied	14 (20.8%)	10 (15.4%)	9 (13.8%)	7 (10.8%)	12 (18.5%)
Neutral	5 (7.7%)	3 (4.6%)	10 (15.4%)	4 (6.2%)	7 (10.8%)
Dissatisfied	10 (15.4%)	14 (20.8%)	11 (16.9%)	7 (10.8%)	15 (23.1%)
Strongly dissatisfied	28 (43.1%)	17 (26.2%)	24 (36.9%)	34 (52.3%)	12 (18.5)

IGB: intra-gastric balloon

Table 3. Satisfaction and IGB/BMI/gender/age/weight/baseline

	Satisfied	Unsatisfied	p
Age (mean)	39.46 (\pm 13.6)	38.74 (\pm 11.00)	0.8
Baseline BMI (mean)	32.01 (\pm 4.5)	33.54 (\pm 4.6)	1.2
Weight lost at IGB removal (mean)	13.77 (\pm 6.8)	8.61 (\pm 7.9)	<0.05
Male gender	5 (35.7%)	9 (64.3%)	0.7
Female gender	21 (42.0%)	30 (58.0%)	

IGB: intra-gastric balloon; BMI: body mass index

as the maintenance or further increase of their weight loss, whereas 48 out of 61 patients (78.7%) did not achieve long-term expectations.

DISCUSSION

Obesity is an alarming health problem with a significant social and health-related impact. It is associated with several conditions, including diabetes, hypertension, and metabolic syndrome (9). An increasing number of affected individuals are seeking medical and dietary advices to help them lose their excess weight, thus increasing the medical costs of management of both obesity and obesity-related diseases, which reached \$113.9 billion in 2008 in the United States (10), hence the importance of good weight loss measures. We have shown in our study that although IGB is one of the weight loss modalities, however, the vast majority of patients (78.7%) regained weight after the IGB removal or resorted to further bariatric measures, and when assessing the long-term results, only 39% of patients were satisfied with the procedure.

The maximal weight loss achieved after the IGB insertion in our study was observed at approximately 4 months into the treatment period, averaging 11.1 kg. This justifies the recommendation of a 6-month therapeutic period with IGB observed in a most recent systemic review by Yorke for a satisfactory, short-term weight reduction (10,16). The average weight lost at the IGB removal time was 10.7 kg, corresponding to an average drop in the baseline BMI by 3.6 units, which was consistent with the results from other studies (5-7,9,10,17). However, the weight loss numbers achieved were by far less than the numbers reported by the studies that included in their protocol a strict diet of 1000Kcal/day for 6 months post-IGB insertion, under the supervision of a dietician (20,21). Despite these results, less than 50% of patients were satisfied with the weight loss achieved, which could be

explained by several factors. On the one hand, patients might have had higher expectations regarding the outcomes of IGB, possibly because they might have not been properly informed on what to expect. On the other hand, a significant number of patients were contacted long after the IGB removal by which time they might have regained some of the weight they originally lost. These factors would have affected their statements concerning satisfaction with the procedure increasing the numbers of dissatisfied individuals.

At the time of the follow-up, we noticed an average weight recovery of 5.7kg from the weight at the time of the IGB removal. Patients who did not undergo additional interventions to lose weight had a weight difference at the time of the call ranging from -15 to 30 kg. Similar to the findings by Kim (9), only 22% of the patients maintained or had a further decrease in weight compared to their weight at the end of the treatment period. The remaining 78% had either gained weight or had a second intervention, which in the case of our population consisted of having a second IGB (7%) or some type of bariatric surgery (30.8%). These results fall in line with previous studies to support the limitation of IGB as a tool for long-lasting weight reduction, making it only a temporary measure with adequate capabilities that could be deemed sufficient mainly for a short time (4,6,18,24) and should be mainly offered to patients who would accept undergoing bariatric surgery in case of the IGB failure (20).

In addition, a significant percentage of patients found IGB to be cost effective. Many patients attributed this to the fact that if they combined the fees of a dietician and a trainer, it would cost them around the same, and if they compared them to the costs of surgical options, they would be far less expensive. This answer proves that patients were not using IGB as an aid and addition to diet and exercise, but rather as a replacement to these important measures that should have been continued after the IGB insertion as advised by providers in our institution.

The IGB treatment for obesity could represent a swift solution for patients who find diet and exercise alone insufficient or unsatisfactory by boosting their weight reduction during the treatment period. However, it is important to know that the IGB treatment is better when performed in the right patient population (women with class I obesity), as it was shown in a study by Mitura and Garnysz (23), and also IGB would have far better results when assisted by a balanced diet and physical exercise;

these must continue beyond the treatment period if the patient hopes to maintain the achieved weight post-removal time. Otherwise, patients should expect a gradual weight regain after the IGB removal (19,22), unless they opt for other solutions, (25) as 37.7% of our population did when they reverted to either a second IGB insertion or bariatric surgery.

Another important endpoint assessed in our study was the evaluation of patients' satisfaction with the IGB experience. More than half of our patients were not satisfied with the overall IGB experience, in contrast to the study by Mitura and Garnysz (21) in which the vast majority of patients were satisfied with IGB. Multiple studies have already measured the degree of satisfaction with the adopted procedures; however, the longer available follow-up periods were 1.5 years in a study done by Palmisano (10) in 2016 and up to 2.5 years in a study by Dastis (17) in 2009. In our study, at the time of the interview, 75% of our patients were having a follow-up period longer than 1.5 years, and 66% were having a follow-up period longer than 2.5 years. This longer follow-up period provides additional proof to the limitations of IGB in a long-term obesity treatment and may explain why the majority of patients in our cohort were dissatisfied with this obesity treatment modality.

It is important to note that none of our patient reported significant or life-threatening adverse effects. Most of patients who had a premature removal of the IGB did it because of the initial intolerance, including excessive nausea, vomiting, and dehydration that were all relieved after the IGB removal.

Study limitations

This study looked into new aspects of the IGB experience that were not completely covered in previous studies. Our study, however, has several limitations. These include a relatively small number of patients. In addition, the method of reporting the changes resulting from the IGB insertion was subjective claims by patients, who were trying to recall information from the past.

In conclusion, our study showed that the IGB treatment for obesity is a good short-term and rapid weight-reduction method; however, the long-term follow up proved that the weight loss achieved was limited and only temporary unless assisted by other means. Finally, a low patient satisfaction is likely the reflection of suboptimal long-term results.

Ethics Committee Approval: Ethics committee approval was obtained for this study from the Institutional Review Board of American University of Beirut Medical Center.

Informed Consent: Verbal informed consent was obtained from the patients who participated in this study.

Peer-review: Externally peer-reviewed.

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