Short-term results of intragastric balloon for management of Egyptian obese patients

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Background
Obesity is considered one of the major health problems because of its high incidence and associated comorbidities. Various therapeutic options are available for obesity management, and there has been advancement in bariatric surgery with introduction and development of new techniques.
Objective
To evaluate the short-term outcomes of intragastric balloon (IGB) in terms of weight loss, tolerance, complications, and its effect on comorbidities.
Patients and methods
This study included 86 morbidly obese patients who were subjected to IGB with follow-up for a minimum of 1 year. Follow-up was in the form of recording of postprocedure symptoms, complications, and the effect of the procedure on weight loss after 6 months and at 1 year in the form of percentage excess weight loss and percentage excess BMI loss.
Results
Preoperative BMI ranged from 35.2 to 57.8 kg/m^2, with a mean of 42.9±4.8 kg/m^2. At 6 months, BMI decreased to 29.4–50.8 kg/m^2, with a mean of 37.1±4.2 kg/m^2, whereas at the 12 months, it significantly increased to 29.8–51.6 kg/m^2, with a mean of 38.7±4.5 kg/m^2 when compared with 6 months postoperatively.
Conclusion
IGB is effective at very short term in weight reduction and improving associated comorbidities with acceptable adverse effects, but weight regain occurred after IGB removal.

Keywords:
bariatric surgery, intragastric balloon, morbid obesity

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Introduction

Obesity is considered one of the major health problems because of its high incidence and associated comorbidities [1]. Various therapeutic options are available for obesity such as diet, drugs, and behavioral changes [1–3].

Surgical management of obesity is best for long-term weight loss and improving its comorbidities [4,5]. However, controversies exist regarding the ideal weight loss procedure, mandating continuous search for new procedures [4–6].

Intragastric balloon (IGB), a device which is introduced by endoscopy, is used to obtain weight loss for temporary obesity management by producing a feeling of satiety [7]. It is advised before any planned surgery in morbidly obese and before obesity surgery, to improve comorbidities and minimize the risk of surgery. Moreover, it is used for super obese patients' who are unfit for obesity surgery [8].

The aim of this study is to evaluate the efficacy of IGB regarding weight loss, tolerance, complications, and patient satisfaction after treatment and its influence on comorbidities.

Patients and methods

This study was done at the Department of Surgery, Medical Research Institute, and Faculty of Medicine, Alexandria University, Egypt, from May 2015 till August 2017. The Ethics Committee of our institutions approved this study.

All patients were subjected to complete history taking, including age of onset of obesity, dietary habits, previous trial of weight reduction and history of obesity comorbidity, clinical examination, blood chemistry, and hormonal profile.

Specific written informed consent approved by our Institution's Ethics Committee was obtained from all the treated patients.

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Inclusion criteria

Patients aged 18–60 years, BMI above 35 kg/m^2, and a history of obesity for more than 5 years with failed nonsurgical treatment for weight loss were included. Preoperative assessment by internists, dieticians, and psychologists was done before the procedure.

Exclusion criteria

Previous bariatric or hiatal hernia surgery, peptic ulceration, large hiatal hernia (>5 cm), inflammatory bowel disease, active gastrointestinal bleeding, coagulative disorder, variceal disease, uncontrolled diabetes, cardiovascular risks, and drug or alcohol abuse were the exclusion criteria.

Technique

First, diagnostic esophagogastroduodenoscopy was performed to exclude patient with any contraindications. MedSil (Novomytishchinski, Mytischi, Moscow region, Russia) balloon was implanted under sedation with propofol 2 mg/kg and local anesthetic throat spray with the patient in lateral decubitus position. Then, introduction of the empty balloon inside the stomach under endoscopic vision was done; the balloon was filled with 600–700-ml saline and 10-ml methylene blue solution. After implantation, the patient stayed 2 h in the recovery room for observation. After 6 months, the balloon was removed by endoscopy.

Postoperative course

Immediately following IGB insertion, 500-ml intravenous saline, with pantoprazole (40 mg) and ondansetron (8 mg), was given to all patients. Patients were discharged with drug therapy, pantoprazole (40 mg/day) and domperidone tablets, and asked to follow-up with a dietitian.

Outcome measurement and follow-up

Follow-up was done in the form of recording of postprocedure symptoms, complications, and the effect of the procedure on weight loss after 6 months and at 1 year in the form of percentage excess weight loss (%EWL) and percentage excess BMI loss (%EBMIL). Improvement or resolution of comorbidities was recorded.

Statistical analysis

Statistical analysis was performed using the statistical package for the social sciences (SPSS) version 20 software (SPSS Inc., Chicago, Illinois, USA). Quantitative variables such as age, BMI, and weight were summarized by mean and median as measures of central tendency and SD, minimum, and maximum as measures of dispersion.

Repeated measure analysis of variance test was used to study if there is a statistically significant difference in the mean weight, %EWL, BMI, and %EBMIL preoperatively, at 6 months, and at the 1 year. Post-hoc tests were used for pairwise comparison for significant results. All statistical tests were judged at 0.05 significance level.

Results

This study included 97 patients with a preoperative diagnosis of morbid obesity, and they were subjected to IGB. Eleven patients were excluded from the study because of lost to follow-up, and 86 patients who completed their follow-up were included (Table 1).

Preoperative BMI ranged from 35.2 to 57.8 kg/m^2, with a mean of 42.9±4.8 kg/m^2. At 6 months, BMI decreased to 29.4–50.8 kg/m^2, with a mean of 37.1±4.2 kg/m^2, whereas at the 12 months, it significantly increased to 29.8–51.6 kg/m^2, with a mean of 38.7±4.5 kg/m^2, when compared with 6 months postoperatively and was significantly less than preoperative BMI (Table 2).

%EWL decreased significantly from 0 to 61.2%, with a mean of 31.4±11.8%, at 6 months to −21 to 55.6%, with a mean of 22.1±14.9%, at 12 months (Table 2).

%EBMIL decreased significantly from 0 to 65.8%, with a mean of 33.9±12.5%, at 6 months to −18.6 to 60%, with a mean of 24.3±15.4%, at 12 months (Table 2).

Postoperatively, nausea was encountered in 18 (20.9%) patients. Twelve (14.0%) patients experienced excessive vomiting. Abdominal pain was encountered in 11 (12.8%) patients. Intolerance was encountered in seven (8.1%) patients to the degree that balloon was

Table 1 Preoperative patient characteristics

	N=86
Sex	
Male	14 (16.3%)
Female	72 (83.7%)
Age (years)	
Median (minimum–maximum)	35 (18–55)
Mean±SD	34.7±8.9
Weight (kg)	
Median (minimum–maximum)	110 (95–160)
Mean±SD	114.6±15.9
BMI (kg/m^2)	
Median (minimum–maximum)	41.6 (35.2–57.8)
Mean±SD	42.9±4.8
Follow-up (months)	
Median (minimum–maximum)	12 (12–15)
Mean±SD	12.8±1

Table 2 Weight loss before and after treatment

	Preoperative	Postoperative		*P*
		6 months	12 months	
Weight (kg)				<0.001*
Median (minimum–maximum)	110 (95–160)	98 (77–140)	100 (80–155)	
Mean±SD	114.6±15.9	99.1±14[a]	103.2±15[a]	
BMI (kg/m^2)				<0.001*
Median (minimum–maximum)	41.6 (35.2–57.8)	36.1 (29.4–50.8)	38.1 (29.8–51.6)	
Mean±SD	42.9±4.8	37.1±4.2[a]	38.7±4.5[a]	
%EWL				<0.001*
Median (minimum–maximum)	–	32.8 (0–61.2)	22 (–21 to 55.6)	
Mean±SD		31.4±11.8	22.1±14.9	
%EBMIL				<0.001*
Median (minimum–maximum)	–	35.5 (0–65.8)	24.6 (–18.6 to 60)	
Mean±SD		33.9±12.5	24.3±15.4	

%EBMIL, percentage of excess BMI loss; %EWL, percentage of excess weight loss. Significance between periods was assessed using post-hoc test (least significant difference). [a]Statistically significant with preoperative. *$P \leq 0.05$, statistically significant.

removed within the first 2 weeks following insertion. Spontaneous IGB deflation occurred in three (3.5%) cases, which was suspected by presence of bluish urine and confirmed by abdominal ultrasound, and the cases were managed by immediate endoscopic removal of IGB. Gastric erosions were found in 20 (23.3%) cases. No mortality was found.

Preoperatively type 2 diabetes mellitus was present in one (1.16%) case, hypertension was present in two (2.32%) cases, and osteoarthritis was present in seven (8.13%) cases.

By the end of the study, type 2 diabetes mellitus was not affected, hypertension was improved in one case and not affected in the other case, and osteoarthritis was cured in two cases and improved in five cases.

Discussion

Obesity is an avoidable metabolic disorder having bad effects on health with many associated comorbidities [9]. Bariatric surgery is the most fruitful, sustainable long-term therapeutic option for obesity. Among these included Roux-en-Y gastric bypass, mini-gastric bypass, or sleeve gastrectomy [10,11]. Although it has efficacy in achieving weight loss and resolution of associated comorbidities, only minority of those obese patients are eligible for surgery [12]. Difficult accessibility, cost, patient's refusal or nonpreference, morbidity, and mortality are the major drawbacks for surgery [11]. Thus, there is continuous search for novel, safe, and effective methods for weight loss, like endoscopic approaches, including IGB [13].

Since the introduction of first IGB in 1985 with many adverse effects occurring with its use, there has been continuous development in advanced, innovative, safe, and effective versions of balloon, with its approval for managing obesity, leading to its widespread use all over the world [14]. IGB has become an effective modality for weight loss in obese patients by decreasing the amount of eaten food by producing sense of fullness, thus reducing food consumption through centrally transmitted signals via the vagus nerves by activated gastric stretching receptors. It is hypothesized that IGB results in restriction of gastric capacity, and delaying gastric emptying [15]. Additionally, it produces early satiety because of gastric distention [16,17]. It may affect gastric emptying and satiety by altering gut hormones like leptin, cholecystokinin, ghrelin, and pancreatic polypeptide [18,19].

Kim *et al.* [13] in their review, discussed different types of IGB and their efficacy on weight loss. The mean weight loss ranged between 12 and 26.3 kg after 6 months following the introduction of BioEnterics Intragastric Balloon (BIB) [20,21], whereas a Spanish study with 60 obese patients revealed a weight loss of 16.6±9.33 kg 6 months after placement of the ReShape Duo double-balloon system [22]. A pilot trial showed 15.6 and 24.4 kg of mean weight loss at 6 and 13 months after Spatz adjustable balloon deployment [23], and in another study, %EWL was 45.7% at 12 months [24]. A total of 57 morbidly obese patients underwent adjustable totally implantable intragastric prosthesis placement. Mean EWL was 28.7% at 6 months (38 patients) and 39.2% at 12 months (20 patients) [25]. The Obalon showed median weight losses after 1, 2, and 3 months as 2.2, 4.0, and 5 kg, respectively [26].

In this study, IGB placement for 6 months resulted in a statistically significant weight loss. The mean weight

loss, BMI, and %EWL were 15.3 kg, 5.8 kg/m^2, and 31.4±11.8, respectively, which is similar to Bužga *et al.* [27], who obtained mean weight loss and BMI of 18.4 kg and 5.5 kg/m^2, respectively, as they have the same type of IGB, MedSil, like us. Moreover, this agrees with the results of Kim *et al.* [13]. A slight weight regain was noticed 6 months after IGB removal, with a decrease in %EWL from 31.4±11.8 to 22.1 ±14.9%, which is similar to other studies [13,27]. Abdominal pain, nausea, and vomiting were common with BIB and ReShape Duo IGB, like our study, which responded to medical management. Moreover, balloon migration was 2%, and small bowel obstruction occurred in 0.3% with BIB, whereas spontaneous IGB deflation occurred in 6% of patients with ReShape Duo and 3.5% in our study but without balloon migrations. Early balloon removal occurred in 9.1% with ReShape Duo IGB, whereas it was reported in 8.1% of our patients because of intolerance. Perforation and death were not reported in our study, but with BIB at 0.1 and 0.08%, respectively [28,29].

Although IGB was effective in achieving an acceptable loss of weight, many studies have reported that the results lasted for a brief period, and most of the patients regained weight after IGB removal like our findings [21,30]. Furthermore, advances in balloon properties and procedural techniques are required to improve its safety and efficacy.

Limitations of this study included the lack of long-term data regarding the durability of the procedure in terms of weight loss and control of associated comorbidities.

Conclusion

IGB is effective at very short term in weight reduction and improving associated comorbidities with acceptable adverse effects, but weight regain occurred after IGB removal.

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Nil.

Conflicts of interest

There are no conflicts of interest.

References

1 Xavier Pi-Sunyer F, Becker DM, Bouchard C, Carleton RA, Colditz GA, Rocchini AP, *et al.* Clinical guidelines on the identification, evaluation and treatment of overweight and obesity in adults. The evidence reports. National Heart, Lung and Blood Institute Education Initiative. Obes Res 1998; 6:51S–209S.

2 Glenny AM, O'Meara S, Melville A, Sheldon TA, Wilson C. The treatment and prevention of obesity: a systematic review of the literature. Int J Obes Relat Metab Disord 1997; 21:715–737.

3 Rucker D, Padwal R, Li SK, Curioni C, Lau DCW. Long-term pharmacotherapy for obesity and overweight: updated meta-analysis. BMJ 2007; 335:1194–1199.

4 Buchwald H, Avidor Y, Braunwald E, Jensen Pories W, Fahrbach K, Schoelles K. Bariatric surgery: a systematic review and metaanalysis. JAMA 2004; 292:1724–1737.

5 DeMaria EJ. Bariatric surgery for morbid obesity. N Engl J Med 2007; 356:2176–2183.

6 Tsigos C, Hainer V, Basdevant A, Finer N, Fried M, Mathus-Vliegen E, *et al.* Management of obesity in adults: European Clinical Practice Guidelines. Obes Facts 2008; 1:106–116.

7 Doldi SB, Miceletto G, Perrini MN, Rapetti R. Intragastric balloon: another option for treatment of obesity and morbid obesity. Hepatogastroentrology 2004; 51:294–297.

8 Mathus-Vliegen EM, Tytgat GN. Intragastric balloon for treatment resistant obesity: safety, tolerance, and efficacy of 1-year balloon treatment followed by a 1-year balloon-free follow-up. Gastrointest Endosc 2005; 61:19–27.

9 Pi-Sunyer X. The medical risks of obesity. Postgrad Med 2009; 121:21–33.

10 Ochner CN, Gibson C, Carnell S, Dambkowski C, Geliebter A. The neurohormonal regulation of energy intake in relation to bariatric surgery for obesity. Physiol Behav 2010; 100:549–559.

11 Chang SH, Stoll CR, Song J, Varela JE, Eagon CJ, Colditz GA. The effectiveness and risks of bariatric surgery: an updated systematic review and meta-analysis. JAMA Surg 2014; 149:275–287.

12 Buchwald H, Oien DM. Metabolic/bariatric surgery worldwide2011. Obes Surg 2013; 23:427–436.

13 Kim SH, Chun HJ, Choi HS, Kim ES, Keum B, Jeen YT. Current status of intragastric balloon for obesity treatment. World J Gastroenterol 2016; 22:5495–5504.

14 Gleysteen JJ. A history of intragastric balloons. Surg Obes Relat Dis 2016; 12:430–435.

15 Mathus-Vliegen EM. Endoscopic treatment: the past, the present and the future. Best Pract Res Clin Gastroenterol 2014; 28:685–702.

16 Geliebter A, Westreich S, Gage D. Gastric distention by balloon and test-meal intake in obese and lean subjects. Am J Clin Nutr 1988; 48:592–594.

17 Geliebter A, Melton PM, McCray RS, Gage D, Heymsfield SB, Abiri M, Hashim SA. Clinical trial of silicone-rubber gastric balloon to treat obesity. Int J Obes 1991; 15:259–266.

18 Mathus-Vliegen EM, Eichenberger RI. Fasting and meal suppressed ghrelin levels before and after intragastric balloons and balloon-induced weight loss. Obes Surg 2014; 24:85–94.

19 Mathus-Vliegen EM, de Groot GH. Fasting and meal-induced CCK and PP secretion following intragastric balloon treatment for obesity. Obes Surg 2013; 23:622–633.

20 De Castro ML, Morales MJ, Del Campo V, Pineda JR, Pena E, Sierra JM, *et al.* Efficacy, safety, and tolerance of two types of intragastric balloons placed in obese subjects: a double-blind comparative study. Obes Surg 2010; 20:1642–1646.

21 Giardiello C, Borrelli A, Silvestri E, Antognozzi V, Iodice G, Lorenzo M. Air-filled vs water-filled intragastric balloon: a prospective randomized study. Obes Surg 2012; 22:19161919.

22 Lopez-Nava G, Bautista-Castaño I, Jimenez-Baños A, Fernandez-Corbelle JP. Dual intragastric balloon: single ambulatory center spanish experience with 60 patients in endoscopic weight loss management. Obes Surg 2015; 25:2263–2267.

23 Machytka E, Klvana P, Kornbluth A, Peikin S, Mathus-Vliegen LE, Gostout C, *et al.* Adjustable intragastric balloons: a 12-month pilot trial in endoscopic weight loss management. Obes Surg 2011; 21:1499–1507.

24 Brooks J, Srivastava ED, Mathus-Vliegen EM. One-year adjustable intragastric balloons: results in 73 consecutive patients in the UK. Obes Surg 2014; 24:813–819.

25 Gaggiotti G, Tack J, Garrido AB, Palau M, Cappelluti G, Di Matteo F. Adjustable totally implantable intragastric prosthesis (ATIIP)-Endogast for treatment of morbid obesity: one-year follow-up of a multicenter prospective clinical survey. Obes Surg 2007; 17:949–956.

26 Mion F, Ibrahim M, Marjoux S, Ponchon T, Dugardeyn S, Roman S, Deviere J. Swallowable Obalon® gastric balloons as an aid for weight loss: a pilot feasibility study. Obes Surg 2013; 23:730–733.

27 Bužga M, Evžen M, Pavel K, Tomáš K, Vladislava Z, Pavel Z, Švagera Z. Effects of the intragastric balloon MedSil® on weight loss, fat tissue, lipid metabolism, and hormones involved in energy balance. Obes Surg 2014; 24:909–915.

28 Ponce J, Woodman G, Swain J, Wilson E, English W, Ikramuddin S, *et al.* The REDUCE pivotal trial: a prospective, randomized controlled pivotal trial of a dual intragastric balloon for the treatment of obesity. Surg Obes Relat Dis 2015; 11:874–881.

29 Abu Dayyeh BK, Edmundowicz SA, Jonnalagadda S, Kumar N, Larsen M, Sullivan S, *et al.* Endoscopic bariatric therapies. Gastrointest Endosc 2015; 81:1073–1086.

30 Genco A, López-Nava G, Wahlen C, Maselli R, Cipriano M, Sanchez MM, *et al.* Multi-centre European experience with intragastric balloon in overweight populations: 13 years of experience. Obes Surg 2013; 23:515–521.