Outcomes of intragastric adjustable balloon (SPATZ) in the management of obesity: preliminary results

Moharam Abdelsamie

Department of General Surgery, Faculty of Medicine, Menoufia University, Menoufia, Egypt

Correspondence to Moharam Abdelsamie, MD, Department of General Surgery, Faculty of Medicine, Menoufia University, Menoufia, 32951, Egypt. Mob: 00971585824470; fax: 0482317508; e-mail: m.abdelsamie76@yahoo.co.uk

Received: 1 November 2020
Revised: 25 November 2020
Accepted: 28 November 2020
Published: 18 May 2021

The Egyptian Journal of Surgery 2021, 40:272–277

Introduction
Obesity has high incidence and prevalence all over the world. It is a major and serious problem that is associated with different comorbidities, affecting the lifestyle of obese patients and disease control. Different therapeutic options are encountered in the management of obese patients in an effective manner. Intragastric balloon is one of the minimal invasive procedures with accepted outcomes and results. This procedure became widely used and preferred on patient selection basis, and this encouraged different companies in the manufacturing of different types of balloon ranging from 6 to 12 months of intragastric duration.
Patients and methods
In a period of time from March 2018 to September 2019, 117 obese patients were managed by insertion of adjustable intragastric balloon (SPATZ) of 12-month duration of intragastric stay. The patients were observed for outcomes in terms of tolerability, efficacy in weight loss, and adverse effects such as nausea, vomiting, hematemesis, gastric ulceration, rupture, and intestinal obstruction.
Results
Overall, 101/117 patients tolerated this adjustable balloon for 1 year. The preoperative BMI mean was 38.9±7.8 and decreased to 31.6±2.6 after 1 year duration of insertion. Follow-up for further 6 months after balloon removal showed BMI was noticed to be slightly elevated to 33.5±3.5. Gastric ulceration was noticed in nine patients within the first 3 months of insertion. A total of 16 patients did not complete follow-up for 12 months or more.
Conclusion
Intragastric adjustable SPATZ balloon is a good minimal invasive procedure for weight loss, with minimal and acceptable adverse effects. Slight weight regain was noticed within the following 6 months after balloon removal in less than 30% of patients, and acceptable satisfactory results were achieved in more than 65% of patients (patient satisfaction).

Keywords:
balloon, BMI, endoscopic, obesity, SPATZ, weight loss

Egyptian J Surgery 40:272–277

1110-1121

Introduction

Obesity is a major health problem all over the world, with high incidence among different age groups, and is associated with many comorbidities such as diabetes, fatty liver disease, hypertension, heart disease, cerebrovascular disease, and metabolic syndrome [1].

Obesity management is a complex process. Different therapeutic options are used in the management of obesity, including conservative, such as diet, drugs, regimen, exercise, or lifestyle changes, or nonconservative, such as minimal invasive endoscopic and other surgical procedures [2,3].

Surgical intervention for obesity is one of the best therapeutic modalities with satisfactory long-term weight loss [4].

Despite the clear benefits of bariatric surgery, there are some pitfalls. Importantly, bariatric surgery is associated with significant morbidity and substantial costs [5].

In addition, bariatric surgery is not available to patients with a BMI less than 35 kg/m^2 even with clinically significant comorbidities. Current research is focused on the development of alternative methods of obesity treatment that are less invasive, more cost-effective, and associated with a lower operative risk. Such methods should also be efficacious, durable, repeatable, reversible, and safe [6].

Endo-luminal interventions performed entirely through the gastrointestinal tract, using flexible endoscopy, offer the potential for ambulatory weight loss procedures that may be safer and more cost-effective than current laparoscopic approaches [7].

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 [8].

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 [9].

Patients and methods

This prospective study was conducted on 117 patients subjected to IGB insertion as a treatment option for management of obesity with the time period from March 2018 to September 2019. The study was conducted in the General Surgery Department, Menoufia University, Egypt, and ACDS Medical Center – Abu Dhabi, under one surgeon. Complete history taking was done, with complete physical examination and investigations, emphasizing on duration of obesity, dietary habits, previous trials of weight loss, comorbidities, endocrinal dysfunction, and hormonal profile assessment.

A total of 29 patients were subjected to IGB insertion in Menoufia University Hospitals within the first 8 months of study from March 2018 to October 2018, whereas in the period from November 2018 to June 2019, 71 patients were subjected to IGB in ACDS – Abu Dhabi. In the last 3 months of our study from July 2019 to September 2019, only 17 patients were subjected to IGB in ACDS – Abu Dhabi and 11 of them did not complete their follow-up. This may be because they were referred to us from other emirates and cities. So, nearly all patients (95/101) completed about 15 months or more as a follow-up after balloon removal and six patients completed 1 year after balloon removal.

Inclusion criteria

Patients aged above 18 years old with BMI above 30 kg/m^2, as well as documented history of failed conservative dietary and lifestyle regimen were included. Reported consultations from endocrinologist, dietitian, and psychologist were done before the process of IGB insertion, and free initial endoscopy is one of the inclusion criteria.

Exclusion criteria

Previous gastric surgery for bariatric or nonbariatric causes, peptic ulceration, severe chronic gastritis, gastric and esophageal varices, large hiatus hernia (>5 cm), drug abuse, alcoholism, bleeding tendency, and discontinued follow-up of less than 12 months postoperatively were the exclusion criteria.

Consents

All consents were taken for each patient – approved by our facilities and our institution ethical committee – after complete discussion with him/her all expected side effects and complications, either minor, such as nausea and vomiting, or major, such as intestinal obstruction, gastric ulceration, and failure to lose weight.

Procedure and technique

Under deep anesthesia with propofol infusion, an initial diagnostic endoscopy was performed as a part of the procedure of balloon insertion to rule out gastric causes of IGB contraindications such as severe gastritis, large hiatus hernia, gastric varices, and gastric ulceration. SPATZ balloon was dislodged from covering plastic tube and adjusted to the side wall of the flexible endoscope and fixed to the side part of the tip of the endoscope by rolling the plastic cover over both the endoscope and the adjacent balloon. Intravenous infusion line was attached to the valve of the balloon from one side, and the other side of the intravenous infusion line was fixed to triple-way device and saline syringe with methylene blue. Lubricant was used to facilitate entry of the endoscope with side attachment of the balloon. The endoscope was slowly introduced under complete vision to the stomach. J maneuver of the endoscope was done to see the whole balloon inside the stomach. Methylene blue saline infusion was initiated after confirmation of totally IGB. At volume of balloon filling saline of 400 ml, the balloon was usually dislodged from the endoscope. Extraction of the endoscope was done, with continued further filling of the balloon by saline mixed with methylene blue (5 ml methylene blue: 500 ml saline) as needed (range of filling, 400–700 ml).

The volume of the balloon was adjusted at 600 ml for all patients as the preferred volume for our technique with readjustment according to patient tolerability or failure of weight loss.

Disconnection of the balloon valve from the infusion line was done after complete balloon filling. Gentle manual introduction of the stretched balloon valve and follow it by endoscope to be sure that it was settled inside the stomach. Further revision by endoscopic view to finalize the procedure without any structure

injury. We discussed with each patient liability of readjustment of volume of balloon may be required if there is no tolerability in first 2 weeks of insertion or no further weight loss during regular follow-up.

Postoperative follow-up was done for up to 6 h inside the facility with infusion of normal saline, proton pump inhibitors (PPI), antiemetic, and antispasmodic (saline +pantoprazole 40 mg+ondansetron 8 mg+hyoscine amp.). Patients were discharged 6–8 h after balloon insertion. This infusion mixture was usually advised for the first 3 days postoperative once daily. Daily communication with the patients was done for early detection of any serious or nontolerable adverse effects of balloon such as repeated vomiting, severe agonizing continued hurt burn, hematemesis, and melena. Continued follow-up for all patients was done, with recorded measurements of BMI and percentage of excess weight loss (%EWL) at 6, 12, and 18 months postoperatively. Follow-up of comorbidities such as DM, osteoarthritis, and hypertension was done within the study period and follow-up period.

All patients were advised to continue on medical treatment including proton pump inhibitor (Nexium 40 mg) and antispasmodic drugs (buscopan compositum). Antiemetics were prescribed for the first 2 weeks and discontinued if there is no nausea or vomiting.

Statistical analysis

The statistical package for the social sciences (SPSS), version 20, software (SPSS Inc., Chicago, Illinois, USA) was used in statistical analysis of our retrospective study.

Quantitative variables such as central tendency of age, BMI, and weight were measured by mean and median, whereas dispersion of these quantitative variables was measured by SD, minimum, and maximum measures.

Results

Our study included 117 patients with a preoperative diagnosis of morbid obesity, and they were subjected to IGB and fulfilled all required criteria of the study. Overall, 16 (13%) of 117 patients were excluded from the study because they did not complete their follow-ups for 12 months or more. Overall, 11% of the studied patients (11/101) did not tolerate the balloon and required to remove it within 2 months of insertion.

A total of 101 patients (101/108) were included in our study as they fulfilled all inclusion criteria (Table 1). Male to female ratio was 12 : 89, with average age from 19 to 53 years, and median±SD was 36±17.

Of 101 patients, 46 (46%) were exposed to balloon readjustment within the first 6 months of first balloon insertion. Moreover, 39 (39/101) (39%) patients needed to increase the volume to more than 600 ml to obtain satisfactory weight loss, whereas seven (7%) patients needed to decrease the intraballoon volume to be tolerated, and it was successful in all seven patients, with no detectable gastric ulceration among them.

We measured BMI preoperatively and at 6, 12, and 18 months postoperatively. The range of preoperative BMI was 30.5–49.8 kg/m^2, with a mean of 38.9±7.8 kg/m^2. At 6 months, BMI decreased to 30–41 kg/m^2, with a mean of 34.2±3.8 kg/m^2. Further weight loss was noticed at 12 months of follow-up, with range of BMI from 28 to 34 kg/m^2 and the mean was 31.6 ±2.6 kg/m^2.

At 18 months of follow-up, a slight insignificant weight gain and elevated BMI parameters were noticed within range from 29 to 39.5 kg/m^2, and its mean was 33.5±3.5 kg/m^2 (Table 2).

There was a significant decrease in %EWL from 0 to 48%, with a mean of 35±11%, at 6 months of balloon insertion and from 0 to 31%, with a mean of 19±12%, at 12 months, but after 6 months of balloon removal, there were variant measures for %EWL, as the range was recorded as −11 to 21%, with a mean of 12±9 (Table 2).

In this study, a significant decrease in the percentage of excess BMI loss was noticed from 0 to 52%, with a mean of 32±13%, at 12 months, to −11 to 39%, with a mean of 23±12%, at 18 months (Table 2).

Of 101 patients, 11 (11%) patients could not tolerate the balloon and asked to remove it in the first 2 months after procedure owing to intractable persistent pain with persistent vomiting not relieved by medication.

Table 1 Patient characteristics and comorbidities

		n/N (%) (101)
Age	Average	19–53
	Mean±SD	36±17
Sex	Female	89 (89)
	Male	12 (12)
Hypertensive patients	29/101	29
Diabetic patients	16/101	16
Osteoarthritic patients	13/101	13

Table 2 Studied parameters preoperatively and at postoperative follow-ups of 6 and 12 months

Parameters	Preoperative	Postoperative		*P* value
		At 6 months	At 12 months	
Weight				
Average	89–143	76–129	69–115	
Mean±SD	102+14	85+12	73+12	
BMI				<0.0001
Average	30.5–49	30–41	28–34	
Mean±SD	38.9±7.8	34.2±3.8	31.6±2.6	
%EWL	–			<0.0001
Average		0–48%	0–31%	
Mean±SD		35±11	19±12	
% EBMIL	–			
Average		0–58%	0–52%	
Mean±SD		31±12	32±13%	

EBMIL, excess BMI loss; EWL, excess weight loss.

Table 3 Different adverse effects of intragastric balloon in our study

Adverse effects	*n*/*N* (%)
Nausea	49/101 (49)
Vomiting	31/101 (31)
Abdominal pain	64/101 (64)
Gastric ulcer	9/101 (9)
Spontaneous balloon rupture	3/101 (3)
Balloon intolerability and removal	11/101 (11)
Failure in weight loss	16/101 (16)
Pancreatitis	1/101 (1)
Hospital admission	3/101 (3)

Table 4 Patient satisfaction

Degree of patient satisfaction	*n*/*N* (%) (101)
Excellent	10/101 (13)
Happy with the result	54/101 (67)
Satisfied	8/101 (11)
Not satisfied	29/101 (29)

After balloon insertion in our study, nausea was recorded in 49% (49/101) of cases, whereas vomiting was experienced detected in 31% (31/101). Abdominal pain was encountered in 64/101 (64%) patients. Failure of weight loss was detected in 16 (16%) patients.

Overall, three patients noticed no weight loss after a period of time, with early detection of bluish discoloration of urine, and asked for medical advice. Spontaneous deflation of the balloon was suspected. Ultrasound was done and confirmed deflated balloon, and immediate endoscopic removal of the deflated balloon was required. Gastric ulcer was found in nine cases (of the 11 patients needed to balloon removal), with no intestinal obstruction nor mortality detected (Tables 3 and 4).

Discussion

IGBs are usually static technology except for newly developed adjustable ones. It is difficult to choose the balloon volume in fixed manner, but it is done at the time of implantation, as there no fixed threshold for nausea, vomiting, or abdominal pain. These adverse effects are usually not measurable or predictable. Different studies detected the loss of IGBs in the first 3 months [10–12], which is considered a major drawback.

Genco *et al.* [13] reported further drop in BMI of 3.9 points after second balloon insertion. In these static IGB, each case, in the study by Genco and his colleagues, needed two balloons and four endoscopic procedures.

An adjustable balloon, such as SPATZ balloon, offers dynamic bariatric therapy and needs only one balloon and three endoscopic procedures if the patient status required balloon adjustment.

Our study has shown the safety and efficacy of an adjustable SPATZ balloon. Volume additions succeeded to overcome weight loss plateau in more than 80% of cases (33/39 needed to increased IGB volume).

Successful management of intolerance was obtained by downward IGB volume adjustment in seven (7%) cases. These patients regained their comfort and tolerated the balloon and weight loss obtained after adjustment.

Regarding risk of intestinal obstruction after spontaneous balloon deflation, in our study, we detected three cases of spontaneous balloon deflation but without intestinal obstruction, whereas 19 incidents with intestinal obstruction were reported in the largest BIB series [13].

Two critical reviews of IGBs have been reported in the literature, with similar overall positive results [14,15]. IGBs are an established successful weight loss therapy with 5000 patients reported in the literature over the last 17 years [16–20]. Only a handful of studies report negative or equivocal results [21–23].

Balloon removal was reported in 4.2% in 13 of the reviewed articles, and 6.7% in other reviews [24]. However, in our study, balloon removal was encountered in 11% of cases. This may be owing to developed gastric ulceration, high pain threshold in these patients, missed *Helicobacter pylori* infection, and incomplete routine use of PPIs after balloon insertion.

Each patient has his adequate, comfortable balloon volume that is tolerated by his/her stomach. The adjustable balloon offers this value, and so, we can start with small volume with expected reendoscopic adjustment of the balloon if needed. In our study, we adjusted the balloon in 46 patients, in 28 of them to increase the volume. Of these 46 patients, 30 were among the first 50 patients in our beginnings and 16 patients were among the next 50 patients of our study. Readjustment is a good offer introduced by the adjustable balloon.

The 2008 Mathus-Vliegen [14] review reported a 3.3–8% balloon deflation rate within 6 months. However, in our study, spontaneous balloon deflation was noted in 3% with no harmful effects as they were managed early by endoscopic extraction of deflated balloon. The SPATZ balloon 'anchor' enhances endoscopic retrieval of a deflated balloon and will diminish the risk of bowel obstruction [24].

There is no safeguard for preventing migration – other than methylene blue, causing a change in urine color. The SPATZ balloon is the first IGB to attempt a mechanical means to prevent balloon migration.

Weight loss maintenance after balloon extraction has been reported with mixed results [24–26]. One year after IGB removal, patients regained 75% (25), 41% (24), and 28% (25) of their lost weight. However, in our study, weight regain within 6 months after balloon removal was insignificant and reported in 23% of patients.In our study, gastric ulceration was detected in nine (9%) patients, which was similar to the results of the study by Kumar *et al.* [27], which was 10%. Spontaneous IGB deflation was reported in 3% in our study, which was less than those reported in Yab Kannan and Nutt [28], which was 5% with unclear definitive causes.

IGB programs stress continued follow-up for behavior modification, which has limited success in the postextraction period. Longer implantation times afford longer behavior modification times, which can presumably reap better weight loss maintenance results.

On the contrary, some studies revealed little benefit of IGB in weight loss and noted weight regain after balloon removal such as in the study by Kim *et al.* [29] and Giardiello *et al.* [30]. Many studies have reported weight regain after short period of time, such as in the study by Genco *et al.* [31].

Conclusion

The IGB offers an interventional weight loss alternative to patients who do not want, or who are not fit for bariatric surgery or obese patients not amenable to bariatric surgery with failed conservative treatment. The more overweight individuals have better outcomes. Further research is required to identify factors associated with adverse events following IGB insertion.

In our review, the common complications of IGBs were nausea, vomiting, and discomfort, especially during their insertion and removal; however, the long-term weight loss benefits are yet to be proven. Further studies focusing on reducing the adverse effects of IGBs and enhancing the long-term weight loss benefits of IGBs and outcomes of repeated IGB insertion should be conducted.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1 Choi SJ, Choi HS. Various intragastric balloons under clinical investigation. Clin Endosc 2018; 51:407–415.

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 Ng M, Fleming T, Robinson M, Thomson B, Graetz N, Margono C. Global, regional, and national prevalence of overweight and obesity in children and

adults during a systematic analysis for the global burden of disease study 2013. Lancet 2014; 384:766–781.

6 Ashrafian H, Monnich M, Stephen T, Braby BH, Smellie J. Intragastric balloon outcomes in super-obesity: a 16-year city center hospital series. Surg Obes Relat Dis 2018; 14:1691–1699.

7 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.

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

9 Buchwald H, Oien DM. Metabolic/bariatric surgery worldwide 2011. Obes Surg 2013; 23:427–436.

10 Bonazzi P, Petrelli MD, Lorenzini I, Peruzzi E, Nicolai A, Galeazzi R. Gastric emptying and intragastric balloon in obese patients. Eur Rev Med Pharmacol Sci 2005; 9(5 Suppl 1):15–21.

11 Alfalah H, Philippe B, Ghazal F, Jany T, Arnalsteen L, Romon M. Intragastric balloon for preoperative weight reduction in candidates for laparoscopic gastric bypass with massive obesity. Obes Surg 2006; 16:147–150.

12 Mui WL, Ng EK, Tsung BY, Lam CH, Yung MY. Impact on obesity-related illnesses and quality of life following intragastric balloon. Obes Surg 2010; 20:1128–1132.

13 Genco A, Cipriano M, Bacci V, Maselli R, Paone E, Lorenzo M. Intragastric balloon followed by diet vs. intragastric balloon followed by another balloon: a prospective study on 100 patients. Obes Surg 2010; 20:1496–1500.

14 Mathus-Vliegen EM. Intragastric balloon treatment for obesity: what does it really offer? Dig Dis 2008; 26:40–44.

15 Imaz I, Martínez-Cervell C, Alvarez EE, Sendra-Gutiérrez J, González-Enríquez J. Safety and effectiveness of the intragastric balloon for obesity. A meta-analysis. Obes Surg 2008; 18:841–846.

16 Doldi SB, Micheletto G, Di Prisco F. IGB in obese patients. Obes Surg 2010; 10:578–581.

17 Al-Momen A, El-Mogy I. IGB for obesity; a retrospective evaluation of tolerance and efficacy. Obes Surg 2005; 15:101–105.

18 Herve J, Wahlen CH, Schaeken A, Dallemagne B, Dewandre JM, Markiewicz S. What becomes of patients 1 year after the IGB has been removed? Obes Surg 2005; 15:864–870.

19 Melissas J, Mouzas J, Filis D, Daskalakis M, Matrella E, Papadakis J. The IGB—smoothing the path to bariatric surgery. Obes Surg 2006; 16:897–902.

20 Busetto L, Segato G, De Luca M, Bortolozzi E, MacCari T, Magon A. Preoperative weight loss by IGB in super obese patients treated with laparoscopic gastricbanding: a case control study. Obes Surg 2004; 14:671–676.

21 Martinez-Brocca MA, Belda O, Parejo J, Del Valle A, Pereira JL, Garcia-Pesquera F. Intragastric balloon-induced satiety is not mediated by modification in fasting or postprandial plasma ghrelin levels in morbid obesity. Obes Surg 2007; 17:649–657.

22 Ganesh R, Rao AD, Baladas HG, Leese T. The Bioenteric® Intragastric Balloon(BIB®) as a treatment for obesity: poor results in Asian patients. Singapore Med J 2007; 48:227.

23 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.

24 Machytka E, Klvana P, Kornbluth A, Peikin S, Lisbeth EM, Gostout C. Adjustable intragastric balloons: a 12-month pilot trialin endoscopic weight loss management. Obes Surg 2011; 21:1499–1507.

25 Segula D. Complications of obesity in adults: a short review of the literature. Malawi Med J 2014; 26:20–24.

26 Al Kahtani K, Khan MQ, Helmy A, Al Ashgar H, Rezeig M, Al Quaiz M. Bio-enteric intragastric balloon in obese patients: a retrospective analysisof King Faisal Specialist Hospital experience. Obes Surg 2010; 20:1219–1226.

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

28 Yap Kannan R, Nutt M. Are intra-gastric adjustable balloon system safe? A case series. Int J Surg Case Rep 2013; 4:936–938.

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

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

31 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.