SURGERY FOR OBESITY AND RELATED DISEASES

ELSEVIER

Surgery for Obesity and Related Diseases xxx (2018) xxx–xxx

Original article

Intragastric balloon outcomes in super-obesity: a 16-year city center hospital series

Q1 Hutan Ashrafian, B.Sc.(Hons.) M.R.C.S., M.B.A., Ph.D.*, Maren Monich, B.Sc., M.B.Ch.B., Thomas Stephen Braby, B.Eng.(Hons.), M.B.B.Ch., James Smellie, M.D., F.R.C.S., Gianluca Bonanomi, M.D., F.R.C.S., Evangelos Efthimiou, M.Sc., F.R.C.S.

Department of Bariatric and Metabolic Surgery, Chelsea and Westminster Hospital, Chelsea, London

Received 17 November 2017; received in revised form 28 June 2018; accepted 9 July 2018; Available online xxx

Abstract

Background: Intragastric balloons represent an endoscopic therapy aimed at achieving weight loss by mechanical induction of satiety. Their exact role within the bariatric armamentarium remains uncertain.

Objective: Our study aimed to evaluate the use of intragastric balloon therapy alone and before definite bariatric surgery over a 16-year period.

Setting: A large city academic bariatric center for super-obese patients.

Methods: Between January 2000 and February 2016, 207 patients underwent ORBERA intragastric balloon placement at esophagogastroduodenoscopy. Four surgeons performed the procedures, and data were entered prospectively into a dedicated bariatric database. Patients' weight loss data were measured through body mass index (BMI) and excess weight loss and recorded at each clinic review for up to 5 years (60 mo). Treatment arms included intragastric balloon alone with lifestyle therapy or intragastric balloon and definitive bariatric surgery: gastric banding, sleeve gastrectomy, or Roux-en-Y gastric bypass. An additional treatment arm of analysis included the overall results from intragastric balloon followed by stapled procedure.

Results: One hundred twenty-nine female and 78 male patients had a mean age of 44.5 (±11.3) years and a mean BMI of 57.3 (±9.7) kg/m^2. Fifty-eight percent of patients suffered from type 2 diabetes. Time from initial or first balloon insertion to definitive surgical therapy ranged between 9 and 13 months. Seventy-six patients had intragastric balloon alone, and 131 had intragastric balloon followed by definitive procedure. At 60 months postoperatively the intragastric balloon alone with lifestyle changes demonstrated an excess weight loss of 9.04% and BMI drop of 3.8; intragastric balloon with gastric banding demonstrated an excess weight loss of 32.9% and BMI drop of 8.9. Intragastric balloon and definitive stapled procedure demonstrated a BMI drop of 17.6 and an excess weight loss of 52.8%. Overall, there were 3 deaths (1.4%), 2 within 10 days due to acute gastric perforation secondary to vomiting and 1 cardiac arrest at 4 weeks postoperatively.

*Correspondence: Hutan Ashrafian, The Department of Bariatric and Metabolic Surgery, Chelsea and Westminster Hospital, 369 Fulham Rd, Chelsea, London SW10 9 NH.

E-mail address: h.ashrafian@imperial.ac.uk (H. Ashrafian).

https://doi.org/10.1016/j.soard.2018.07.010

Conclusion: Intragastric balloons can offer effective weight loss in selected super-obese patients within a dedicated bariatric center offering multidisciplinary support. Balloon insertion alone offers only short-term weight loss; however, when combined with definite bariatric surgical approaches, durable weight loss outcomes can be achieved. A strategy of early and continual vigilance for side effects and a low threshold for removal should be implemented. Surgeon and unit experience with intragastric balloons can contribute to "kick starting" successful weight loss as a bridge to definitive therapy in an established bariatric surgical pathway. (Surg Obes Relat Dis 2018;xxx:xxx–xxx.)

Keywords: Bariatric; Intragastric; Balloon; Weight loss; Endoscopic

As global rates of obesity and its associated metabolic dysfunction have risen [1], there have been several surgical approaches designed to decrease obesity in light of the limitations with diet and lifestyle therapies. While bariatric surgery demonstrates very consistent rates of obesity decrease and control, the perceived degree of operative trauma associated with these operations and the significant anesthetic and operative risk associated with super-obese (SO) patients has led to alternative approaches to manage dietary caloric intake. One approach based on an endoscopic insertion platform includes intragastric balloons (IGB) designed to induce persistent mechanical satiety in obese patients.

A collaborative analysis showed that a raised body mass index (BMI) is associated with an average mortality increase of roughly 30% per 5 kg/m^2 in BMIs >25 kg/m^2 [2,3]. Supported by a wealth of evidence including randomized control trials and observational studies, bariatric surgery has been in the U.S. clinical guidelines since 1991 [4]. Surgery has been shown to be the only effective long-term approach to obesity and carries additional benefits, such as reduction in mortality and co-morbidities including sleep apnea, cardiovascular risk factors, and diabetes [5–8]. However, there are significant risks involved with bariatric surgery [5], and there has therefore been interest in developing less invasive methods, such as endoscopic interventions, one of which is the IGB.

The first commercially available balloon was the Garren-Edwards gastric bubble. Made of polyurethane and filled with 200 to 220 mL of air, these were first put to use in the United States in 1985 [9]. However, they had significant adverse effects and disappointing weight loss results. They were therefore removed from the market [9,10]. New and improved devices have been developed since, with a variety of balloons currently available, each consisting of 1 or 2 silicon-based spheres filled with air, helium, or fluid. Most are endoscopically placed; however, newer models can be swallowed with an attached catheter. Balloons are in regular use throughout Europe; in contrast, the U.S. Food and Drug Administration only approved the first new balloon in July 2015 [11]. So far in the United States, 3 balloons have been approved: ReShape Integrated Dual Balloon System, Orbera Intragastric Balloon System, and the Obalon balloon system [12].

IGBs are relatively new tools for U.S. bariatric teams, and there is a need for further data to evaluate their effectiveness and determine which role they fulfill within bariatric pathways. Meta-analyses show that the IGBs approved in the United States meet minimum requirements for incorporation into clinical practice [13]; however, there is a lack of data looking at the long-term weight loss post-IGB removal [14]. IGBs have been shown to produce significant weight loss of between 34% and 50% excess weight loss (EWL) initially [12]. However, the results are short lasting, with evidence of weight gain postremoval [10]. Results 12 months after removing the Orbera balloon have been between 14.2% and 27.2% EWL [10]. The morbidities noted are flatulence, abdominal fullness, abdominal pain, abdominal discomfort, and gastric ulceration [15].

IGB patients in the United Kingdom in our central city (London) bariatric unit's pathway are of the SO category and classified with a BMI >50 kg/m^2. These patients suffer from complex health issues, and bariatric procedures in this population are often unsatisfactory [16] and accompanied by increased morbidity and mortality [17–19]. A retrospective analysis from 1 bariatric center identified that in a 5-year period the SO population had 4 times the number of complications experienced in the obese group, and 80% of all deaths related to bariatric surgery occurred in the SO group [20]. In addition to the increased morbidity and mortality, SO patients also stay longer in hospital, have increased readmission rates, and require longer operation times [21,22]; they therefore accrue increased costs.

The increased risks associated with SO patients are related to greater technical difficulty in surgery, increased prevalence of co-morbidities, and limited mobility [20] of patients during the immediate recovery period. Due to these risks, most centers require a preoperative weight loss of approximately 10%, which has been shown to reduce risks [22] and reduce postoperative complications [23]. Weight loss has also been shown to be associated with a reduction in liver size [24], which reduces surgical complexity [25], and shorter operating times [26,27], shorter hospital stays [28], and less deviation from planned surgery [29]. Methods to achieve this goal include diet and exercise, pharmacologic interventions, hospitalization with calorie restriction, and the use of endoscopic bariatric procedures, such as the insertion of IGBs. IGBs have been shown to effectively reduce liver size in SO patients [30], and a recent systematic review concluded that they were more effective than low-calorie diets [31]. Therefore, IGBs appear to be a beneficial addition to a bariatric pathway by reducing the need for invasive operations at SO weight categories by presenting them at lower, more manageable levels of obesity (morbid obesity and lower), thereby reducing operative risks.

The purpose of this study was to describe our results using IGBs alone and before definite weight loss surgery in a large city academic bariatric center.

Methods

Intragastric balloon technique and follow-up

After the bariatric multidisciplinary decision to perform IGB therapy, informed consent was obtained from patients. General anesthesia was administered, and complete diagnostic gastroduodenoscopy was performed assessing the esophagus, stomach, and duodenum. If no contraindications to balloon insertion were present (e.g., macroscopically visible gastrointestinal pathology or large hiatus hernia), the endoscope was removed and, with anesthetic guidance, a prerolled silicone balloon (ORBERA; Apollo Endosurgery, Inc.) was inserted into the stomach. The endoscope was then reintroduced; under direct observation, the balloon placed at the fundus was filled with saline mixed with 2% methylene blue (500 mL for an initial balloon and 700 mL for a second balloon). Patients were admitted for monitoring of tolerance to the balloon, initial intravenous antiemetics, and proton pump inhibitors. If patients recovered well, they would be discharged with view to early clinic review within a week and prescription of a liquid diet for 2 weeks after insertion. Specific post-IGB medication prescribed was based on our institutional protocol and consisted of an antihistamine (cyclizine), an antimuscarinic (hyoscine), a dopamine receptor antagonist (metoclopramide), a 5 HT3 receptor antagonist (ondansetron), and, when necessary, an NK1 receptor antagonist (Aprepitant). Urgent readmission and balloon explantation was performed if there were any signs of persistent nausea, fluid intolerance, uncontrolled vomiting, or risk of perforation. Six months after insertion, the balloon was removed. Based on extent of weight loss and progress, either a second balloon was inserted to achieve further weight loss or, if adequate weight loss was achieved (minimum 20% EWL), patients found by the MDT to be appropriate and willing would undergo definitive bariatric surgery (gastric banding, sleeve gastrectomy, or Roux-en-Y gastric bypass). After initial follow-up within the first week of insertion, patients would have a baseline monthly follow-up. If necessary, more frequent and ad hoc follow-up would be instigated based on regular communication with the patient and clinical status.

Methods and statistical analysis

Patient demographic characteristics, weight indices, clinical status, and metabolic scores were entered prospectively into an institutional bariatric database setup at the millennium and completed for review of all patients over a 16-year period. Institutional review board approval for data review and analysis was obtained. The mean and standard error of BMI and the EWL of patients was calculated at baseline and at sequential monthly time points after insertion of IGBs for up to 60 months (5 yr) after initial insertion. As patients did not attend follow-up assessments at exactly equivalent time points after insertion of IGBs, overall patient results at set postinsertion time points were imputed and calculated using polynomial regression. All analyses were performed in the statistical package R (R Core Team, Vienna, Austria). Patient weight loss results were tabulated and presented graphically. Analysis included the results of IGB alone with lifestyle therapy or IGB and definitive bariatric surgery (gastric banding, sleeve gastrectomy, or Roux-en-Y gastric bypass). An additional treatment arm of analysis included the overall results from IGB followed by a definitive stapled procedure (either sleeve gastrectomy or Roux-en-Y gastric bypass) as this would allow comparison of results with gastric banding due to the differential mechanisms associated with weight loss between the 2 categories of procedures. A subgroup of patients required 2 balloons before definitive surgery; however, due to the limited number of patients in this group, it was not possible to perform a statistical comparison of those who had 1 versus 2 balloon insertions before surgery.

Results

Patient characteristics

Two hundred seven patients were included in the study, of whom 76 (31%) underwent IGB placement only, 51 (21%) had IGB followed by gastric band, 53 (22%) had IGB followed by gastric bypass surgery, and 27 (11%) had IGB followed by gastric sleeve surgery. The choice of intervention was based on a discussion in a dedicated bariatric MDT as well as patient preference. Although the aim of the insertion of gastric balloons was to ultimately prepare patients for definitive bariatric surgery, in certain cases the decision was made not to proceed with further intervention. This depended on clinical status and

Table 1
Demographic characteristics of patients included in study, according to surgical procedure Q9

	Total	Balloon only	Band	Bypass	Sleeve
Number of patients					
n (%)	207 (100)	76 (37)	51 (25)	53 (26)	27 (13)
Age					
Mean (SD)	44.9 (±11.6)	44.7 (±13.0)	45.8 (±10.8)	42.6 (±10.7)	48.2 (±10.0)
Sex					
Male	78 (38%)	32 (42%)	20 (39%)	17 (32%)	9 (33%)
Female	129 (62%)	44 (58%)	31 (61%)	36 (68%)	18 (67%)
Race*					
White	142 (69%)	50 (66%)	40 (78%)	38 (72%)	14 (52%)
Black	18 (9%)	5 (7%)	3 (6%)	6 (11%)	4 (15%)
South Asian	10 (5%)	4 (5%)	2 (4%)	3 (6%)	1 (4%)
Mixed/other	20 (10%)	9 (12%)	4 (8%)	4 (8%)	3 (11%)
Not stated	17 (7%)	8 (11%)	2 (4%)	2 (4%)	5 (19%)
T2D					
None	127 (61%)	45 (59%)	36 (71%)	30 (57%)	16 (59%)
Impaired glucose tolerance	10 (5%)	2 (3%)	1 (2%)	5 (9%)	2 (7%)
Oral treatment	48 (23%)	20 (26%)	8 (16%)	12 (23%)	8 (30%)
Insulin	13 (6%)	5 (7%)	5 (10%)	3 (6%)	0 (0%)
Missing	9 (4%)	4 (5%)	1 (2%)	3 (6%)	1 (4%)
Initial weight, kg					
Median (IQR)	161.4 (143.0–178.4)	163.5 (141.2–184.7)	150.6 (139.9–169.2)	161.4 (148.0–173.0)	175.8 (164.5–193.2)
Initial BMI, kg/m², mean (SD)	57.5 (±9.8)	57.7 (±11.5)	53.9 (±6.9)	57.3 (±8.1)	64.4 (±9.3)
Time before next procedure, mo, median (IQR)	11.5 (8.1–16.1)	N/A	11.1 (8.0–17.1)	13.1 (9.0–16.8)	9.5 (7.5–12.8)
Follow-up					
Mean follow-up time, mo	44.3 (±37.1)	20.5 (±20.7)	69.6 (±37.2)	57.9 (±37.7)	36.7 (±28.5)

SD = standard deviation; T2D = type 2 diabetes; IQR = interquartile range; BMI = body mass index; N/A = .
* Self-reported.

inappropriate weight loss with balloon, as determined by the MDT.

Mean age was 44.5 (standard deviation [SD] ±11.3) years, ranging from a mean of 42.6 (SD ±10.7) for the bypass group to 48.2 (SD ±10.0) for the sleeve group. The majority of patients were female (64%). Most patients (68%) were white.

Starting weight median was 161.4 kg (interquartile range [IQR], 143.0–178.2), with a mean BMI of 57.3 (SD ±9.7) kg/m^2.

Follow-up was performed at regular intervals, depending on the protocol of the final surgery performed. Overall, there was a total of 2734 data points at which the patients were weighed. The mean follow-up time was 50.5 months (±40.1), ranging from a mean of 20.5 months for IGB alone to a mean of 69.6 months for those undergoing IGB followed by gastric band insertion.

For those patients (69%) in whom a second procedure was performed, the mean time from initial IGB insertion to conversion to second procedure was 11.1 months (IQR, 8.0–16.1). The second procedure was performed at a minimum of 3 weeks and maximum of 2 months postremoval of IGB. In the interval, the patients were put on a liver shrinkage diet. Further demographic characteristics of the patient populations are shown in Table 1.

Weight loss

We assessed weight loss according to decrease in BMI and EWL (in percent) in the following groups: IGB alone, IGB + gastric banding, IGB + sleeve gastrectomy, IGB + Roux-en-Y gastric bypass, and IGB + stapled procedures (either sleeve gastrectomy or Roux-en-Y gastric bypass). The choice was made to combine the analysis of the stapled procedures in a separate analysis arm due to their distinct metabolic effects. The weight loss measured at specific follow-up time points can be seen in Table 2.

Balloon only and lifestyle interventions

Thirty-one percent of patients were in the group that underwent balloon insertion combined with lifestyle intervention alone. Their EWL after 12 months was 17.6% (standard error ±1.8), and this was maintained at 24 months, with EWL of 17.2% (standard error ±2.1). However, follow-up >2 years showed some reduction in weight loss, with an EWL at 60 months of 9% only (Fig. 1).

Balloon and gastric banding

Fifty-one patients had balloon insertion and gastric banding. The band was inserted at a mean of 11.1 months

Table 2
Weight loss results according to decrease in body mass index (BMI) and excess weight loss

BMI decrease							
Follow-up, mo	2	6	12	18	24	36	60
Proportion of postoperative follow-up	98%	91%	83%	66%	61%	45%	30%
IGB + lifestyle	4.3	5.0	6.1	6.6	6.8	5.4	3.8
IGB + gastric banding	4.7	5.8	7.0	7.7	8.0	7.5	8.9
IGB + sleeve gastrectomy	5.4	8.1	12.6	18.1	22.2	20.1	14.1
IGB + Roux-en-Y gastric bypass	3.9	7.8	12.5	16.1	18.5	19.5	18.4
IGB + stapled procedure	4.1	8.0	13.0	16.8	19.2	19.7	17.6
Excess weight loss, %							
Follow-up, mo	2	6	12	18	24	36	60
IGB + lifestyle	14.2	14.5	17.6	17.9	17.2	12.0	9.0
IGB + gastric banding	16.2	19.4	22.9	25.2	26.2	25.4	32.9
IGB + sleeve gastrectomy	10.6	19.6	31.6	41.7	47.1	43.7	39.8
IGB + Roux-en-Y gastric bypass	11.2	22.1	35.9	46.6	53.8	58.4	56.0
IGB + stapled procedure	10.5	21.3	35.0	45.4	51.6	54.8	52.8

IGB = intragastric balloon.

after IGB insertion (IQR, 8.0–17.1). In this group weight loss at month 12 was 22.9% EWL. After 60 months this had increased even further to 32.9% EWL. This was equivalent to a change in BMI of −8.9 kg/m^2 (Fig. 1).

Balloon and sleeve gastrectomy

Twenty-seven patients had IGB insertion followed by sleeve gastrectomy. The definite surgical procedure was performed a mean of 9.5 (IQR, 7.5–12.8) months after initial IGB insertion. This cohort had lost a mean of 31.6% of excess weight after 12 months. At year 5, this number had increased to 39.8% EWL, with a peak at 36 months with mean EWL 43.7% (Fig. 1).

Balloon and Roux-en-Y gastric bypass

Fifty-three patients had IGB followed by Roux-en-Y gastric bypass. On average the bypass was performed 13.1 (IQR, 9.0–16.8) months after IGB insertion. At 12 months these patients had an average of 35.9% EWL. At 5 years this had increased to a mean of 56.0% EWL (Fig. 1).

Balloon and stapled procedures

Combining the 2 stapled procedures gives a total number of 80 patients. This cohort had a mean of 35.0% EWL at year 1 and 52.8% EWL at year 5 (Fig. 1).

Early explant rate

The early explant rate in this cohort of patients was 3.8%, with 8 explants within 14 days after insertion for the following reasons: (1) excess vomiting, (2) fluid intolerance, (3) coffee ground vomiting, and (4) persistent abdominal pain.

Mortality

The mortality rate in this cohort of patients was 1.4%, with a total of 3 deaths over 16 years. Two of these occurred within 10 days due to acute gastric perforation secondary to excess vomiting. One patient suffered cardiac arrest at 4 weeks postoperatively.

Discussion

Our results demonstrate the long-term weight loss efficacy of IGB when used as an initial weight loss trigger in the context of an established bariatric pathway with definitive bariatric procedures (such as Roux-en-Y gastric bypass and sleeve gastrectomy). While the application of IGBs before definite bariatric surgery is an accepted practice in some centers [32–34], our results further support this approach, with additional evidence demonstrating the durability of IGBs in SO as a bridge to definitive procedures through a stapled weight loss operation.

The weight loss effects of IGBs have been reported in previous studies with high variability in reported outcomes and differ considerably with the reported outcomes of stapled bariatric operations where there are more consistent long-term weight loss effects at 1 and 5 years [8]. This may be partly explained by the predominant retrospective reporting and the heterogeneity of patient demographic characteristics, co-morbidities, and initial BMIs. One meta-analysis of 16 studies revealed an average of 32.1% EWL at balloon removal [35], while a 2016 systematic review estimated EWL at 36.2% [22]. However, the long-term results of IGBs without subsequent bariatric procedures are more disappointing, with 1 study demonstrating that only 23% of participants retained an EWL of >20% after 5 years, despite 83% of patients having had this degree of initial weight loss [36], whereas 85% of patients with class

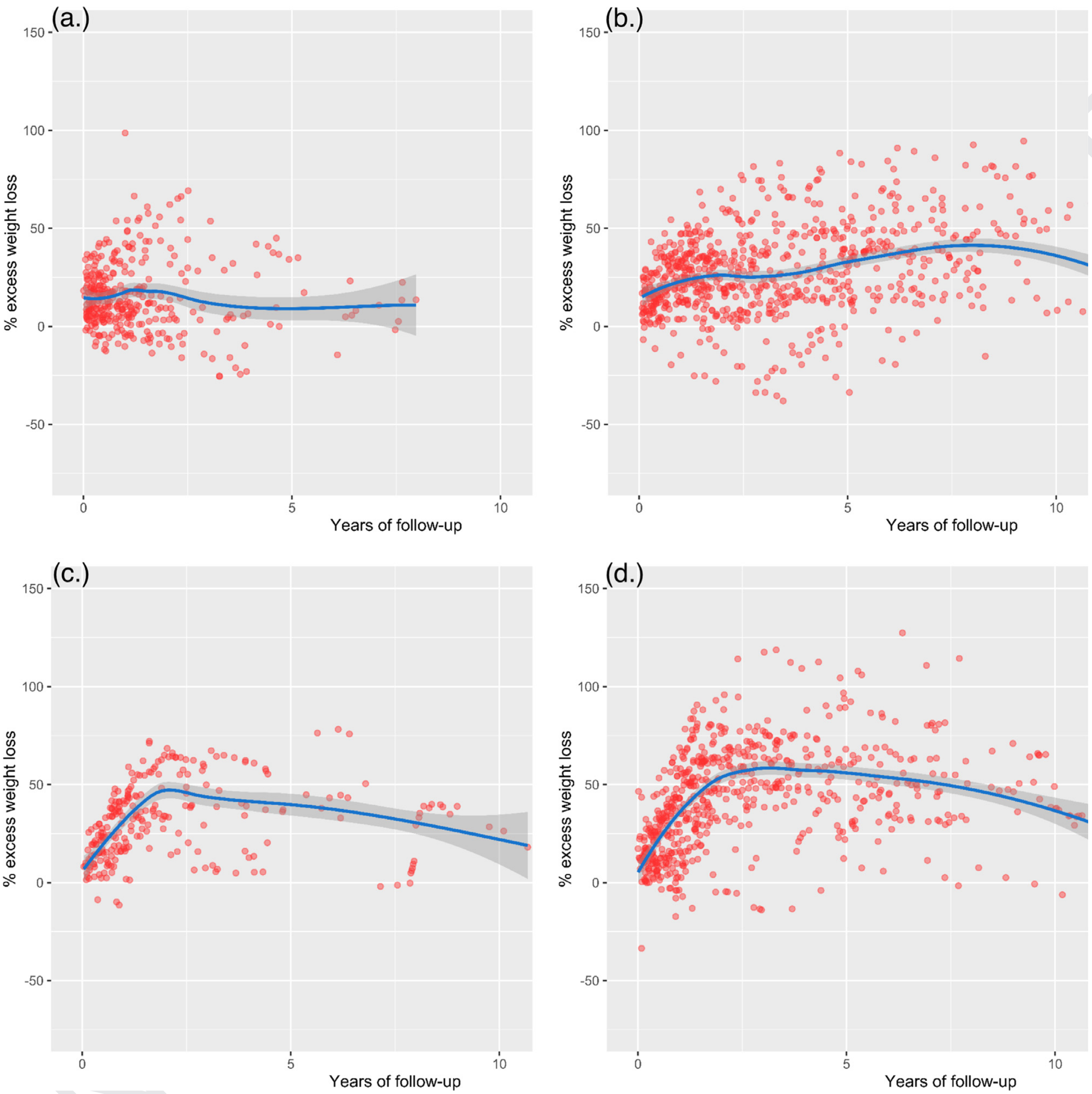

Fig. 1. Excess weight loss results after intragastric balloon insertion. (a) Balloon only. (b) Balloon and gastric banding. (c) Balloon and sleeve gastrectomy. (d) Balloon and Roux-en-Y gastric bypass.

III obesity demonstrated weight regain within 2 years of balloon treatment [37].

Our data are consistent with these studies demonstrating that IGBs give fast short-term weight reduction, with EWL after 18 months at 17.9% (BMI decrease of 6.1 from baseline); however, the effects are transient, and the majority of patients regain weight after removal. At 5 years after IGB insertion, the average EWL was only 9% (BMI decrease of 3.8 from baseline). Conversely, with IGB and subsequent stapled bariatric procedure, the 5-year average EWL was 52.8% (BMI decrease of 17.6 from baseline). Based on our data, we suggest the use of definite bariatric surgery after IGB removal to continue weight loss and maintain a lower weight over a long time period.

Our results also demonstrate superior weight loss effect with Roux-en-Y gastric bypass (EWL of 56% and BMI decrease of 18.4) compared with sleeve gastrectomy (EWL of 39.8% and BMI decrease of 14.1) after IGB insertion. Yet patients undergoing either of these as a stapled bariatric

Please cite this article as: Hutan Ashrafian et al., Intragastric balloon outcomes in super-obesity: a 16-year city center hospital series, Surgery for Obesity and Related Diseases (2018), https://doi.org/10.1016/j.soard.2018.07.010

procedure demonstrated superior weight loss results compared with IGB with lifestyle and IGB with gastric banding. However, these results were not directly comparable as the study patients were not matched for this comparison, and further research is necessary to assess any difference between postoperative outcomes in IGB patients who undergo these procedures. Additionally, as with patients undergoing bariatric surgery without IGBs, our cohort who had IGBs also demonstrated a degree of weight regain over a 5-year period. Nonetheless, it is likely that the mechanisms of weight loss and metabolic enhancement in patients undergoing a definitive bariatric operation after balloon weight may resemble that of weight loss in nonballoon patients. These include the immediate BRAVE effects (bile flow changes, restriction of stomach size, anatomic gastrointestinal rearrangement, vagal manipulation, enteric hormonal modulation) of surgery that then lead to the multiple downstream effects of metabolic procedures ranging, including changes in the gut microbiome to local metabolic physiology shifts (intestinal gluconeogenesis) and adipokine fluxes [38].

While the application of IGBs has been applied as a safe approach to reduce weight, and thereby reduce bariatric operative risk [39], these endoscopically inserted devices carry their own risks. Systematic reviews have estimated early removal at between 3.5% and 7% [13,22]. The most common complications included nausea/vomiting, abdominal pain, and GORD. Serious complications are rarer; however, they include events such as mortality, gastric perforation, gastric necrosis, and bowel obstruction [22]. Adverse events may be more common in the SO population due to the risk profile of these patients, including a higher prevalence of serious co-morbidities.

A strategy of early and continual vigilance for side effects and a low threshold for removal should be implemented. This includes suspicion of persistent vomiting, pain and signs preempting perforation, and other serious events. While we had an early explant rate of 3.8%, our overall series had 3 mortalities. This resulted in our institutional implementation of a strict 1-week liquid diet after IGB insertion, early clinic review within 7 days of discharge, and regular communication with patients through telephone reviews by our nurse clinician. Furthermore, medical management is key in lowering incidence of complications, and a regime of antiemetics and long-term proton pump inhibitors has been noted to reduce these symptoms [40,41]. Our institutional protocol includes rigorous antivomiting blockade of the neurologic vomiting pathway. These include antihistamines (e.g., cyclizine), antimuscarinics (e.g., hyoscine), dopamine receptor antagonists (e.g., metoclopramide or domperidone), 5 HT3 receptor antagonists (e.g., ondansetron), and, where necessary, NK1 receptor antagonists (e.g., Aprepitant). All patients also receive proton-pump inhibitor therapy while the balloon is in situ.

The mortality rate noted in our cohort (1.4%) is below that noted by other researchers in SO patients at 30 days postoperatively (~2% in some centers) [18], although other rates of 1.4% have also been quoted [20,42,43]. However, as this surgical approach nevertheless represents a significant risk, decisions about such management should be taken by a dedicated bariatric team and the management approach mentioned earlier should be stringently adopted. Close patient monitoring and urgent intervention upon suspicion of significant side effects is essential. Other methods for reducing weight preoperatively may also be considered, such as the use of a very low calorie diet (VLCD). This is less invasive than IGBs, but it does present its own issues, such as frequent side effects and poor adherence. Furthermore, a recent systematic review showed that IGBs are more effective than VLCD in reducing liver volume before surgery; however, the authors do note the need for further high-powered evidence in comparing weight loss methods and the practicality of a VLCD approach. Based on our anecdotal experience of poor adherence to the VLCD approach in SO patients, we believe that IGBs offer a better method of triggering weight loss before bariatric surgery in this group of patients. Furthermore, it has been noted by other researchers that due to the need for significant preoperative weight loss in the SO cohort of patients, the use of IGB is likely to be the most effective method in this cohort [31].

Our study carries limitations of the lack of randomization and inequality in numbers of patients between groups, as well as the methodologic bias of performing retrospective analysis. These data allow us to look at the weight loss maintained several years beyond previous studies. However, these patients had a variable follow-up, and there is likely to be a tendency toward longer follow-up for those patients who were unsatisfied with their results or experienced complications. Therefore, the data may underestimate the true weight loss achieved for these groups in the long term.

A further limitation is the lack of data on complications in this study. Due to the long-term nature of data collection, there has not been a consistent way of cataloguing morbidity associated with the procedures. We are therefore unable to comment on this aspect beyond noting the mortality.

Conclusion

In this paper, we report our long-term, single-institute experience in using the IGB alone and as a precursor to definite bariatric surgery for SO patients at a large city specialist bariatric center. We show a small effect in weight loss when using IGB and lifestyle changes alone, and these effects appear to be short term. However, a large and sustained weight loss effect is shown when IGBs are combined with definite bariatric surgery, in particular stapled procedures. We suggest that IGBs have utility in a wider bariatric context and are an effective bridge to definitive therapy but require appropriate follow-up in a dedicated center. The future in this field includes more robust research in higher quality studies identifying the exact weight and metabolic outcomes and side-effect characteristics of these procedures at multiple weight categories and patient co-morbidities. The role of the IGB is gaining increased definition; however, its role continues to evolve in an era of multiple new antiobesity and metabolic enhancing strategies designed to combat the growing problem of worldwide obesity and its associated metabolic dysfunction.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

References

[1] NCD Risk Factor Collaboration (NCD-RisC) Trends in adult body-mass index in 200 countries from 1975 to 2014: a pooled analysis of 1698 population-based measurement studies with 19.2 million participants. Lancet 2016;387(1006):1377–96.
[2] Whitlock G, Lewington S, Sherliker P, et al. Body-mass index and cause-specific mortality in 900 000 adults: collaborative analyses of 57 prospective studies. Lancet 2009;373(9669):1083–96.
[3] Flegal KM, Kit BK, Orpana H, Graubard BI. Association of all-cause mortality with overweight and obesity using standard body mass index categories: a systematic review and meta-analysis. JAMA 2013;309(1):71–82.
[4] Peterson K, Anderson J, Ferguson L, Erickson K, Humphrey L. Evidence brief: the comparative effectiveness of bariatric surgery in super obesity (BMI >50 kg/m^2). US Department of Veterans Affairs. Health Services Research & Development: Evidence-based Synthesis
Q11 Program; 2015 .
[5] 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, 2003-2012. JAMA Surg 2014;149(3):275–87.
[6] Colquitt JL, Pickett K, Loveman E, Frampton GK. Surgery for weight loss in adults. Cochrane Database Syst Rev 2014(8):CD003641.
[7] Sjöström L, Narbro K, Sjöström CD, et al. Effects of bariatric surgery on mortality in Swedish obese subjects. N Engl J Med 2007;357(8):741–52.
[8] Sjöström L, Peltonen M, Jacobson P, et al. Bariatric surgery and long-term cardiovascular events. JAMA 2012;307(1):56–65.
[9] Gleysteen JJ. A history of intragastric balloons. Surg Obes Relat Dis 2016;12(2):430–5.
[10] 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(24):5495–504.
[11] U.S. Food and Drug Administration CfDaRH, Office for Device Evaluation. Reshape Integrated Dual Balloon System Approval Let-
Q12 ter, P140012.
[12] Laing P, Pham T, Taylor LJ, Fang J. Filling the void: a review of intragastric balloons for obesity. Dig Dis Sci 2017;62(6):1399–408.
[13] Abu Dayyeh BK, Kumar N, Edmundowicz SA, et al. ASGE Bariatric Endoscopy Task Force systematic review and meta-analysis assessing the ASGE PIVI thresholds for adopting endoscopic bariatric therapies. Gastrointest Endosc 2015;82(3) 425-38.e5.
[14] Neylan CJ, Dempsey DT, Tewksbury CM, Williams NN, Dumon KR. Endoscopic treatments of obesity: a comprehensive review. Surg Obes Relat Dis 2016;12(5):1108–15.
[15] Saber AA, Shoar S, Almadani MW, et al. Efficacy of first-time intragastric balloon in weight loss: a systematic review and meta-analysis of randomized controlled trials. Obes Surg 2017;27(2):277–87.
[16] Risstad H, Søvik TT, Engström M, et al. Five-year outcomes after laparoscopic gastric bypass and laparoscopic duodenal switch in patients with body mass index of 50 to 60: a randomized clinical trial. JAMA Surg 2015;150(4):352–61.
[17] Peterson K, Anderson J, Boundy E, Ferguson L, Erickson K. Rapid evidence review of bariatric surgery in super obesity (BMI $\geq$ 50 kg/m^2). J Gen Intern Med 2017;32(Suppl 1):56–64.
[18] Arterburn D, Livingston EH, Schifftner T, Kahwati LC, Henderson WG, Maciejewski ML. Predictors of long-term mortality after bariatric surgery performed in Veterans Affairs medical centers. Arch Surg 2009;144(10):914–20.
[19] Martins-Filho ED, Katz L, Amorim M, Ferraz AA, Ferraz EM. Prediction of severe complications and death in superobese patients undergoing open gastric bypass with the Recife Score. Arq Gastroenterol 2011;48(1):8–14.
[20] Santo MA, Riccioppo D, Pajecki D, Cleva R, Kawamoto F, Cecconello I. Preoperative weight loss in super-obese patients: study of the rate of weight loss and its effects on surgical morbidity. Clinics (Sao Paulo) 2014;69(12):828–34.
[21] Ballantyne GH, Svahn J, Capella RF, et al. Predictors of prolonged hospital stay following open and laparoscopic gastric bypass for morbid obesity: body mass index, length of surgery, sleep apnea, asthma, and the metabolic syndrome. Obes Surg 2004;14(8):1042–50.
[22] Yorke E, Switzer NJ, Reso A, et al. Intragastric balloon for management of severe obesity: a systematic review. Obes Surg 2016;26(9):2248–54.
[23] Van Nieuwenhove Y, Dambrauskas Z, Campillo-Soto A, et al. Preoperative very low-calorie diet and operative outcome after laparoscopic gastric bypass: a randomized multicenter study. Arch Surg 2011;146(11):1300–5.
[24] Colles SL, Dixon JB, Marks P, Strauss BJ, O'Brien PE. Preoperative weight loss with a very-low-energy diet: quantitation of changes in liver and abdominal fat by serial imaging. Am J Clin Nutr 2006;84(2):304–11.
[25] Edholm D, Kullberg J, Haenni A, et al. Preoperative 4-week low-calorie diet reduces liver volume and intrahepatic fat, and facilitates laparoscopic gastric bypass in morbidly obese. Obes Surg 2011;21(3):345–50.
[26] Alami RS, Morton JM, Schuster R, et al. Is there a benefit to preoperative weight loss in gastric bypass patients? A prospective randomized trial. Surg Obes Relat Dis 2007;3(2):141–5 discussion 5–6.
[27] Huerta S, Dredar S, Hayden E, et al. Preoperative weight loss decreases the operative time of gastric bypass at a Veterans Administration hospital. Obes Surg 2008;18(5):508–12.
[28] Still CD, Benotti P, Wood GC, et al. Outcomes of preoperative weight loss in high-risk patients undergoing gastric bypass surgery. Arch Surg 2007;142(10):994–8 discussion 9.
[29] Liu RC, Sabnis AA, Forsyth C, Chand B. The effects of acute preoperative weight loss on laparoscopic Roux-en-Y gastric bypass. Obes Surg 2005;15(10):1396–402.
[30] Frutos MD, Morales MD, Luján J, Hernández Q, Valero G, Parrilla P. Intragastric balloon reduces liver volume in super-obese patients, facilitating subsequent laparoscopic gastric bypass. Obes Surg 2007;17(2):150–4.
[31] van Wissen J, Bakker N, Doodeman HJ, Jansma EP, Bonjer HJ, Houdijk AP. Preoperative methods to reduce liver volume in bariatric surgery: a systematic review. Obes Surg 2016;26(2):251–256.

Please cite this article as: Hutan Ashrafian et al., Intragastric balloon outcomes in super-obesity: a 16-year city center hospital series, Surgery for Obesity and Related Diseases (2018), https://doi.org/10.1016/j.soard.2018.07.010

[32] Saruç M, Böler D, Karaarslan M, et al. Intragastric balloon treatment of obesity must be combined with bariatric surgery: a pilot study in Turkey. Turk J Gastroenterol 2010;21(4):333–7.

[33] Doldi SB, Micheletto G, Perrini MN, Librenti MC, Rella S. Treatment of morbid obesity with intragastric balloon in association with diet. Obes Surg 2002;12(4):583–7.

[34] Spyropoulos C, Katsakoulis E, Mead N, Vagenas K, Kalfarentzos F. Intragastric balloon for high-risk super-obese patients: a prospective analysis of efficacy. Surg Obes Relat Dis 2007;3(1):78–83.

[35] Imaz I, Martínez-Cervell C, García-Alvarez EE, Sendra-Gutiérrez JM, González-Enríquez J. Safety and effectiveness of the intragastric balloon for obesity. A meta-analysis. Obes Surg 2008;18(7):841–6.

[36] Kotzampassi K, Grosomanidis V, Papakostas P, Penna S, Eleftheriadis E. 500 intragastric balloons: what happens 5 years thereafter? Obes Surg 2012;22(6):896–903.

[37] Mitura K, Garnysz K. In search of the ideal patient for the intragastric balloon - short- and long-term results in 70 obese patients. Wideochir Inne Tech Maloinwazyjne 2016;10(4):541–7.

[38] Ashrafian H, Harling L, Toma T, Athanasiou C, Nikiteas N, Efthimiou E, et al. Type 1 diabetes mellitus and bariatric surgery: a systematic review and meta-analysis. Obes Surg 2016;26(8):1697–704.

[39] Bazerbachi F, Vargas Valls EJ, Abu Dayyeh BK. Recent clinical results of endoscopic bariatric therapies as an obesity intervention. Clin Endosc 2017;50(1):42–50.

[40] Genco A, Cipriano M, Bacci V, et al. BioEnterics Intragastric Balloon (BIB): a short-term, double-blind, randomised, controlled, crossover study on weight reduction in morbidly obese patients. Int J Obes (Lond) 2006;30(1):129–33.

[41] Ponce J, Woodman G, Swain J, 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(4):874–81.

[42] Kakarla VR, Nandipati K, Lalla M, Castro A, Merola S. Are laparoscopic bariatric procedures safe in superobese (BMI $>/=50$ kg/m^2) patients? An NSQIP data analysis. Surg Obes Relat Dis 2011;7(4):452–8.

[43] Stephens DJ, Saunders JK, Belsley S, et al. Short-term outcomes for super-super obese (BMI >or$=60$ kg/m^2) patients undergoing weight loss surgery at a high-volume bariatric surgery center: laparoscopic adjustable gastric banding, laparoscopic gastric bypass, and open tubular gastric bypass. Surg Obes Relat Dis 2008;4(3):408–15.

Please cite this article as: Hutan Ashrafian et al., Intragastric balloon outcomes in super-obesity: a 16-year city center hospital series, Surgery for Obesity and Related Diseases (2018), https://doi.org/10.1016/j.soard.2018.07.010