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Outcomes in Sequential Intragastric Balloon Treatment for Patients With Super Obesity - A Single Centre Retrospective Analysis

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Abstract

Objective

We aimed to assess outcomes in patients undergoing sequential intragastric balloon (IGB)treatment for obesity.

Methods

Consecutive patients who underwent treatment between May 2014 and February 2023 were identified. We recorded outcomes including: weight at 3-monthly intervals, progression to definitive bariatric procedure and morbidity.

Results

45 patients were identified. Median weight loss with first IGB was 15.2kg (8.8%). 11 patients (26.7%) had a second IGB, with median weight loss of 3.3kg (1.9%). 21 patients (46.7%) weresuitable for definitive surgery after first IGB treatment. One further patient (2.2%) was suitable for surgery after a second IGB.

During first IGB, median weight loss was observed during the each of the first three quartiles(months 0-3: 10.1kg; months 3-6: 2.3kg; months 6-9: 4.2kg). There was a median 2kg weightgain during months 9-12.

Conclusions

Greatest weight loss was achieved during first IGB treatment. Sequential IGB treatment didnot lead to beneficial weight loss or progression to surgery. Weight loss with first IGB wasnot uniform across the 12 month period of treatment, with net weight gain during the last quartile.

Introduction

Obesity is quantitatively defined as a body mass index (BMI) of 30 kg/m^2 or above [1]. Obesity has become a 'global epidemic', particularly prevalent in Western populations 1. In 2022, 25.9% of adults aged 18 years or over in England were estimated to be obese, with prevalence rising and equal distribution reported amongst women (26.1%) and men (25.8%) [2]. Crucially, obesity is associated with development of health complications, including cardiac and vascular disease, diabetes mellitus, cancer and mortality [1].

The literature suggests that bariatric surgery provides the most weight loss-sustaining, and hence heath-benefiting, choice for obesity [3,4]. The most common bariatric operations of choice in the UK, at the present time, are Roux-en-Y gastric bypass and sleeve gastrectomy [3,4]. Bariatric surgery, however, carries risk of morbidity and mortality [3,4]. Indeed, patients may be too obese to proceed directly to weight-loss surgery and/or deemed too high risk candidates for definitive operations [3]. Prospective cohort studies report the intragastric balloon (IGB) as a safe and effective temporary bridging therapy to achieve sufficient weight loss in order to proceed to definitive bariatric surgery [5,6,7,8]. IGBs reduce stomach capacity, promoting the feeling of satiety through stimulation of gastric mechanoreceptors, facilitating weight loss [9].

If patients do not lose sufficient weight to safely progress to definitive bariatric surgery, consideration may be given to a second sequential period of IGB treatment. Several studies [5,6,7] have failed to reach a consensus on the efficacy of sequential IGBs.

Prior to the Covid-19 pandemic, IGBs were endoscopically removed after 6 months 10. However, during the period of restrictions which led to limited patient interactions and the postponement of elective bariatric surgery [10], duration of IGB treatment increased from 6 to 12 months at our bariatric centre and many other centres around the UK following consultations with balloon suppliers.

We retrospectively reviewed of clinical outcomes for patients with obesity and super obesity who have undergone IGB insertions in a single bariatric centre. The study period accounts for the changes in IGB removal protocol that resulted during the Covid-19 pandemic. The primary outcome was percentage of total body weight loss (%WL) following insertion of sequential IGBs. A sub analysis was performed assessing weight loss trends during different phases of the first balloon treatment. The secondary outcome was to assess safety of sequential balloon treatment.

Methods

Patients were identified by comprehensive reviews of the hospital electronic theatre management system to identify all patients who had undergone any form of endoscopic balloon insertion and removal between 2014-2023. Only patients deemed fit enough for potential adjuvant bariatric surgery at presentation were included in the study.

Baseline data was collected including patient demographics, co-morbidities and initial weight upon booking into the bariatric pathway. Weights and BMIs were recorded at 3 monthly intervals until the date of balloon removal, and for any subsequent periods of balloon treatment. Our trust uses the Orbera365 Non-Surgical Weight Loss Balloon System® filled with saline and methylene blue dye, for up to 12 months treatment duration.

We recorded weight loss, percentage weight loss (%WL), length of treatment, complications and eventual patient outcome, including progression to definitive bariatric surgery (laparoscopic Roux-en-Y gastric bypass, laparoscopic sleeve gastrectomy or laparoscopic single anastomosis bypass).

Results

In total, 45 patients were identified between May 2014 and February 2023 who underwent an insertion of an IGB.

As with the typical bariatric population, the majority were female (73.3%). Approximately one third were diagnosed with type 2 diabetes (31.1%) or hypertension (33.3%). Detailed demographics as well

Table 1. Patient demographics and initial weights

Demographics	Total	%	Median	Range
	45			
Male	12	26.7		
Female	33	73.3		
Age			50	23 - 71
ASA			2	1 – 3
Ethnicity				
White British	38	84.4		
White Other	2	4.4		
Asian	4	8.9		
Other Group	1	2.2		
Co-morbidities				
Type 2 Diabetes	14	31.1		
Hypertension	15	33.3		
Obstructive sleep apnoea	10	22.2		
Weights				
Booking weight (kg)			176	113.5 - 242.5
Booking BMI (kg/m^2)			62.4	40.3 – 83.75
Balloon insertion weight (kg)			168	110-250
Balloon insertion BMI (kg/m^2)			62	41.4 - 90

as initial weights are shown in Table 1. The median balloon fill volume was 610ml, ranging from 540ml to 660ml.

From this cohort 8 had the balloon removed within one month of insertion and were excluded from subsequent analysis. 5 of these were due to vomiting, 2 were due to acute kidney injury with serum electrolyte disturbance and 1 was due to a perforated gastric ulcer. There was no mortality related to any of these complications, including the perforated gastric ulcer patient who was managed non-operatively with intravenous antibiotics, proton pump inhibitor infusions and endoscopic closure using clips. This patient did however have a prolonged total length of stay of 19 days. This patient's subsequent contrast study revealed no evidence of ongoing leak related to the ulcer.

37 patients completed longer than 1 month of initial IGB treatment. The median duration was 237 days (33.9 weeks or 7 months). Median weight loss with initial balloon treatment was 15.2kg (8.8%WL), ranging from 54.8kg (31%) of weight loss to 30.9kg (19.7%) of weight gain.

Overall, 11 patients (24.4%) went onto have a second IGB. Of these, one balloon was removed after 14 days due to vomiting and electrolyte imbalance, one balloon burst during balloon treatment and another patient has not yet completed their balloon treatment, these patients are excluded from subsequent analysis.

Table 2. Outcomes of intragastric balloon treatment

	1st IGB	2nd IGB
Number of patients	37	8
Median length of balloon		
Days	237	234
Weeks	33.9	33
Months	7	7.5
Weight loss (kg)		
Median	15.2	3.3
Range	-54.8 to +30.9	-21.2 to +5.6
Weight loss (%)		
Median	8.8	1.9
Range	-31 to +19.7	-15.5 to +2.8

Median weight on day of insertion of second IGB was 184kg. The median length of second balloon treatment was 234 days (33 weeks or 7.5 months). Median weight loss with secondballoon was 3.3kg (median 1.9%WL), ranging from 21.2kg loss to 5.6kg gain (15.5%WL to 2.8% weight gain). Table 2 shows the comparative outcomes with first vs second IGB.

In terms of final outcomes of therapy 22 patients (48.8%) were deemed suitable for surgeryfollowing their balloon treatment of which only one required a second IGB. 17 went on to have surgery (12 Roux -en-Y gastric bypass, 5 sleeve gastrectomy), 3 patients were offered surgery but declined and one patient had an abandoned Roux-en-Y gastric bypass due to limited intra-abdominal space. One patient is current awaiting surgery (Roux-en-Y gastric bypass). Table 3 shows outcomes at the end of the bariatric pathway.

Table 3. patient outcomes in the bariatric pathway for the study period

Outcome	**Number**	**%**
Bariatric procedure	17	35.6
Roux-en-Y Gastric Bypass	12	26.7
Sleeve Gastrectomy	5	11.1
Surgery abandoned	1	2.2
Listed for surgery	1	2.2
Declined by patient	3	6.7
Discharged by bariatric MDT	16	35.6
Discharged to private sector	2	4.4
Remain under MDT	2	4.4
Lost to follow up	1	2.2
Second balloon still in situ	2	4.4

Table 4. Balloon complications

	1st IGB		2nd IGB	
Complication		**%**		**%**
Vomiting with electrolyte disturbance / AKI	3	6.6	1	2.2
Perforated gastric	1	2.2		
ICU admission	1	2.2		
Burst balloon			1	2.2

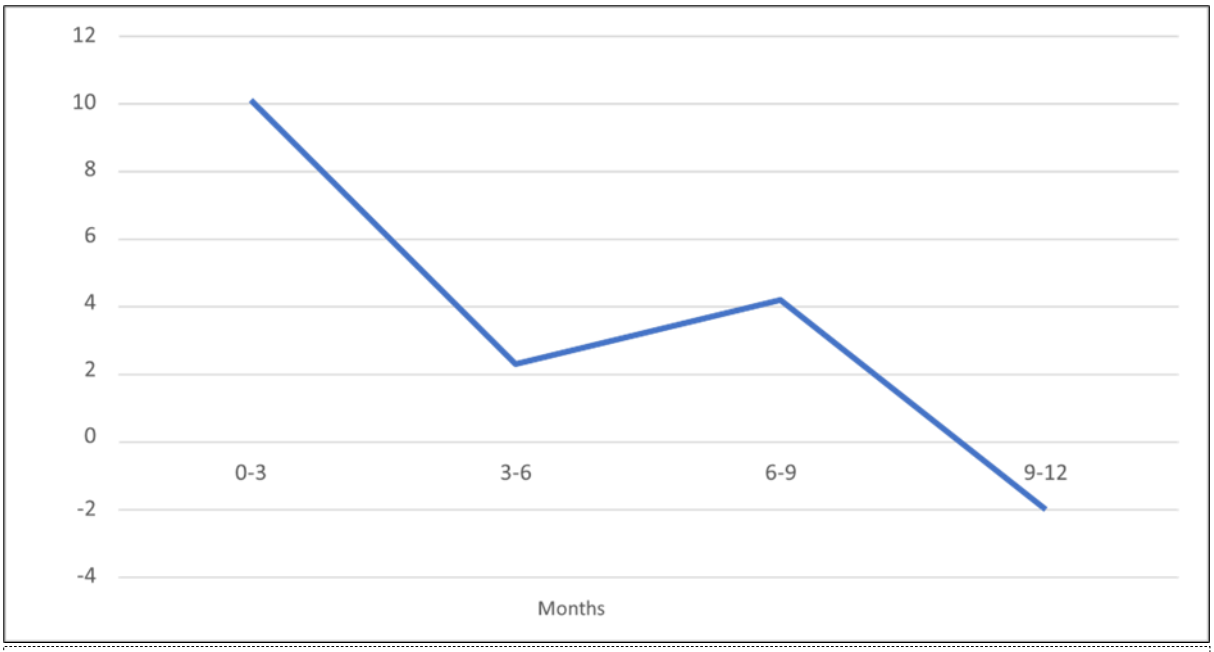

Figure 1. Weight loss (kg) by quartiles (first intragastric balloon)

We analysed the weight loss with first IGB across the 12 month treatment period, broken down into quartiles. Greatest weight loss was observed in the initial 3 months of balloon treatment (median 10.1kg, 7.1%). During months 9-12 of balloon treatment the median weight change was a gain of 2kg (1%). This is shown in figure 1.

Analysis of weight loss by quartiles was not performed due to the small number of patients undergoing a second IGB insertion.

Across the study period, 14 (31.1%) initial balloons were removed prior to 12 months due to complications (8 vomiting, 5 acute kidney injury with serum electrolyte disturbance and 1 perforated gastric ulcer). Of which 9 (20%) of these were within the first month of balloon treatment. One patient was admitted to intensive care due to severe electrolyte disturbance. The overall complication rate requiring re-attendance to hospital but not necessarily removal of IGB was 40%. 6 patients (13.3%) had multiple hospital attendances with complications. Median length of stay related to balloon complications was 1 (range 0 – 19) day. The median time from insertion of IGB to presentation with a complication was 14 (range 1 to 272) days. Balloon complications are shown in table 4.

Discussion

There is limited literature on the effect of sequential IGBs on weight loss [5,6,7]. Genco et al. recruited 83 patients with a mean BMI 43kg/m^2, in whom conservative medical obesity management had failed and definitive bariatric surgery declined by patients [6]. The criterion for insertion of sequential IGBs was regain of > or equal to 50% of weight loss achieved withthe previous IGB [6]. Up to 4 sequential IGBs, each for a 6 month treatment period, were inserted and all patients underwent insertion of a second IGB [6]. The study found that after first IGB treatment, statistically significant weight loss was achieved (P<0.001), with mean reduction in BMI of 7.8kg/m^2 [6]. No statistically significant weight loss was found following the second IGB 6. Moreover, the mean BMI (37.6kg/m^2) upon completion of the 72 month study period was similar to the mean BMI of patients prior to insertion of the second IGB (37.9kg/m^2) [6]. The present study differs from Genco et al. in that sequential IGBs were considered in patients as a bridging therapy to definitive bariatric surgery; significant weightgain was considered as failure of IGB treatment and in fact indication for removal, and therewas no interval balloon-free period between IGBs. Nevertheless, the findings of the present study concur and build on the findings of Genco et al., highlighting the limited effect of sequential IGB treatment on weight loss when an IGB is left in-situ for 12 months. In addition, the present study assesses how weight loss is distributed over 12 months, important for evaluating the optimal treatment period for IGBs, questioning whether treatment beyond 9 months facilitates weight loss.

The safety of IGB treatment is a prominent consideration across the literature. One systematic review by Yorke at al. aimed to evaluate the safety of IGBs left in-situ for 6 months [11]. It concluded that 'IGBs are associated with marked short-term weight loss with limited serious complications' [11]. However, the review did not specify whether sequential IGBs were included or excluded in the selection criteria, unlike the focus of the present study. In a separate prospective cohort study, Wiggins et al. assessed the safety of IGBs left in-situ for 12 months in 1100 patients [12]. The study found that 60 patients (5.2%) had an adverse outcome, including 50 patients (4.3%) who required early IGB removal due to intolerance, irrespective of anti-emetic treatment [12]. 38 of these patients (3.4%) underwentIGB removal between 8 and 38 days post-insertion [12]. There were 8 cases of IGB rupture (0.7%) and these affected patients passed the balloon spontaneously [12]. There were 2 severe complications (0.1%) of gastric outlet obstruction which resolved with conservative management, and gastric perforation requiring laparotomy [12]. This study utilised an Obera365 IGB, as in the present study [12], with similarity in the nature and profile of complications experienced across both studies. Importantly, both studies highlight the tendency of most complications, such as intolerance, to occur 1-2 months post-insertion, and hence unrelated to the 12 month treatment duration. However, significant differences inpatient characteristics between the studies should be highlighted and may account for the difference in outcomes. In Wiggins et al, the median BMI was 36.3kg/m^2 and the majority ofpatients did not have any obesity-related complications [12]. By comparison, the mean BMI was 62.4kg/m^2 in the present study, and a third of patients had type 2 diabetes and hypertension respectively. Hence, the present study adds greater weight to the argument for the overall tolerability and acceptability of IGBs as a bridging treatment to definitive bariatricsurgery.

Genco et al. considered safety of sequential IGBs as a secondary outcome in their aforementioned prospective cohort study, [6]. In this study, all 83 patients (100%) underwent treatment with a second IGB, 18 patients (22.2%) undertook a third IGB, and 1 patient (1.2%) had a fourth IGB [6]. The study reported a longer duration of complications - nausea, vomiting and epigastric pain - with the second IGB (4.0

days) compared to the first IGB (2.5 days) 6. These symptoms were effectively medically managed 6, but it is unclear whether thisrequired hospital admission. No major complication, such as gastric ulcer, perforation or death, was reported 6. 1 patient (1.45%) underwent early IGB removal for intolerance, but inthe absence of IGB rupture, oesophagitis or uncontrolled vomiting 6. Each sequential IGB was left in-situ for 6 rather than 12 months in Genco et al. [6] , but this does not explain thelower incidence of complications in comparison with the present study, given most complications presented one month from the time of IGB insertion. Super obesity (BMI >60kg/m^2) and associated co-morbidity of patients in the present study might havecontributed to complication risk and help account for the difference in findings.

There are limitations of our present study, the overall number of patients who underwent sequential IGB treatment was small. This is in keeping with current practice in our centre where, in the absence of contraindications, definitive surgery is the treatment of choice. Thelongitudinal nature of the study (9 years) demonstrates the reasonably small number of patients who undergo IGB insertion as a bridging treatment to definitive bariatric surgery, and the even smaller number of patients who may be offered sequential IGBs. The present study also provides a retrospective overview of the practice and clinical outcomes at one bariatric centre.

Proposals for future work could include a prospective longitudinal study evaluating the useof IGBs in different regional bariatric centres in the post-Covid-19 pandemic era. Differencesin brands of IGB used, IGB treatment duration, use of sequential IGBs, their effect on weightloss, and complication rates could be evaluated. Conclusions could help inform IGB use in clinical practice to optimise weight loss outcomes. That being said, it is foreseeable increased use of injectable pharmacological therapies for weight loss within the coming years, which may in fact surpass the IGB in terms of efficacy and acceptability as a bridging therapy to definitive surgery. Once injectables are more widely available a study comparing outcomes with IGB vs injectables would aid decision making in the context of bridging therapies.

Conclusion

The present study concludes that, although not associated with increased complication risk, sequential IGB use as a bridging treatment to definitive bariatric surgery does not significantly contribute to weight loss in super obese patients. Optimal treatment is achievedwith a single IGB, although weight loss is not uniform across a 12 month treatment period and weight gain can result after 9 months.

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