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ORIGINAL CONTRIBUTIONS

Effectiveness of Intra-Gastric Balloon as a Bridge to Definitive Surgery in the Super Obese

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Abstract

Background British National guidelines (NICE) recommend bariatric surgery for patients with a body mass index (BMI) > 40 kg/m2, or BMI > 35 kg/m2 with any comorbidities of the metabolic syndrome. Intra-gastric balloons (IGB) can be used in super obese patients as a first step, before definitive surgery.

Aims Quantify weight loss 6 months after IGB placement, measure progression to definitive surgery and identify complications.

Methods Data collected retrospectively on 50 patients. Forty-six proposed for definitive bariatric surgery, four patients excluded. Analysis performed using SPSS v23.0.

Results Median weight decreased from 165.5 to 155 kg (range 78 to 212, $p < 0.01$), BMI from 57.4 to 52.15 (range 32.9 to 70.5, $p < 0.01$), percentage excess weight loss (%EWL) was 12.9% (range − 3.3 to 64.66%, $p < 0.01$) and BMI reduction was 4.25 kg/m2 (range − 1.3 to 13.9, $p < 0.01$). Twenty-nine out of 46 patients (63%) progressed to definitive bariatric surgery. Ten out of 46 patients (21.7%) had complications requiring readmission. Seven of these patients required early balloon removal and six failed to progress to definitive surgery. Six patients had a second balloon placement, their actual weight loss was less successful, with some regaining weight.

Discussion IGB is useful to aid weight loss prior to definitive bariatric surgery. Results from first balloon placement are encouraging and comparable with other studies "as reported by Genco et al. (*Int J of Obes* 30:129–133, 2006)." Readmission due to nausea, vomiting, dehydration and poor compliance may be associated with poor weight loss and failure to progress to definitive surgery. Second balloon placements were less successful.

Conclusion IGB as bridging therapy is a safe and useful adjunct. Sequential IGBs do not seem to provide additional benefit.

Keywords Intra-gastric balloon · Super morbid obesity · Bridge to surgery

Introduction

Obesity is associated with multiple medical problems including type 2 diabetes, cardiovascular disease, osteoarthritis and sleep apnoea. In addition, it has a significant socio-economic impact for the patient (depression, stigma, low self-esteem, work absence, unemployment) [1]. Obesity-related complications and their management are

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predicted to cost the British National Health Service (NHS) £9.7 billion by 2030 [1].

Bariatric surgery is available on the NHS for patients fulfilling NICE criteria:

- BMI ≥ 40 kg/m2
- BMI ≥ 35 kg/m2 with a serious health condition that could be improved with weight loss (e.g. type 2 diabetes or high blood pressure)

All patients receive medical, multidisciplinary, multicomponent weight management services (Tier 3) as advised by the National Institute for Health and Care Excellence (NICE) prior to consideration for surgical intervention [2]. The most popular bariatric operations in the UK according to the UK National Bariatric Surgery Registry (NBSR) are the laparoscopic Roux-en-Y gastric bypass (RYGB) and the sleeve gastrectomy (SG) [3]. Intra-gastric balloons (IGB) have been used for patients who either want a less invasive procedure to achieve weight loss, or to reduce weight before definitive surgery. This may be the case in patients with super obesity, or patients suffering with marked central obesity. IGB may also be placed to provide weight loss in patients awaiting other surgical procedures, such as a hip or knee replacement.

Several studies demonstrate the safety and efficacy of IGB [4–6]. A recent meta-analysis of 20 RCTs further confirmed that IGB placement was effective in the short term, but failed to demonstrate long-term maintained weight loss [7]. Ashrafian et al. [8] have shown that IGB insertion offers effective temporary weight loss but is most effective when combined with definitive bariatric surgical procedures, which is in line with our protocol for IGB insertion.

Two other studies [9, 10] reported that weight loss from intra-gastric balloons is sustained 6 months after removal which would allow time to plan definitive surgery in selected patients. In contrast, a recent review of eight randomised controlled trials concluded that IGBs had an adverse event rate of 28.5% and a relatively small percentage total body weight loss [11]. An area which is currently less well understood is the role of IGB as a first step before definitive surgery. Bariatric surgery may be challenging in some morbidly obese and super obese patients. Additionally, some patients with central obesity may prove difficult to laparoscope safely. If the intra-abdominal views during surgery are less than satisfactory, the surgeon may need to abandon the procedure, rather than risking potential complications. We postulate that using IGB prior to surgery may provide additional weight loss and make surgery safer. Our study aims to quantify weight loss 6 months after IGB placement, subsequent progression to definitive surgery and identify complications.

Table 1 Comorbidities and sex distribution of the 50 patients that had IGB insertion

Comorbidity	Male	Female	Total
Nil	1	4	5
Pre-diabetes/diabetes	10	11	21
Hypertension	11	7	18
Obstructive sleep apnoea	7	11	16
Asthma	3	3	6
Ischaemic heart disease	1	1	2
Dyslipidaemia	3	2	5
Osteoarthritis	0	2	2
Other	7	10	17

Methods

Fifty patients underwent IGB (ORBERA® Apollo Endosurgery, Inc.) insertion. However, four out of the 50 patients were excluded from the study, for the following reasons: three had IGB inserted for weight loss prior to cancer surgery and therefore would not be considered for definitive bariatric surgery. One patient with learning disabilities underwent IGB for weight control, but did not wish to pursue further treatment. The remaining 46 patients were morbidly obese (BMI > 40) and in some cases their BMI > 70. Patients were admitted on the day of procedure. The IGB was placed endoscopically under general anaesthesia and filled to a maximum volume of 650 ml of saline, containing 10 ml of methylene blue. We acknowledge that other bariatric centres may use volumes between 500 and 700 ml. As no difference in outcomes has been reported when using different volumes, our centre uses 650 ml as per manufacturer's instructions. Prophylactic anti-emetics were given in theatre and each patient was discharged with an IGB patient information leaflet, anti-emetics, antispasmodics and proton-pump inhibitors for regular use in the first month.

Data was retrospectively collected. It included pre-existing comorbidities, body mass index (BMI), weight and number of

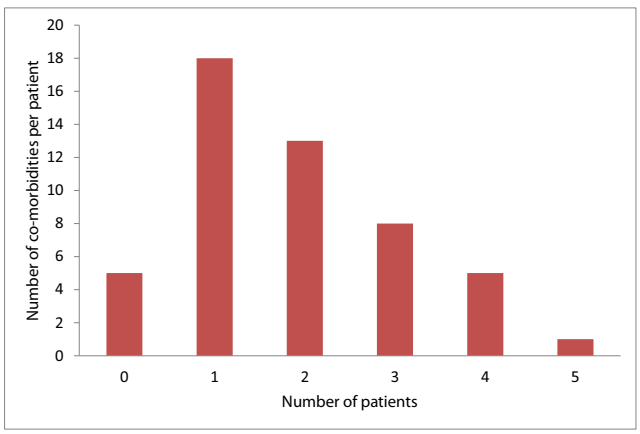

Fig. 1 Number of comorbidities per patient

Table 2 Results of weight loss for first and second IGB placement shown as median and ranges. In the second IGB group, this data represents six patients. Weight is in kg and BMI in kg/m^2

	First IGB			Second IGB		
	Before IGB	After IGB	*p* value	Before IGB	After IGB	*p* value
Median wt range	165.5 (102–229)	155 (78–212)	< 0.01	179 (165–212)	180 (146–229)	0.826
Median BMI range	57.4 (39.6–75.3)	52.15 (32.9–70.5)	< 0.01	63.95 (52.2–65)	62.25 (42.7–73)	0.765

days IGB in situ. The primary end-point was whether definitive surgery was performed after the IGB. Other outcomes analysed included balloon-related complications and readmission data. There were no mortalities to record. SPSS computer software version 23.0 was used for statistical analysis using paired *t* tests and independent *t* tests where appropriate.

Results

The cohort had initially 50 patients, with a median age of 47 years (range = 24–74), 31 were female and 19 were male. Four patients were excluded from the study.

Table 1 and Fig. 1 show comorbidities with sex distribution and number of comorbidities per patient respectively.

Forty-six patients underwent the first IGB placement, which resulted in significant weight loss. Their median weight before undergoing IGB was 165.5 kg (range 102 to 229) and their BMI was 57.4 (range 39.6 to 75.3). Following balloon insertion, their median weight decreased to 155 (range 78 to 212, $p < 0.01$) and their BMI to 52.15 (range 32.9 to 70.5, $p < 0.01$). Median EBW was 93 kg (range 38 to 148, $p < 0.01$), median actual weight loss was 13 kg (range − 3 to 42, $p < 0.01$), median %EWL was 12.89% (range − 3.3 to 64.66, $p < 0.01$) and the median BMI reduction was 4.25 kg/m^2 (range − 1.3 to 13.9, $p < 0.01$). The median length of hospital stay (LOS) after the first IGB placement was 2 days (range 1 to 6). The median number of days the patients kept the balloon in was 189 (range 2 to 307).

Six patients underwent a second IGB placement. This did not result in significant added weight loss. Their median weight loss was − 6 kg (range − 22 to 33 kg, $p = 0.826$), median BMI reduction − 1.3 kg/m2 (range − 8.5 to 2.5, $p = 0.765$), median EBW was 108 kg (range 94 to 119), median actual weight loss was − 6 kg (range – 22 to 33, $p < 0.826$), median %EWL was − 4.85% (range − 21.6 to 34.96) and the median number of days the second balloon was in situ was 183 (range 161 to 210). Results are summarised in Table 2.

One patient had a third IGB inserted. His initial weight was 213.45 kg (BMI 70.52 kg/m^2); he only lost 3.33 kg, after keeping the balloon for 210 days.

Following successful weight loss with the IGB, it was the intention to offer the 46 patients the option of definitive bariatric surgery. A total of 29 out of 46 (63%) patients progressed to definitive bariatric surgery after IGB placement; 14 (48%) had a laparoscopic Roux-en-y gastric bypass and 15 (52%) had a laparoscopic sleeve gastrectomy.

Seventeen (36%) patients did not progress to surgery. Out of these, 12 patients (26%) did not tolerate the IGB. Two patients were not suitable for bariatric surgery, due to psychological issues that required further management. Two patients declined bariatric surgery and one patient had significant abdominal wall hernias and was unsuitable for surgery.

Comparison was made between the group who progressed to bariatric surgery versus the group that did not. No

Table 3 Comparison between those patients that progressed to definitive bariatric surgery after IGB versus those who did not. (This data does not include the four patients in whom IGB was inserted for non-bariatric surgery)

	Patients that progressed to surgery	Patients that did not progress to surgery	*p* value
Number	29	17	
Age	48 (27–74)	44 (24–61)	$p = 0.092$
Sex	17F:12M	13F:4M	
Pre-balloon weight (kg)	165.5 (120.8–229)	164 (102–224)	$p = 0.761$
Pre-balloon BMI (kg/m^2)	57.4 (39.6–71)	57.7 (41.4–75.3)	$p = 0.468$
EBW	92.5 (38–148)	95 (41–144)	$p = 0.950$
%EWL	14.2 (0–39.6)	10.53 (− 3.3–64.66)	$p = 0.333$
Median number of days patient kept balloon	189 (39–263)	189 (2–240)	$p = 0.321$
Complications	4/29 (13.8%)	6/17 (35.3%)	$p = 0.126$
Days stay due to complications	4.5 (2–9), 20 days total	3 (2–26), 40 days total	

significant differences were found between the patients that progressed to surgery and those that did not (Table 3).

Complications

Ten patients (21.7%) were readmitted as a result of nausea and vomiting after IGB. They required a median inpatient stay of three (range 2 to 26) days. One of these patients needed three separate acute admissions totalling 9 days. The patient who had 26 inpatient days was admitted 14 days following IGB placement with vomiting; the balloon was removed 24 days post placement. This patient remained admitted for 15 days following IGB removal due to oculogyric crisis, secondary to prochlorperazine. Of all patients readmitted, seven had early removal of their IGB and six failed to progress to surgery. The median number of days post placement that these readmissions occurred was 8 days (range 0 to 52). In the group readmitted for complications, median %EWL was 2.16 (range − 3.3 to 19.5) and median number of days the balloon was inserted was 41.5 (range 2 to 240).

Discussion

This study aimed at understanding the role of the IGB as the first stage in the management of patients with super obesity. Most of our patients underwent IGB insertion for weight loss prior to definitive bariatric surgery. Our results from IGBs demonstrated significant weight loss and reduction in BMI following the first balloon placement. However, a second IGB placement did not provide any significant added weight loss. The reasons behind this difference are unclear. However, our results are comparable with those of other studies. Coffin et al. [12] reported a median BMI reduction of 2.8 kg/m^2 after the first 3 months of insertion which plateaus up to removal at 6 months. This may suggest that the majority of weight loss may occur in the early stages after insertion. Subsequently, we currently no longer offer a second IGB to our patients.

It was also noted that our cohort achieved greater weight loss (13 kg vs. 4.6 kg) and BMI reduction (4.25 vs. 1.59 kg/m^2) than patients from other studies (Sabre et al. [7]). This may be due to the fact that we offered IGBs to the most obese patients.

Sixty-three percent 63% of patients who had an IGB inserted for the intention of subsequent bariatric surgery progressed to definitive bariatric surgery. The reasons that prevented other patients to engage in further surgery included two patients refused, two were unsuitable due to psychological reasons and one patient had large hernia which precluded bariatric surgery. We acknowledge that some patients may achieve their expectations after IGB and intense medical management at tier 3 level. Others do not feel ready to cope with the challenges of the bariatric journey. When comparing those who progressed to bariatric surgery versus those who did not, there was no statistical difference between the groups in terms of age, comorbidities, pre-balloon BMI or pre-balloon weight. However, there was an apparent, but not statistically significant, difference in readmissions due to complications and poor %EWL between these two groups. This may suggest that readmissions and poor %EWL may be indicators for early balloon removal and failure to progress to definitive surgery. For those who do progress, IGB may make subsequent surgery safer, particularly in the super obese patients.

A minority of patients had complications from IGB insertion requiring readmission. These were all due to nausea and vomiting and resulted in seven patients having early balloon removal and six patients not progressing to surgery. There were no mortalities. The majority of readmissions were after the first week following placement; this would suggest that a postoperative inpatient stay would not alter success rate.

Conclusion

Intra-gastric balloon placement in morbidly obese patients as bridging therapy for definitive surgery (bariatric or other) is successful in the majority of patients this may make subsequent surgery safer and easier. We report reduction in %EWL and BMI, comparable with that of other studies. Readmission and failure to achieve %EWL may be predictors for early removal and failure to progress to surgery. Second balloon placements do not provide added benefit and are probably not justified.

Compliance with Ethical Standards

Conflict of Interests The authors declare that they have no conflict of interest.

Research involving human participants, ethical approval statement This report was produced form aretrospective service evaluation/clinical audit and did not involve anything being done to patients beyondtheir normal clinical management and therefore did not require formal ethical approval. Study was approvedby institutional review board.

Informed consent This was a retrospective study. For this type of study, formal consent is not required.

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