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REVIEW ARTICLE

Intragastric Balloon for Management of Severe Obesity: a Systematic Review

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Abstract Older models of intragastric balloons (IGBs) had unacceptably high complication rates and inconsequential weight loss. With FDA approval of newer models, we aimed to systematically examine the literature regarding the efficacy of IGB therapy for obesity. A comprehensive electronic database search was completed. Title searching was restricted to the following keywords: bariatric, gastric, gastric bypass, gastric band, sleeve gastrectomy, and intragastric balloon. Twenty-six primary studies (n = 6101) were included. At balloon removal, mean change in weight and BMI were 15.7 ± 5.3 kg and 5.9 ± 1.0 kg/m^2. The most common complications were nausea/vomiting (23.3 %) and abdominal pain (19.9 %). Serious complications were rare: mortality (0.05 %) and gastric perforation (0.1 %). IGBs are associated with marked short-term weight loss with limited serious complications.

Keywords Intragastric balloon · Obesity · Weight loss · Outcomes

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Introduction

Bariatric surgery is an established treatment modality for severe obesity [1] with long-term efficacy in sustainable weight loss [2]. However, increasing severity of obesity is associated with higher surgical morbidity and mortality, longer hospitalization and increasing rates of 30-day readmission due to comorbidities such as diabetes, coronary artery disease, and obstructive sleep apnea [3–5]. In addition, a thicker abdominal wall, increased visceral fat and massive hepatomegaly make the surgery itself more technically challenging [6]. Conse quently, some severely obese patients may not qualify for bariatric surgery, as the risks outweigh the benefits. In light of this, most bariatric multidisciplinary care clinics require preoperative weight loss in an attempt to minimize complication rates and decrease the technical difficulties of surgery. The minimal preoperative weight loss of approximately 10 % of total body weight that is required at most centers is associated with improvement in cardiovascular disease [7], reduced perioperative morbidity, a technically easier operation with a reduction in overall liver volume [8], and shorter operating times [9].

Minimally invasive, non-surgical options for weight loss are gaining popularity as a mechanism to help achieve this preoperative weight loss. One of the most widely studied of the endoscopic therapies for obesity is the intragastric balloon (IGB). The physiologic concept of an IGB was first described by Nieben in 1982 with his idea of the placement of an artificial gastric bezoar, as a space occupying device [10]. It was based on the concept that the mechanical gastric distension from the IGB will increase satiety and thereby decreases food intake [11–13]. Older models of the IGB were initially promising; however, they were eventually taken off the market due to an unacceptably high number of complication rates such as gastric perforations, gastric ulcers, small bowel obstruction, esophageal lacerations, balloon migration, vomiting, and abdominal pain. To date, the concept and technique of the IGB has evolved considerably since its inception. In August 2015, it was approved by the Food and Drug Administration (FDA) as a primary weight-loss intervention. These FDA-approved IGBs are endoscopically placed, saline-filled, spherical balloons with volumes varying between 400 and 700 ml.

Our aim was to systematically review the literature to determine the efficacy and safety of IGB therapy for obesity.

Methods

Data Sources

A comprehensive search of MEDLINE, EMBASE, SCOPUS, the Cochrane Library, and Web of Science from 1946 to July 2015 was completed. Title searching was restricted to the following keywords and terms: bariatric surgery, gastric bypass, gastric band, sleeve gastrectomy, and intragastric balloon.

Selection Criteria

Two reviewers (ES, NS) screened the studies based on title and abstract. The preliminary search identified 570 studies potentially relevant studies. These studies were then screened based on title and abstract and 147 studies were selected for evaluation by full text. All comparison studies included in the systematic review were assessed by three reviewers (EY, NS, RG) for methodological quality. Disagreements were resolved by re-extraction.

Inclusion criteria were English speaking studies, with ≥25 patients, where IGB was a primary weight-loss agent and patients had not had previous bariatric interventions. Any study that required patients to have placement of more than one IGB simultaneously during the initial 6-month treatment duration was excluded.

Data Extraction

Basic patient demographics, weight loss outcomes, and adverse events were collected from each study. Patient demographics consisted of total number of patients in each study, mean patient age, percentage of females in the study, mean preoperative weight, mean preoperative body mass index (BMI), and type of IGB used (3 air-filled, 23 fluid-filled). The primary outcome of interest was weight change at 6 months or IGB removal. Weight change outcomes consisted of mean weight, mean BMI, and percent excess weight loss (%EWL). Secondary outcomes collected were perioperative adverse outcomes. Adverse events included rates of early removal, IGB intolerance, IGB migration, spontaneous IGB deflation, nausea/vomiting, abdominal pain, gastro-esophageal reflux disease (GERD), clinical dehydration, gastric ulcers, gastric perforation, and patient mortality. Specifically, early removal is defined as endoscopic removal of the IGB before the completion of the 6-month treatment duration.

Statistical Analysis

Descriptive categorical variables were expressed as percentages and continuous variables were expressed as weighted mean ± standard deviation (SD) where appropriate. Meta-analysis was used to compare the patient demographics pre-IGB placement to the outcomes after removal at 6 months. The estimated effects were calculated using the latest version of RevMan software.

Results

Twenty-six studies were included in this systematic review (n = 6101): 1 randomized controlled trials [14], and 25 case series [15–39] (Table 1). Mean patient age was 37.8 ± 2.5 years, with 71 ± 9 % of patients being female (Table 2). The mean preoperative weight and BMI of patients were 119.0 ± 21.7 kg and 42.6 ± 5.4 kg/m^2, respectively.

Weight-Loss Outcomes

At the time of IGB removal, patients experiences statistically significant weight loss ($p < 0.00001$), with a postoperative mean weight and BMI change of 15.7 ± 5.3 kg and 5.9 ± 1.0 kg/m^2, respectively (Figs. 1 and 2). The %EWL at IGB removal was 36.2 ± 6.3 % (Table 3). Mean time to removal of band was 6.0 ± 0.4 months. It is important to note that in the meta-analysis, the heterogeneity between trials was significant for reported BMI outcomes, while it was not for reported weight loss in kilogram outcomes (Figs. 1 and 2).

Complications

Three and a half percent of patients underwent early IGB removal, most commonly due to abdominal pain (17.3 %), nausea/vomiting (13.8 %), balloon deflation (12.8 %), and balloon intolerance (12.0 %) (Table 4). The most common complications experienced by patients that underwent the full duration of treatment were as follows: nausea/vomiting (23.3 %), abdominal pain (19.9 %), and GERD (14.3 %). Other complications included diarrhea/constipation (10.4 %), deflation of the IGB with resulting displacement of their balloon (1.9 %), and spontaneous deflation of the IGB without migration of the device (0.7 %). Serious complications were

Table 1 List of papers reviewed

Author	Publication date	Study design	Balloon type	Number of patients in study
Alfredo [15]	2014	Multicenter case series	BIB	611
Al-Momen [16]	2005	Case series	BIB	44
Angrisani [17]	2006	Case series	BIB	175
Coskun [18]	2008	Case series	BIB	100
Crea [38]	2009	Case series	BIB	143
Dastis [19]	2009	Case series	BIB	100
de Goederen-van der Meij [20]	2007	Case series	BIB	40
Fuller [14]	2013	RCT	Fluid-filled IGB	31
Gaggiotti [39]	2007	Case series	Endogast (air-filled)	57
Genco [21]	2005	Case series	BIB	2515
Giuricin [22]	2012	Case series	Heliosphere	45
Gottig [23]	2009	Case series	BIB	190
Herve [24]	2005	Case series	BIB	100
Koerner [25]	2013	Case series	BIB	99
Lecumberri [26]	2011	Case series	Heliosphere	82
Loffredo [27]	2001	Case series	BIB	77
Lopez-Nava [28]	2011	Case series	BIB	714
Mathus-Vliegen [29]	1990	Case series	Air-filled IGB	60
Mion [30]	2007	Case series	Air-filled IGB	32
Peker [31]	2010	Case series	BIB	31
Roman [32]	2004	Case series	BIB	176
Sallet [33]	2004	Case series	BIB	323
Spyropoulos [34]	2007	Case series	BIB	26
Stimac [35]	2011	Case series	BIB	171
Tai [36]	2013	Case series	BIB	33
Totte [37]	2001	Case series	BIB	126

BIB bioenteric intragastric balloon (fluid-filled)

rare: mortality (0.05 %), gastric ulcers (0.3 %), gastric perforations (0.1 %), and balloon migration (0.09 %). (Table 5).

Discussion

While there are studies published on IGBs as a weight-loss system, our systematic review is the most up to date systematic reporting of the primary evidence. We found that the IGB achieved a mean weight loss of 11.5 kg in the 6-month duration of therapy. It appears that the mean weight loss increases at higher levels of BMI, indicating that the IGB balloon is most effective in the more obese cohort. While this review did not examine long-term maintenance of weight loss, it showed that the IGB was successful in achieving modest short-term weight reduction in the severely obese patient.

Laparoscopic surgery in extremely obese patients is technically complex, and as a result operative times are significantly longer. Reasons for the additional challenge include technical limitations of instrument length, reduced ability to reach the angle of his, visibility restraints from the increased visceral fat, and the thickness of the abdominal wall impairing

Table 2 Basic patient demographics

BMI class	Percentage female patients (%)	Number of patients	Mean age (years)	Mean preoperative BMI (kg/m^2)	Mean preoperative weight (kg)
30.0–34.9	79.4	309	35.9 ± 1.6	32.5 ± 1.5	95.9 ± 0
35.0–39.9	76.1	1651	37.7 ± 2.7	37.1 ± 1.6	104.5 ± 6.8
≥40.0	67.4	4141	38.4 ± 4.2	48.2 ± 7.2	140.4 ± 24.7

Study or Subgroup	Pre Mean	Pre SD	Pre Total	Post Mean	Post SD	Post Total	Weight	Mean Difference IV, Random, 95% CI
2.1.1 Water Filled								
Coskun 2008	113.2	24.8	100	100.46	26.1	100	8.8%	12.74 [5.68, 19.80]
Dastis 2008	96.5	18.8	100	83.9	35.7	100	7.2%	12.60 [4.69, 20.51]
de Goederen Van 2007	142.4	25.5	40	124.1	21.9	40	4.3%	18.30 [7.88, 28.72]
Giuricin 2012	114.7	21.4	45	102	35.7	45	3.2%	12.70 [0.54, 24.86]
Koerner	151.4	29.2	99	129.8	35.7	99	5.6%	21.60 [12.51, 30.69]
Loffredo 2001	128	29.2	77	113.4	35.7	77	4.4%	14.60 [4.30, 24.90]
Lopez-nava 2011	106.3	21.5	714	94.7	22	714	43.5%	11.60 [9.34, 13.86]
Peker 2010	119.3	22.5	31	104.31	2.3	31	7.1%	14.99 [7.03, 22.95]
Spyropoulos 2007	193.9	29.2	26	164.9	35.7	26	1.5%	29.00 [11.27, 46.73]
Stimac 2011	123.2	27.1	171	106.3	27.3	171	12.5%	16.90 [11.13, 22.67]
Subtotal (95% CI)			**1403**			**1403**	**98.1%**	**14.30 [11.84, 16.75]**
Heterogeneity: Tau² = 2.83; Chi² = 11.08, df = 9 (P = 0.27); I² = 19%								
Test for overall effect: Z = 11.42 (P < 0.00001)								
2.1.2 Air Filled								
Mion 2007	97	29.2	32	87	35.7	32	1.9%	10.00 [−5.98, 25.98]
Subtotal (95% CI)			**32**			**32**	**1.9%**	**10.00 [−5.98, 25.98]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.23 (P = 0.22)								
Total (95% CI)			**1435**			**1435**	**100.0%**	**13.93 [11.70, 16.15]**
Heterogeneity: Tau² = 1.63; Chi² = 11.23, df = 10 (P = 0.34); I² = 11%								
Test for overall effect: Z = 12.28 (P < 0.00001)								
Test for subgroup differences: Chi² = 0.27, df = 1 (P = 0.60), I² = 0%								

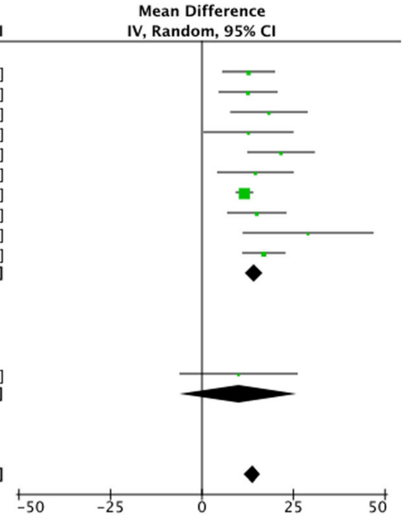

Fig. 1 Forest plots of comparison of reported weight loss outcomes (in kg) of pre-IGB implantation versus removal at 6 months

fine laparoscopic movements [40]. There is also an association between obesity, non-alcoholic steatohepatitis (NASH), and left lobe hepatomegaly, which increases the liver's susceptibility to surgical injury and makes visualization and manipulation of organs in the liver's vicinity more difficult. A 5–10 % preoperative weight loss reduces liver size and decreases visceral fat. This modest weight loss is also known to decrease the co-morbidities that affect perioperative risk, such as hypertensive crises, diabetes mellitus, thromboembolic risk, and obstructive sleep apnea [8, 41]. Preoperative weight loss in bariatric surgery has also been correlated with decreased operating times, less surgical blood loss, and a shorter hospital stay [41]. Importantly, Liu et al. showed that a modest preoperative weight loss of approximately 5 % led to the operation deviating significantly less from the planned procedure [42]. Thus, the IGB can play a significant role in maintaining the standard of care operation, decreasing complications, and operative times.

Serious complications such as mortality, ulceration, perforation, and balloon migration were rare and this makes the IGB an acceptable option as a weight-loss intervention. A significant proportion of patients experienced nausea/

Study or Subgroup	Pre Mean	Pre SD	Pre Total	Post Mean	Post SD	Post Total	Weight	Mean Difference IV, Random, 95% CI
1.1.1 Water Filled								
Alfredo 2015	42.5	8.2	611	37.9	13.4	611	8.3%	4.60 [3.35, 5.85]
Angrisani 2006	54.4	8.1	175	47.3	8.1	175	7.4%	7.10 [5.40, 8.80]
Coskun 2008	39.28	7	100	34.7	11	100	5.6%	4.58 [2.02, 7.14]
Crea 2009	36.2	5.7	143	29.6	4.6	143	8.3%	6.60 [5.40, 7.80]
de Goederen Van 2007	46.5	5.7	40	40.5	5.6	40	5.8%	6.00 [3.52, 8.48]
Genco 2005	44.4	14.7	2515	35.4	11.8	2515	9.1%	9.00 [8.26, 9.74]
Giuricin 2012	40.22	5.7	45	35.9	5.8	45	6.0%	4.32 [1.94, 6.70]
Koerner	53.6	14.7	99	47.7	13.4	99	3.6%	5.90 [1.98, 9.82]
Loffredo 2001	46.6	14.7	77	41.2	13.4	77	3.1%	5.40 [0.96, 9.84]
Lopez-nava 2011	37.6	5.7	714	31.1	7.2	714	9.2%	6.50 [5.83, 7.17]
Peker 2010	41.84	8.3	31	36.4	7.4	31	3.6%	5.44 [1.53, 9.35]
Sallet 2004	38.2	9.4	323	32.9	8.3	323	8.0%	5.30 [3.93, 6.67]
Spyropoulos 2007	65.3	9.8	26	54.3	9.9	26	2.3%	11.00 [5.65, 16.35]
Stimac 2011	41.6	7.5	171	35.8	7.9	171	7.5%	5.80 [4.17, 7.43]
Tai 2013	32.4	3.7	33	28.5	3.7	33	7.2%	3.90 [2.11, 5.69]
Subtotal (95% CI)			**5103**			**5103**	**95.0%**	**6.01 [5.03, 6.98]**
Heterogeneity: Tau² = 2.44; Chi² = 73.69, df = 14 (P < 0.00001); I² = 81%								
Test for overall effect: Z = 12.10 (P < 0.00001)								
1.1.2 Air Filled								
Gaggiotti 2007	48.9	9.5	57	40.5	6.2	57	5.0%	8.40 [5.46, 11.34]
Subtotal (95% CI)			**57**			**57**	**5.0%**	**8.40 [5.46, 11.34]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 5.59 (P < 0.00001)								
Total (95% CI)			**5160**			**5160**	**100.0%**	**6.13 [5.18, 7.07]**
Heterogeneity: Tau² = 2.40; Chi² = 75.02, df = 15 (P < 0.00001); I² = 80%								
Test for overall effect: Z = 12.73 (P < 0.00001)								
Test for subgroup differences: Chi² = 2.29, df = 1 (P = 0.13), I² = 56.3%								

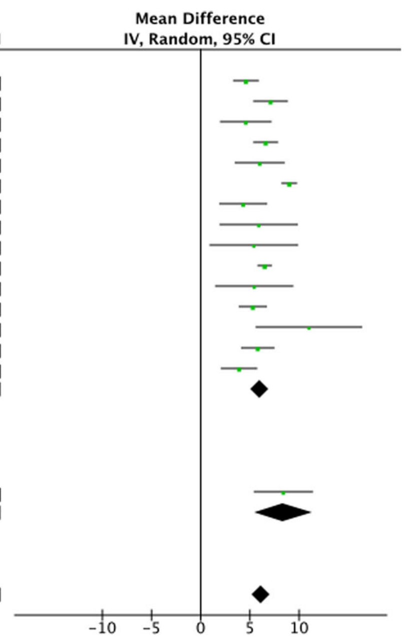

Fig. 2 Forest plots of comparison of reported BMI outcomes of pre-IGB implantation versus removal at 6 months

Table 3 Weight loss outcomes

BMI class	Mean treatment duration (months)	Mean weight at IGB removal (kg)	Mean BMI at IGB removal	Mean change in weight (kg)	Mean change in BMI (kg/m^2)	%EWL (mean)
30.0–34.9	6.8	*	33.3 ± 6.8	10.8 ± 1.8	*	39.0 ± 1.2
35.0–39.9	5.8	91.5 ± 7.5	32.1 ± 2.2	14.2 ± 2.6	5.1 ± 0.4	38.0 ± 13.0
≥40	5.9	120.7 ± 22.1	41.2 ± 6.1	18.2 ± 5.7	7.2 ± 0.1	30.6 ± 5.4

*Data set for this BMI class was not available for the papers reviewed

vomiting, abdominal pain, and GERD. Hence, we recommend close clinical monitoring during the full duration of IGB treatment.

This review has important implications, as IGBs are associated with marked short-term weight loss with limited serious complications. If a patient is able to tolerate the balloon, then the IGB has potential as a bridging therapy to help achieve preoperative weight loss in the extremely obese patient and facilitate an easier bariatric surgical procedure with fewer complications. The purpose of this study was not to speak to the IGB as a long-term resolution to obesity and its co-morbidities, but rather a short-term solution.

To further explore the role of IGB as a bridge to surgery, future studies should look at weight loss results of the IGB as the first step, in a two-step planned sequence with either the gastric bypass or sleeve gastrectomy, compared to medical management followed by surgery. Studies should also examine the optimal time to surgery after IGB removal to avoid the weight regain that can happen after IGB extraction.

Limitations

This review has a number of limitations. First, the adverse events and complication rates were not consistently reported in the publications of the studies. For instance, some papers defined intolerance as a physical discomfort, while others defined it as a psychological barrier. For the purposes of this review, we included both these definitions under the same term. To add to the potential heterogeneity of the data, our review did not differentiate the type of IGB, either air-filled or saline-filled IGB. Only three studies (n = 149) used air-filled balloons, thus we did not expect this to affect weight loss outcomes. Another limitation is that the weight gain after balloon removal was not consistently studied in these studies. Thus, it is difficult to predict the optimal time to have a definitive surgery if the IGB were being used as a bridging therapy. Most importantly, the lack of primary controlled studies and the heterogeneity seen amongst studies limits the strength of the conclusions made by this paper.

Table 4 Reason for early removal of IGB

Reason for early removal	Percent (%)
Other	21.9
Abdominal pain	17.3
Nausea/vomiting	13.8
Balloon deflation	12.8
Patient intolerance	12.0
Inefficacy	8.3
Gastric ulcer	5.8
Gastroparesis	4.4
Gastric perforation	3.19
Voluntary by patient	0.4

Conclusions

IGBs are associated with marked short-term weight loss with limited serious complications. IGB may have a potential role as the first step in a two-step process with a planned bariatric

Table 5 Complications in patients that underwent the full duration of treatment

Complication	Percent (%)
Nausea/vomiting	23.3
Abdominal pain	19.9
GERD	14.3
Diarrhea/constipation	10.4
Gastric stasis	8.3
Hypokalemia	6.1
Dehydration	4.7
Early removal	3.5
Esophagitis	2.8
Gastritis	2.8
Deflation with displacement	1.9
Obstruction	0.8
Deflation without displacement	0.7
Gastric ulcer	0.3
Gastric perforation	0.1
Migration	0.09
Mortality	0.05
Migration	0.6

operation in the extreme BMI populations. Further studies should be directed at determining how soon weight regain occurs after IGB removal and the optimal time to perform the definitive bariatric surgery after IGB removal.

Compliance with Ethical Standards This article does not contain any studies with human participants or animals performed by any of the authors.

For this type of study formal consent is not required.

Conflict of Interest Ekua Yorke, Noah J. Switzer, Artan Reso, Xinhe Shi, Christopher de Gara, and Richdeep Gill declare that they have no conflict of interest.

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