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Usefulness of the ReShape intragastric balloon for obesity

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ABSTRACT

Intragastric balloon (IGB) is approved for weight reduction in obesity patients who have a body mass index (BMI) of 30 to 40 kg/m^2. The effectiveness of IGB in various degrees of obesity is not well established. We aimed to study the effect and safety of IGB in different groups of obese patients. A retrospective study was performed. All patients who underwent placement of the ReShape^{TM} gastric balloon and completed a 6-month follow-up were included. There were 35 gastric balloons in 34 patients who had a baseline body weight of 106.5 ± 23.5 kg and a BMI of 37.1 ± 5.5 kg/m^2. After IGB removal, total body weight was reduced 6.8 ± 7.3% ($P <$ 0.001) and the BMI reduction was 2.7 ± 2.9 kg/m^2 ($P <$ 0.001). Subgroup analysis showed that patients with BMI >40 kg/m^2 also had significant reduction of total body weight and BMI. The diastolic blood pressure was reduced by 4.7 ± 12.3 mm Hg ($P =$ 0.03) after balloon removal. The most common complication was nausea in 22.9%. One patient had balloon migration leading to small bowel obstruction. One patient had a bleeding gastric ulcer. In summary, IGBs are an effective method to assist in weight loss in patients with various degrees of obesity, even with a BMI >40 kg/m^2, with minor adverse effects.

KEYWORDS Endoscopic bariatric surgery; intragastric balloon; minimally invasive; ReShape; weight loss; weight reduction

Obesity has grown into a major health problem in the USA, with substantial medical expenses to treat obesity-related conditions.[1] To restore a normal weight in obese patients is challenging. An intragastric balloon (IGB) is a minimally invasive device that has been approved to assist with weight reduction. Most studies of IGBs were performed in obese participants with body mass indexes (BMIs) in the range of 30 to 40 kg/m^2.[2,3] The experience with IGBs in extreme BMI is not known. To investigate the effectiveness and safety of IGBs in different classes of obesity, we performed a retrospective review of outcomes in our center.

METHODS

All patients who underwent placement of a ReShape^{TM} IGB and completed 6 months of follow-up (or until balloon removal) between May 2016 and April 2018 were included in the study. Diet control and exercise were implemented before IGB placement. Patients who failed lifestyle modification were offered IGB placement. There were 1- and 3-month follow-ups with a gastroenterologist prior to balloon removal. Data, including baseline characteristics, comorbidities, pre- and post-IGB weights and BMI, and complications of IGB, were retrieved from electronic medical records.

The ReShape IGB is a temporary implant of a fluid-filled balloon, designed to facilitate weight reduction by occupying space in the stomach. The balloon is delivered transorally with endoscopy. Once the balloon is positioned, it is inflated with sterile saline and methylene blue, which is used as an indicator if the balloon is accidentally deflated or leaks. The balloon is left in the stomach for up to 6 months. Contraindications include previous gastrointestinal surgery, inflammatory diseases of the gastrointestinal tract (i.e., esophagitis, gastric ulceration, duodenal ulceration, Crohn's disease), a large hiatal hernia, a gastric mass, and severe coagulopathy.

The primary outcome was total body weight loss, measured by the percentage reduction from baseline body weight and the mean difference before and after IGB placement at 6-month follow-up. Statistical significance was determined by 95% confidence intervals (CIs) and a P value <0.05.

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Table 1. Baseline characteristics of 34 patients receiving the ReShape intragastric balloon

Demographic characteristic	Value
Sex: male	6 (18%)
Age (years), mean ± SD	48.2 ± 12
Weight (kg), mean ± SD	105.8 ± 23.5
Body mass index (kg/m^2), mean ± SD	36.9 ± 5.5
25.0–29.9	3 (8%)
30.0–34.9	10 (29%)
35.0–39.9	10 (29%)
>40	12 (34%)
Hypertension[a]	13 (38%)
Type 2 diabetes mellitus	5 (15%)
Hyperlipidemia[b]	11 (32%)
Gastroesophageal reflux disease	12 (35%)
Obstructive sleep apnea	6 (18%)

[a]Defined as blood pressure ≥130/80 mm Hg.
[b]Defined as low-density lipoprotein ≥190 mg/dL.

Secondary outcomes included the absolute change of blood pressures and metabolic panels, including triglycerides, low-density lipoprotein, high-density lipoprotein, fasting blood sugar, and hemoglobin A1c, compared before and after IGB placement. Complications from IGB, including nausea, gastric ulcer, or balloon migration, were recorded. Subgroup analysis was performed for patients with a BMI >40 kg/m^2 for primary and secondary outcomes.

Continuous variables are reported with means and standard deviations. Categorical variables are reported with percentages and frequencies. Pre- and post-IGB body weight, BMI, and other metabolic parameters were compared using the paired *t* test with a 0.05 two-sided significance level and 95% CI. All statistical analyses were computed using SPSS Statistics version 23.0.

RESULTS

A total of 35 IGBs were successfully placed in 34 patients. Eleven patients (12 IGBs) had BMIs >40 kg/m^2. One patient who had a BMI >40 kg/m^2 had the balloon placed twice at 10 weeks after first balloon removal due to patient preference. The mean age was 48.2 years, and 82% of the patients were women. Their mean baseline body weight was 106 kg, and the mean BMI was 37 kg/m^2 (minimum 27.6, maximum 49.17). Comorbidities are reported in *Table 1*. Two patients had early IGB removal before 6-month follow-up, at week 4 and week 8, because of severe nausea and vomiting. After the exclusion of these two patients, the mean duration of IGB placement was 25.7 ± 2.9 weeks (minimum 19.4 weeks and maximum 33.3 weeks).

Mean body weight decreased 6.8% ± 7.3% or 7.3 kg (95% CI, 4.5–10.1; $P < 0.001$) after 6 months. Mean BMI decreased 7.0% or 2.7 kg/m^2 (95% CI, 1.6–3.7; $P < 0.001$). Mean systolic blood pressure reduction was 4.5 ± 22.6 mm Hg (95% CI, −3.3 to 12.24; $P = 0.25$), and the mean diastolic blood pressure decreased 4.7 ± 12.3 mm Hg (95% CI, 0.5–8.9; $P = 0.03$). As shown in *Table 2*, there was a decrease in all metabolic parameters. Only fasting blood sugar and blood pressure had an adequate number of measurements to calculate the mean difference and only diastolic blood pressure was statistically significant.

Subgroup analysis of patients with BMIs >40 kg/m^2 demonstrated similar outcomes in terms of significant reduction in both total body weight and BMI *(Table 2)*. The mean percentage total body weight reduction and the mean percentage BMI reduction were 7.2% and 6.9%, respectively. The mean total body weight reduction and BMI reduction were 8.9 ± 8.4 kg (95% CI, 3.5–14.2; $P = 0.004$) and 3.0 ± 3.3 kg/m^2 (95% CI, 0.9–5.1; $P = 0.008$). Systolic blood pressure, diastolic blood pressure, and fasting blood sugar decreased, but the pre/post difference was not statistically significant. Other metabolic parameters were not compared due to insufficient data to perform analysis.

Nausea was the most common side effect and occurred in 23% of patients *(Table 3)*. Two patients required balloon removal because of severe nausea and vomiting at week 4 and week 8. Other minor complications included heartburn (3%) and gastric erosion (3%). Two patients had major complications. One had balloon migration causing small bowel obstruction and required surgery to remove the balloon. The other patient had a gastric ulcer requiring two units of red blood cell transfusion; however, this patient also had a history of *Helicobacter pylori* and nonsteroidal anti-inflammatory drug use.

DISCUSSION

In our study, we used the ReShape Integrated Dual Balloon System. ReShape was approved by the US Food and Drug Administration in July 2015 for weight reduction, in conjunction with diet and exercise for obese patients with BMIs in the range of 30 to 40 kg/m^2. A randomized controlled trial of the ReShape IGB in 326 participants (the REDUCE pivotal trial) showed significant weight loss in patients who received IGB plus diet control and exercise, compared to diet and exercise alone, with a 7.6% ± 5.5% reduction of total body weight and a 2.7 ± 1.9 kg/m^2 decrease in BMI.[4] We had similar findings with a 6.8% ± 7.3% reduction in total body weight and 2.7 ± 2.9 kg/m^2 reduction in BMI.

The IGB device has an effect on obesity-related disorders and underlying comorbidities. Our study found decreased systolic and diastolic blood pressures after IGB removal with significant reductions in diastolic blood pressures. However, other metabolic tests did not have enough data to perform mean difference calculations. The REDUCE trial demonstrated improvement in hemoglobin A1c, high-density lipoprotein, low-density lipoprotein, systolic and diastolic blood pressure,

Table 2. Weight loss and metabolic parameters before and after placement of an intragastric balloon

Variable	Mean ± SD			*P* value
	Pre-IGB	Post-IGB	Difference	
All patients				
Total body weight (kg), $n=35$	106.5 ± 23.5	99.2 ± 23.1	7.3 ± 8.0	<0.001
BMI (kg/m^2), $n=35$	37.1 ± 5.5	34.4 ± 5.5	2.7 ± 2.9	<0.001
Triglycerides (mg/dL), $n=7$	216 ± 118	117 ± 35.1	N/A	N/A
LDL (mg/dL), $n=7$	128.4 ± 49.9	99.2 ± 30.2	N/A	N/A
HDL (mg/dL), $n=7$	54.2 ± 41.1	47.0 ± 20.3	N/A	N/A
Fasting blood sugar (mg/dL), $n=15$	112.9 ± 43.6	106 ± 21.7	7.0 ± 22.3	0.44
Hemoglobin A1c (%), $n=4$	8.3 ± 1.3	6.0 ± 0.7	N/A	N/A
Systolic BP (mm Hg), $n=35$	135 ± 16	131 ± 19	4.5 ± 22.6	0.25
Diastolic BP (mm Hg), $n=35$	85 ± 11	80 ± 11	4.7 ± 22.3	0.03
Subgroup of patients with BMI >40 kg/m^2				
Total body weight (kg), $n=12$	127.9 ± 23.9	119.0 ± 25.2	8.9 ± 8.4	0.004
BMI (kg/m^2), $n=12$	42.8 ± 2.8	39.8 ± 3.5	3.0 ± 3.3	0.008
Fasting blood sugar (mg/dL), $n=3$	119 ± 28	126 ± 25.5	7.0 ± 22.3	0.64
Systolic BP (mm Hg), $n=12$	143 ± 13	132 ± 20	10.1 ± 20.8	0.12
Diastolic BP (mm Hg), $n=12$	90 ± 12	83 ± 14	7.4 ± 14.8	0.11

BMI indicates body mass index; BP, blood pressure; HDL, high-density lipoprotein; IGB, intragastric balloon; LDL, low-density lipoprotein; SD, standard deviation.

Table 3. Complications after placement of an intragastric balloon

Type	Complication	*n* (%)
Minor	Nausea	8 (23%)
	Severe nausea leading to early balloon removal	2 (6%)
	Heartburn	1 (3%)
	Gastric erosion	1 (3%)
Major	Gastric ulcer with bleeding	1 (3%)
	Small bowel obstruction due to balloon migration	1 (3%)

weight, and hip circumference. These beneficial effects persisted through 48 weeks of follow-up. Similar improvements in metabolic panels were also found in other studies of IGB in addition to improved quality of life.[5,6]

There are a few studies on IGB effectiveness in extremely obese patients who have a BMI >40 kg/m^2. In our subgroup analysis, IGB showed the same effects with significant body weight and BMI reduction. Systolic blood pressures and metabolic panels in our study were not significantly decreased after balloon removal. This might be related to the small numbers of patients in our study. A case-control study in extremely obese patients with BMI >60 kg/m^2 used IGB for 6 months prior to laparoscopic gastric bypass.[7] Patients who received preoperative IGB placement had a 6.8 ± 3.8 kg weight loss at the time of surgery, an hour shorter operative time, and lower laparotomy conversion rates. IGB might be considered an adjuvant therapy before gastric bypass surgery.

Potential adverse events from IGB include gastric ulceration, esophageal perforation, gastric bleeding, nausea, vomiting, and dysphagia. The most common adverse effect we found in our study was nausea. The REDUCE trial reported nausea, vomiting, and abdominal discomfort/pain that generally resolved in 3 to 7 days. Early retrievals for intolerance occurred in 9.1% of all treated patients. In our study, we had 2 cases (5.7%) with early retrievals. There was no report of intestinal obstructions or device migration in the REDUCE trial. However, we had one case of IGB migration leading to small bowel obstruction that required laparotomy to remove the balloon.

IGB placement is an effective method to assist in weight loss in patients with various degrees of obesity. Regardless of BMI, patients had significant weight loss. Our study showed significant weight loss in the subgroup of patients with a BMI >40 kg/m^2; however, more clinical studies of effectiveness and safety in extremely obese patients is recommended.

Although several patients had nausea and heartburn, severe complications were rare.

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