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Original Research Article

Lack of efficacy of dual intragastric balloon therapy on weight loss and patient dissatisfaction

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ABSTRACT

Background: Dual intragastric balloon (DIGB) therapy is a non-surgical, restrictive method of weight loss. We evaluated weight loss and patient satisfaction after DIGB removal.
Methods: Between 2016 and 2019, 35 patients had DIGB therapy. A retrospective review of weight loss at balloon removal and follow-up, adverse events during DIGB therapy, and patient satisfaction was performed.
Results: At follow-up after balloon removal (22.3 ± 10.5 months), mean percent excess weight loss (%EWL) was significantly decreased compared to %EWL at removal (4.7 ± 42.7% vs 32.4 ± 38.8%, p = .001). Weight regain occurred in 22/31 (71%) patients. Adverse events during DIGB therapy included: nausea, abdominal pain, reflux, pancreatitis, and gastric outlet obstruction. Twenty-five (71.4%) patients completed a satisfaction questionnaire. Only 3/25 (12%) patients were satisfied, and 92% would not choose DIGB for weight loss.
Conclusion: Weight loss achieved from DIGB on average was not maintained after balloon removal. Most patients were not satisfied and would not choose DIGB again.

Introduction

Obesity continues to be a growing worldwide health problem. Intragastric balloon (IGB) therapy has become an option for those patients who are not eligible for or who do not want to undergo bariatric surgery.[1]

IGB therapy is a non-surgical, temporary method of inducing weight loss. Saline or gas filled balloons are placed in the stomach to promote restriction and the feeling of satiety.[1] The ReShape Dual Balloon System (ReShape Lifesciences, San Clemente, CA) received FDA approval in 2015. Other FDA approved intragastric balloons include the Orbera (Apollo Endosurgery, Austin, TX) and Obalon (Obalon Therapeutics Inc, Carlsbad, CA) systems. The Orbera system consists of one balloon containing 400–700 ml of saline. The Obalon system consists of up to three gas filled balloons containing 250 ml each that are placed under fluoroscopy and does not require sedation or endoscopy for placement. The dual intragastric balloon (DIGB) system differs from other intragastric balloons in that it is composed of two independent balloons that are connected by a shaft. If one balloon deflates, the connected second balloon prevents the device from migrating out of the stomach for increased safety.[1]

The REDUCE pivotal trial found that the DIGB system was more effective than diet and exercise alone for weight loss.[2] It is less clear the degree to which this weight loss is sustained over time after removal of the balloon. Studies evaluating patient satisfaction are conflicting with none specifically evaluating the DIGB.[3–7]

The primary objective of this study was to evaluate the efficacy of DIGB therapy on weight loss at time of balloon removal and whether this weight loss was maintained over time. The secondary objectives were to measure patient satisfaction and identify any adverse events associated with DIGB therapy.

Methods & materials

A retrospective evaluation of 35 consecutive patients who had a DIGB inserted and removed from 2016 to 2019 by a single surgeon was conducted. All patients received nutritional counseling and were encouraged to follow lifestyle modifications including diet

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and exercise. Monthly ongoing follow up with a registered dietician was made available.

Technique

The DIGB is placed with endoscopic guidance while under sedation. A guidewire is placed into the duodenum via esophagogastroduodenoscopy. The balloon system is then deployed over the guidewire and positioned in the stomach along the greater curvature. The balloons are then each filled with 350–450 ml of saline mixed with methylene blue depending on the patient's height. Methylene blue serves as an indicator in case of balloon deflation where the urine color becomes green due to its absorption. The recommended therapy period is six months, after which the balloons are deflated and removed endoscopically under sedation.

Medical records were reviewed and data was collected, including pre-balloon insertion baseline weight and BMI, age, sex, duration of balloon therapy period, weight and BMI at time of balloon removal, and any adverse events. A follow-up weight and BMI were identified as well as the length of the follow-up period. Patient satisfaction data was identified from routine follow-up, where patients answered a set of standardized, non-validated questions (Fig. 1).

Statistical analysis

Descriptive statistics were calculated to characterize the patients. Continuous variables were described as the mean with standard deviation. Categorical variables were described as frequency distributions. Changes in measurements of patients' body habitus over time were assessed using the paired *t*-test. Factors affecting whether weight loss was maintained and patient satisfaction were assessed using the Student's t-test. A p-value of 0.05 or less was considered to indicate statistical significance.

Results

Of the 35 patients, 29 (83%) were females, and 6 (17%) were males. The mean age of patients was 45.2 ± 13.5 years. The mean baseline weight was 98.1 ± 17.8 kg. The mean baseline BMI was 35.0 ± 4.6 kg/m2 with a range between 27 and 47.8.

The mean DIGB therapy period was a duration of 8.7 ± 5.1 months. Duration of balloon therapy and the amount of weight lost was weakly positively correlated, although this was not statistically significant ($r = 0.14$, $p = .43$) (Fig. 2). The mean weight loss was 6.9 ± 7.4 kg. Weight was significantly decreased at removal compared to baseline (91.2 ± 18.7 kg vs 98.1 ± 17.8 kg, $p < .001$). BMI was also significantly decreased at removal compared to baseline (32.4 ± 4.9 vs 35.0 ± 4.6, $p < .001$). The mean percent of total body weight loss (%TBWL) at the end of the balloon therapy period was 7.1 ± 7.4%. The mean percent excess weight loss (%EWL) was 31.6 ± 36.6%. Fifteen patients (43%) had >25% EWL. Six patients (17%) had increased weight at the end of the balloon therapy period.

Adverse events during the DIGB therapy period were reported in 51% of the patient's medical records, including nausea (11), abdominal pain (5), reflux (3), gastric ulcers (2), pancreatitis (1), and gastric outlet obstruction (1). Balloon rupture was seen in two patients, with one DIGB requiring premature endoscopic removal and one migrating through the intestinal tract and self-expelling without complication. Hospitalization or emergency department visit was required in 26% (9/35) due to one or more of these adverse events. Early balloon removal before six months occurred in 14% (5/35) due to pancreatitis, gastric ulcer, balloon rupture, nausea, and abdominal pain.

At follow-up, weight was identified on 31 out of 35 patients (89%). The mean follow-up period was 22.4 ± 10.6 months after balloon removal. There was no significant correlation between follow-up time and the amount of weight lost or regained ($r = .19$, $p = .31$). The mean %TBWL was significantly decreased compared to %TBWL at time of removal (0.9 ± 9.4 vs 7.0 ± 7.82, $p < .001$). The mean %EWL was also significantly decreased compared to %EWL at time of removal (4.7 ± 42.7 vs 32.4 ± 38.8, $p = .001$).

At follow-up, 71% of patients (22/31) had gained weight after balloon removal, and 55% (17/31) had regained weight up to or above their pre-balloon baseline. There was no significant difference in mean age, baseline BMI, initial weight loss, therapy duration, and length of follow-up between those that regained weight vs those that maintained weight loss below baseline (Table 1). The group that maintained weight loss below baseline at follow-up had greater initial %TBWL and %EWL at balloon removal compared to the group that regained weight (Table 1). Two patients went on to have a second balloon placed. Seven patients subsequently underwent laparoscopic sleeve gastrectomy.

Twenty-five out of 35 patients provided satisfaction questionnaire responses. Three (12%) patients were satisfied with DIGB therapy. Twenty-two (88%) patients were not satisfied. There was no difference among mean age, baseline BMI, weight loss at removal, weight loss at follow-up, therapy duration, and length of follow-up between those that were satisfied and those that were not satisfied (Table 2). Two (8%) patients were satisfied with the cost effectiveness of the DIGB, and 23 (92%) patients were not satisfied with the cost effectiveness. Twenty-three (92%) patients, in retrospect, would not choose the DIGB for weight loss therapy.

1. How would you rate your weight loss results with the dual intragastric balloon?
   ____ Satisfied ____ Neutral ____ Dissatisfied
2. How would you rate the cost effectiveness of the dual intragastric balloon?
   ____ Satisfied ____ Neutral ____ Dissatisfied
3. How would you rate your overall satisfaction with the dual intragastric balloon?
   ____ Satisfied ____ Neutral ____ Dissatisfied
4. If you could go back in time, would you still choose to use the dual intragastric balloon for weight loss?
   ____ Yes ____ No

Fig. 1. Patient satisfaction questions.

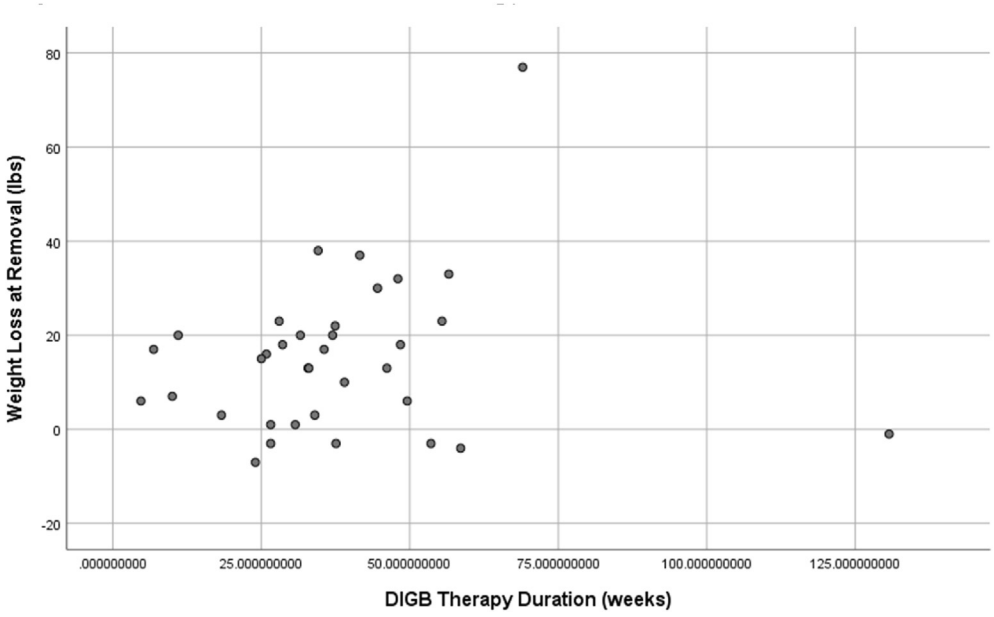

Fig. 2. Weight loss at removal vs duration of therapy.

Discussion

In our study the mean %EWL at balloon removal was 31.6% which is comparable to the 27.9% EWL of the REDUCE trial.[2] It is evident that DIGB therapy does confer a degree of weight loss, however, many of these patients do not maintain their weight loss after balloon removal.

The REDUCE trial reported two-thirds of weight loss was maintained on average through 6 months of follow-up.[2] Agnihotri et al. did not demonstrate significant weight gain at 6 months after balloon removal, although their follow-up data was limited.[8] It is possible that more weight gain post-removal was not seen with these two studies due to the relatively shorter follow-up time and the lack of data in the latter study. Our study had a longer follow-up period (mean 22.3 months) and demonstrated maintenance on average of only 15% of the weight lost at the completion of DIGB therapy. We also observed that a majority of patients gained some weight after removal with many regaining weight up to their pre-balloon baseline or even higher. Only 14.3% of the patients in our study maintained $\geq$10% TBWL at time of follow-up.

The majority of our patients that provided satisfaction questionnaire responses were not satisfied with the DIGB as a weight loss tool nor with its cost effectiveness. There were no differences in initial weight loss, and weight loss at follow-up between the groups of satisfied vs not satisfied patients. Thus, even some patients that were able to maintain weight loss after DIGB therapy were not satisfied. It is possible that some patients did not find the cost nor the side effects associated with the DIGB to be worth the amount of weight loss achieved. Multiple studies have evaluated patient satisfaction with other types of IGB with varying results. The two studies that demonstrated a majority of satisfied patients had satisfaction evaluated right upon balloon removal.[3,4] Whereas the studies that had mostly dissatisfied patients evaluated the satisfaction after a period of follow-up (6–18 months).[5–7] It would seem that the limited durability of weight loss with the IGB over time may contribute to decreased satisfaction.

Accommodative symptoms such as nausea, vomiting, and abdominal discomfort are common with the IGB, but they are not without consequence. Twenty-six percent of our patients required hospital admission or emergency department visit primarily due to these symptoms. The intent of the dual balloon design is to prevent device migration in case of balloon rupture. Agnihotri et al. reported one device migration causing small bowel obstruction leading to surgical intervention.[8] Our study observed one device migration, which did not lead to intestinal obstruction and was self-expelled without complication.

It is important to note that in our study, the duration of balloon therapy was variable with the DIGB left in place longer than 7 months in 63% of patients and longer than 12 months in 17%. There was no significant correlation between amount of weight loss and duration of balloon therapy. The prolonged duration was mainly due to patient refusal and reluctance to have the balloon removed after the 6-month recommended therapy period. One patient was initially lost to follow-up after having moved out of state and subsequently presented after 30 months with gastric outlet obstruction. This poses an interesting dilemma: what should be

Table 1
Follow-up weight comparison (*t*-test).

	Gained weight up to or above baseline, mean (n = 17)	Maintained weight loss below baseline, mean (n = 14)	p value
Age, years	49.2 ± 13.9	39.8 ± 13.1	.063
Baseline BMI, kg/m2	35.3 ± 4.2	33.9 ± 4.3	.361
Weight loss at removal, kg	4.4 ± 5.2	9.3 ± 9.5	.077
%TBWL at removal	4.5 ± 5.5	10 ± 9.3	.048
%EWL at removal	17.9 ± 25.9	49.9 ± 45.1	.02
Balloon therapy duration, months	8.7 ± 6.3	8.9 ± 3.6	.916
Length of follow-up, months	21 ± 10.4	24 ± 10.9	.434

Table 2
Satisfaction comparison (*t*-test).

	Satisfied (n = 3)	Not Satisfied (n = 22)	p value
Age, years	40.7 ± 16.6	47.3 ± 14.3	.466
Baseline BMI, kg/m2	37.2 ± 4.3	34.4 ± 4.1	.294
Weight loss at removal, kg	2.7 ± 5.6	6.0 ± 5.7	.355
Balloon therapy duration, months	9.3 ± 2.7	8.3 ± 5.4	.753
Weight loss at follow-up, kg	4.5 ± 9.9	0.3 ± 8.7	.391
Length of follow-up, months	26.7 ± 0.8	22.9 ± 10.5	.537

done when the patient refuses to have the balloon removed or does not respond to repeated follow-up attempts to schedule balloon removal? Two patients were excluded from analysis in this study because the balloons have yet to be removed due to patient refusal, each having been in place longer than 12 months.

Fourteen percent of our patients went on to have bariatric surgery. The IGB may serve as a path to surgery for those who are initially hesitant to undergo bariatric surgery but do not have success with the less invasive IGB option.[9] Another role for IGB may be as a bridge to provide temporary weight loss in those with BMI ≥50 kg/m2 to optimize the patient prior to definitive bariatric surgery, although this is currently not an FDA approved indication.[10]

Limitations of this study include the retrospective design and small sample size. Furthermore, follow-up weight data was lacking on 4 out of 35 patients, and the questionnaire response rate was only 71% (25 out of 35 patients). This study lacked data regarding comorbidities and any impact that the DIGB therapy may have had on them. We were also not able to ascertain the patients' level of commitment to diet and exercise or how often they visited with a registered dietician. Also, of note is that ReShape Lifesciences is no longer marketing the DIGB.

Conclusion

Dual intragastric balloon therapy was associated with weight loss in the majority of patients, however, on average this weight loss was not maintained over time after the DIGB was removed. The majority of patients were not satisfied with the DIGB as a method of weight loss.

Ethics approval

The hospital Institutional Review Board determined this study to be exempt (category #4(iii)) according to federal regulations. Routine follow-up of these patients was done in accordance with the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) requirements of the American College of Surgeons.

Declaration of competing interest

The authors declare that they have no conflicts of interest. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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