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BRIEF COMMUNICATION

Comorbidity Remission Following Intragastric Dual Balloon Placement

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Abstract

The intragastric dual balloon was FDA approved in 2015 for the treatment of obesity. The objective of this study was to report the weight loss, comorbidity remission, and biochemical improvements experienced by 28 patients following intragastric dual balloon placement at a single institution between September 2015 and June 2017. Demographic data were collected preoperatively. Anthropometric, clinical, and biochemical data were collected preoperatively and 3 and 6 months postoperatively. Two patients were lost to data follow-up. Participants experienced significant improvements in blood pressure and lipid profiles, in addition to substantial weight loss 6 months after balloon insertion. The results of this study underscore the promise of the intragastric dual balloon as an efficacious intervention for weight loss and comorbidity remission in patients with early-stage obesity.

Keywords Intragastric balloons · ReShape · Bariatric surgery · Weight loss · Obesity

Introduction

The dual intragastric balloon was approved by the FDA in 2015 for the treatment of obesity in patients with a body mass index (BMI) of 30–40 kg/m^2 [1]. Following endoscopic insertion, this saline-filled device is thought to enhance early satiety and diminish caloric intake by occupying physical space within the stomach [2, 3]. The prevalence of obesity among United States (US) adults was 40% in 2015–2016 [4], but less than 1% of eligible patients with obesity underwent bariatric surgery in 2015 [5]. Since previous guidelines have reserved bariatric procedures to patients with a BMI ≥ 40 kg/m^2 or a BMI ≥ 35 kg/m^2 with a qualifying comorbidity [6], the intragastric balloon serves as a novel strategy for the treatment of obesity and simultaneously expands access to patients previously ineligible for bariatric treatment. However, limited published studies exist for dual intragastric balloon devices in the USA, with most available data originating from Europe or South America [7, 8]. The purpose of this study was to report weight loss, comorbidity, and biochemical data from patients who underwent intragastric dual balloon placement.

Methods

Data for this study were obtained at a single academic medical center in California. All participants ($n = 28$) had a preoperative BMI > 30 kg/m^2 and underwent intragastric dual balloon placement between September 2015 and June 2017. The ReShape™ intragastric balloon was inserted endoscopically and removed approximately 6 months later. Demographic data collected preoperatively included age, gender, race/ethnicity, and insurance status. Given small sample sizes, participants were categorized as non-Hispanic White or non-White. Anthropometric characteristics measured preoperatively and 3 and 6 months after bariatric surgery included weight, blood pressure, BMI, percent excess weight loss (%EWL), and percent total body weight loss (%TWL). Biochemical characteristics measured preoperatively and 3 and 6 months after bariatric surgery included total cholesterol, LDL cholesterol, HDL cholesterol, and hemoglobin A1c. Electronic medical records were reviewed to document use of prescription weight loss medications. Remission of comorbidities was assessed at 3 and 6 months postoperatively. The remission of diabetes was defined as a value of hemoglobin A1c < 6.5%. The remission of hyperlipidemia was defined as a value of total cholesterol < 200 mg/dL. The remission of hypertension was defined as

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blood pressure < 130/80. Participants' characteristics were summarized using means, standard deviations, counts, and percentage frequencies. Two-tailed, paired *t* tests were conducted to assess differences between preoperative and follow-up measures of anthropometric and biochemical characteristics. Statistical analyses were performed using SAS Studio Version 4.3. This study was approved by the appropriate university institutional review board, and participants completed written, informed consent.

Results

Participants recruited for this study were primarily female (57%), White (71%), and privately insured (86%; Table 1). The mean participant age at surgery was 49 years (SD = 13.4). Two participants were lost to data follow-up. On average, the intragastric balloon was placed for 6.4 months (SD = 1.0). All intragastric balloons were inserted endoscopically, without complications or 90-day readmissions, and removed at the 6-month timeframe. Prior to surgery, the mean participant weight was 242 lbs (SD = 48.6), the mean BMI was 37.9 kg/m^2 (SD = 6.3), and the mean excess body weight was 82.5 lbs (SD = 40.5). The average %EWL after 6 months of follow-up was 50% (SD = 21.4). The average %TWL after 6 months of follow-up was 15.5% (SD = 5.5). Most patients (89%) used prescription weight loss medications during the study period. On average, patients used prescription weight loss medications for 4.1 months (SD = 1.9). Statistically significant reductions in participants' absolute weights were observed at 3 months ($\bar{x}$ = 213 lbs, SD = 42.2; $p < 0.0001$) and 6 months ($\bar{x}$ = 207 lbs, SD = 40.9; $p < 0.0001$) relative to baseline measures, for a total absolute difference of 35 lbs at 6 months. Compared to baseline measures, statistically significant reductions in levels of LDL cholesterol ($\bar{x}$ = 207 mg/dL, SD = 40.9; $p < 0.028$) and total cholesterol ($\bar{x}$ = 207 mg/dL, SD = 40.9; $p < 0.014$) were also observed after 6 months of follow-up. Prior to surgery, the average systolic blood pressure was 136 mmHg (SD = 17.5), compared to 128 mmHg (SD = 12.0) after 6 months of follow-up ($p = 0.022$). Comorbidity remission occurred in 2 of 3 (66%) of patients with diabetes, 5 of 11 (45.5%) patients with hyperlipidemia, and 6 of 10 (60%) patients with hypertension after 6 months of follow-up.

Conclusion

The results of this study illustrate the efficacy of the intragastric dual balloon for substantial weight loss 6 months after balloon placement. Study participants also experienced promising and statistically significant improvements in glucose control, lipid profiles, and blood pressure, leading to the remission of diabetes, hyperlipidemia, and hypertension. The limitations to this study include small number of study subjects and single-center and long-term follow-up. However, given the paucity of data for comorbidity remission following balloon placement, this brief communication can add to literature.

Previous studies indicate that a %TWL greater than 10% improves the likelihood of clinically significant improvements in obesity-related comorbidities [9], and the bariatric literature commonly defines surgical success as a %EWL > 50% [10]. On average, participants in this study achieved a %TWL of 15.5% and a %EWL of 50% after 6 months of follow-up; these findings

Table 1 Changes in comorbidity following intragastric balloon placement

	Preoperative *N* (%) or $\bar{x}$ ± SD	3 months *N* (%) or $\bar{x}$ ± SD	6 months *N* (%) or $\bar{x}$ ± SD
Comorbidities			
Diabetes	3 (10.7)	2 (7.1)	1 (3.6)
Hypertension	10 (35.7)	4 (14.3)	4 (14.3)
Hyperlipidemia	11 (39.3)	9 (32.1)	6 (21.4)
Clinical characteristics			
SBP (mmHg)	136 ± 17.5	127 ± 12.6	128 ± 12.0
DBP (mmHg)	83.4 ± 7.7	80 ± 7.9	81 ± 10.3
Weight (lbs)	242 ± 48.6	213 ± 42.2	207 ± 40.9
BMI (kg/m^2)	37.9 ± 6.3	33.3 ± 5.4	32.2 ± 5.3
%EWL	–	36.6 ± 14.8	50.0 ± 21.4
%TWL	–	11.2 ± 4.1	15.5 ± 5.5
Serology			
A1c (%)	5.9 ± 1.1	5.6 ± 0.5	5.4 ± 0.3
HDL (mg/dL)	50.8 ± 12.4	58.3 ± 18.4	52.3 ± 18.7
LDL (mg/dL)	118 ± 30.9	102 ± 26.3	94.3 ± 26.9
Total cholesterol (mg/dL)	197 ± 38.5	187 ± 7.9	161 ± 37.0

underscore the importance and illustrate the efficacy of the intragastric dual balloon as an important treatment for obesity. Subsequent studies are necessary to validate these findings in more diverse patient populations across longer follow-up periods.

This study describes significant weight loss, biochemical improvement, and blood pressure control following placement of the intragastric dual balloon in US adults. With the most recent estimates by the Centers for Disease Control and Prevention indicating that 4 out of 10 US adults are obese [4], the intragastric dual balloon holds promise as an important aid in combatting the obesity epidemic in the USA—particularly among patients who may not otherwise qualify for alternative bariatric procedures.

Compliance with Ethical Standards

This study was approved by the appropriate university institutional review board, and participants completed written, informed consent.

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

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