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ORIGINAL CONTRIBUTIONS

Performance Characteristics of Endoscopic Sleeve Gastroplasty in Patients with Prior Intragastric Balloon: Results of a Propensity Score Matched Study

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Abstract

Introduction The performance characteristics of endoscopic sleeve gastroplasty (ESG) for weight recurrence after intragastric balloon (IGB) are unknown.

Methods This is a retrospective propensity score matched study of ESG after IGB (IGB-to-ESG) vs ESG without prior IGB (ESG-only). The primary outcome was total weight loss (TWL) at 12 months. Secondary outcomes included TWL at 3 and 6 months, 12-month excess weight loss (EWL), procedural characteristics, and safety.

Results Thirty-nine adults underwent ESG from August 2020 to September 2022 after IGB explantation a median of 24 months (range 2–56 months) prior and a median post-IGB nadir weight increase of 100.0% (range 0 to 3200%). An ESG-only 2:1 age- sex- and BMI- propensity score matched cohort was derived from 649 patients (Pearson's goodness-of-fit: 0.86). TWL for IGB-to-ESG vs. ESG-only was 12.3 ± 13.5% vs. 12.4 ± 3.7% at 3 months ($p = 0.97$), 10.1 ± 7.1% vs. 15.4 ± 4.6% at 6 months ($p < 0.001$), and 8.7 ± 7.7% vs. 17.1 ± 5.7% at 12 months ($p < 0.001$). Twelve-month EWL for IGB-to-ESG vs ESG-only was 27.8 ± 46.9% vs 62.0 ± 21.0% ($p < 0.001$). There was no difference in mean procedural duration of ESG; however, more sutures were used with IGB-to-ESG vs. ESG-only (7 vs. 6, $p < 0.0002$). There were no serious adverse events in either cohort.

Conclusion ESG after IGB produces safe, acceptable weight loss but with an attenuated effect compared to ESG alone. Further study is required to understand the factors driving this discrepancy.

Keywords Intragastric balloon · Endoscopic sleeve gastroplasty · Weight recurrence · Obesity

Introduction

The intragastric balloon (IGB) is a temporary, space-occupying device used to treat obesity. Given the chronic, progressive nature of obesity and the transient nature of the balloon, weight recurrence after IGB explantation is common, leading many patients to seek subsequent weight loss procedures [1–3]. The endoscopic sleeve gastroplasty (ESG) is a US FDA-authorized, minimally invasive endoscopic procedure that narrows and shortens the stomach through full-thickness suturing to create a sleeve-like construct, and it facilitates approximately 13–16% total weight loss (TWL) at 1 year [4, 5]. Patients may seek out ESG after IGB given its more pronounced, durable effect on weight loss [6]; furthermore, they may be more amenable to ESG over metabolic and bariatric surgery to treat weight recurrence after IGB as surgery, while safely performed after IGB therapy, has limited

Key Points
- Patients may seek endoscopic sleeve gastroplasty (ESG) for weight recurrence after intragastric balloon (IGB) therapy, but the performance characteristics of ESG after IGB are unknown.
- ESG after IGB was technically feasible and safe; however, compared with patients who underwent ESG without prior IGB therapy, those who underwent ESG after IGB treatment had attenuated weight loss at 6 and 12 months. In addition, the clinical response at 12 months from ESG was suboptimal in the majority who had prior IGB therapy based on total weight loss parameters.
- In patients with prior IGB therapy, a higher body mass index at the time of ESG predicted greater weight loss from ESG.
- While ESG produced safe weight loss after IGB, patients should be counseled on the potential for diminished weight loss effects from ESG when used after IGB therapy.

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penetrance into the eligible population due concerns about invasiveness and risk [7–10]

The efficacy and safety of ESG after IGB therapy have not been reported. Both the IGB and ESG influence weight loss through similar perturbations to gastric sensorimotor function [11–13], but it is not known if these overlapping mechanisms—or other influences—may contribute to an attenuated weight loss response from these tools used in succession, a phenomenon observed in sleeve gastrectomy following IGB [14]. Furthermore, IGBs induce changes to the gastric tissue, including tissue hypertrophy and fibrosis of the tunica muscularis, as well as increased inflammation [15, 16]. Patients treated with IGB before sleeve gastrectomy had a longer length of hospital stay than those undergoing sleeve gastrectomy without prior IGB [16]. It is unknown if this post-IGB histologic phenomenon induces global elasticity changes that present technical challenges or adverse outcomes with subsequent ESG.

To address the performance of ESG after IGB therapy, we conducted a retrospective review of prospectively collected efficacy, safety, and technical feasibility data on patients with prior IGB treatment who underwent ESG at a single center with expertise in bariatric endoscopy. This was compared with a propensity score matched cohort of patients who underwent ESG at the same center in the same time period and who had not had prior IGB therapy. We further investigated predictors of weight loss response from ESG among patients with prior IGB therapy.

Methods

Study Design and Patient Selection

The study was approved by an Institutional Review Board (WCG IRB, Puyallup, WA) and was performed in accordance with the ethical standards of the 1964 Declaration of Helsinki. Informed consent was obtained from all individual participants included in the study. Patients with any prior IGB therapy who underwent ESG using the OverStitch endoscopic suturing system (Apollo Endosurgery, Austin, TX, USA) by an experienced bariatric endoscopist at a single center from August 2020 to September 2022 were included (IGB-to-ESG cohort). Patients were excluded if they used anti-obesity medications within the 12 months following their ESG. ESG was performed as reported previously [17]. Patients were followed longitudinally after ESG by registered dieticians for lifestyle and nutritional counseling. Patients also received regular follow-up by a medical team comprised of a physician and nurse practitioners. Given that all study participants had ESGs performed at our center during the coronavirus-19 pandemic, all follow-up visits were conducted in a virtual format. Weights were reported by patients at follow-up visits. Safety events were reported to the medical team at follow-up visits or between visits to the on-call medical team member.

Outcomes

The primary outcomes were TWL at 12 months and serious adverse events (SAEs), according to standard definitions [18]. Secondary outcomes included TWL at 3 and 6 months; clinical response rates at 12 months (< 5%, 5–9.99%, 10–14.99%, and ≥ 15% TWL); excess weight loss (EWL) at 12 months, percent of IGB-to-ESG cohort achieving an EWL ≥ 25%; number of sutures used; duration of ESG procedure; technical success of ESG, which was defined as a completed ESG without early termination due to technical challenges or complications [19]; and predictors of 6-month and 12-month TWL response from ESG in patients with prior IGB therapy. Subject accountability (SA) for data available at a specific time point was reported with each outcome. Removal of an IGB was considered early if < 150 days. At 12 months from ESG, TWL < 5% was considered non-response, < 10% was considered suboptimal response, ≥ 10% was considered clinically meaningful, and ≥ 15% was considered optimal response.

Analysis and Propensity Score Matching

Using propensity score matching with logistic regression and covariates of age, sex, and body mass index (BMI), a 2:1 comparator group was derived from 649 patients who underwent ESG with the same endoscopist during the same time frame (ESG-only cohort). Patients were excluded if they used anti-obesity medications within 12 months of ESG. The regression showed more than adequate model fit via Pearson's goodness-of-fit statistic of 0.86. Groups were compared on continuous variables using Wilcoxon's rank sum tests or *t*-tests, as appropriate. In addition, groups were compared on categorical variables using chi-square tests or Fisher's exact tests, as appropriate. Univariable linear regression models were used to assess the relationship of patient characteristics with TWL, *p*-values, and *R*-squared statistics were reported. No adjustments for multiple comparisons were planned. Results with a *p*-value less than or equal to 0.05 were considered statistically significant.

Results

Patient Characteristics

Thirty-nine adults who underwent ESG from August 2020 to September 2022 were identified as having had prior IGB therapy with the following balloon types (*n*, %): Orbera (33, 84.6%), Spatz (1, 2.6%), Obalon (2, 5.2%), ReShape (1, 2.6%), unknown (2, 5.2%), four of which had been performed at our center. From pre-IGB weight to post-IGB weight nadir, this cohort had experienced a mean TWL of 16.7 ± 7.8% (SA 82.1%). The average

dwell time for the IGB was 189 days (range 31–547 days) (SA 92.3%). Six subjects (15.4%) had IGB duration consistent with early removal, with a mean of 72 days (range 31–120 days). Subjects underwent ESG at a median of 24 months (range 2–56 months) from balloon explantation, with a median weight increase of 100.0% of weight lost from IGB (range 0 to 3200%) (SA 79.5%). Patient, procedural, and clinical characteristics of IGB-to-ESG and ESG-only groups are shown in Table 1.

Procedural, Clinical, and Safety Outcomes

Technical success of ESG was 100% in both cohorts, and there was no difference in mean procedure duration between groups; however, median suture number was greater in the IGB-to-ESG cohort compared to the ESG-only cohort (7 vs. 6 sutures). For the IGB-to-ESG cohort, SA for 3-, 6-, and 12-month weight data was 81.6%, 66.7%, and 64.1%, respectively. For the ESG-only cohort, SA for 3-, 6-, and 12-month weight data was 88.5%, 84.6%, and 75.6%, respectively. TWL for IGB-to-ESG vs. ESG-only was 12.3 ± 13.5% vs. 12.4 ± 3.7% at 3 months ($p = 0.97$), 10.1 ± 7.1% vs. 15.4 ± 4.6% at 6 months ($p < 0.001$), and 8.7 ± 7.7% vs. 17.1 ± 5.7% at 12 months ($p < 0.001$) (Fig. 1). Clinical responder rates at 12 months are shown in Fig. 2. Among the IGB-to-ESG cohort, over one quarter had non-response, and over half had suboptimal response to ESG at 12 months; less than 4 in 10 subjects achieved a clinically meaningful response (≥ 10% TWL) by 12 months. EWL for IGB-to-ESG vs. ESG-only at 12 months was 27.8 ± 46.9% vs. 62.0 ± 21.0% ($p < 0.001$). At 12 months, 36.0% of the IGB-to-ESG cohort had an EWL < 25%. There were no SAEs in either cohort.

Predictors of Response to ESG After IGB

For patients with prior IGB treatment, increased BMI at the time of ESG predicted greater TWL at 6 months ($p = 0.027$,

Table 1 Patient and procedural characteristics. Values expressed as mean + standard deviation or median, range

Variable	Group		*p*-value*
	ESG after IGB $n = 39$	ESG-only $n = 78$	
Mean % TWL from IGB	16.7 ± 7.8	.	.
Median duration from IGB removal to ESG (months)	24, 2–56	.	.
Median % weight recurrence of weight lost from IGB at time of ESG	100, 0–3200	.	.
Mean age at ESG (years)	48.2 ± 8.6	48.8 ± 7.7	0.697
No. of female subjects (%)	34 (87.2%)	68 (87.2%)	1.000
Mean BMI at ESG (kg/m^2)	35.0 ± 4.1	35.4 ± 3.7	0.786
Mean weight at ESG (lbs)	210.3 ± 34.3	213.9 ± 29.3	0.548
Median no. of sutures in ESG	7.0, 4.0–9.0	6.0, 4.0–9.0	0.000
Mean ESG procedure duration (min)	39.7 ± 9.3	48.2 ± 39.3	0.546

TWL, total weight loss; *IGB*, intragastric balloon; *ESG*, endoscopic sleeve gastroplasty; *BMI*, body mass index

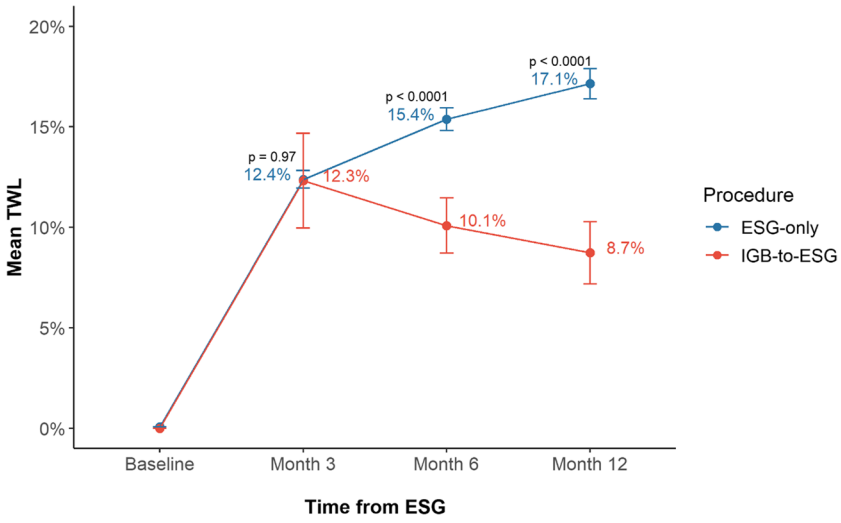

Fig. 1 Total weight loss from ESG over study duration by cohort

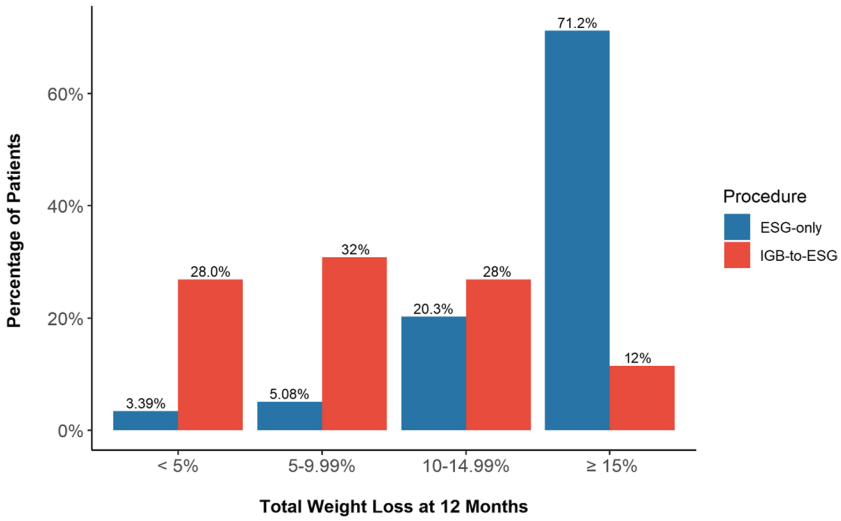

Fig. 2 Clinical responder rate by cohort at 12 months from ESG

$R^2 = 0.18$), with a numerical trend at 12 months ($p = 0.053$, $R^2 = 0.15$). Increased duration from IGB removal to ESG predicted greater TWL at 6 months ($p = 0.002$, $R^2 = 0.36$) but not at 12 months ($p = 0.10$). Age, sex, TWL from IGB, and percent weight recurrence from post-IGB nadir did not predict TWL at 6 months or 12 months after ESG.

Discussion

This is the first published appraisal of the efficacy, safety, and procedural characteristics of ESG after IGB therapy for weight loss in adults with obesity. Major findings included similar safety profiles and technical success of ESG between those who underwent ESG following IGB and those who underwent ESG without prior IGB therapy; however, notably, there was an attenuated weight loss response at 6 and 12 months following ESG if a patient had prior IGB therapy compared to those who underwent ESG only.

This attenuated weight loss may result from varying physiologic, histologic, and hormonal factors. From a physiologic perspective, IGB and ESG facilitate weight loss through overlapping mechanisms—namely, perturbations in gastrointestinal sensorimotor functions known to modify appetite, particularly satiety-enhancing delay in gastric emptying [11–13]. While gastric emptying has been observed to return to baseline following IGB removal [12, 20], there may be lingering effects on localized gastric emptying, gastric accommodation, or other sensorimotor effects that diminish the intensity of such changes from ESG after IGB. Because patients follow a modified, liquid/low-residue diet for 7 weeks after ESG in our program, this may mask the differences in weight loss between cohorts in the first months [21]. Another explanation may lie in the histologic changes in gastric tissue after IGB, which include gastric wall hypertrophy and fibrosis [15, 16]. Plication integrity is critical to the durability of the ESG construct, and submucosal and muscularis fibrosis from IGB may impede mucosal to mucosal apposition from ESG and lead to early sleeve dilation, especially after advancement from the liquid/low-residue diet. From a hormonal perspective, one study demonstrated attenuated weight loss at 1 and 2 years in patients with various bariatric surgeries if there was pre-treatment with an IGB, and it was postulated that this might result from suppressed leptin levels from IGB pre-treatment [14].

Another plausible explanation for the diminished weight loss effect for ESG after IGB is that obesity is a chronic, progressive, and relapsing disease influenced by many factors, including but not limited to neurohormonal, socio-behavioral, and environmental inputs [2]. While the temporary nature of the IGB is often underscored as the driving factor for weight recurrence following balloon explantation, the fact remains that even following traditional metabolic and bariatric surgeries—the most effective therapies for weight loss currently practiced—we still see weight recurrence [22–24]. Here, we could invoke potential patient-related factors. For example, ostensibly, patients who are less successful in implementing the dietary and lifestyle changes necessary to sustain long-term weight loss after the IGB may similarly be less successful in implementing the dietary and lifestyle changes required to sustain long-term weight loss after a second endoscopic weight loss tool. In this regard, weight loss outcomes in the IGB-to-ESG population may more closely resemble outcomes in the ESG revision population, where the early published experience suggests diminished weight loss [25].

Ultimately, the attenuated response to ESG after IGB is most likely multifactorial. It does not appear to be the result of initial poor response to IGB—noting that average TWL was > 16% from IGB therapy in the IGB-to-ESG cohort, and there was no relationship between TWL from IGB and 6- or 12-month TWL from ESG. Because greater duration from IGB removal to ESG correlated with greater TWL at 6 months, this may support recovery from histologic,

hormonal, and sensorimotor changes from IGB; and because this was not observed to be associated with 12-month TWL suggests that external factors may be influential longer term in a patient's weight loss trajectory.

Studies comparing the weight loss response to metabolic and bariatric surgery in patients with and without IGB pre-treatment have had mixed results. For instance, there was no observable difference in weight loss outcomes with or without preceding IGB in bypass surgery [26] or laparoscopic adjustable gastric band [27]; however, in another study, there was an attenuated weight loss at 1 and 2 years in patients with various metabolic and bariatric surgeries if there was pre-treatment with an IGB [14]. Unfortunately, the applicability of these results to our present study is limited insofar as published accounts of IGB preceding surgery are often in the context of a bridge therapy (rather than step-up therapy, as it was here) and involve patients with higher BMI and shorter periods between IGB and subsequent intervention.

Patients and physicians should be reassured by the safety and technical feasibility of performing an ESG after IGB therapy. While it has been shown that IGB therapy induces gastric wall hypertrophy and fibrosis, this did not lead to notable procedural challenges or adverse events [15, 16]. This comports to multiple accounts of surgery being as safe or safer following IGB than without IGB pre-treatment [14, 26–28]. While surgical operative time has been shown to both increase [26] and decrease [27, 28] with IGB pre-treatment, this effect was not observed in our study. It is unclear if a post-IGB effect drove the increased suture number in ESG after IGB compared to ESG alone, and we suspect that, ultimately, this is of limited clinical significance. Suture rows in ESG are placed from the angle of the incisura to the border of the gastric body and fundus, but the number of sutures is influenced by various factors, including length and width of the stomach, the responsiveness of tissue, and whether the endoscopist used a greater number of straight (anterior to posterior) or U-shaped (anterior to posterior to anterior) suture rows, as the latter covers a larger surface area. If gastric tissue was less responsive due to gastric wall fibrosis, the endoscopist may have to use more straight suture rows to avoid strain on a U-shaped row, which could increase the number of sutures used; however, our study does not have the precision to account for the difference in this level of procedural technique.

Strengths of this study included the propensity score matched cohort that provided a comparator group that was similar for age, sex, and BMI characteristics, as well as subject accountability rates, which exceeded 60% for all baseline characteristics and weight loss results. This study was primarily limited by its retrospective nature, as well as the use of patient-reported weights during virtual follow-up visits. Given that the cohorts in this study were derived from ESGs at our center from August 2020 to September 2022, which corresponded to the coronavirus-19 pandemic, all follow-up visits were conducted virtually. As such, we relied on patient-reported weight loss; however, this applied to both cohorts, and self-reported weights have been shown to be reliable [29–31]. The external application of our findings is limited by procedure-specific factors: first, the majority use of a single type of IGB (Orbera), so it is not apparent if this relationship exists for patients with prior treatment with other IGBs; and second, use of a single endoscopic greater curvature plication technique (i.e., the Apollo ESG™), so it is unclear if other greater curvature plication techniques—the mechanisms of which are not yet known [32]—would have an attenuated weight loss effect.

Based on the findings of this study, endobariatric physicians should have a thoughtful, realistic discussion about the benefits and limitations of an ESG in a patient with preceding IGB therapy. While safe, the potential for an attenuated response should be disclosed, especially for those patients with lower classes of obesity. Overall, ESG after IGB achieved a 12-month mean EWL of 27.8% in this study, which satisfies expert-level consensus guidelines on clinical adoption of an endobariatric therapy that state EWL should exceed 25% at 1 year [7]; however, it is noteworthy that over one-third of the cohort did not reach that threshold, and the majority of IGB-to-ESG subjects had a TWL-based clinical responder rates in the suboptimal range at 12 months. This observation may provide the rationale for the concomitant use of anti-obesity medications with ESG if a patient has had a weight recurrence following IGB removal and wishes to pursue ESG rather than traditional metabolic and bariatric surgery.

Conclusion

ESG after IGB produces safe, acceptable weight loss but with an attenuated effect compared to ESG alone, particularly after 6 months. It is unclear if this derives from patient-related histologic, hormonal, or physiologic mechanisms or from external influences driving the chronic, progressive nature of obesity. Patients should be counseled on the potential for diminished clinical efficacy of ESG after IGB.

Author Contribution DBM—protocol preparation, manuscript preparation; AW—protocol preparation, manuscript revision; DL—data collection, manuscript revision; CW—protocol preparation, manuscript revision; LLD—manuscript revision; BC—manuscript revision; CEM—study conceptualization, protocol preparation, manuscript revision.

Data Availability Upon request, relevant data and documentation to verify results can be provided.

Declarations

Ethics Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Consent to Participate Informed consent was obtained from all individual participants included in the study.

Conflict of Interest Author 1 and Author 7 are or have been consultants for and have received honorarium from Apollo Endosurgery, the organization that makes the Orbera intragastric balloon and the Overstitch endoscopic suturing system used to create the endoscopic sleeve gastroplasty.

IRB The study was approved by an Institutional Review Board (WCG IRB, Puyallup, WA).

Writing Assistance None.

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