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Practice patterns and outcomes of endoscopic sleeve gastroplasty based on provider specialty

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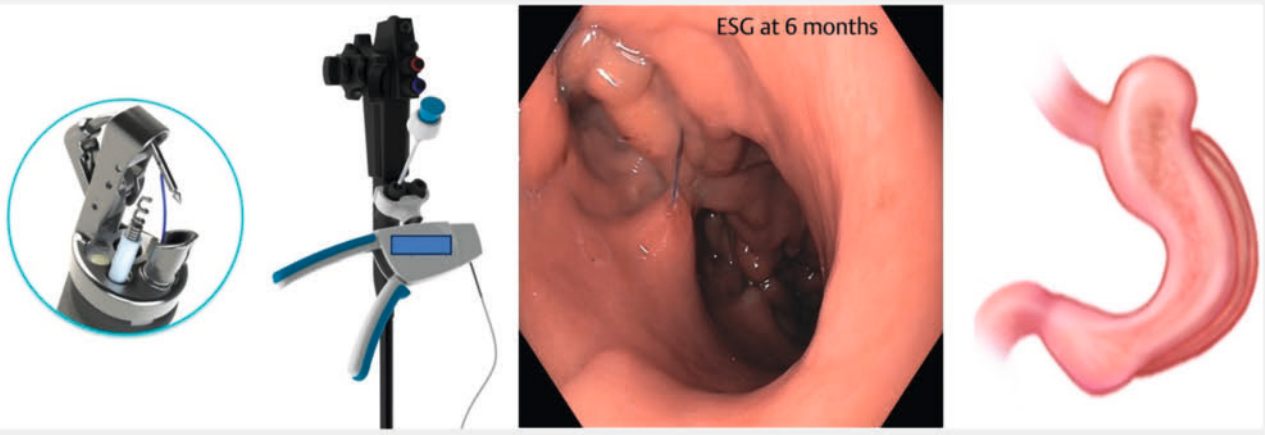
ABSTRACT

Background and study aims Endoscopic sleeve gastroplasty (ESG) is performed in clinical practice by gastroenterologists and bariatric surgeons. Given the increasing regulatory approval and global adoption, we aimed to evaluate real-world outcomes in multidisciplinary practices involving bariatric surgeons and gastroenterologists across the United States.

Patients and methods We included adult patients with obesity who underwent ESG from January 2013 to August 2022 in seven academic and private centers in the United States. Patient and procedure characteristics, serious adverse events (SAEs), and weight loss outcomes up to 24 months were analyzed. SPSS (version 29.0) was used for all statistical analyses.

Results A total of 1506 patients from seven sites included 235 (15.6%) treated by surgeons and 1271 (84.4%) treated by gastroenterologists. There were no baseline differences between groups. Gastroenterologists used argon plasma coagulation for marking significantly more often than surgeons (P<0.001). Surgeons placed sutures in the fundus in all instances whereas gastroenterologist placed them in the fundus in less than 1% of the cases (P<0.001>). Procedure times were significantly different between groups, with surgeons requiring approximately 20 minutes more during the procedure than gastroenterologists (P<0.001). Percent total body weight loss (%TBWL) and percent responders achieving >10 and >15% TBWL were similar between the two groups at 12, 18, and 24 months. Rates of SAEs were low and similar at 1.7% for surgeons and 2.7% for gastroenterologists (P>0.05).

Conclusions Data from a large US cohort show significant and sustained weight loss with ESG and an excellent safety profile in both bariatric surgery and gastroenterology practices, supporting the scalability of the procedure across practices in a multidisciplinary setting.



▶ **Fig. 1** Endoscopic sleeve gastroplasty. Panel includes Overstitch device, endoscopic and illustrative appearance of the completed sleeve.

Introduction

The rapidly growing disease burden of obesity necessitates the development, widespread adoption, and increased utilization of newer therapeutic modalities. Several treatment options other than lifestyle modifications have been developed over the last few decades to combat this pandemic of obesity. These include anti-obesity medications (AOMs), bariatric surgery, and endoscopic bariatric therapy (EBT). AOMs often represent the initial treatment strategy for many patients, with currently nine US Food and Drug Administration-approved medication options [1]. However, the efficacy of AOMs is limited and it is frequently not sustained after discontinuation [2]. Bariatric surgery is the most effective therapeutic option for obesity and related comorbidities. Unfortunately, due to limited access and utilization, only a small fraction of eligible patients undergo bariatric surgery [3, 4].

The last decade has seen the emergence of EBTs in the management of obesity. These are novel, minimally invasive techniques and devices delivered endoscopically. Endoscopic sleeve gastroplasty (ESG) is an innovative technique that uses an endoscopic suturing device (OverStitch, Apollo Endosurgery, Austin, Texas, United States) to plicate the greater curvature of the stomach (▶ **Fig. 1**). It is an effective and safe technique for obesity, resulting in > 15% total body weight loss (%TBWL) in the short and mid-term [5].

Performing ESG involves a high level of complexity and additional risks compared with diagnostic procedures; hence, the American Society for Gastrointestinal Endoscopy considers ESG a major skill [6]. In the United States, most endoscopists are gastroenterologists. However, endoscopy is also an important part of the practice in bariatric surgery, thus more surgeons have been gaining experience with ESG [7]. Given the increasing regulatory approval and global adoption, our aim is to evaluate real-world outcomes and practice patterns comparing bariatric surgeons and gastroenterologists in ESG performance across the United States.

Patients and methods

Study design, setting, and participants

We performed a retrospective analysis of patients who underwent ESG across seven different sites in the United States from January 2013 through August 2022. These sites included academic and private institutions, and procedures were performed by gastroenterologists and bariatric surgeons. The institutional review board at the primary site approved the study and waived the need for informed consent owing to its minimal-risk nature. Institutional review board approval was also obtained at other sites. All adult patients who had undergone ESG using a standard technique with the primary goal of weight loss were included.

Study variables and data sources

Patient demographic and medical information were abstracted from the electronic medical records. Indications for and technical details about each procedure were collected. Baseline weight was defined as weight on the day of the intervention. Weight was recorded at baseline, 6, 12, 18, and 24 months after the procedure. Both intra-procedure and post-procedure adverse events (AEs) were recorded. %TBWL and %excess weight loss (%EWL, based upon body mass index [BMI] = 25 kg/m^2) were calculated based on baseline weight at the procedure. Responders to treatment were defined as reaching a predetermined threshold for %TBWL at 12 and 24 months. Each responder group included the number of patients that satisfy those criteria (i. e., 10% = patients who achieved ≥ 10% TBWL). The patients were divided into groups based on their provider (gastroenterologist or surgeon).

The primary aim of our study was to assess and compare weight loss outcomes in patients in both groups. We also reviewed the procedure techniques and AEs between both groups.

Statistical analysis

All continuous data are summarized as means and 95% confidence intervals (CIs). Analyses by provider type at each follow-up period were performed using one-way analysis of variance with Bonferroni correction to identify significant comparisons or Chi-square. Significance was defined as $P<0.05$. Imputation methods were used to evaluate the impact of missing data from the results. The last observation carried forward (LOCF) reported the responder level at the last recorded visit. Patients did not return for any visit were considered non-responders at x % TBWL. The best-case scenario was defined such that subjects for whom data were missing were considered responders at x% TBWL, while the worst-case scenario was defined such that subjects for whom data were missing were not considered responders at x% TBWL. SPSS (IBM Corp. Released 2021. IBM SPSS Statistics for Windows, Version 29.0. Armonk, New York, United States: IBM Corp) was used for all statistical analyses.

Results

Participants

Our cohort comprised 1506 patients with a mean age of 45.68 ± 10.25 years, predominantly female (84.5%) and White (69.6%). Mean weight and BMI at baseline were 107.3 ± 21.42 kg and 38.43 ± 6.22 kg/m^2, respectively. Two-hundred and thirty-five patients (15.6%) were treated by surgeons and 1,271 patients (84.4%) by gastroenterologists.

Baseline characteristics

Baseline characteristics are described in ▶ **Table 1**. When divided by provider type, there was no difference with respect to sex, race, or age between the two groups ($P = 0.48$, 0.49, and 0.23, respectively). There was a significant difference in the percentage of patients that received medication co-therapy by provider type (15.7% surgeons vs. 8.7% gastroenterologists, $P < 0.001$). Baseline weight, height, and BMI were similar between the groups.

Procedure technique

We evaluated differences in procedural technique with respect to provider type (▶ **Table 2**). Gastroenterologists used argon plasma coagulation for marking significantly more often than surgeons ($P<0.001$). Surgeons placed sutures in the fundus in all instances whereas gastroenterologists placed them in the fundus in less than 1% of the cases ($P < 0.001$). There were no differences between provider types concerning the use of the Overtube, adjunct therapy during the procedure, or intra-procedure complications (< 1% for both groups). The mean number of sutures was seven, which was similar between cohorts ($P=0.909$). Procedure times were significantly different between groups, with surgeons requiring approximately 20 minutes more during the procedure, compared with gastroenterologists ($P<0.001$).

Weight loss outcomes by provider type

Weight loss parameters by provider type are reported for BMI, %TBWL, and %EWL (▶ **Fig. 2a–c**). The overall mean %TBWL was 15.4 (15.0, 15.7), 17.1 (16.6, 17.6), 16.8 (16.0, 17.6), and 15.3 (14.3, 16.5) for 6, 12, 18, and 24 months, respectively. There was a significant difference in %TBWL between the groups at 6 months (16.5% vs. 15.2%, $P = 0.01$), where patients treated by surgeons had higher weight loss. There was no other significant difference in %TBWL outcomes between the two groups.

▶ **Fig. 2d**, ▶ **Table 3**, and **Supplementary Table 2S** describe data concerning responders to treatment. At 12 and 24 months, a total of 83.2% and 69.9% of patients achieved ≥ 10% TBWL, respectively. Considering ≥ 15% TBWL, 60.9% and 46.3% of patients were responders at 12 and 24 months, respectively. When analyzed by provider type, no significant differences were observed. Over 80% of patients in both groups were responders at 12 months with TBWL ≥ 10% and over 50% were responders with TBWL ≥ 15%. At 24 months, the percent responders decreased in both groups. Imputation methods were used to evaluate the impact of missing data from the results. Only patients who should have completed a 24-month visit were included in these imputation methods, which included the LOCF, best-case scenario, and worst-case scenario (▶ **Table 3**).

Adverse events

Only events that were reported as either device and/or procedure-related were included in the analysis below (**Supplementary Table 1S**). Two-hundred and fifty-six patients experienced 360 events. A total of 173 patients (73.6%) treated by surgeons experienced 134 events. A total of 83 patients (6.5%) treated by gastroenterologists experienced 125 events.

Of note, one of the surgical sites reported the initial accommodative symptoms for all patients (abdominal pain, nausea, vomiting), which were not reported by other sites. However, there were no statistical differences in serious AEs (SAEs). Thirty-nine patients (2.6%) experienced at least one AE requiring hospitalization (51 events) for treatment: four patients with six events treated by surgeons (1.7%) and 35 patients with 45 events treated by gastroenterologists (2.7%) ($P>0.05$). The majority of these included pharmacological therapy for symptom management and fluid replacement. Three of the 51 events (one from a surgeon and two from gastroenterologists) required surgical interventions.

Discussion

Our data from a large US cohort showed significant and sustained weight loss with ESG and excellent safety profiles for both bariatric surgery and gastroenterologist practices. To the best of our knowledge, this is the first report of weight loss outcomes analyzed by provider type. The %TBWL at 12 months for our cohort was 17% or higher for patients in either group, which is consistent with previously reported weight loss outcomes for ESG [5, 8]. More than 80% of patients in both cohorts also had > 10% TBWL at 12 months, which is generally consid-

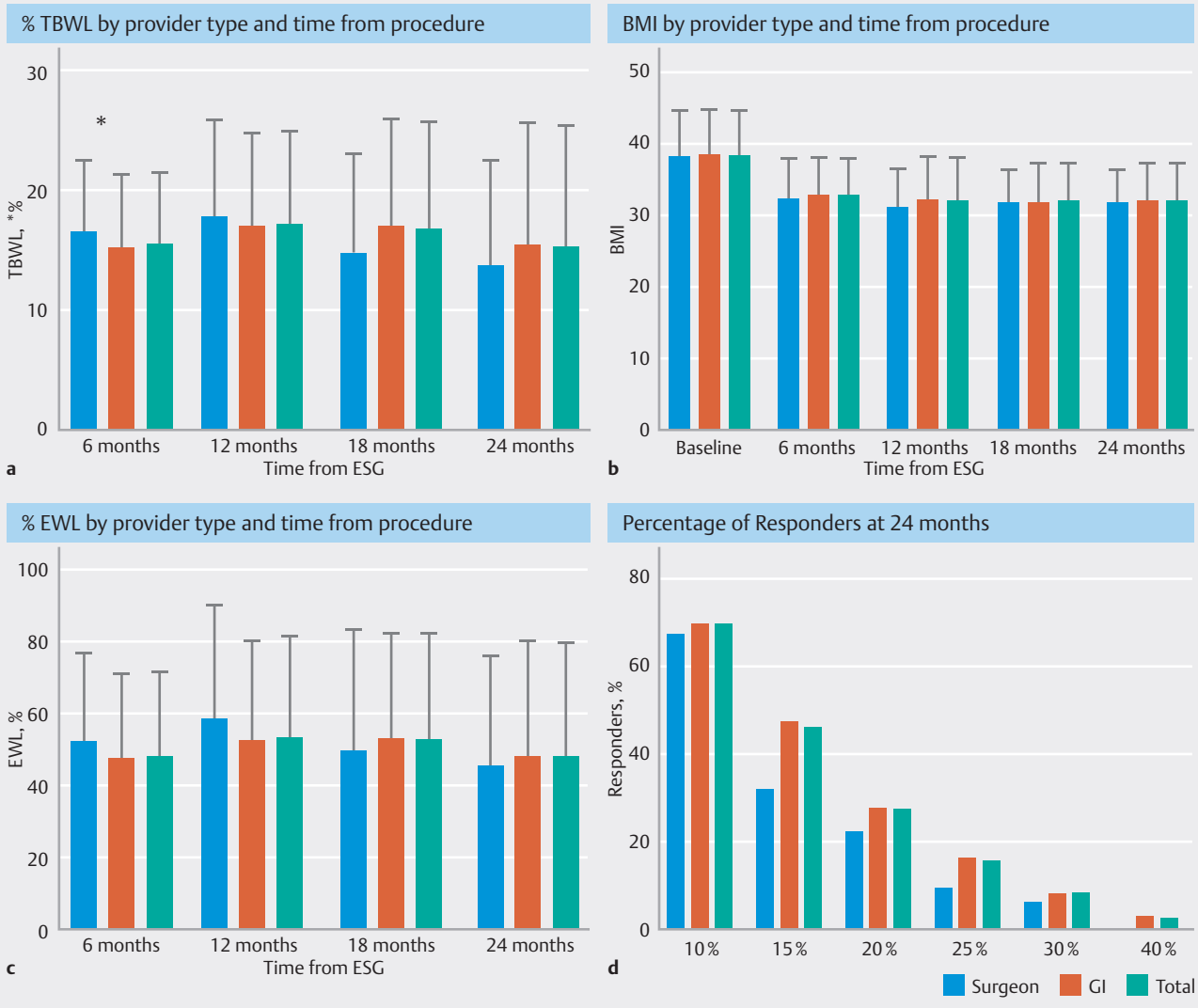
▶ **Table 1** Baseline demographics by provider type.

Description	Surgeon (N = 235)	Gastroenterologist (N = 1271)	Total (N = 1506)
Sex		*	*
Male	37 (15.7%)	196 (15.4%)	233 (15.5%)
Female	198 (84.3%)	1074 (84.6%)	1272 (84.5%)
Race			
N	45	1271	1316
White	28 (62.2%)	888 (69.9%)	916 (69.6%)
African American	6 (13.3%)	208 (16.4%)	214 (16.3%)
Asian	1 (2.2%)	22 (1.7%)	23 (1.7%)
Hispanic	5 (11.1%)	20 (1.6%)	25 (1.9%)
Other	1 (2.2%)	26 (2.0%)	27 (2.1%)
Not reported	4 (8.9%)	107 (8.4%)	111 (8.4%)
Obesity class			
Class I	85 (36.2%)	416 (32.7%)	501 (33.3%)
Class II	78 (33.2%)	468 (36.8%)	546 (36.3%)
Class III	72 (30.6%)	387 (30.4%)	459 (30.5%)
Medication co-therapy			
Yes	37 (15.7%)	110 (8.7%)	147 (9.8%)
No	198 (84.3%)	1161 (91.3%)	1359 (90.2%)
Age (years)	*		*
Mean (STD)	46.41 (9.95)	45.54 (10.31)	45.68 (10.25)
Min, max	19.0, 68.8	17.2, 73.6	17.2, 73.6
95% CI	45.1–47.7	45.0–46.1	45.2–46.2
Height (m)			
Mean (STD)	1.67 (0.09)	1.67 (0.09)	1.67 (0.09)
Min, max	1.4–1.9	1.3–2.0	1.3–2.0
95% CI	1.66–1.68	1.66. 1.67	1.66–1.67
Weight (kg)			
Mean (STD)	106.9 (21.17)	107.4 (21.47)	107.3 (21.42)
Min, max	72.1–190.8	66.2–240.4	66.2–240.4
95% CI	104.2–109.6	106.2–108.6	106.2–108.4
Ideal weight (kg)			
Mean (STD)	69.7 (7.12)	69.7 (7.42)	69.7 (7.37)
Min, max	48.8–93.2	42.0–98.1	42.0–98.1
95% CI	68.8–70.7	69.3–70.1	69.4–70.1
Excess weight (kg)			
Mean (STD)	37.1 (18.11)	37.6 (17.86)	37.6 (17.90)
Min, max	12.0–128.8	12.0–152.1	12.0–152.1
95% CI	34.8–39.5	36.7–38.6	36.7–38.5
BMI (kg/m^2)			

▶ **Table 1** (Continuation)

Description	Surgeon (N = 235)	Gastroenterologist (N = 1271)	Total (N = 1506)
Mean (STD)	38.30 (6.40)	38.45 (6.19)	38.43 (6.22)
Min, max	30.00–76.93	30.04–111.10	30.00–111.10
95% CI	37.47–39.12	38.11–38.79	38.11–38.74

CI, confidence interval; BMI, body mass index.



▶ **Fig. 2** **a** Percentage TBWL by provider type and time from procedure. **b** BMI by provider type and time from procedure. **c** Percentage EWL by provider type and time from procedure. **d** Responders at 12-month follow-up by provider type.

▶ **Table 2** Procedure characteristics by provider type.

Description	Surgeon (N = 235)	Endoscopist (N = 1271)	Total (N = 1506)
Use of overtube			
Yes	45 (19.1%)	252 (19.8%)	297 (19.7%)
No	190 (80.9%)	1019 (80.2%)	1209 (80.3%)
APC for marking			
Yes	8 (3.4%)	442 (34.8%)	450 (29.9%)
No	227 (96.6%)	829 (65.2%)	1056 (70.1%)
Sutures in fundus			
Yes	235 (100.0%)	5 (0.4%)	240 (15.9%)
No	0 (0%)	1265 (99.6%)	1265 (84.1%)
Adjunct therapy			
Yes	0 (0%)	42 (3.4%)	42 (2.8%)
No	235 (100.0%)	1211 (96.6%)	1446 (97.2%)
Intra-procedure complications			
Yes	1 (0.4%)	12 (0.9%)	13 (0.9%)
No	234 (99.6%)	1259 (99.1%)	1493 (99.1%)
Number of sutures		*	*
N	45	1231	1276
Mean (STD)	7.1 (1.7)	7.0 (2.21)	7.0 (2.19)
Min, max	5, 11	3, 28	3, 28
95% CI	6.6, 7.6	6.9, 7.2	6.9, 7.2
Procedure time (minutes)			
N	90	942	1032
Mean (STD)	74.9 (20.18)	53.7 (26.40)	55.6 (26.59)
Min, max	17, 142	15, 205	15, 205
95% CI	70.7, 79.1	52.0, 55.4	53.9, 57.2

APC, argon plasma coagulation; CI, confidence interval.

ered the threshold for improvement of obesity-related comorbidities [9].

At 6 months, patients treated by surgeons had a higher % TWL (16.5% vs. 15.2%, $P = 0.010$); however, this was not sustained at future time points. This initial difference in weight loss may be attributable to the differences in procedure techniques between provider types, increased use of AOMs by surgeons, and differences in multidisciplinary teams. Also, despite being statistically different, one must consider if that is a clinically relevant result. Our large sample at baseline allowed for the detection of statistical significance even when the results are numerically similar (or not clinically relevant). Regardless, outcomes at longer follow-up time points were similar independent of the provider.

We noted that procedure techniques varied between types of providers. Surgeons placed fundal sutures more frequently compared with gastroenterologists, who placed them in < 1% of cases. Suturing the fundus yields a final anatomical appearance more similar to a surgical sleeve gastrectomy, which is presumably the reason that surgeons choose this technique. In addition, gastroenterologists are generally reluctant to suture the fundus, given the thin wall thickness [10], and the fear of AEs such as leaks, perforation, and perigastric fluid collections, and the contradictory benefit of it [11]. In our cohort, fundal suturing did not increase such AEs in the surgeon group; actually, gastroenterologists reported a higher incidence of gastric perforation and perigastric collections (4 [0.3%] and 2 [0.2%], respectively), compared with surgeons (one gastric leak [0.4%]). Nonetheless, our study corroborates previous data

▶ **Table 3** Responders at 24-month follow-up by provider type.

Completers analysis			
Responder definition	**Surgeon (n = 31)**	**Endoscopist (n = 308)**	**Total (n = 339)**
10%	67.7% (21)	70.1% (216)	69.9% (237)
15%	32.3% (10)	47.7% (147)	46.3% (157)
20%	22.6% (7)	28.2% (87)	27.7% (94)
25%	9.7% (3)	16.6% (51)	15.9% (54)
30%	6.5% (2)	8.8% (27)	8.6% (29)
40%	0% (0)	3.2% (10)	2.9% (10)
Last observation carried forward (LOCF)			
Responder definition	**Surgeon (n = 67)**	**Endoscopist (n = 559)**	**Total (n = 626)**
10%	52.2% (35)	63.0% (352)	61.8% (387)
15%	29.9% (20)	41.0% (229)	39.8% (249)
20%	20.9% (14)	21.1% (118)	21.1% (132)
25%	9.0% (6)	10.7% (60)	10.5% (66)
30%	4.5% (3)	5.7% (32)	5.6% (35)
40%	0% (0)	2.0% (11)	1.8% (11)
Best-case scenario			
Responder definition	**Surgeon (n = 67)**	**Endoscopist (n = 559)**	**Total (n = 626)**
10%	85.1% (57)	83.5% (467)	83.7% (524)
15%	32.3% (10)	47.7% (147)	46.3% (157)
20%	22.6% (7)	28.2% (87)	27.7% (94)
25%	9.7% (3)	16.6% (51)	15.9% (54)
30%	6.5% (2)	8.8% (27)	8.6% (29)
40%	0% (0)	3.2% (10)	2.9% (10)
Worst-case scenario			
Responder definition	**Surgeon (n = 67)**	**Endoscopist (n = 559)**	**Total (n = 626)**
10%	31.3% (21)	38.6% (216)	37.9% (237)
15%	14.9% (10)	26.3% (147)	25.1% (157)
20%	10.4% (7)	15.6% (87)	15.0% (94)
25%	4.5% (3)	9.1% (51)	8.6% (54)
30%	3.0% (2)	4.8% (27)	4.6% (29)
40%	0% (0)	1.8% (10)	1.6% (10)

showing that fundal sutures result in no additional weight loss and lead to longer procedure times [12]. There is also physiological evidence showing that the fundic pouch delays gastric emptying and may be crucial in weight loss [13]. Currently, there is significant heterogeneity in endoscopy training between general surgery, bariatric surgery, gastroenterology, and advanced endoscopy fellowships [14, 15]. This may account for some of the technical differences noted between groups of providers. As bariatric and metabolic endoscopy evolves as a field, further insight into practice patterns of differently trained providers is warranted.

We also compared the safety of ESG among providers. The higher AE rate in patients treated by surgeons can primarily be attributable to heterogeneity in the report. One surgical site classified accommodative complaints on the day of the procedure as AEs, while all other sites did not. Currently, mild-to-moderate nausea, cramps, and abdominal pain are expected within the normal post-procedure course. Therefore, most centers did not consider them AEs. Importantly, there were no differences in the SAEs, and in fact, the rate was lower in the surgeon group. The consistency of recording and reporting AEs in endoscopy continues to be a challenge, but is key to assess safety of procedures and enable future research and comparisons [16]. One analysis of the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) database had findings of similar AE rates at 30 days, although they reported that surgeons had a trend toward a higher rate of reoperations within 30 days, and patients treated by gastroenterologists had more emergency room visits [17]. In our study, the rates of SAEs are far below 5% in either group, which is the standard of safety recommended by the American Society of Gastrointestinal Endoscopy, further emphasizing the remarkable safety profile of ESG across practice settings [18].

In the United States, the number of surgeons performing routine endobariatrics is still limited, which accounts for the differences seen in the number of procedures performed by groups in our cohort. However, as ESG and other endobariatric procedures continue to evolve in their techniques and indications, many bariatric surgery practices have an interest in incorporating these therapeutic modalities into their armamentarium. Training in bariatric endoscopy is still in its infancy, with very few formal training programs. Most providers interested in performing these procedures gain experience through short apprenticeships or courses. The limited access to training modalities may be one reason for the lower number of surgeons practicing bariatric endoscopy. Although there are no specific thresholds for competency described in the literature, one study describes the learning curve for an experienced endoscopist for ESG to be 29 to 38 procedures to attain efficiency, and 55 procedures to attain mastery [19]. However, these numbers will likely vary based on background endoscopy training and the stage of the career of the provider. Different training tools like ex vivo and live animal models are used routinely to supplement training; in the future, the use of simulators and virtual reality platforms may standardize and improve access to training in bariatric endoscopy.

Our study has several strengths. We used data from the largest cohort of patients to have undergone ESG in the United States, with only a few other registries of this scale across the globe [20, 21]. Our data are gathered from seven different academic and private sites and, as such, are fairly representative of the current practice of ESG in the United States. We have a follow-up of 2 years and used multiple statistical models to compensate for the attrition of patients. The inherent limitations of retrospective data are present in our study. The number of procedures performed by surgeons compared with gastroenterologists was significantly lower; however, it represents the current practice in the United States. The effects of additional therapies, such as intensive lifestyle modification or anti-obesity medication, were not considered during our analysis. Pharmacotherapy after ESG usually prevents weight regain but does not lead to significant additional weight loss; hence, we believe that our findings continue to be representative of real-world outcomes [22].

Conclusions

There is an urgent need for expanding care for patients with obesity, with many reports demonstrating an abysmally low rate of appropriate management [23]. ESG has gained global acceptability as a safe and effective treatment for obesity [24]. In particular, it can be a viable option for patients who do not wish to undergo bariatric surgery or who have upfront contraindications to surgery, and it could be incorporated into multidisciplinary bariatric practice. Our data support the scalability of this procedure across provider backgrounds and practices.

Conflict of Interest

AS has research grants from Apollo Endosurgery, Boston Scientific, Endogenex, Enterasense, OnePass, and is a consultant for Apollo Endosurgery, Boston Scientific, Endogenex, Endo-TAGSS, MGI Medical, Olympus, Intuitive, Medtronic, Microtech. MU is a board member for Boston Scientific, is a paid consultant for Olympus and Cook, and receives payment for lectures from Medtronic, Gore and Erbe. PK is a consultant for Boston Scientific, Medtronic, and Olympus. RS is consultant for Boston Scientific, Cook Medical, and Lumendi. BV is consultant for Apollo Endosurgery. DM is consultant for Apollo Endosurgery BAD is consultant for DyaMx, Boston Scientific, USGI Medical, and Endo-TAGSS; gets research support from Boston Scientific, USGI Medical, Apollo Endosurgery, Spatz Medical, GI Dynamics, Cairn Diagnostics, Aspire Bariatrics, and Medtronic; is speaker for Johnson and Johnson, Endogastric Solutions, and Olympus. Other authors do not have a conflict of interest or disclosures.

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