American Society for Gastrointestinal Endoscopy–European Society of Gastrointestinal Endoscopy guideline on primary endoscopic bariatric and metabolic therapies for adults with obesity

ESGE ASGE

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published online 19.4.2024

Bibliography
Endoscopy 2024; 56: 437–456
DOI 10.1055/a-2292-2494
ISSN 0013-726X

This article is being published jointly in *Gastrointestinal Endoscopy* and *Endoscopy*.
This article is published by Thieme.
Georg Thieme Verlag KG, Rüdigerstraße 14, 70469 Stuttgart, Germany

Supplementary Material
Supplementary Material is available under https://doi.org/10.1055/a-2292-2494

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ABSTRACT

This joint ASGE-ESGE guideline provides an evidence-based summary and recommendations regarding the role of endoscopic bariatric and metabolic therapies (EBMTs) in the management of obesity. The document was developed using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) framework. It evaluates the efficacy and safety of EBMT devices and procedures that currently have CE mark or FDA-clearance/approval, or that had been approved within five years of document development. The guideline suggests the use of EBMTs plus lifestyle modification in patients with a BMI of ≥30 kg/m^2, or with a BMI of 27.0–29.9 kg/m^2 with at least 1 obesity-related comorbidity. Furthermore, it suggests the utilization of intragastric balloons and devices for endoscopic gastric remodeling (EGR) in conjunction with lifestyle modification for this patient population.

ABBREVIATIONS

AE	adverse event
AOM	antiobesity medication
ASGE	American Society for Gastrointestinal Endoscopy
AT	aspiration therapy
BMI	body mass index
CE	Conformité Européenne
CI	confidence interval
DJBL	duodenal-jejunal bypass liner
DMR	duodenal mucosal resurfacing
EBMT	endoscopic bariatric and metabolic therapy
EGR	endoscopic gastric remodeling
ESG	endoscopic sleeve gastroplasty
ESGE	European Society of Gastrointestinal Endoscopy
FDA	U.S. Food and Drug Administration
GLP-1Ras	glucagon-like peptide 1 receptor agonists
IGB	intragastric balloon
IOP	Incisionless Operating Platform
LM	lifestyle modification
MD	mean difference
PPI	proton pump inhibitor
RCT	randomized controlled trial
SAE	serious adverse event
T2DM	type 2 diabetes mellitus
TPS	transpyloric shuttle
TWL	total weight loss

The rising burden of obesity [1–4] and its related comorbidities, such as type 2 diabetes mellitus [5] (T2DM) and metabolic dysfunction–associated steatotic liver disease [6, 7], constitute a major public health issue globally. It is predicted that by 2030 the number of people suffering from obesity will have doubled since 2010, reaching over 1 billion adults worldwide [8]. Obesity is a significant risk factor for all-cause mortality [9], driven mainly by cardiovascular diseases and cancer. Therefore, expanding treatment options for obesity is paramount.

Traditionally, the primary modalities for the treatment of obesity include lifestyle modification (LM), antiobesity medications (AOMs), and bariatric and metabolic surgery. Weight loss

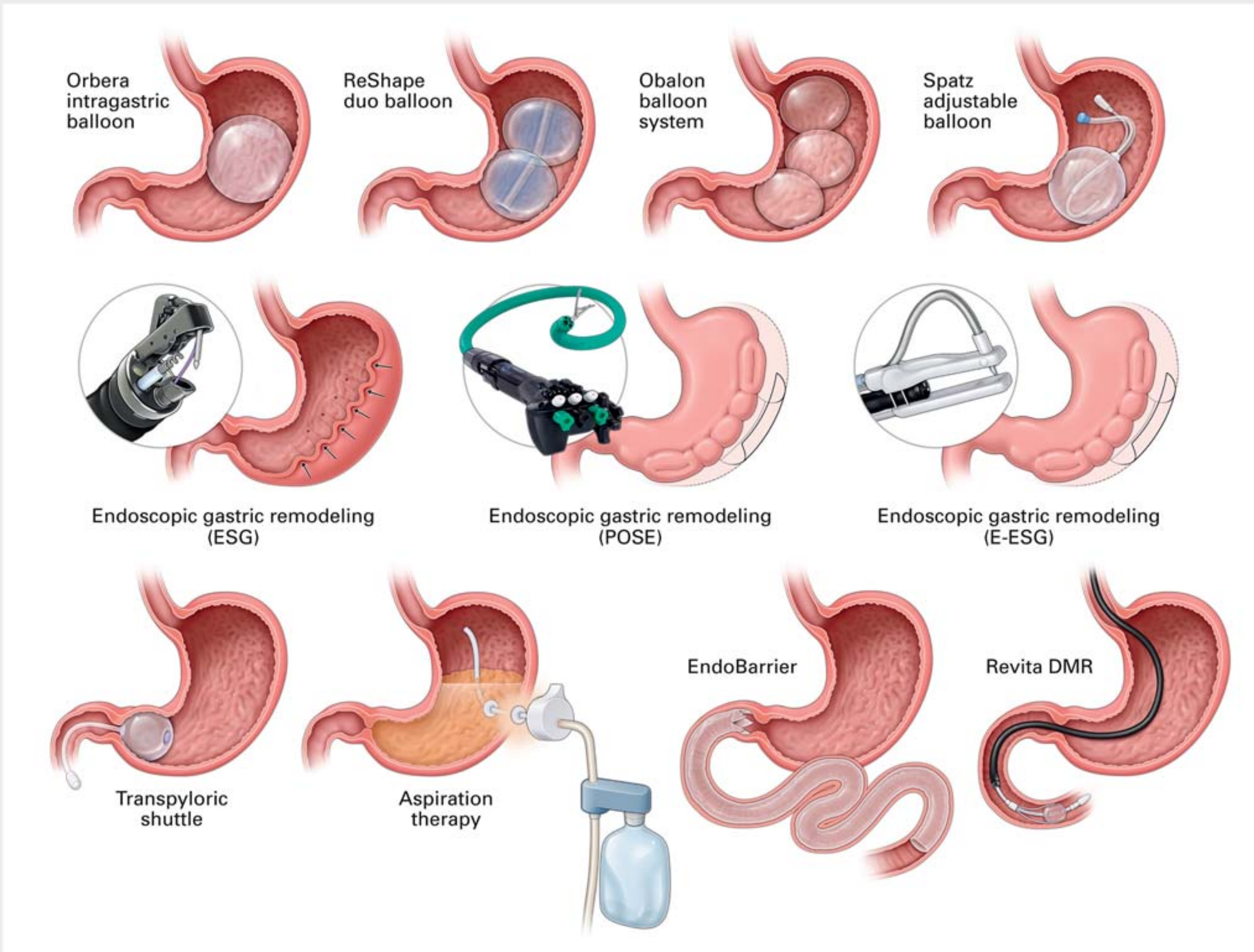
▶ **Table 1** ASGE–ESGE recommendations on primary endoscopic bariatric and metabolic therapies for the management of obesity.

Recommendations	Strength of recommendation	Quality of evidence
1. In adults with overweight or obesity, the ASGE–ESGE suggests the use of endoscopic bariatric and metabolic therapies plus LM over LM alone for patients with a BMI ≥ 30 kg/m2 with or without an obesity-related comorbidity or a BMI of 27 to 29.9 kg/m2 with at least 1 obesity-related comorbidity.	Conditional	Very low
2. In adults with obesity, the ASGE–ESGE suggests the use of an IGB plus LM over LM alone.	Conditional	Moderate
3. In adults with obesity undergoing IGB placement, the ASGE–ESGE suggests the use of antiemetics periprocedurally.	Conditional	Very low
4. In adults with obesity undergoing IGB placement, the ASGE–ESGE suggests the use of pain medications periprocedurally.	Conditional	Very low
5. In adults with obesity undergoing IGB placement, the ASGE–ESGE suggests the use of proton pump inhibitors while the IGB is in place.	Conditional	Very low
6. In adults with obesity, the ASGE–ESGE suggests treatment with EGR plus LM over LM alone.	Conditional	Moderate
7. In adults with obesity undergoing EGR, the ASGE–ESGE suggests the use of antiemetics periprocedurally.	Conditional	Very low
8. In adults with obesity undergoing EGR, the ASGE–ESGE suggests the use of pain medications periprocedurally.	Conditional	Very low
9. In adults with obesity undergoing EGR, the ASGE–ESGE suggests the use of prophylactic antibiotics periprocedurally.	Conditional	Very low
10. In adults with obesity undergoing EGR, the ASGE–ESGE suggests the use of short-term proton pump inhibitors periprocedurally.	Conditional	Very low
11. In adults with obesity, the ASGE–ESGE suggests treatment with aspiration therapy plus LM over LM alone.	Conditional	Low
12. In adults with obesity, the ASGE–ESGE recommends treatment with a transpyloric shuttle only in the context of a clinical trial.	No recommendation	Knowledge gap
13. In adults with obesity and concomitant type 2 diabetes mellitus, the ASGE–ESGE suggests treatment with a duodenal-jejunal bypass liner plus LM over LM alone.	Conditional	Moderate
14. In adults with type 2 diabetes mellitus, the ASGE–ESGE recommends treatment with duodenal mucosal resurfacing only in the context of a clinical trial.	No recommendation	Knowledge gap

ASGE, American Society for Gastrointestinal Endoscopy; *ESGE*, European Society of Gastrointestinal Endoscopy; *LM*, lifestyle modification; *IGB*, intragastric balloon; *EGR*, endoscopic gastric remodeling.

through LM is the first-line treatment for obesity. Nevertheless, even high-intensity LM encompassing calorie restriction, increased physical activity, and a structured behavior change program (≥ 14 sessions in the first 6 months of therapy) is associated with only minimal to moderate weight loss [10], with most patients unable to sustain a long-term weight loss of at least 5 % [11]. Barriers such as ongoing cost and time commitment also contribute to limited sustained weight loss with LM [12]. Newer AOMs, in particular glucagon-like peptide 1 receptor agonists (GLP-1RAs), which induce greater weight loss compared with previous AOMs, are increasingly being prescribed for patients with an inadequate response to LM [13–16]. Despite their efficacy, the use of GLP-1RAs is somewhat limited because of costs, drug shortages, insurance coverage, and intolerance [17]. Additionally, long-term efficacy and safety are unclear, including concerns regarding potentially irreversible GI motility disorders [18]. Finally, bariatric and metabolic surgery is considered the most effective treatment for class II and class III obesity [19, 20] and its related comorbidities [21–23]. Nevertheless, because of a variety of reasons, including cost, patient access, and potentially perceived invasiveness, less than 2 % of eligible patients currently choose to undergo surgery per year [24].

Endoscopic bariatric and metabolic therapies (EBMTs) have been developed and refined over the past 3 decades and are now increasingly performed worldwide. EBMTs are classically divided into gastric and small-bowel devices and procedures, with the former focusing primarily on weight loss with secondary effects on metabolic conditions and the latter focusing on metabolic conditions with or without weight loss [25, 26]. However, despite the increasing popularity of EBMTs over recent years, to date, there is no overarching guideline focusing on the field. This evidence-based guideline was jointly prepared by the American Society for Gastrointestinal Endoscopy (ASGE) and the European Society of Gastrointestinal Endoscopy (ESGE) and sought to address the efficacy and safety endpoints of gas-



▶ **Fig. 1** Gastric and small bowel endoscopic bariatric and metabolic therapies. ESG: endoscopic sleeve gastroplasty, POSE: primary obesity surgery endoluminal, DMR: duodenal mucosal resurfacing.

tric and small-bowel EBMTs as well as periprocedural care (▶ **Table 1**).

Target Goals for EBMTs

The amount of weight loss is the most important predictor for improvement in obesity-related comorbidities such as cardiovascular disease [27, 28], metabolic disorders (T2DM) [29], metabolic dysfunction–associated steatotic liver disease [30], and cancer [31]. Specifically, an improvement in comorbidity clinical endpoints starts at a weight loss of ≥ 5 %, which is associated with a decrease in serum glucose, insulin, triglyceride, and alanine transaminase [32]. In the Diabetes Prevention Program study, patients at risk for developing T2DM who were randomized to intensive LM and achieved ≥ 7 % total weight loss (TWL) at 12 months experienced a significant reduction in the cumulative incidence of T2DM [33]. In a post-hoc analysis of the Look AHEAD randomized clinical trial (RCT), which evaluated the effect of the amount of weight loss on cardiometabolic risk factors (n = 1428), patients with ≥ 8 % TWL at 1 year had the greatest reduction in hemoglobin A1c (HbA1c). They also sustained the most reduction in HbA1c at 4 years without or with partial recurrent weight gain (–.57 % and –.32 %, respectively) compared with those who achieved < 8 % TWL [34]. Similarly, another post-hoc analysis of this RCT found that patients who experienced ≥ 10 % TWL had a significant reduction in cardiovascular disease–related and all-cause mortalities [28]. For metabolic dysfunction–associated steatohepatitis [35], a study with paired liver biopsy samples before and at 52 weeks after LM (n = 261) found a dose-responsive improvement in metabolic dysfunction–associated steatohepatitis histologic features. Specifically, in patients with ≥ 10 % TWL, 90 % had resolution of metabolic dysfunction–associated steatohepatitis and 45 % had regression in liver fibrosis [30].

Target goals for EBMTs depend on the type of intervention. Specifically, for gastric interventions (intragastric balloons [IGBs], endoscopic gastric remodeling [EGR], aspiration therapy [AT], and transpyloric shuttle [TPS]), the primary efficacy endpoint is weight loss. For small-bowel interventions (duodenal-jejunal bypass liner [DJBL] and duodenal mucosal resurfacing [DMR]), glycemic improvement is the primary efficacy endpoint, with weight loss as a co-primary or secondary endpoint for DJBL. Given the scope of this document with all relevant interventions included, cardiometabolic improvements were not analyzed independently. Nevertheless, the pooled weight loss of each intervention was assessed and compared with the 5 % to 10 % TWL threshold. If an intervention was associated with ≥ 5 % TWL, this suggested an improvement in cardiometabolic outcomes based on the findings described above.

Methods

This document represents the official recommendations of the ASGE and ESGE. It was developed by the primary EBMT guideline panel and approved by the ASGE and ESGE governing boards. The guideline was developed using the Grading of Recommendations Assessment, Development and Evaluation framework. The relevant clinical questions were developed a priori and listed in the PICO format, which outlined the specific patient population (P), intervention (I), comparator (C), and outcome (O) for each question (**Supplementary Table 1**, available online).

This document focused on EBMTs categorized by procedure type and not by specific device. Specifically, EBMTs that were approved or cleared by the U.S. Food and Drug Administration (FDA) or had a Conformité Européenne (CE) mark at the time of a literature search and 5 years before were included. The included procedures were IGB (Orbera IGB, Orbera365 IGB, Obalon IGB, Reshape IGB, and Spatz IGB), EGR (endoscopic sleeve gastroplasty [ESG] using the Overstitch Endoscopic Suturing System (Apollo Endosurgery, Austin, Tex, USA), primary obesity surgical endoluminal [POSE] using the Incisionless Operating Platform (IOP, USGI Medical, San Clemente, Calif, USA), and endoscopic gastric plication using the Endomina system (Endo Tools Therapeutics, Gosselies, Belgium)), aspiration therapy (AT) using the AspireAssist System (Aspire Bariatrics, King of Prussia, Penn, USA), Transpyloric Shuttle (TPS, BAROnova INC, Goleta, Calif, USA), Duodenal Jejunal Bypass Liner (DJBL, GI Dynamics, Lexington, KY, USA) and duodenal mucosal resurfacing (DMR) using the Revita (Fractyl Health, Lexington, Mass, USA) (▶ **Fig. 1**). Evidence was presented to a panel of experts representing various stakeholders including bariatric endoscopy, bariatric surgery, obesity medicine, bariatric psychology, and nutrition. A patient advocate was also included. All panel members were required to disclose potential financial and intellectual conflicts of interest, which were addressed according to ASGE policies.

In developing these recommendations, we took into consideration the magnitude and certainty of evidence of benefits and harms of each intervention, feasibility, patient values and preferences, acceptability, resource requirement, cost, cost-effectiveness, and the impact on health equity. The final wording of the recommendation including direction and strength was approved by all members of the panel and the ASGE and ESGE governing boards. According to the Grading of Recommendations Assessment, Development and Evaluation approach, recommendations are labeled as "strong" or "conditional" and are phrased as "we recommend" or "we suggest," accordingly (▶ **Table 2** and ▶ **Table 3**). Further details of the methodology used for this guideline including, and results from all meta-analyses are presented in Appendix 1 (available online).

Results and Summary of Recommendations

A summary of all recommendations is provided in ▶ **Table 1**.

RECOMMENDATION 1

In adults with overweight or obesity, the ASGE–ESGE suggests the use of EBMTs plus LM over LM alone for patients with a body mass index (BMI) of ≥ 30 kg/m² or BMI of 27.0 to 29.9 kg/m² with at least 1 obesity-related comorbidity. *(Conditional recommendation, very low certainty)*

Implementation considerations

- For patients with a BMI of 27.0 to 29.9 kg/m² with at least 1 obesity-related comorbidity, data were available for IGB, EGR, and DJBL.
- For patients with class III obesity, data were available for IGB, EGR, AT, and DJBL.

Summary of the evidence

For the subgroup with BMIs of 27.0 to 29.9 kg/m², 6 observational studies were used to inform this PICO (IGB studies [55, 56], EGR study [57], and DJBL studies [58, 60]). Of these, 6 studies were used to assess safety [55–60], 4 studies for percentage of TWL [55–57, 59], and 3 studies for the change in HbA1c [58–60]. All studies on IGB and EGR only included patients who were overweight (BMI of 25.0–29.9 kg/m² or 27.0–29.9 kg/m²). All DJBL studies included patients who were both overweight (starting BMI of 27.0 or 28.0 kg/m²) and had obesi-

▶ **Table 2** Interpretation of the certainty in evidence of effects using the Grading of Recommendations Assessment, Development and Evaluation framework

Certainty	Description
High	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate	We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.
Very low	We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

From Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. J Clin Epidemiol 2011;64:401–6.

▶ **Table 3** Interpretation of strong and conditional recommendations using the Grading of Recommendations Assessment, Development and Evaluation framework

Implications	Strong recommendation	Conditional recommendation
For patients	Most individuals in this situation would want the recommended course of action and only a small proportion would not.	Most individuals in this situation would want the suggested course of action, but many would not.
For clinicians	Most individuals should receive the intervention. Formal decision aids are not likely to be needed to help individuals make decisions consistent with their values and preferences.	Different choices will be appropriate for individual patients consistent with their values and preferences. Use shared decision-making. Decision aids may be useful in helping patients make decisions consistent with their individual risks, values, and preferences.
For policy-makers	The recommendation can be adapted as policy or performance measure in most situations.	Policymaking will require substantial debate and involvement of various stakeholders. Performance measures should assess whether decision-making is appropriate.

From Schünemann HJ, Mustafa RA, Brozek J, et al. GRADE guidelines: 22. The GRADE approach for tests and strategies-from test accuracy to patient-important outcomes and recommendations. J Clin Epidemiol 2019;111:69–82; Grunvald E, Shah R, Hernaez R, et al. AGA clinical practice guideline on pharmacological interventions for adults with obesity. Gastroenterology 2022;163:1198–225.

ty. Mean age ranged from 38 to 52 years and BMI from 29.7 to 43.1 kg/m^2. All studies prescribed concomitant LM, except for Moore et al [56], where the intensity of LM varied across sites given the nature of real-world experience (**Supplementary Table 2**, available online).

For the subgroup with classes I and II obesity, 17 RCTs were used to inform this PICO (IGB studies [39–44], EGR studies [45–47, 62], AT studies [48, 52], TPS studies [49], DJBL studies [50, 51, 63], and DMR studies [64]). Of these, 15 studies were used to assess safety [39, 40, 42–46, 49–52, 61–64], 14 studies for percentage of TWL [39–47, 49–52, 64], and 2 studies for the change in HbA1c [50, 51]. All IGB, EGR, and TPS studies only included patients with classes I and II obesity. Otherwise, the remainder included a combination of different classes of obesity (classes II and III for AT; classes I, II, and III for DJBL; and overweight and classes I and II for DMR). Mean age ranged from 38 to 58 years and BMI from 31.5 to 42.0 kg/m^2. Most studies compared EBMTs with LM alone, whereas Sullivan et al [44], Ponce et al [43], Sullivan et al [47], Rothstein et al [49], Thompson et al [50], and Mingrone et al [64] compared EBMTs with sham (**Supplementary Table 3**, available online).

For the subgroup with class III obesity, 31 observational studies and RCTs (interventional arms only) were used to inform this PICO (IGB studies [55, 56, 61, 65–73], EGR studies [57, 74], AT studies [48, 52, 75], and DJBL studies [50, 51, 58, 59, 63, 76–84]). Of these, 26 studies were used to assess safety [48, 50–52, 57–59, 63, 67–84], 20 studies for percentage of TWL [48, 50–52, 55–57, 59, 61, 65–69, 71–75, 81], and 10 studies for the changes in HbA1c [50, 51, 58, 59, 79–84]. All IGB and EGR studies only included patients with class III obesity, whereas AT and DJBL studies included both class III and other classes of obesity (class II ± class I). Mean age ranged from 33 to 58 years and BMI from 34.6 to 69.1 kg/m^2. All studies prescribed concomitant LM, except for Moore et al [56], where the intensity of LM varied across sites given the nature of real-world experience (**Supplementary Table 4**, available online).

Benefits

For the subgroup with BMIs of 27.0 to 29.9 kg/m^2, 4 observational studies (n = 692) informed the outcomes of percentage of TWL at 6 months (for IGB) or 12 months (for EGR and DJBL) and 3 studies (n = 436) for HbA1c reduction at 12 months (for DJBL) [55–60]. The pooled weight loss at 6 to 12 months was 11.9 % TWL (95 % confidence interval [CI], 7.7–16.0) (**Supplementary Fig. 1**, available online) and pooled HbA1c reduction at 12 months was 1.0 % (95 % CI, .6–1.5) (**Supplementary Fig. 2**, available online).

For the subgroup with classes I and II obesity, 14 RCTs (n = 2787) informed the outcomes of percentage of TWL at 12 months [39–47, 49–52, 64] and 2 studies (n = 490) for HbA1c reduction at 12 months [50, 51]. A total of 1636 subjects were in the EBMT plus LM group and 1151 in the LM group. The mean difference (MD), which represented the difference between the pooled percentage of TWL in the EBMT arm minus the control arm, at IGB removal or 12 months after EGR, AT, DJBL, or TPS was 7.1 % (95 % CI, 5.4–8.8) in favor of EBMT (**Supplementary Fig. 3**, available online). The mean TWL of the EBMT arm ranged from 5.0 % to 18.6 % at IGB removal or 12 months for EGR, DJBL, AT, or TPS. The MD, which represented the difference between the pooled HbA1c reduction in the EBMT arm minus the control arm, at 12 months was .7 % (95 % CI, .4–1.1) in favor of EBMT (**Supplementary Fig. 4**, available online). The mean HbA1c reduction of the EBMT arms ranged from 1.1 % to 1.5 % at 12 months.

For the subgroup with class III obesity, 20 observational studies (n = 2776) informed the outcomes of percentage of TWL at 6 to 12 months [48, 50–52, 55–57, 59, 61, 65–69, 71–75, 81] and 10 studies (n = 815) for HbA1c reduction at 12 months [50, 51, 58, 59, 79–84]. The pooled TWL at 6 to 12 months was 13.1 % (95 % CI, 10.8–15.4) (**Supplementary Fig. 5**, available online) and pooled HbA1c reduction at 12 months was 1.3 % (95 % CI, 1,0–1.6) (**Supplementary Fig. 6**, available online).

Harms

For the subgroup with BMIs of 27.0 to 29.9 kg/m^2, 6 observational studies informed the outcome of serious adverse events (SAEs; n = 7416) [55–60]. SAEs were defined by the investigators and reported in the original studies. The pooled estimate for SAEs showed an event rate of 2.7 % (95 % CI, 1.2–6.0) (**Supplementary Fig. 7**, available online).

For the subgroup with classes I and II obesity, 16 RCTs informed the outcome of SAEs (n = 1464) [39, 40, 42–46, 49–52, 62–64]. The pooled estimate for SAEs showed an absolute risk of 14 additional SAEs per 1000 subjects [6, 30] in the EBMT group (111/2135) compared with the control group (6/1464) (**Supplementary Fig. 8**, available online).

For the subgroup with class III obesity, 26 studies informed the outcome of SAEs (n = 2042) [48, 50–52, 57–59, 63, 67–84]. The pooled estimate for SAEs showed an event rate of 6.9 % (95 % CI, 5.7–8.2) (**Supplementary Fig. 9**, available online).

Certainty of evidence assessment

The certainty in the evidence of effects of EBMTs in the subgroup with BMIs of 27.0 to 29.9 kg/m^2 with at least 1 comorbidity, subgroup with classes I to II obesity, and subgroup with class III obesity was very low, low, and very low, respectively (**Supplementary Table 5**, available online). Therefore, the overall certainty in the evidence of this PICO (ie, the effects of EBMTs for patients with a BMI of ≥ 30 kg/m^2 or 27.0–29.9 kg/m^2 with ≥ 1 comorbidity) was deemed to be very low.

In the subgroup with BMI of 27.0 to 29.9 kg/m^2, for the weight loss outcome, there was a concern for confounding bias in some studies as well as inconsistency and indirectness because some studies reported the amount of weight loss in both the overweight and obesity groups combined. For the HbA1c outcome, there was a concern for inconsistency, indirectness (because of a mixed overweight and obesity population in some studies), and imprecision (because of a small total number of patients). For harms, there was a very low certainty in evidence given the inconsistency, indirectness (because of a mixed overweight and obesity population in some studies), and imprecision (because of a small number of SAEs) (**Supplementary Table 6**, available online).

In the subgroup with classes I and II obesity, there was inconsistency in the amount of weight loss, which was likely explained by the heterogeneity among different EBMT devices and/or procedures pooled. For the HbA1c outcome, there was imprecision because the CI crossed the line of no difference. For harms, the certainty of evidence was downgraded twice for imprecision because of a low event rate and wide CI (**Supplementary Table 7**, available online).

In the subgroup with class III obesity, for the weight loss outcome, there was a concern for confounding bias in some studies as well as inconsistency and indirectness because some studies reported the amount of weight loss of both class III obesity and other classes combined. For the HbA1c outcome, there was a concern for inconsistency and indirectness with some studies reporting the outcomes of both class III obesity and other classes combined. For harms, there was a very low certainty in evidence given the inconsistency, indirectness, and imprecision because of a small number of SAEs (**Supplementary Table 8**, available online).

Discussion

To assess the patient populations in which EBMTs should be considered, we divided the potential populations into 3 categories based on BMI: BMI of 27.0 to 29.9 kg/m^2 with at least 1 obesity-related comorbidity, classes I and II obesity, and class III obesity. Because most EBMTs included in this guideline were approved or cleared for classes I and II obesity, only RCTs were included for this population. In contrast, for the BMI of 27.0 to 29.9 kg/m^2 and class III obesity subgroups, no RCTs specifically assessed the effect of EBMTs in these 2 populations. Therefore, observational studies were evaluated.

For the overweight category, whereas Moore et al [56] and Barrichello et al [57] included patients with BMIs of 25.0 to 29.9 kg/m^2, most studies included patients starting at BMIs of 27 or 28 kg/m^2 [55–60]. Additionally, half of the studies included patients with at least 1 obesity-related comorbidity (T2DM). Therefore, the panel decided to use a conservative cutoff for this patient population with a starting BMI of 27 kg/m^2 with at least 1 comorbidity. For the class III obesity category, all IGB and EGR studies [55–57, 61, 65–74] only included patients with class III obesity, whereas AT and DJBL studies [48, 50–52, 58, 59, 75, 79–84] included both class III and class II ± class I obesity. Although some studies had a cutoff for the highest BMI at 50 or 55 kg/m^2 [48, 50–52, 55–59, 61, 63, 69, 70, 74, 76–84], some did not and recruited patients with BMIs up to 70 or 78 kg/m^2 [65–68, 71–73, 75, 82]. The panel accepted the heterogeneity in this patient population. However, given that EBMTs may be used for either primary therapy or bridge therapy before bariatric surgery, the panel agreed to not having an upper limit of BMI for consideration of EBMTs.

The amount of weight loss after EBMT was determined to be moderate for all BMI subgroups. Specifically, the amount of weight loss was 11.9 % (95 % CI, 7.7–16.0) and 13.1 % (95 % CI, 10.8–15.4) TWL in the BMI of 27.0 to 29.9 kg/m^2 and class III obesity subgroups, respectively. For the subgroup with classes I and II obesity, the MD, representing the difference between the pooled percentage of TWL in the EBMT arm minus the control arm, was 6.3 % (95 % CI, 5.3–7.3) in favor of EBMT, with the absolute percentage of TWL in the EBMT arm ranging from 5.0 % to 18.6 % at 12 months. For the BMI of 27.0 to 29.9 kg/m^2 and class III obesity studies, the lower CI of percentage of TWL was 7.7 % and 10.8 %, respectively. Given the pooled average of 3.2 % TWL for the historical control subjects from all EBMT RCTs (**Supplementary Fig. 10**, available online), the MD of the amount of weight loss between the EBMT and control groups in these 2 populations should remain above the 3 % TWL minimal important difference threshold (MDs of 4.5 % and 7.6 % TWL, respectively). Similarly, for the subgroup with classes I and II obesity, not only did the lower CI of the overall MD lie above the 3 % TWL minimal important difference threshold, but our sensitivity analysis also showed that the lower CI of the MD of every EBMT also lay above this threshold (**Supplementary Fig. 3**). Additionally, all studies but IGB reported the weight loss outcome at 12 months. For IGB, all studies reported percentage of TWL at the time of IGB removal (6–8 months). Although Nunes et al [85] reported percentage of TWL in the subgroups with overweight and class III obesity at 12 months (ie, 6 months after IGB removal), this study evaluated the effect of IGB plus a very-low-calorie diet, which likely biased the magnitude of weight loss [86]. Therefore, this study was excluded. The effect of IGB on weight loss after IGB removal in the subgroups with overweight and class III obesity therefore remains to be assessed. The panel also noted inconsistency in the amount of weight loss, especially for class III obesity. This was believed to be because of a heterogeneity of the patient populations, with some studies including patients with BMIs up to 55 kg/m^2 for a primary therapy as an alternative to bariatric surgery [48, 50–52, 55–59, 61, 63, 69, 70, 74, 76–84] and others including patients with BMIs up to 78 kg/m^2 for bridge therapy before bariatric surgery [65–68, 71–73,75,82]. The certainty of evidence was downgraded because of this inconsistency.

The SAE rate was 2.7 % (95 % CI, 1.2–6.0) and 6.9 % (95 % CI, 5.7–8.2) for the BMI of 27.0 to 29.9 kg/m^2 and class III obesity subgroups, respectively. For the subgroup with classes I and II obesity, the risk ratio of SAEs in the EBMT arm compared with the control arm was 4.4 (95 % CI, 2.4–8.2), which was equivalent to 14 additional events per 1000 subjects. The SAE rate in the EBMT arm ranged from 0 % to 10.6 %. Of note, the panel found that the wide CIs for pooled SAE rates were likely because of the difference in SAE definitions used by the authors, especially for DJBL studies. For example, although most DJBL studies defined SAEs as those resulting in early device explantation, Stratmann et al [82] only reported the rate of early device explantation and Roehlen et al [77] only reported the rate of SAEs without reporting the number of early device explantations. In contrast, early removal of IGBs has not been considered as a SAE in most trials, and specifically in the United States, RCTs would not meet the FDA categorization of SAE by itself.

Currently, the number of studies evaluating the cost-effectiveness of EBMTs is limited. Saumoy et al [87] and Kelly et al [88] demonstrated that ESG was cost-effective compared with LM alone in class II obesity in the United States and United Kingdom, respectively. Haseeb et al [89] showed that ESG was cost-effective compared with GLP-1RA and sleeve gastrectomy in class II obesity in the United States. Although currently no study has specifically evaluated the cost-effectiveness of EBMTs in other obesity classes or in an overweight population, the panel agreed that EBMTs would most likely be cost-effective, especially when compared with LM, in these other BMI categories.

The panel considered the current state of EBMTs to be associated with reduced equity for all BMI subgroups. This is solely because of the lack of insurance coverage for EBMTs in most countries. This leads to inequity between those patients who are able to afford the procedures and those who are not and potentially between the nonminority and minority. The panel noted that with universal insurance coverage, EBMTs will improve equity by providing better access to safe and effective care for more patients who suffer from obesity or overweight with at least 1 obesity-related comorbidity.

RECOMMENDATION 2
In adults with obesity, the ASGE–ESGE suggests the use of an IGB plus LM over LM alone.
(*Conditional recommendation, moderate certainty*)

Rationale

A conditional recommendation is driven primarily by moderate variability in patient values and preferences. Specifically, although the IGB is generally acceptable among most patients suffering from obesity, some may prefer a less-invasive treatment approach (ie, LM) despite a lower weight loss than seen with the IGB. Therefore, treatment options should be discussed to encourage shared decision-making.

Summary of the evidence

We identified a recently published guideline on IGB, which conducted a systematic review and meta-analysis with a comprehensive search strategy (MEDLINE, Embase, and Cochrane Library) from inception to January 2020 [36, 90]. We updated the search to March 2021 and found no additional RCTs that met our inclusion and exclusion criteria. Therefore, 7 RCTs assessing the safety and efficacy of IGB were used to inform this PICO [39–44, 91]. All 7 studies reported percentage of TWL at the time of IGB removal (6–8 months), and 2 studies reported percentage of TWL at 12 months [40, 41]. Mean age and BMI of the intervention arm ranged from 38.7 to 44.4 years and from 30.3 to 53.9 kg/m^2, respectively. The interventional arm of all studies underwent concomitant LM. The control arms of Sullivan et al [44] and Ponce et al [43] underwent a sham procedure with concomitant LM, whereas the rest of the studies underwent LM alone (**Supplementary Table 9**, available online).

Benefits

Seven RCTs informed the outcome of percentage of TWL at the time of IGB removal (6–8 months) [39–44, 91], and 2 RCTs informed the outcome of percentage of TWL at 12 months [40, 41]. Seven hundred seventy-nine subjects were in the IGB plus LM group and 654 in the LM group. The MD, representing the difference between the pooled percentage of TWL in the IGB arm minus the control arm at the time of IGB removal (6–8 months), was 6.9 % TWL (95 % CI, 4.1–9.7) in favor of the intervention (**Supplementary Fig. 11**, available online). This represented a 3.1 times greater weight loss in the IGB arm compared with the control arm (pooled weight loss of 10.7 % TWL in the IGB arm vs 3.4 % TWL in the control arm). The MD for percentage of TWL at 12 months was 4.4 % TWL (95 % CI, 2.9–6.0) (**Supplementary Fig. 12**). This represented a 2.4 times greater weight loss in the IGB arm compared with the control arm (pooled weight loss of 7.9 % TWL in the IGB arm vs 3.3 % TWL in the control arm).

Harms

Seven RCTs informed the outcome of SAEs [39–44, 91]. SAEs were defined by the investigators and reported in the original studies. The pooled estimate for SAEs showed an absolute risk of 32 additional SAEs per 1000 subjects (95 % CI, 7–114) in the IGB group (58/1028) compared with the control group (0/798) (**Supplementary Fig. 13**, available online). Selected examples of SAEs from studies that reported particular SAE outcomes included esophageal mucosal injury (4/473), gastric ulcer/bleeding (5/650), severe dehydration (5/704), aspiration pneumonia (2/42), perforation (2/653), gastric outlet/bowel obstruction (1/802), and mortality (0/741) (**Supplementary Table 10**, available online).

Certainty of evidence assessment

The overall certainty in the evidence of effects for IGB was moderate (**Supplementary Tables 11** and **12** and **Supplementary Fig. 14**, available online). For benefits at 6 months, we found imprecision with weight loss because of the wide CI and some inconsistency that was not deemed of serious concern by itself, and no additional downgrading was performed. For benefits at 12 months, imprecision was found because of a small sample size and CI that crossed the line of no difference. For harms, there was moderate certainty in evidence given a small number of SAEs with a wide CI.

Discussion

The first IGB approved for use was the Garren-Edwards Gastric Bubble (American Edwards Laboratories, Irvine, Calif, USA) in 1985, an air-filled balloon made of polyurethane in a cylindrical shape that was removed from the market in 1988 because of SAEs and lack of effective weight loss [92–94]. Current IGBs have been designed to mitigate AEs and have demonstrated weight loss efficacy in sham-controlled trials as noted in the summary of evidence. The next generation of IGBs approved in the United States and Europe came in 2015 and 2017, respectively, but IGBs have been used around the world since the 1990 s.

The mechanism of action of IGBs for weight loss is likely multifactorial. Early data suggested that at least 400 mL of space occupation in the stomach was required to reduce meal volume [95]. Subsequent analysis of gastric emptying has demonstrated that the effects of fluid-filled IGBs are also in part because of a reduction in the rate of gastric emptying during balloon implantation [96]. These mechanisms may help explain the recurrent weight gain that can occur after balloon removal, because the currently understood mechanisms for weight loss require balloon presence.

The magnitude of weight loss with IGB at 6 months was determined to be moderate, with a wide CI based on the mix of sham-controlled and open-label RCTs included in the analysis. An analysis comparing open-label and sham IGB RCTs found that the sham study design lowered weight loss compared with open-label studies [97]. Combining open-label and sham-controlled studies in this analysis may underestimate the true effect of IGB in a clinical setting; however, this is the most conservative approach. Additionally, the panel noted that weight loss was lower at 12 months (6 months after IGB removal) than at IGB removal. Although weight loss at the 12-month time point was still significant, patients considering IGB therapy should be made aware of the likely regain of some weight within 6 months of IGB removal. Studies have evaluated repeated use of IGB for longer term obesity treatment [98, 99], but repeated IGB therapy was not evaluated in this recommendation.

SAEs were also discussed by the panel. The SAE rate was 5.6 %, but safety varied across the gas-filled compared with fluid-filled balloons [39, 40,43,44]. Of note, most SAEs were related to short-term accommodative symptoms including nausea and vomiting, leading to dehydration and abdominal pain. Although these did meet the FDA criteria for SAEs, they were short-lived and resolved without sequelae, leading the panel to determine the reported rates of SAEs were acceptable.

The panel also found current reduced equity related to IGB treatment. This is solely because of the lack of insurance coverage of IGB in most countries. This leads to inequity between those patients who are able to pay out of pocket for IGB treatment and those patients who are not. The panel noted that insurance coverage is crucial to reduce inequity and improve access to recommended obesity treatments. The panel found that acceptability of IGBs was high with the caveat of some recurrent weight gain 6 months after IGB removal and noted that some patients favor the shorter duration of treatment with no permanent changes to the anatomy of the GI tract.

RECOMMENDATION 3
In adults undergoing IGB placement, the ASGE–ESGE suggests the use of antiemetics periprocedurally.
(*Conditional recommendation, very low certainty*)

Further details regarding the rationale for this recommendation including the results of systematic reviews, expert survey, and evidence profile are presented in Appendix 2 (available online).

RECOMMENDATION 4
In adults undergoing IGB placement, the ASGE–ESGE suggests the use of pain medications periprocedurally.
(*Conditional recommendation, very low certainty*)

Further details regarding the rationale for this recommendation including the results of systematic reviews, expert survey, and evidence profile are presented in Appendix 3 (available online).

RECOMMENDATION 5
In adults undergoing IGB placement, the ASGE–ESGE suggests the use of proton pump inhibitors (PPIs) while the IGB is in place over no PPIs.
(*Conditional recommendation, very low certainty*)

Further details regarding the rationale for this recommendation including the results of systematic reviews, expert survey, and evidence profile are presented in Appendix 4 (available online).

RECOMMENDATION 6
In adults with obesity, the ASGE–ESGE suggests treatment with EGR plus LM over LM alone.
(*Conditional recommendation, moderate certainty*)

Implementation consideration

- EGR may be performed using the Overstitch Endoscopic Suturing System (Apollo Endosurgery), Incisionless Operating Platform (IOP; USGI Medical), or Endomina System (Endo Tools Therapeutics). Prolene sutures are placed in the stomach to reduce its volume in all cases. The procedures have been generally referred to as endoscopic gastric plication or ESG, originally described with the Overstitch Endoscopic Suturing System. The primary obesity surgery endoluminal (POSE) procedure specifically referred to a procedure with the IOP; however, these also have been referred to as plication ESG in the literature. Evidence is insufficient to specifically recommend 1 device over another. The choice of device is based on clinical context, patient values, availability, and operator experience.

Rationale

A conditional recommendation is driven primarily by moderate variability in patient values and preferences. Specifically, although EGR is generally acceptable among most patients suffering from obesity, some may prefer a less-invasive treatment approach (ie, LM) despite lower weight loss than seen with the EGR. Therefore, treatment options should be discussed to encourage shared decision-making. In addition, insurance coverage is frequently lacking. A greater number of patients would elect to get EGR if it were universally covered by insurance. Furthermore, insurance coverage would reduce healthcare inequity.

Summary of the evidence

Four RCTs assessing the safety and efficacy of EGR were used to inform this PICO [45–47, 62]. Of these, 4 studies were used to assess safety [45–47, 62], and 3 studies were used to assess efficacy [45–47, 62]. In Huberty et al [62], the control arm was offered a crossover to the intervention arm at 6 months; therefore, the efficacy, which is the difference in mean weight loss between 2 two arms at 12 months, was not able to be assessed. Of the 4 studies, 1 study [45] used the Overstitch suturing device, 2 studies [46, 47] used the IOP plication system, and 1 study [62] used the Endomina plication system to perform EGR. Mean age and BMI of the intervention arm ranged from 38 to 47 years and from 34.8 to 36.2 kg/m^2, respectively (**Supplementary Table 9**). The intervention arm of all studies underwent concomitant LM (moderate intensity for all studies except for Sullivan et al [47], which underwent concomitant low-intensity LM). The control arm of Sullivan et al [47] underwent a sham procedure with concomitant low-intensity LM, whereas in the remaining studies moderate-intensity LM alone was used (**Supplementary Table 9**).

Benefits

Three RCTs informed the outcome of percentage of TWL at 12 months [45–47]. Three hundred forty subjects were in the EGR plus LM group and 245 in the LM group. The MD, representing the difference between the pooled percentage of TWL in the EGR arm minus the control arm at 12 months, was 8.0 % TWL (95 % CI, 3.4–12.6) in favor of the intervention (**Supplementary Fig. 15**, available online). This represented a 4.4 times greater weight loss in the EGR arm compared with the control arm (pooled weight loss of 10.5 % TWL in the EGR arm vs 2.4 % TWL in the control arm).

A separate meta-analysis including only observational studies was conducted. Twenty-one studies with 5250 patients reported percentage of TWL at 12 months after EGR and were included [57, 74, 100–116, 133, 134]. Of these, 16 studies (4880 patients) used the Overstitch suturing device, 4 studies (319 patients) used the IOP plication system, and 1 study (51 patients) used the Endomina plication system to perform EGR. Mean age ranged from 34 to 56 years and BMI from 32.5 to 49.9 kg/m^2. At 12 months, the pooled average weight loss was 17.3 % TWL (95 % CI, 16.2–18.4) (**Supplementary Fig. 16A**, available online). A subgroup analysis based on the device demonstrated the efficacy of EGR performed using the Overstitch endoscopic suturing device, IOP, and Endomina plication system to be 18.2 % TWL, 16.5 % TWL and 7.0 % TWL, respectively, at 12 months (**Supplementary Fig. 16B**).

Harms

Four RCTs informed the outcome of SAEs [45–47, 62]. SAEs were defined by the investigators and reported in the original studies. The pooled estimate for SAEs showed a relative risk of 5.6 (95 % CI, 1.1–30.1) when comparing the EGR group (14/435) with the control group (1/253) (**Supplementary Fig. 17**, available online). Selected examples of SAEs from the ESG study included abdominal abscess treated with endoscopy (1/131), upper GI bleeding managed conservatively (1/131), and malnutrition treated with endoscopic reversal of the ESG (1/131). Selected examples of SAEs from the largest plication ESG study included extraluminal bleeding treated with laparoscopy (1/221), hepatic abscess treated with percutaneous drainage (1/221), and abdominal pain, nausea, or vomiting requiring prolonged hospitalization (9/221) (**Supplementary Table 13**, available online).

Certainty of evidence assessment

The overall certainty in the evidence of effects for EGR was moderate (**Supplementary Tables 11** and **14** and **Supplementary Fig. 18**, available online). For benefits, we found indirectness for weight loss, making us rate the certainty in evidence down to moderate. Specifically, whereas Abu Dayyeh et al [45] used the current technique with placing stitches in the gastric body to reduce its volume, Miller et al [46] and Sullivan et al [47] used the former technique, which focused on placing plications in the fundus. This difference in techniques likely explained inconsistency and imprecision of the MD in weight loss. Additionally, the control group in Sullivan et al [47] underwent a sham procedure with concomitant low-intensity LM, which has been shown to be associated with a smaller MD in weight loss compared with a non-sham control group. For harms, there was moderate certainty in evidence given a small number of SAEs with a wide CI.

Discussion

This analysis included several types of devices for gastric remodeling including the Overstitch suturing device, IOP plication device, and Endomina plication device. Although these devices create tissue plications differently, the result is similar. All procedures reduce the width and length of the stomach and are believed to delay gastric emptying [74, 123, 124]. Currently, the Overstitch has a CE mark and FDA De Novo marketing authorization for the treatment of obesity, whereas the IOP and Endomina have a CE mark and FDA 510(k) clearance for tissue approximation of the GI tract.

For EGR, the MD in weight loss, representing the difference between the pooled percentage of TWL in the EGR arm minus the control arm, at 12 months was 8.0 % TWL (95 % CI, 3.4–12.6) in favor of the intervention. The certainty of this evidence was rated moderate. Variability was seen across the 3 RCTs on EGR likely because of several factors. First, the trial with the lowest weight loss in the intervention arm was a sham-controlled study (4.95 % ± 7.04 % TWL). Within that trial, a lead-in group of 34 subjects who were unblinded to their treatment achieved 40 % more weight loss than the treatment patients who were blinded to study assignment [47]. Additionally, the same technique was used in a different trial included in the analysis. Treatment patients achieved significantly more weight loss in this open-label RCT (13.0 %; 95 % CI, 10.3–15.8) [46], supporting the hypothesis that the sham study design artificially reduces weight loss in the treatment arm of an EBMT study. Including the randomized sham-controlled study therefore may have artificially lowered the weight loss compared with what can be expected in clinical practice but is the most conservative analysis.

Four RCTs with at least 6 months of data were included in the safety analysis with a low SAE rate of 3.2 %. Additionally, some of these SAEs were because of accommodative symptoms of nausea and vomiting causing dehydration and abdominal pain, which were short-lived and resolved without sequelae.

Similar to IGBs, the panel agreed that EGR currently reduces equity solely because it is not covered by the national health system or insurance in most countries. Therefore, in most countries only patients who can pay out of pocket have access to this therapy. Equity would substantially increase by expanding options and accessibility to a wider range of patients with obesity, including the under-represented minority patients with obesity, and if this procedure was covered universally by national health systems and insurance companies. The panel also agreed that acceptability of endoscopic suturing/plication remodeling of the stomach is high among patients seeking obesity treatment.

RECOMMENDATION 7
In adults undergoing EGR, the ASGE–ESGE suggests the use of antiemetics periprocedurally.
(*Conditional recommendation, very low certainty*)

Further details regarding the rationale for this recommendation including the results of systematic reviews, expert survey, and evidence profile are presented in Appendix 5 (available online).

RECOMMENDATION 8
In adults undergoing EGR, the ASGE–ESGE suggests the use of pain medications periprocedurally.
(*Conditional recommendation, very low certainty*)

Further details regarding the rationale for this recommendation including the results of systematic reviews, expert survey, and evidence profile are presented in Appendix 6 (available online).

RECOMMENDATION 9
In adults undergoing EGR, the ASGE–ESGE suggests the use of short-term antibiotics periprocedurally.
(*Conditional recommendation, very low certainty*)

Further details regarding the rationale for this recommendation including the results of systematic reviews, expert survey and evidence profile are presented in Appendix 7 (available online).

RECOMMENDATION 10
In adults undergoing EGR, the ASGE–ESGE suggests the use of short-term PPIs after the procedure over no PPIs.
(*Conditional recommendation, very low certainty*)

Further details regarding the rationale for this recommendation including the results of systematic reviews, expert survey and evidence profile are presented in Appendix 8 (available online).

RECOMMENDATION 11
In adults with obesity, the ASGE–ESGE suggests treatment with AT plus LM over LM alone depending on device availability.
(*Conditional recommendation, low certainty*)

Further details regarding the rationale for this recommendation including the results of systematic reviews, meta-analyses, and evidence profile are presented in Appendix 9 (available online).

RECOMMENDATION 12
In adults with obesity, the ASGE–ESGE recommends treatment with TPS only in the context of a clinical trial.
(*No recommendation, knowledge gap*)

Summary of the evidence

One RCT assessing the safety and efficacy of TPS was used to inform this PICO [49]. The study included subjects with class I obesity with at least 1 comorbidity and class II obesity with or without a comorbidity. Mean age and BMI of the intervention arm were 43 years and 36.8 kg/m^2, respectively. The intervention arm underwent concomitant moderate-intensity LM, whereas the control arm underwent a sham procedure with concomitant moderate-intensity LM (**Supplementary Table 9**).

Benefits

One RCT informed the outcome of percentage of TWL at 12 months [49]. One hundred eighty-one subjects were in the TPS plus LM group and 89 in the sham plus LM group (**Supplementary Table 9**). The MD, representing the difference between the mean percentage of TWL in the TPS arm minus the control arm at 12 months, was 6.7 % TWL (95 % CI, 4.5–8.9) in favor of the intervention (**Supplemental Fig. 19**, available online).

Harms

One RCT informed the outcome SAEs [49]. SAEs were defined by the investigators and reported in the original study. The SAEs showed an absolute risk of 18 additional SAEs per 1000 subjects (95 % CI, 3–380) in the TPS group (6/213) compared with the control group (0/89) (**Supplementary Fig. 20**, available online). These SAEs included esophageal rupture requiring a surgical repair (1/213), upper abdominal pain/device impaction (1/213), vomiting/device impaction (1/213), gastric ulcer/device impaction (1/213), device intolerance (1/213), and device impaction (1/213) (**Supplementary Table 15**, available online).

Certainty of evidence assessment

The overall certainty in the evidence of effects for TPS was low (**Supplementary Tables 11** and **16**, available online). Risk of bias was judged as not serious (**Supplementary Fig. 21**, available online). The only limitation of the efficacy evidence was imprecision because of a small number of patients included in the study. For harms, there was a low certainty in the evidence given a small number of SAEs with a wide CI that crossed the line of no difference.

Discussion

The TPS is a gastric device with FDA approval in the United States; however, it has not yet been commercialized. Unlike the IGB, it is not a space-occupying device. The mechanism of action is related to the device causing intermittent gastric outlet obstruction with the larger portion of the device, bobbing between the antrum and pylorus with gastric contractions. Because the larger portion of the device is filled with silicone, it does not have a risk of deflation and has FDA approval for 12 months of dwell time. However, only 1 RCT was available for analysis of the current generation of the TPS [49]. One previous pilot study was performed evaluating an earlier design of the device, but that device was associated with a high rate of ulceration that occurred in 50 % of patients [127] and necessitated the design change to its current form. The U.S. multicenter randomized sham-controlled trial demonstrated significant weight loss over sham and a low SAE rate of 2.8 %, but there were only 213 patients who received the device either in the active arm or an open-label extension arm and 89 control patients. Moreover, because the device has not been commercialized, only a few members of the panel had any experience with the device, and this experience was limited to the study setting. Because of the insufficient real-world experience with the device, the panel recommended using this device for treating obesity only in the context of a clinical trial.

RECOMMENDATION 13
In adults with obesity and T2DM, the ASGE–ESGE suggests treatment with the DJBL plus LM over LM alone.
(*Conditional recommendation, moderate certainty*)

Implementation considerations

- The DJBL is an EBMT device for the treatment of T2DM and obesity. The current generation is designed for a 12-month implant duration period.

Summary of the evidence

Three RCTs assessing the safety and efficacy of the DJBL were used to inform this PICO [50, 51, 63]. Of these, 3 studies were used to assess safety [50, 51, 63], and 2 studies were used to assess efficacy [50, 51]. In Koehestanie et al [63], the DJBL was implanted for 6 months. Therefore, the efficacy, which is the difference in HbA1c reduction and percentage of TWL between the 2 arms at 12 months, was not able to be assessed. Otherwise, both Thompson et al [50] and Ruban et al [51] had the DJBL implanted for 12 months. All studies included subjects with obesity and concomitant T2DM. Mean age, BMI, and HbA1c of the intervention arm ranged from 49.5 to 53 years, 34.6 to 38.4 kg/m^2, and 8.3 % to 8.9 %, respectively. In Thompson et al [50], the intervention arm underwent DJBL implantation and concomitant low-intensity LM, whereas the control arm underwent low-intensity LM alone (**Supplementary Table 9**).

Benefits

Two RCTs informed the outcomes of HbA1c reduction and percentage of TWL at 12 months [91, 93]. Two hundred ninety-eight subjects were in the DJBL plus LM group and 192 in the LM group. The MD, representing the difference between the pooled HbA1c reduction in the DJBL arm minus the control arm at 12 months, was .73 % (95 % CI, .39–1.06) in favor of the intervention (**Supplementary Fig. 4**, available online). The MD, representing the difference between the pooled percentage of TWL in the DJBL arm minus the control arm at 12 months, was 5.4 % TWL (95 % CI, 4.1–6.7) in favor of the intervention (**Supplementary Fig. 22**).

A separate meta-analysis including the active arm of the RCTs and observational studies of DJBL studies of the same patient population (obesity with concomitant T2DM) was previously conducted [128]. Fourteen studies with 412 DJBL patients were included with a median implantation duration of 33 weeks (range, 12–52). Mean age ranged from 36 to 54 years, BMI from 30.0 to 48.9 kg/m^2, and HbA1c from 6.7 % to 9.2 %. At the time of DJBL explantation, the pooled HbA1c reduction and weight loss were 1.3 % (95 % CI, 1.0–1.6) and 18.9 % TWL (95 % CI, 7.2–30.6), respectively.

Harms

Three RCTs informed the outcome of SAEs [50, 51, 63], which were defined as events that resulted in early explant. In Ruban et al [51], the rate of early explant was not reported. Therefore, the worldwide registry was reviewed, and the SAEs were categorized based on the AGREE classification and need for early explantation. The pooled estimate for SAEs showed an absolute risk of 24 additional SAEs per 1000 subjects (95 % CI, 8–59) in the DJBL group (26/331) compared with the control group (0/232) (**Supplementary Fig. 23**, available online). Selected examples of SAEs from the U.S. pivotal study (ENDO trial) included intolerance (8/212), hemorrhage (6/212), hepatic abscess (5/212), DJBL obstruction (3/212), pancreatitis (2/212), intestinal perforation (1/212), and ulceration (1/212) (**Supplementary Table 17**, available online).

Certainty of evidence assessment

The overall certainty in the evidence of effects for DJBL implantation was moderate (**Supplementary Tables 11** and **18** and **Supplementary Fig. 24**, available online). For benefits, because the lower 95 % confidence limit for HbA1c reduction crossed the minimal clinically important difference of .5 %, the evidence was rated down for imprecision. The certainty of evidence for percentage of TWL, otherwise, was rated as high. For harms, there was moderate certainty in the evidence given a small number of SAEs with a wide CI.

Discussion

As noted in the Introduction, the small bowel plays a role in glucose homeostasis, and treatments targeting the small bowel likely have effects that are independent of weight loss. In an effort to mimic the effects of Roux-en-Y gastric bypass where the duodenum and part of the jejunum are bypassed, more than 1 device has been developed to bypass the jejunum with or without bypassing other portions of the GI tract. Only 1 of these devices, the DJBL, has been studied in RCTs and was previously approved for use in Europe with a CE mark that was obtained in 2010. The CE mark was lost in 2017 because of administrative issues and not related to a concern about safety or efficacy, and efforts are underway to regain approval in Europe. A previous U.S. multicenter randomized sham-controlled trial was stopped early by the company because of concerns of hepatic abscesses despite meeting the primary endpoints, but a new multicenter RCT for FDA approval is ongoing as of the time of writing of this guideline. The DJBL is also being studied for approval in India.

The magnitude of HbA1c improvement at 12 months in patients with obesity and concomitant T2DM was evaluated in 2 RCTs with an additional improvement of .73 % (95 % CI, .39–1.06) above the control. A previous meta-analysis that included a combination of 14 observational and RCTs with data on glycemic control between 12 and 48 weeks of implantation found an absolute improvement in HbA1c of 1.3 % (95 % CI, 1.0–1.6) compared with baseline [128]. In a subgroup analysis of the RCTs with implantation between 12 and 48 weeks, the additional improvement in HbA1c in the interventional arm was .90 % (95 % CI, .5–1.3) above the control arm, consistent with the present analysis despite the shorter duration of device implantation. Although small-bowel therapies are categorized separately from gastric devices because of their weight loss–independent effects, the DJBL also has an effect on weight loss. The present analysis demonstrated a difference of 5.4 % TWL (95 % CI, 4.1–6.7) in the device arm over the control arm.

The rate of SAEs evaluated across 3 RCTs with at least 6 months of device implantation time was 8.5 %, with a wide CI. The panel noted that the original U.S. multicenter RCT was stopped early by the company because of a higher than anticipated rate of hepatic abscesses. An analysis performed by the sponsor found that the high doses of PPIs used for bleeding prophylaxis in the United States, but not in other countries, contributed to a biofilm on the device with a high bacterial load. The U.S. multicenter RCT ongoing at the time of writing of this guideline has several infection mitigation strategies to reduce hepatic abscesses. Furthermore, given the risks of suboptimal T2DM management and that only about half of patients with T2DM are able to achieve glycemic control on medications [129], the panel believed the benefits of the DJBL outweighed the risks.

The panel found no negative effects on equity at the present time solely because the device is not commercially available at this time. However, if it were commercially available and not covered by national health systems or insurance companies, it would decrease equity because of lack of affordability by many patients. Physicians with experience using the device reported patient acceptability of the device was high both because of the lowering of the HbA1c during implantation and the durability of HbA1c change up to 6 months after device removal [128].

RECOMMENDATION 14

In adults with T2DM, the ASGE–ESGE recommends treatment with DMR only in the context of a clinical trial.
(*No recommendation, knowledge gap*)

Summary of the evidence

One RCT assessing the safety and efficacy of DMR was used to inform this PICO [64]. The study included subjects with T2DM and BMIs between 24 and 40 kg/m^2. Mean age, BMI, and HbA1c of the intervention arm were 58 years, 31.5 kg/m^2, and 8.2%, respectively. The intervention arm underwent concomitant low-intensity LM, whereas the control arm underwent a sham procedure with concomitant low-intensity LM (**Supplementary Table 9**).

Benefits

One RCT informed the outcome of HbA1c reduction at 6 months [64]. Fifty-six subjects were in the DMR plus LM group and 52 in the sham plus LM group. The MD, representing the difference between the mean HbA1c reduction in the DMR arm minus the control arm at 6 months, was .3% (95% CI, −1.1 to 1.7) in favor of the intervention (**Supplemental Fig. 25**, available online).

Harms

One RCT informed the outcome of SAEs [64], which were defined by the investigators and reported in the original study. The SAEs showed an absolute risk of 15 additional events per 1000 subjects (95% CI, 3–375) in the DMR group (2/56) compared with the control group (0/52) (**Supplementary Fig. 26**, available online). These SAEs included precautionary hospitalization for hematochezia later found to be because of external hemorrhoids (1/56) and jejunal perforation requiring surgical repair (1/56) (**Supplementary Table 19**, available online).

Certainty of evidence assessment

The overall certainty in the evidence of effects for DMR was low (**Supplementary Tables 11** and **20**, available online). Risk of bias was judged as not serious (**Supplementary Fig. 27**, available online). The only limitation of the efficacy evidence was imprecision because of a small number of patients and the lower 95% confidence limit for HbA1c reduction crossing the minimal clinically important difference of .5%. For harms, there was low certainty given inconsistency because the data were derived from 1 RCT only and imprecision because of a small number of SAEs with a wide CI.

Discussion

DMR is one of several potential therapies that directly treat the abnormally hypertrophied small-bowel mucosa that is hypothesized to drive the enteral contribution to poor glycemic control. The Revita DMR is the only DMR therapy that has undergone an RCT at this time. A few issues were found with the RCT. The trial was small, with 108 patients randomized to either the active or control arm, and was performed at sites in Europe and Brazil, which were found to be too heterogenous to be combined into 1 analysis and were stratified by region. Moreover, glycemic control was only reported out to 24 weeks. In a meta-analysis of single-arm studies, the absolute change in HbA1c from baseline was 1.72% (95% CI, .25–3.19) at 3 months and .94% (95% CI, .68–1.21) at 6 months, with a small change in weight that was not sufficient to explain the improvement in HbA1c [130]. One single-arm study reported a change in HbA1c of −10 ± 2 mmol/mol at 12 months in 36 patients [131]. Finally, another small single-arm study performed in biopsy sample–proven nonalcoholic steatohepatitis patients [132] (11 patients, 82% of patients with T2DM) found neither significant reduction of HbA1c nor weight loss reduction.

However, because of the limited number of patients in the RCT, patient heterogeneity between regions, and only a 24-week study duration, the panel believed the data were insufficient to make a recommendation for or against DMR in a clinical setting and that the device should be used in a trial setting only. At the time of the writing of this guideline, a U.S. and European multicenter RCT evaluating the effect of DMR on glycemic control is ongoing. This study may provide the additional data needed to determine whether recommendations should be made for or against this therapy for the treatment of T2DM.

Discussion

Management strategies for obesity have significantly expanded over the past decades to include AOMs, EBMTs, and bariatric surgery. From an EBMT standpoint, several devices have been developed and received FDA clearance or approval and/or a CE mark. Nevertheless, at the time of writing of this guideline, only IGBs and EGR devices are commercially available and routinely used in clinical practice. Of note, in this document, different IGBs and devices for performing EGR were grouped together for analyses regardless of the manufacturer of the balloon or suturing/plication device given their similar mechanisms. This was similar to how previous guidelines grouped all types of IGBs or sleeve gastrectomy together regardless of the brand of the balloon or stapler. It is also important to offer EBMTs in conjunction with LM consisting of dietary interventions, physical activity, and behavioral therapy to achieve and maintain weight loss. Furthermore, a multidisciplinary approach for the treatment of obesity is crucial where bariatric endoscopists work closely and collaboratively with dietitians, exercise physiologists, behavioral experts, obesity medicine experts, and bariatric surgeons to optimize outcomes. Finally, as noted in the Discussions for both IGB and EGR, reduced equity because of a lack of widespread national health coverage or commercial insurance is a major factor leading to the conditional recommendation. Improved equity, in particular for under-represented minorities, will require widespread coverage of these procedures to increase patient access.

Regarding durability, although EGR procedures have been shown to be effective up to at least 5 years [133], it is important to acknowledge that, similar to most obesity treatments, inadequate weight loss and recurrent weight gain after EBMTs may occur. Multiple options are available for management of this condition, including repeat procedures, adding AOMs, intensifying LM therapy, or switching to a different device or procedure. These options, however, are not evaluated in this guideline. It is also important to note that EBMTs do not prevent patients from undergoing bariatric surgery, if needed in the future [134].

There are several key evidence gaps in the field of EBMTs. First, data appear to be limited on the long-term effect of EBMTs on comorbidities, including cardiovascular events, cancer risk, and mortality. Nevertheless, weight loss has been shown to improve these endpoints independent of how the weight loss was achieved. Therefore, it is likely that the weight loss achieved by EBMTs could be sufficient to improve comorbidity outcomes. Second, future studies evaluating the effect of combination therapy of different EBMTs or of an EBMT with another obesity intervention (such as AOMs) are warranted. Additionally, with an increasing number of EBMTs being developed and becoming available, it is important to understand how to personalize these interventions for each patient based on his or her characteristics and comorbidities. Furthermore, data on periprocedural care before and after EBMTs are limited. In this document, expert surveys were conducted to achieve the best practice consensus. Nevertheless, future studies on these topics would help further guide periprocedural care around EBMT procedures. Last but not least, studies evaluating cost-effectiveness are important to understanding the healthcare system benefit of these therapies, and further research on this area is needed.

The present guideline serves as a corollary to several contemporary guidelines on the topic of obesity management. Specifically, in 2013 the American Heart Association, American College of Cardiology, and The Obesity Society published the "Guideline for the Management of Overweight and Obesity in Adults" focusing on LM and bariatric surgery [10]. In 2015, the Obesity Society and European Society of Endocrinology published "Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline" focusing on AOMs that were available at that time [135]. With newer GLP-1RAs being available, the American Gastroenterological Association recently published "Clinical Practice Guideline on Pharmacological Interventions for Adults with Obesity," focusing on all available AOMs including these newer injection agents [17]. In 2021, the American Gastroenterological Association also published the "AGA Clinical Practice Guidelines on Intragastric Balloons in the Management of Obesity." [36] The present guideline expands on the American Gastroenterological Association guideline on IGB by also evaluating other EBMTs that have had FDA clearance or approval or a CE mark. Most recently, in 2022, the American Society for Metabolic and Bariatric Surgery and International Federation for the Surgery of Obesity and Metabolic Disorders published "Indications for Metabolic and Bariatric Surgery," focusing on BMI indications and long-term results of bariatric surgery [136].

In summary, EBMTs are an evolving category of obesity treatments. IGBs and devices for EGR are recommended for use by the ASGE–ESGE in conjunction with LM and are currently commercially available. These therapies should be performed with the appropriate peri- and postprocedural management as outlined in this guideline to optimize clinical outcomes. Additionally, AT and DJBL therapies would be recommended for use if they were to return to the market, and further recommendations regarding TPS, DMR, and other procedures will be made once real-world data are available.

Conflict of interest

The following authors disclosed financial relationships: P. Jirapinyo: Consultant for Apollo Endosurgery, Boston Scientific Corporation, Erbe, and Spatz Medical; advisory board for Apollo Endosurgery; research support from Apollo Endosurgery, Boston Scientific Corporation, GI Dynamics, Fractyl, and USGI Medical. A. Hadefi: Research support from Endo Tools Therapeutics. C. C. Thompson: Consultant for Apollo Endosurgery, Boston Scientific Corporation, Medtronic, Endoquest Robotics, Fractyl, FujiFilm, GI Dynamics, EnVision Endoscopy, Olympus/Spiration, Softac, USGI Medical, Xenter, Enterasense Ltd, and Lumendi; research support from Apollo Endosurgery, Boston Scientific Corporation, Endoquest Robotics, Erbe, Fractyl, FujiFilm, GI Dynamics, Olympus/Spiration, USGI Medical, and Lumendi; advisory board for Fractyl and USGI Medical; founder of Bariendo, BlueFlame Healthcare Venture Fund, ELLES, EnVision Endoscopy, GI Windows, Society for Metabolic and Bariatric Endoscopy Inc, and Enterasense Ltd, and GI Windows; board member for Bariendo, ELLES, EnVision Endoscopy, GI Windows, and Enterasense Ltd; ownership in Bariendo, ELLES, EnVision Endoscopy, GI Windows, Society for Metabolic and Bariatric Endoscopy Inc, Softac, Xenter, and Enterasense Ltd; partner in BlueFlame Healthcare Venture Fund; president of the Society for Metabolic and Bariatric Endoscopy Inc; Scientific Advisory Board for Xenter. R. Pannala: Research support from Fractyl Labs; general payments from Boston Scientific Corporation; consultant for HCL Technologies; advisory board for Nestle Healthsciences and Bluestar Genomics. S. K. Goelder: Travel compensation from Apollo Endosurgery. V. Kushnir: Consultant for BSCI, Noah Medical, Steres, and ConMed. M. Barthet: Consultant for Boston Scientific Corporation, Endotools, and Taewoong. C. M. Apovian: Advisory board for Altimmune, Inc, CinFina Pharma, Inc, Cowen and Company, LLC, Currax Pharmaceuticals, LLC, EPG Communication Holdings Ltd, Form Health, Inc, Gelesis, Srl, L-Nutra, Inc, NeuroBo Pharmaceuticals, Inc,

Novo Nordisk, Inc, OptumRx, Inc, Pain Script Corporation, Palatin Technologies, Inc, Pursuit By You, ReShape Lifesciences Inc, Riverview School, and Xeno Biosciences; research support from the National Institutes of Health, Patient-Centered Outcomes Research Institute, and GI Dynamics, Inc. I. Boskoski: Consultant for Boston Scientific Corporation (Apollo Endosurgery), Nitinotes, and EndoTools. C. G. Chapman: Consultant for Boston Scientific Corporation, Olympus, Steris, and Apollo Endosurgery; speaker for Apollo Endosurgery. V. Kumbhari: Consultant for Boston Scientific Corporation. J. Esker: Consultant for Pendulum Therapeutics. A. D. Pryor: Speaker for Gore, Medtronic, and Stryker. R. Maselli: Consultant for Apollo Endosurgery. A. R. Schulman: Consultant for Apollo Endosurgery, Boston Scientific Corporation, Olympus, and MicroTech; research support from GI Dynamics and Fractyl. N. Thosani: Consultant for Boston Scientific Corporation, Ambu, and Pentax America; royalties from UpToDate; ownership in ROSEAId. V. Huberty: Shareholder in, board member for, and research support from EndoTools Therapeutics. S. Sullivan: Consultant for Allurion Technologies, Biolinq, BariaTek, Pentax, Fractyl, and Endo Tools Therapeutics; research support from Allurion Technologies, ReShape Medical/Obalon Therapeutics, and Rebiotix; stock ownership in Biolinq. All other authors disclosed no financial relationships.The following authors disclosed financial relationships: P. Jirapinyo: Consultant for Apollo Endosurgery, Boston Scientific Corporation, Erbe, and Spatz Medical; advisory board for Apollo Endosurgery; research support from Apollo Endosurgery, Boston Scientific Corporation, GI Dynamics, Fractyl, and USGI Medical. A. Hadefi: Research support from Endo Tools Therapeutics. C. C. Thompson: Consultant for Apollo Endosurgery, Boston Scientific Corporation, Medtronic, Endoquest Robotics, Fractyl, FujiFilm, GI Dynamics, EnVision Endoscopy, Olympus/Spiration, Softac, USGI Medical, Xenter, Enterasense Ltd, and Lumendi; research support from Apollo Endosurgery, Boston Scientific Corporation, Endoquest Robotics, Erbe, Fractyl, FujiFilm, GI Dynamics, Olympus/Spiration, USGI Medical, and Lumendi; advisory board for Fractyl and USGI Medical; founder of Bariendo, BlueFlame Healthcare Venture Fund, ELLES, EnVision Endoscopy, GI Windows, Society for Metabolic and Bariatric Endoscopy Inc, and Enterasense Ltd, and GI Windows; board member for Bariendo, ELLES, EnVision Endoscopy, GI Windows, and Enterasense Ltd; ownership in Bariendo, ELLES, EnVision Endoscopy, GI Windows, Society for Metabolic and Bariatric Endoscopy Inc, Softac, Xenter, and Enterasense Ltd; partner in BlueFlame Healthcare Venture Fund; president of the Society for Metabolic and Bariatric Endoscopy Inc; Scientific Advisory Board for Xenter. R. Pannala: Research support from Fractyl Labs; general payments from Boston Scientific Corporation; consultant for HCL Technologies; advisory board for Nestle Healthsciences and Bluestar Genomics. S. K. Goelder: Travel compensation from Apollo Endosurgery. V. Kushnir: Consultant for BSCI, Noah Medical, Steres, and ConMed. M. Barthet: Consultant for Boston Scientific Corporation, Endotools, and Taewoong. C. M. Apovian: Advisory board for Altimmune, Inc, CinFina Pharma, Inc, Cowen and Company, LLC, Currax Pharmaceuticals, LLC, EPG Communication Holdings Ltd, Form Health, Inc, Gelesis, Srl, L-Nutra, Inc, NeuroBo Pharmaceuticals, Inc, Novo Nordisk, Inc, OptumRx, Inc, Pain Script Corporation, Palatin Technologies, Inc, Pursuit By You, ReShape Lifesciences Inc, Riverview School, and Xeno Biosciences; research support from the National Institutes of Health, Patient-Centered Outcomes Research Institute, and GI Dynamics, Inc. I. Boskoski: Consultant for Boston Scientific Corporation (Apollo Endosurgery), Nitinotes, and EndoTools. C. G. Chapman: Consultant for Boston Scientific Corporation, Olympus, Steris, and Apollo Endosurgery; speaker for Apollo Endosurgery. V. Kumbhari: Consultant for Boston Scientific Corporation. J. Esker: Consultant for Pendulum Therapeutics. A. D. Pryor: Speaker for Gore, Medtronic, and Stryker. R. Maselli: Consultant for Apollo Endosurgery. A. R. Schulman: Consultant for Apollo Endosurgery, Boston Scientific Corporation, Olympus, and MicroTech; research support from GI Dynamics and Fractyl. N. Thosani: Consultant for Boston Scientific Corporation, Ambu, and Pentax America; royalties from UpToDate; ownership in ROSEAId. V. Huberty: Shareholder in, board member for, and research support from EndoTools Therapeutics. S. Sullivan: Consultant for Allurion Technologies, Biolinq, BariaTek, Pentax, Fractyl, and Endo Tools Therapeutics; research support from Allurion Technologies, ReShape Medical/Obalon Therapeutics, and Rebiotix; stock ownership in Biolinq. All other authors disclosed no financial relationships.

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