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GUIDELINES

Multi-society consensus conference and guideline on the treatment of gastroesophageal reflux disease (GERD)

Bethany J. Slater[1] · Amelia Collings[2] · Rebecca Dirks[2] · Jon C. Gould[3] · Alia P. Qureshi[4] · Ryan Juza[5] · María Rita Rodríguez-Luna[6] · Claire Wunker[7] · Geoffrey P. Kohn[8] · Shanu Kothari[9] · Elizabeth Carslon[10] · Stephanie Worrell[11] · Ahmed M. Abou-Setta[12] · Mohammed T. Ansari[13] · Dimitrios I. Athanasiadis[2] · Shaun Daly[14] · Francesca Dimou[15] · Ivy N. Haskins[16] · Julie Hong[17] · Kumar Krishnan[18] · Anne Lidor[5] · Virginia Litle[19] · Donald Low[10] · Anthony Petrick[20] · Ian S. Soriano[21] · Nirav Thosani[22] · Amy Tyberg[23] · Vic Velanovich[24] · Ramon Vilallonga[25] · Jeffrey M. Marks[26]

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Abstract

Background Gastroesophageal reflux disease (GERD) is one of the most common diseases in North America and globally. The aim of this guideline is to provide evidence-based recommendations regarding the most utilized and available endoscopic and surgical treatments for GERD.

Methods Systematic literature reviews were conducted for 4 key questions regarding the surgical and endoscopic treatments for GERD in adults: preoperative evaluation, endoscopic vs surgical or medical treatment, complete vs partial fundoplication, and treatment for obesity (body mass index [BMI] ≥ 35 kg/m^2) and concomitant GERD. Evidence-based recommendations were formulated using the GRADE methodology by subject experts. Recommendations for future research were also proposed.

Results The consensus provided 13 recommendations. Through the development of these evidence-based recommendations, an algorithm was proposed for aid in the treatment of GERD. Patients with typical symptoms should undergo upper endoscopy, manometry, and pH-testing; additional testing may be required for patients with atypical or extra-esophageal symptoms. Patients with normal or abnormal findings on manometry should consider undergoing partial fundoplication. Magnetic sphincter augmentation or fundoplication are appropriate surgical procedures for adults with GERD. For patients who wish to avoid surgery, the Stretta procedure and transoral incisionless fundoplication (TIF 2.0) were found to have better outcomes than proton pump inhibitors alone. Patients with concomitant obesity were recommended to undergo either gastric bypass or fundoplication, although patients with severe comorbid disease or BMI > 50 should undergo Roux-en-Y gastric bypass for the additional benefits that follow weight loss.

Conclusion Using the recommendations an algorithm was developed by this panel, so that physicians may better counsel their patients with GERD. There are certain patient factors that have been excluded from included studies/trials, and so these recommendations should not replace surgeon–patient decision making. Engaging in the identified research areas may improve future care for GERD patients.

Keywords Antireflux surgery · Fundoplication · Gastroesophageal reflux · GERD · Obesity · Proton pump inhibitor

Abbreviations

ARM	Anti-reflux medication
ARS	Anti-reflux surgery
CI	Confidence interval
EGD	Esophagogastroduodenoscopy
MSA	Magnetic sphincter augmentation
GERD	Gastroesophageal reflux disease
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HREM	High-resolution esophageal manometry
KQ	Key question
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses

Bethany J. Slater and Amelia Collings are co-first authors.

✉ Bethany J. Slater
bjslater1@gmail.com

Extended author information available on the last page of the article

QoL	Quality of life
PPI	Proton pump inhibitor
LES	Lower esophageal sphincter
LA	Los Angeles
Stretta procedure	Radiofrequency treatment for GERD
RCT	Randomized clinical trial
TIF	Transoral incisionless fundoplication
RYGB	Roux-en-Y gastric bypass
LNF	Laparoscopic Nissen Fundoplication

GERD is defined as a disease associated with symptoms and/or complications due to the reflux of stomach contents into the esophagus [2]. GERD is one of the most common diseases in North America and the world, typically presenting with heartburn and regurgitation, often responsive to proton pump inhibitor therapy (PPI) [2]. While there is considerable geographical variation of GERD, the general prevalence in North America ranges from 18.1 to 27.8%, in Europe 8.8 to 25.9%, in the Middle East 8.7 to 33.1%, in East Asia 2.5 to 7.8%, and 11.6 to 23.0% in Australia [3]. Due to its increasing prevalence, the widespread burden of disease carries both a financial and resource cost. In addition to its societal implications, GERD also adversely impacts patients' quality of life (QoL) [4].

The topics addressed in this guideline, and the associated recommendations, are divided into four key questions (KQ). The first key question (KQ1) is about the identification of patients who will benefit most from surgical and or endoscopic treatment of GERD. The symptoms and pathophysiology of GERD can vary significantly, and response to treatment is not always equal. Although medical treatment (predominantly with proton pump inhibitor (PPI) medications) is the least invasive and most common modality for treating GERD, adverse side effect such as nutritional deficiencies, infectious diseases, and risk of osteoporosis leading to increased fractures have been reported [5]. Additionally, 25–42% of patients are partially or completely unresponsive to medical therapy [6]. In these medically refractory patients, as well as in patients who desire to not be on lifelong medication, laparoscopic anti-reflux surgery (ARS) is highly effective in controlling reflux symptoms long-term [7]. Careful patient selection is essential in the diagnosis and workup of patients with symptomatic GERD and is necessarily reliant on quality of preoperative testing. Currently, no consensus is yet established to direct preoperative workup to reduce unnecessary testing while ensuring optimal postoperative outcomes following ARS.

Multiple surgical techniques and procedures are employed depending on pre-operative testing and surgeon preference. Often these surgeries involve creating an anti-reflux barrier using a portion of the stomach. A newer surgical technique, however, is magnetic sphincter augmentation (MSA) which recreates a reflux barrier using a set of magnetic beads. While successful in the long term, the level of invasiveness precludes this from being first line therapy for all patients. To minimize the invasiveness while maintaining medication free treatment, endoscopic therapies have also been developed including Transoral Incisionless Fundoplication (TIF) and radiofrequency treatment for GERD (Stretta procedure). Comparisons of the surgical, endoscopic, and medical treatments are addressed in key question two (KQ 2).

Multiple surgical techniques and procedures are employed to control GERD symptoms. The choice of which type of fundoplication (complete versus partial) is based on many variables including pre-operative testing, esophageal function, patient's pre-operative symptoms, and surgeon preference. Some surgeons believe that a partial fundoplication offers inferior symptom control with decreased post-operative adverse side effects, while other surgeons argue that the two surgeries have similar rates of symptom resolution [8, 9]. There continues to be significant debate regarding comparison of routine use of Nissen fundoplication to a partial fundoplication or tailored approach with numerous meta-analyses and review articles addressing this issue. [8–11] This debate stems in part from the fact that there are no uniform techniques across surgeons. Key question three (KQ 3) addresses the data comparing outcomes after complete versus partial fundoplication for all patients and specifically those with pre-operative dysphagia.

Morbid obesity, defined as a body mass index (BMI) ≥ 35 kg/m^2, remains endemic in the USA and Europe. Interestingly, the increased prevalence of morbid obesity and GERD in the USA and Europe seem to parallel one another, suggesting that these two processes may be intimately associated with one another [12, 13]. In fact, it is estimated that morbidly obese patients are 2.5 times more likely to experience GERD symptoms relative to their non-obese counterparts [12]. The question of the ideal procedure for patients with pathologically proven GERD, who also suffer from clinically severe obesity, is the focus of key question 4 (KQ4). While traditional anti-reflux procedures focus on augmenting or increasing the barrier to reflux at the esophagogastric junction, Roux-en-Y Gastric Bypass (RYGB) leads to GERD resolution through exclusion of the acid producing cells in the bypassed portion of the stomach while also reducing the risk of bile reflux. Both approaches bring their own unique set of advantages and disadvantages. The purpose of KQ4 is to determine the procedure of choice (RYGB versus laparoscopic Nissen fundoplication (LNF)) to address medically refractory GERD in patients who suffer from clinically severe morbid obesity as well as which of these procedures is best for a failed prior fundoplication (redo fundoplication versus conversion to RYGB). Additionally, GERD prevalence may also be affected by sleeve

gastrectomy, especially due to the risk of de novo or possibly exacerbating pre-existing GERD symptoms [14].

The aim of this guideline is to provide evidence-based recommendations regarding the most utilized and available endoscopic and surgical treatments for gastroesophageal reflux disease (GERD). The purpose is to create a proposed algorithm that standardizes the workup, diagnosis, and treatment of a patient with suspected GERD and to develop and disseminate evidence-based practice guidelines for the management of GERD. By standardizing care for patients using the best available evidence, higher quality care can be achieved.

Methods

The guideline panel determined the certainty of evidence, and the direction and strength of recommendations, with the widely used *Grading of Recommendations Assessment, Development and Evaluation* (GRADE) approach[1, 15, 16] using the GRADE guideline development tool [17, 18]. Reporting of the guideline adheres to the *Essential Reporting Items for Practice Guidelines in Healthcare* (RIGHT) checklist [18]. Evidence addressing the guideline questions was synthesized according to the SAGES Guidelines Committee's standard operating procedure [19]. PubMed, Embase, Cochrane, Clinicaltrials.gov, International Clinical Trials Platform (ICTRP), and Google Scholar databases were searched (1947–2021) to identify randomized control trials and non-randomized comparative studies (Supplement 1). When there was a paucity of retrieved evidence for a question, experts included non-comparative evidence in their systematic reviews.

Two independent reviewers screened retrieved records for eligibility. Screening criteria and "Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)" screening flow diagrams for each KQ are provided in Supplement 3. Study quality was assessed using the Cochrane Risk of Bias and Newcastle Ottawa Scale. Random effects meta-analysis was performed on available comparative data.

Guideline panel organization

International expert surgeons and gastroenterologists developed the evidence-based guideline recommendations. The panel was composed of members from the Society of American Gastrointestinal and Endoscopic Surgery (SAGES), American Society for Gastrointestinal Endoscopy (ASGE), American Society for Metabolic and Bariatric Surgery (ASMBS), European Association for Endoscopic Surgery (EAES), Society for Surgery of the Alimentary Tract (SSAT), and The Society of Thoracic Surgeons (STS). A methodologist with guideline development expertise (M.T.A.) and the SAGES Guidelines Committee Fellow (A.C.) facilitated guideline panel meetings as non-voting members of the panel.

Guideline funding & declaration and management of competing interests

Funding for the methodologists, the librarian, and partial salary support for the fellow were provided by SAGES. The consensus conference is supported by all six project partners, SAGES, ASMBS, ASGE, STS, SSAT, and EAES. The organizations committed to help fund this conference and have provided staff support and meeting space at their respective meetings for the conference preparation and planning. All disclosed potential conflicts of interest are listed in Supplement 2.

Selection of questions and outcomes of interest

The preoperative workup and use of surgical/endoscopic treatment for GERD are the focus of this guideline. The final set of question-specific outcomes were selected by simple majority. Some outcomes, such as QoL, have multiple metrics, thus a standardized effect was used.

Under the guidance of the steering committee (J.M., J.G., A.Q., and B.S.) and guideline methodologist, each group of experts created a list of KQs relating to their specific aspect of GERD using the PICO format (patient-intervention-comparator-outcome). Outcomes "critical" or "important" to decision making for these KQs were defined and reviewed. Given their long-standing experience with patients, panel members provisionally identified question specific patient-centered outcomes that they felt most patient-surgeon dyads would consider important or critical for decision making (Table 1). The importance of these outcomes was re-visited by panel members during the formulation of recommendations after they had reviewed the systematic review evidence.

Screening criteria and Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) figures for each KQ found in Supplement 3.

Determining the certainty of evidence

Methods outlined in the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach handbook were used to judge the certainty of evidence for each outcome of interest [20]. GRADEPro evidence tables were created. The highest level of data available was used for tables, less rigorous data that addressed the same outcomes was considered but not used in decision making. In brief, the guidelines systematic review working group judged the certainty of the body of evidence across the domains of risk of bias across, inconsistency, indirectness,

Table 1 Importance of outcomes by working group

Group	Outcome	Importance
Group 1	Abnormal Findings	Critical
	Change in Intervention	Critical
Group 2	Patient reported reflux symptom resolution-(within 2 year)	Critical
	Need for anti-reflux medication (PPI only)	Critical
	Quality of life Scale-Short-term (< 2 year) and Long-term (≥ 2 year)	Critical
	Patient reported reflux symptom recurrence-Short-term (< 2 year) and Long-term (≥ 2 year)	Critical
	Dysphagia—requiring intervention	Important
	Hiatal hernia recurrence (≥ 3 cm and symptomatic)	Important
	Patient satisfaction	Important
	Dysphagia—patient reported-(> 3mon and ≤ 3 mon)	Important
	Perioperative complications (< 30d)-Clavien Dindo ≥ 2	Important
	Objectively established reflux recurrence	Not important
	Perioperative mortality (< 30 day)	Not important
	Reoperation	Not important
	Cost	Not important
Group 3	Patient reported reflux symptom resolution	Critical
	Objective reflux recurrence	Critical
	Dysphagia requiring intervention	Critical
	Hiatal hernia recurrence	Important
	Gas/bloat/Inability to Vomit	Important
Group 4	Patient reported reflux symptom resolution (< 2 year)	Critical
	Patient reported symptom recurrence – short term (< 2 year) and long term (> 2 year)	Critical
	Objectively established reflux recurrence	Critical
	Progression to Barrett's esophagus	Critical
	Perioperative complications (< 30 days)–Clavien Dindo ≥ 2	Important
	Perioperative Mortality (< 30 days)	Important
	Reoperation	Important
	Dysphagia—requiring intervention	Important
	Hiatal hernia recurrence (≥ 3 cm &/or symptomatic)	Not important
	Need for anti-reflux medication (PPI or H2B)	Not important

imprecision, and publication bias if > 10 studies were available. If there was concern in any one of these domains, the certainty was downgraded. This data was then imported into the Evidence to Decision (EtD) table for each KQ. The EtD tables serve as a framework through which the final recommendations are developed.

Data from these studies were not used in the development of recommendations, but only used for supporting evidence during the discussion of the summary of the evidence.

Assumed values and preferences

As this guideline took a patient-centered perspective, rather than a societal perspective, the panel members used their collective patient experience to determine judgements about patient values and preferences. The panel members recognized that patients may vary in what value they place on an outcome when coming to a clinical decision. Patients were not included in panel discussion and thus physician panel members used their experience as a surrogate for determining patient preferences. The proposed target audience of this guideline are patients and their physicians, both surgeons and gastroenterologists.

Development of recommendations

Panel members were provided with the articles and the results of the systematic review created specifically for the

guideline and pertinent to a KQ in advance of the meetings. During panel meetings, the group reviewed the GRADE evidence profile and summary of findings tables, completed the Evidence-to-Decision (EtD) tables, and generated provisional recommendations. A multi-society conference was held at the SAGES 2021 annual meeting. After presenting the data and audience discussion, participants voted on the proposed recommendations. Consensus conference voting led to minor changes in the recommendations.

Outcomes from the Evidence Tables were imported into GRADEPro EtD tables. To determine the direction of a recommendation (i.e., for or against the intervention vs. the comparator) and its strength (i.e., strong or conditional) in light of the synthesized evidence, the panel deliberated upon various EtD criteria such as the magnitude of desirable and undesirable effects, the overall certainty of evidence, variation in values that may be assigned to outcomes, and the balance of these effects. The panel also discussed acceptability and feasibility considerations for implementing the recommendation. Additional considerations taken either from panel expert experience or interpretation of evidence were noted.

A strong recommendation would be made if high certainty evidence demonstrated that benefits would clearly outweigh harms for almost all patients in general, or for a subgroup of patients with no serious implications related to acceptability and feasibility of the recommendation. A conditional recommendation would be made when there is important variability in patient values and preferences for outcomes such that the balance of benefits and harms is likely to differ for a substantial proportion of patients, the balance between desirable and undesirable consequences is close, or when the overall certainty of evidence is judged low.

Subgroups were further addressed in discussion for the justification for each recommendation and are specified for each KQ below. Full evidence to decision tables are presented in Supplement 4–6 and summarized in the following recommendations. While serial voting was used to come to a consensus on individual criteria of the EtD, a supermajority, defined as 80% panel agreement, was used as the cut-off for formulating recommendations [21].

Guideline document review

This guideline was reviewed and edited by all panel members. Each KQ was developed by a subgroup and then reviewed by the entire group for completeness and accuracy. The revised draft was distributed to the full consensus committee. After incorporating these edits, the final guideline was then submitted to the SAGES Executive Board for approval and published online on its website (www.sages.org) for public comment for additional quality assurance. In addition, for external review, the manuscript was sent to the SAGES Guidelines Quality Assurance Task Force not involved in the guidelines process to minimize the introduction of bias in the recommendations.

Key questions

Key Question 1 (KQ1):	What studies are necessary for preoperative evaluation of adults with GERD?
Key Question 2 (KQ2):	Should endoscopic, surgical, or medical treatment be used in adult patients with GERD?
Key Question 3 (KQ3):	Should complete or partial fundoplication be used in adult patients with GERD?
Key Question 4 (KQ4):	What is the best treatment for adult patients with obesity (BMI $\geq$ 35) and concomitant GERD?

(KQ1) What studies are necessary for preoperative evaluation of adult patients with GERD?

Recommendation

The panel suggests esophagogastroduodenoscopy (EGD), manometry, and pH testing for all patients with esophageal symptoms of medically refractory reflux undergoing preoperative evaluation; however, patients with Los Angeles (LA) grade C or D erosive esophagitis on endoscopy may not require pH testing to confirm the diagnosis of GERD. (Expert Opinion; GRADE recommendation was unable to be determined due to lack of evidence).

The panel suggests that patients with extra-esophageal GERD symptoms or equivocal findings on essential testing require more diligent workup (Expert Opinion; GRADE recommendation was unable to be determined due to lack of evidence).

Summary of the evidence

No direct comparative evidence addressed this question. Qualitative indirect comparisons could also not be made as studies were not designed as diagnostic test evaluations, differed in patient populations, and employed varying GERD severity measurement metrics (e.g., pH, manometric measures, and impedance). As such, expert opinion was generated based on the following data.

Table 2 Summary of Evidence for Key Question 1

Workup modality	Number of studies	Number of patients getting study	% Abnormal findings	% Change in intervention
pH testing	26	4586	51.5	41.8
Manometry	28	5807	29.1	17.3
Impedance	6	511	9.3	20.4
EGD	26	4188	76.8	0

Our systematic review of the literature resulted in 34 observational studies that examined the use of the preoperative studies of interest [22–55]. There were no randomized clinical trials (RCTs) available. In total, there were 7,025 patients included between the sum of these studies. There were a total of 4,586 patients across 26 studies who underwent preoperative pH-monitoring [22–29, 31, 32, 35, 37, 38, 40–47, 49–51, 53, 56]. Of those studies that reported specific pH results, 2474 patients out of 4,803 patients (51.5%) had abnormal findings. A single study reported a change in their planned intervention for 41.8% of patients based on the findings from pH-monitoring (Table 2) [23].

There were 28 studies that reported using manometry in the preoperative work up of 5,807 GERD patients [22–29, 32, 34, 36–38, 40, 40, 41, 41, 42, 42, 43, 43, 44, 44, 45, 45, 46, 46, 47, 47, 48, 48, 49, 49, 50, 50, 51, 51, 55, 57]. Of those studies, there were 16 that reported on specific manometric findings. These studies observed abnormal peristalsis in 1,251 out of 4,303 (29.1%) GERD patients. Nine studies that reported that 17.3% (149 patients out of 860 patients) had a change in intervention based on manometric findings (Table 2). Most commonly, this was a change from a planned complete fundoplication to a partial fundoplication.

There were only six studies that used impedance testing preoperatively in 511 patients with GERD [31, 39, 42, 54, 55, 57]. Four studies described specific findings observing that 9.3% of patients had abnormal findings. Two studies reported that 45 patients had a change from the planned intervention out of 221 that underwent impedance testing [31, 39]. There were no studies that addressed the findings on impedance testing and the need for surgery. Lastly, 26 studies evaluated 4188 GERD patients with preoperative endoscopy, of which 76.8% had abnormal findings, most commonly esophagitis [22–27, 31, 32, 35, 37–42, 44–52, 54]. There were no studies that reported on a change in intervention based on endoscopic findings (Table 2).

Decision criteria and additional considerations

With healthcare costs rising, effective disease diagnosis must take into consideration both efficiency and costs in the measure of quality. Determining the workup strategy that optimizes these factors is paramount. While unnecessary tests increase cost, the omission of necessary tests can have equally deleterious outcomes and financial repercussions. Based on our review of the available literature, EGD, manometry, and pH-testing are essential components of the diagnostic workup for patients with typical esophageal GERD symptoms, i.e., heartburn and/or regurgitation. This is based on available information that the majority of patients with typical GERD symptoms will derive clinical benefit from ARS with a low rate of complications. Manometry is used to rule out other motility disorders such as achalasia. For patients with atypical or extra-esophageal GERD symptoms such as cough, throat clearing, chest pain, or hoarseness, additional workup including pH/impedance testing should be employed, in addition to possible referral to other specialty providers as determined by the physician.

Research recommendations

Preoperative workup, key diagnostic criteria as well as terminology should be standardized to improve diagnostic output and direct future research. The panel agreed that there is a tremendous need for standardized terminology across disciplines, among surgeons, gastroenterologists, and radiologists to facilitate better understanding, communication, and to guide future research. Written documentation of endoscopic findings including Hill grade of the LES, esophageal length, and location of diaphragmatic pinch as well as liberal photo documentation will aid in standardized care of patients with GERD across different physician disciplines. Once there is better classification of patients during their pre-operative workup phase, surgical treatment can be more accurately tailored to the specific patient.

Newer technologies of GERD testing such as high-resolution esophageal manometry (HREM), endo-FLIP, or solid phase upper gastrointestinal study (Marshmallow-Bagel) may be indicated to better evaluate patients prior to offering ARS. High-resolution esophageal manometry is an example of technology outpacing surgical literature. Although regarded as a more accurate measure of esophageal function, without rigorous clinical data to direct choice of surgical wrap, HREM is limited in its capacity to guide effective treatment despite the higher quality data produced.

(KQ2) Should endoscopic, surgical, or medical treatment be used in adult patients with GERD?

2a. Should treatment with MSA versus fundoplication be used for patients with GERD?

Recommendation

The panel suggests that adult patients with GERD may be treated with either MSA or Nissen fundoplication based on

surgeon and patient shared decision making (conditional recommendation, very low certainty evidence).

Summary of the evidence

From 74 studies included in the systematic review, nine short-term observational studies were included for the panel discussion to form the final recommendation [58–66]. There was no informative data for hiatal hernia recurrence, objective reflux recurrence, and peri-operative mortality. *(See evidence profile in the EtD framework, Supplement 4)* All included studies compare MSA to only Nissen fundoplication and not any other wrap types.

Benefits of the intervention

There were five outcomes with desirable effects for MSA as compared to Nissen fundoplication including symptom recurrence, complications, re-operation, patient-reported dysphagia, and cost. Overall, the panel felt that the effects were of small size.

1. *Patient reported symptom recurrence less than 2 years* (1 observational study of 249 participants) absolute difference 98 fewer patients per 1000 (95% CI 117 fewer to 40 fewer) [63]
2. *Perioperative complications* (7 observational studies with 1211 participants) absolute difference 16 fewer patients per 1000 (95% CI 22 fewer to 1 more)[58, 60, 61, 63–69]
3. *Reoperations* (4 observational studies with 534 participants) absolute difference 9 fewer patients per 1000 (95% CI 17 fewer to 18 more) [60, 61, 63, 65]
4. *Patient reported dysphagia greater than 3 months* (3 observational studies with 450 participants) absolute difference 77 fewer patients per 1000 (95% CI 154 fewer to 27 more) [61, 63, 65]

The Expert Panel noted that the evidence was based on short term, observational studies. In addition, symptom recurrence is not an objective outcome and may not accurately reflect true reflux recurrence.

Harms and burdens

There were five outcomes with undesirable effects for MSA relative to Nissen fundoplication. The panel voted that the magnitude of these effects was small.

1. *Quality of life greater than 2 years* (3 observational studies with 610 participants), Standardized Mean Difference (SMD) 0.14 pooled SD lower (95% CI 0.32 lower to 0.04 higher) GERD-HRQL scale was used to measure the quality of life in all of the studies [58, 59, 65]
2. *Patient reported complete reflux symptom resolution less than 2 years* (2 observational studies with 118 participants) absolute difference 40 fewer patients per 1000 (95% CI 173 fewer to 138 more) [61, 66]
3. *Need for PPI* (6 observational studies with 1445 participants) absolute difference 3 more patients per 1000 (95% CI 49 fewer to 86 more) [59–61, 63–65]
4. *Dysphagia requiring intervention* (4 observational studies with 297 participants) absolute difference 56 more per 1000 (95% CI 14 fewer to 186 more) [60, 61, 65, 66]
5. *Patient satisfaction* (5 observational studies with 846 participants) absolute difference 9 fewer patients per 1000 (95% CI 60 fewer to 43 more) [59, 61, 62, 64, 65]

Certainty in the evidence of effects

The certainty of evidence was evaluated as very low based on outcomes namely, symptom recurrence, complications, reoperation, long-term dysphagia (patient-reported), cost, QoL, symptom resolution, PPI use, dysphagia requiring intervention, and patient satisfaction. These outcomes were primarily limited by serious risk of bias and imprecision.

Decision criteria and additional considerations

The preoperative workup for both procedures is the same with two relative contraindications for MSA currently including patients with BMI over 35 kg/m^2 and significantly impaired esophageal motility. Patients with an allergy to nickel and/or titanium are also contraindicated to receive MSA. As there was some discrepancy in terms of patient-reported dysphagia versus dysphagia requiring intervention after MSA, patients with preoperative bloating may benefit from preoperative counseling. In addition, the expert panel felt that patients who have previously undergone a sleeve gastrectomy and have symptomatic GERD and those who require options other than fundoplication could possibly benefit from MSA.

Performing both MSA and fundoplication require knowledge and skills in foregut surgery. There is a nuanced learning curve in appropriately selecting the sizing for MSA placement necessitating adequate training, however, the procedure is less technically demanding than fundoplication. Despite being FDA approved for use, MSA has not been uniformly adopted globally for use in part due to lower rates of insurance authorization and possibly due to the increased up-front costs for the device. Although cost was a non-informative outcome, there were 2 observational studies with 1610 participants that looked at cost information.

MSA demonstrated an absolute difference of $132 USD lower (95% CI $2512.81 lower to $2248.81 higher) than fundoplication [65, 67]. Furthermore, current literature is lacking data comparing MSA to partial fundoplication.

Conclusion

The panel judged that the desirable and undesirable effects were balanced and thus favored neither MSA nor Nissen fundoplication. The choice for either procedure should be made on a patient specific basis and consider other factors such as BMI and esophageal dysmotility, which are relative contraindications for MSA, and areas that are less well delineated such as patient bloating pre-operatively. Both MSA and fundoplication are successful at treating GERD symptoms.

2b. Should treatment with MSA versus medical treatment (PPI) be used for patients with GERD?

Recommendation

The panel suggests that adult patients with GERD may benefit from MSA over continued PPI use. (conditional recommendation, moderate certainty evidence).

Summary of the evidence

From 74 studies there was a single randomized control trial that guided the panel for decision making [68]. This single study included 158 patients that were followed for one year. No observational studies met inclusion criteria. There was not informative data for QoL, patient-reported symptom recurrence, dysphagia, hiatal hernia recurrence, complications, mortality, re-operation rates, and cost.

Benefits of intervention

The panel deemed the desirable effects of MSA compared to PPI to be large despite the small number of patients and the single study evaluated.

1. *Patient reported complete reflux symptom resolution less than 2 years* (1 RCT of 148 participants) absolute difference 795 more patients per 1000 (95% CI 393 to 1, 524 more)
2. *Need for PPI* (1 RCT of 134 participants) absolute difference 910 fewer patients per 1000 (95% CI 960 fewer—770 fewer)
3. *Patient satisfaction* (1 RCT of 134 participants) absolute difference 786 more patients per 1000 (95% CI 181 more to 3,181 more)
4. *Objective reflux recurrence at 6 months*, measured by average number of reflux events (1 RCT of 158 participants) absolute difference 38 fewer patients per 1000 (95% CI 140 fewer to 131 more)

Harms and burdens

No undesirable effects were available for this comparison. Thus, the magnitude of effect is unknown.

Certainty in the evidence of effects

The certainty of evidence was evaluated as moderate based on the reported outcomes for decision making. These outcomes were primarily limited by imprecision, however the RCT had low risk of bias. *(See evidence profile in the EtD framework, Supplement 4).*

Decision criteria and additional considerations

Given that there were no undesirable effects available, it is impossible to say whether the effects favor either MSA or PPI. PPI use is a straightforward and simple treatment with minimal side effects, however long-term use has been associated with osteoporosis and increased risk of fractures among other concerns [5] and thus in this patient population surgical treatment may be warranted. As it is a medical treatment it does not carry the same risk of surgical complications that can occur with MSA. As mentioned in the previous question there is a learning curve for MSA implementation and adequate training is necessary. MSA is currently not recommended for patients with BMI > 35 kg/m^2 and poor esophageal motility which are two subgroups that could be further studied. One aspect that this RCT did not address is the cost differential between these two treatment modalities as the upfront costs of a surgical procedure are much greater than the costs for medical treatment in the short-term, but over the course of a lifetime of medical treatment these cost differentials are unknown.

Conclusion

MSA has improved outcomes over PPI therapy in the short term however the negative effects and long-term data are not available. While a single well performed RCT has provided the first degree of data there is still a large amount unknown about this comparison.

2c. Should endoscopic treatment with TIF 2.0 versus fundoplication be used for patients with GERD?

Recommendation

The panel suggests that adult patients with GERD may benefit from fundoplication over TIF 2.0. (Expert Opinion recommendation; GRADE recommendation was unable to be determined due to lack of evidence).

Summary of the evidence

The systematic review revealed a single non-randomized observational study comparing TIF 2.0 to fundoplication [69]. Due to the small size of the study, the outcomes were non-informative and, thus, an EtD was unable to be created. Recommendations are based only on expert opinion. The panel noted that this lack of evidence could be due to the lack of worldwide adoption of the TIF 2.0 procedure.

Benefits of intervention

The potential benefits of endoscopic treatment with TIF 2.0 include the fact that TIF 2.0 is an endoscopic procedure that can be performed without surgical incisions. In addition, there is evidence of long-term durability with TIF 2.0 [70, 71]. Finally, TIF 2.0 can control regurgitation allowing for withdrawal of PPI use.

Harms and burdens

The harms and burdens associated with this procedure include the fact that the outcomes of endoscopic therapy using TIF 2.0 in patients with dysmotility disorders are unknown. In addition, the insertion of TIF 2.0 may be difficult in patients with a small jaw opening and those who have difficult neck hyperextension. The introduction of the TIF 2.0 device has the potential risk of esophageal laceration during the foreign body insertion [72]. Since TIF 2.0 only has an endoscopic view, inaccurate anchoring of the system to adjacent visceral structures may occur due to the lack of extraluminal visualization. TIF 2.0 as a standalone procedure is currently not recommended in patients with a hiatal hernia of greater than 2 cm, thus limiting this as an option for many patients with GERD. Finally, TIF 2.0 is an advanced endoscopy procedure that requires specialized training.

Conclusion

The low level of worldwide adoption of endoscopic treatment with TIF 2.0 is correlated with lack of sufficient comparative trials. Training and guidance on the TIF 2.0 endoscopic procedure could foster its implementation and adoption globally.

2d. Should endoscopic treatment with TIF 2.0 versus medical treatment (PPI) be used for patients with GERD?

Recommendation

The panel suggests that adult patients with GERD may benefit from TIF 2.0 over continued PPI (conditional recommendation, moderate certainty of evidence).

Summary of the evidence

Four RCTs were used to inform the panel's decision making that included 233 patients comparing TIF 2.0 and PPI [73–76].

Benefits of intervention

The panel deemed there to be moderate desirable effects of TIF 2.0 compared to PPI.

- *Short-term patient reported reflux symptom resolution* (3 RCTs of 216 participants) absolute difference 213 more patients per 1000 (95% CI 30 fewer to 595 more) [73–75]
- *Need of PPI* (3 RCTs with 233 patients) absolute difference 696 fewer patients per 1000 (95% CI 820 fewer to 448 fewer) [73–75]
- *Patient satisfaction* (1 RCT of 57 participants), 51.4% of TIF 2.0 patients vs. 0% of PPI patients reported being satisfied, thus an absolute effect was not estimable [76]
- *Objective reflux recurrence* (1 RCT of 33 participants) absolute difference 517 fewer patients per 1000 (95% CI 591 to 215 fewer) [75]
- *Quality of life less than 2 years* (2 RCTs with 86 participants) SMD −0.5 (95% CI −0.97 to −0.03) [73, 75]
  - *Two QoL scales used*: Quality of Life Reflux and Dyspepsia (QOLRAD) questionnaire and GERD Health Related Quality of Life (GERD-HRQL) scale

Harms and burdens

The expert panel deemed the undesirable effects of TIF 2.0 compared to PPI use to be small.

- *Complications* (2 RCTs with 173 total patients, however, only one study contributed to event data), absolute effect 37 more patients per 1000 (95% CI 9 fewer to 400 more) [73, 74].

Certainty in the evidence of effects

The certainty evidence was evaluated as moderate based on the reported outcomes for decision making. These

outcomes were primarily limited by small sample size and wide confidence intervals. *(See evidence profile in the EtD framework, Supplement 4).*

Decision criteria and additional considerations for KQ2c + d

In evaluating TIF 2.0 as an intervention there is a general paucity of studies that met the inclusion criteria. This could be attributed to the decreased adoption of TIF 2.0 worldwide likely due to a combination of lack of training and insurance coverage. However, there has been extensive use of this procedure in the USA. Implementation of this procedure does require a highly skilled endoscopist and there is a learning curve when adopting it as a new treatment similar to MSA, although there is also a learning curve with the laparoscopic fundoplication.

Relative contraindications for TIF 2.0 include the concurrent presence of obesity and severe esophagitis. Additionally, TIF 2.0 is contraindicated in patients with a hiatal hernia greater than or equal to 2 cm. For this reason, some surgeons and gastroenterologists advocate for a combined TIF 2.0 and minimally in invasive hiatal hernia repair under the same general anesthetic. These procedures are performed sequentially, with the hiatal hernia repaired first and the TIF performed after the intra-abdominal procedure has concluded. The combination of these procedures turns TIF 2.0 from an incisionless procedure to an invasive abdominal procedure. This combination of procedures is an evolving technique, and comparative data was not available for the current analysis.

Additional considerations include that TIF 2.0 is a standalone procedure and is not universally covered by insurance which has been an obstacle to adoption. When TIF fails and repeat intervention is necessary, there is not a consensus as to the best revisional approach. Some advocate for traditional full or partial fundoplication on top of an existing TIF valve, while others advocate taking the TIF down first. There are differences of opinion on the suitability and safety of each of these approaches among experts.

Conclusion

TIF 2.0 is an intervention for those who want to avoid both traditional surgery and lifelong medication. TIF 2.0 has the advantage of being a potentially entirely endoscopic and incisionless intervention. Given widely held opinions about the side effects and risks of traditional fundoplication procedures, additional long-term prospective comparative studies of TIF (and especially combined laparoscopic hiatal hernia repair and endoscopic TIF) versus fundoplication (partial fundoplication in particular) are needed.

2e. Should endoscopic treatment with Stretta versus fundoplication be used for patients with GERD?

Recommendation

The panel suggests that adult patients with GERD may benefit from fundoplication over Stretta. (conditional recommendation, very low certainty of evidence).

Summary of the evidence

Eight non-randomized comparative studies met inclusion criteria and were used for the final recommendation [77–84]. There was no evidence regarding hiatal hernia recurrence or perioperative mortality.

Benefits of Intervention

The panel deemed there to be small desirable effects of Stretta compared to fundoplication.

- *Perioperative complications* (2 observational study with 283 participants) absolute difference 80 fewer patients per 1000 (95% CI 125 fewer to 9 more) [77, 78]
- *Dysphagia requiring intervention* (2 observational study with 279 participants) absolute difference 43 fewer patients per 1000 (95% CI 49 fewer to 94 more) [79, 80]
- *Cost—mean hospital costs* (1 observational study with 140 participants) $1,808 USD after Stretta versus $5,715 USD after laparoscopic Nissen fundoplication [81]

Harms and burdens

The panel deemed there to be moderate undesirable effects of Stretta compared to fundoplication.

- *Quality of Life—Short Term less than 2 years* (1 observational study with 283 participants using the Quality of Life in Reflux and Dyspepsia (QOLRAD) questionnaire) mean difference 0.5 points lower with Stretta (95% CI 0.9 lower to 0.06 lower) [81]
- *Objective Reflux Recurrence—Short Term less than 2 years* (1 observational study with 226 participants assessed with the mean DeMeester Score) mean difference 1.5 points higher with Stretta (95% CI 0.22 higher to 2.78 higher) [78]
- *Subjective Reflux Recurrence—Long Term greater than 2 years* (1 observational study with 57 participants) absolute difference 4 more patients per 1000 (95% CI 91 fewer to 387 more) [77]

- *Subjective Reflux Resolution—Long Term greater than 2 years* (1 observational study with 57 participants) absolute difference 123 fewer patients per 1000 (95% CI 250 fewer to 187 more) [77]
- *Reoperation Required* (2 observational studies with 191 participants) 15.4% (14/91 patients) after Stretta versus 0% (0/100) after fundoplication. Absolute difference not estimable [82, 83]
- *Need for PPI* (3 observational studies with 345 participants) absolute difference 167 more patients per 1000 (95% CI 80 fewer to 905 more) [80, 83, 84]
- *Patient Satisfaction* (2 observational study with 123 participants) absolute difference 179 more patients per 1000 (95% CI 312 fewer to 16 fewer) [77, 83]

Certainty in the evidence of effects

The certainty of evidence was evaluated as very low based on the reported outcomes for decision making. These outcomes were primarily limited by small sample size and wide confidence intervals that spanned several clinically meaningful thresholds (**Supplement 4**).

2f. Should endoscopic treatment with stretta versus medical treatment (PPI) be used for patients with GERD?

Recommendation

The panel suggests that adult patients with GERD may benefit from Stretta over PPI. (conditional recommendation, low certainty of evidence).

Summary of the evidence

A systematic review revealed five RCTs that met inclusion criteria [85–89]. These trials did not report on subjective reflux recurrence, dysphagia requiring intervention, hiatal hernia recurrence, mortality, or cost.

Benefits of intervention

The panel deemed there to be moderate desirable effects of Stretta compared to PPI.

- *Quality of Life-Short Term less than 2 years* (3 RCTs with 89 participants assessed with the 36-Item Short Form Health Survey (SF-36) and the GERD-Health-Related Quality of Life (GERD-HRQL) survey) standardized mean difference 1.6 SD higher with Stretta (95% CI 1.12 higher to 2.1 higher) [85–87]
- *Subjective reflux symptom resolution-short Term less than 2 years* (3 RCTs with 122 participants) absolute difference 58 more patients per 1000 (95% CI 133 fewer to 1008 more) [86–88]
- *Need for PPI* (4 RCTs with 143 participants) absolute difference 144 fewer patients per 1000 (95% CI 297 fewer to 38 more) [86–89]
- *Patient satisfaction* (1 RCT with 20 participants) absolute difference 501 more patients per 1000 (95% CI 6 fewer to 1866 more) [89]

Harms and burdens

The panel deemed there to be small undesirable effects of Stretta compared to PPI.

- *Perioperative complications* (2 RCTs with 86 participants) absolute difference 50 more patients per 1000 (95% CI 10 fewer to 417 more) [86, 88]
- *Dysphagia-patient reported* (1 RCT with 24 participants) 1/12 (8.3%) reported dysphagia after Stretta and zero patients had dysphagia with PPI use. Absolute difference was not estimable [86]
- *Required additional procedures* (1 RCT with 62 participants) absolute difference 253 more patients per 1000 (95% CI 17 more to 582 more), many of these procedures were an additional treatment with Stretta. [88]

Certainty in the evidence of effects

The certainty of evidence was evaluated as low based on the reported outcomes for decision making. Although data originated from RCTs, these studies were primarily limited by small sample sizes, resulting in wide confidence intervals that spanned several clinically meaningful thresholds. *(See evidence profile in the EtD framework, Supplement 4).*

Decision criteria and additional considerations for KQ2e + f

During fundoplication surgeons can concurrently repair a concomitant hiatal hernia, as such Stretta has limited applicability in these patients. There is significantly more long-term data available for fundoplication than there is for Stretta. In addition, Stretta is ineffective in patients with very low lower esophageal sphincter pressure (LES) [78]. There could be a possible placebo effect with Stretta that should be considered due to the lack of physiologic difference change to lower esophageal with Stretta. In the systematic review, there was insufficient data for objective reflux control after Stretta.

The potential benefits of endoscopic treatment with Stretta include the fact that Stretta does not require general anesthesia since it is performed using a standard EGD,

thus should be considered in patients who are otherwise at high risk for surgery or those patients that wish to avoid surgery. In addition, Stretta is easier and a more consistently reproducible procedure than fundoplication with a considerably lower learning curve. Compared to fundoplication, Stretta does not affect surgical anatomy and it may be easier to perform another subsequent procedure if it fails. Furthermore, Stretta is a reasonable option for patients with severe reflux, who may not be candidates for fundoplication, such as post-sleeve gastrectomy. Although the technology associated with Stretta may not be available everywhere, its global adoption makes it feasible to implement in high-, middle-, and low-income countries.

Conclusion for KQ2e + f

Stretta is a still evolving technology that has not been widely adopted. Increased training and proctoring in the technique are needed world-wide before the technology will improve.

Research recommendations for KQ2a-f

There are a number of future research recommendations that the panel felt were needed. Comparative trials (randomized controlled trials where practical and feasible) may be of benefit in strengthening several of these recommendations. Outcomes should be objective, standardized where feasible, and patient centered. There should also be standardization of all the procedures to more reliably be able to compare the different techniques and studies from other institutions. All included studies in KQ2a compared MSA to Nissen fundoplication. To our knowledge, there is no high-level data that compares MSA to partial fundoplication and this is a potential area for future research. More long-term, durability studies would also contribute to our understanding of the pros and cons of the different GERD interventions. Finally, the panel felt that examining the strategy currently advocated by some surgeons and endoscopists of Concomitant Laparoscopic Hiatal Hernia Repair + endoscopic TIF (c-TIF) should be a research priority. In 2017 the FDA expanded the use of TIF to patients with a hiatal hernia greater than 2 cm when performed in combination with a hiatal hernia repair. This allows its use in a broader patient population. This approach was not compared in this guideline.

(KQ3) Should partial or complete fundoplication be used in adult patients with GERD?

3a. Should partial fundoplication versus complete fundoplication be used in adults with GERD?

Recommendation

The panel suggests that adult patients with GERD may benefit from partial fundoplication compared to complete fundoplication. (conditional recommendation, moderate certainty of evidence).

Summary of the evidence

From 70 studies there were 20 RCTs (39 individual studies)[7, 90–112] and 31 observational studies that met inclusion criteria [113–143]. In order to avoid double counting patients in follow-up studies from the same initial trial enrollment, RCTs and their follow-up reports were reviewed and outcomes with the longest follow up or largest sample size were chosen for inclusion in the analysis.

Benefits of the intervention

There were three outcomes with desirable effects for partial as compared to complete fundoplication. Overall, the panel felt that the effects were moderate.

1. *Hiatal Hernia Recurrence* (8 RCTs with 832 participants), absolute effect 30 fewer patients per 1000 (95% CI 43 fewer to 5 fewer) [90–97]
2. *Postoperative dysphagia, requiring intervention* (11 RCTs with 1,045 participants), absolute effect 47 fewer patients per 1000 (95% CI 58 fewer to 24 fewer) [91, 93, 98–106]
3. *Gas/bloat/inability to vomit greater than 1 year* (10 RCTs with 860 participants), absolute effect 115 fewer patients per 1000 (95% CI 186 fewer to 18 fewer) [7, 90, 93, 96, 98, 99, 106–108, 112]

Gathered data did not include how recurrence or hiatal hernia was measured or stratified based on symptomatology, with extraction criteria being recurrence > 3 cm and/or symptomatic recurrence. These factors may have introduced some variability into the data.

Harms and burdens

There were two outcomes with undesirable effects for partial fundoplication relative to complete. The panel voted the magnitude of these effects to be small.

1. *Complete subjective reflux symptom resolution greater than 1 year* (14 RCTs with 1289 participants), absolute effect 16 fewer patients per 1000 (95% CI 48 fewer to 24 more) [90, 93, 94, 97, 102–104, 106–112]. Follow-up in these studies ranged from 1y-20y with 7 of 14 trials having > 5y follow-up

2. *Objective reflux recurrence greater than 1 year* (6 RCTs with 851 participants) absolute effect 45 more patients per 1000 (95% CI 14 fewer to 143 more) [96, 98, 101, 103, 111, 112]

Certainty in the evidence of effects

The certainty of data for these effects was deemed moderate. (See evidence profile in the EtD framework, Supplement 5).

Decision criteria and additional considerations

The consensus is based on the demonstrated decreased postoperative side effects after partial fundoplication compared to the limited differences in long-term reflux control, both of which are supported with moderate strength evidence. Although there were several RCTs contributing evidence to this recommendation, many of the participating surgeons in these studies practiced at academic, tertiary care centers, which may limit the generalizability to the average general surgeon and potentially introduce surgeon bias. Furthermore, the pooled studies included several different types of partial fundoplications, which adds some heterogeneity to the population included, however, this did not appear to translate into any heterogeneity within the outcomes. Nevertheless, for all outcomes, the observational studies included in the systematic review supported the RCT findings. There are many caveats not accounted for in this data, many of which are related to the preoperative evaluation of the patient which can be highly variable. Many patients' primary complaint is related to heartburn and as such the goal is to treat this symptom. This is balanced with patients' desire to avoid dysphagia and other side effects associated with a complete fundoplication, including long-term gas bloat symptoms. These patients may be more satisfied with a partial fundoplication.

Areas of special consideration include patients with objective findings of severe GERD (such as Barrett's esophagus, dysplasia, or severe esophagitis) or those who are post lung transplantation who may value objective GERD resolution in order to prevent progression of their esophageal or lung disease (e.g., graft failure) over fear of postoperative dysphagia, gas bloat, and inability to vomit.

Conclusion and research recommendations

Future research recommendations should focus on improved long-term data with larger sample sizes to better elucidate the treatment effect. In addition, studies should be performed to determine patients' values on outcomes for their treatment of GERD, such as the importance of symptoms and QoL measures. There should also be studies in which there is standardization of procedures (i.e., reviewing videos of techniques) as well as competence-based assessments for training in order to compare procedures adequately. Finally, studies that compare the different partial fundoplication techniques are needed. Significant education to surgeons will also have to be provided to change longstanding practice of some who only perform complete fundoplication.

3b. Should complete fundoplication versus partial fundoplication be used for adult patients with GERD who have esophageal dysmotility on preoperative manometry?

Recommendation

The panel suggests that adult patients with GERD and preoperative dysmotility may benefit from partial over complete fundoplication. (conditional recommendation, low certainty of evidence).

Summary of the evidence

From 7 studies there were 3 RCTs [95, 103, 104, 110] and 4 observational studies that met inclusion criteria [115, 117, 118, 144].

Benefits of the intervention

There were two outcomes with desirable effects for partial as compared to complete fundoplication in patients with preoperative dysmotility. Overall, the panel felt that the effects were moderate.

1. *Complete subjective reflux symptom resolution greater than 1 year* (1 RCT with 100 participants), absolute effect 61 more patients per 1000 (95% CI 91 fewer to 243 more) [103]
2. *Postoperative dysphagia, patient reported* (3 RCTs with 173 participants), absolute effect 144 fewer patients per 1000 (95% CI 215 fewer to 21 fewer) [95, 103, 104, 110]

Although there is some clinical benefit, the CI of complete reflux symptom resolution ranges from small benefits to small harms, thus there was no significant difference between the partial and complete fundoplication.

Harms and burdens

There was one outcome with undesirable effects for partial fundoplication relative to complete. The panel voted the magnitude of these effects to be trivial.

1. *Objective reflux recurrence greater than 1 year,* assessed by median postoperative DeMeester Score (1 observational study with 51 participants) mean difference 5 points higher 95% CI 22.59 lower to 32.59 higher) [144]

Certainty in the evidence of effects

The overall certainty of evidence is low *(See evidence profile in the EtD framework, Supplement 5).*

Decision criteria and additional considerations

When using their collective patient experience to consider patient values, the panel surmised there are groups of patients who may prefer reflux control over worsening dysphagia, including those who had a lung transplant or those with scleroderma. There are also a few other caveats when considering implementing this guideline into clinical practice related to the definition and the cause of the pre-operative dysphagia. There are patients in whom dysmotility may be due to the degree of esophagitis and not an underlying functional disorder. There are also patients with manometric findings of esophageal dysmotility who may or may not have symptoms of dysphagia [145]. There is no standard definition of dysmotility used in the referenced studies and therefore when comparing multiple studies, it is difficult to know if all patients have similar abnormal degrees of motility.

Conclusion and Research Recommendations

Developing a better correlation between dysmotility and dysphagia which would allow for a better understanding of the impact of a complete and partial fundoplication on esophageal motility and is an important future research recommendation. Further future research priorities include the acquisition of better long-term data with larger sample sizes and of data comparing patient symptoms and QoL measures. Again, there is a lack of standard definitions and comparison of types of partial fundoplication. Comparison between anterior versus posterior and degree of partial fundoplication would clarify what partial fundoplication can and should be recommended in patients who would benefit from a partial wrap.

(KQ4) What is the best treatment for adult patients with obesity (BMI ≥ 35) and concomitant GERD?

4a. Should candidate patients with obesity (BMI ≥ 35) and GERD undergo RYGB versus LNF for optimal control of their GERD?

Recommendation

The panel suggests that patients with medically refractory GERD and a BMI ≥ 35 may benefit from either RYGB or fundoplication. (conditional recommendation, very low certainty of evidence).

Summary of evidence

There were two observational, comparative studies that met inclusion criteria [146, 147]. Data from these two studies were used in the creation of our EtD and, subsequently, final recommendations. There was a mean BMI of 46.2 kg/m^2 in the patients who underwent RYGB and 34.7 kg/m^2 in those who underwent fundoplication. Additionally, there were several single-arm case series that observed outcomes in either fundoplication or RYGB for GERD in patients with obesity that were not evaluated in the comparative studies included in our EtD.

The findings of these single arm studies are summarized here. Reported rates of 30-day mortality between the two groups were quite similar, however, this data is further limited by the small event rate [148–157]. There were also similar rates of reoperation; four studies which averaged a 1.93% (range 1.22–3.05%) reoperation rate for fundoplication [149, 150, 158, 159] compared to a rate of 2.54% (range 2.02–3.2%) for the RYGB group [152–154, 157]. There were three studies which averaged a 1.4% (range 0.41–4.73%) hiatal hernia recurrence after fundoplication [148, 158, 159]. However, there were two studies which evaluated hiatal recurrence after RYGB reporting a rate of 43.27% (range 32.48–54.75%) [155, 160]. Overall, these studies had small sample sizes and were composed of heterogeneous populations, therefore no direct comparisons can be made.

Of note, these studies only addressed the question of change in GERD symptoms after the interventions in patients with obesity and no additional aspects of weight loss or other co-morbid conditions were considered.

Benefits of the intervention

There was one outcome in the EtD with desirable effects for RYGB as compared to fundoplication in patients with obesity. Overall, the panel felt that the effects were small.

1. *Complete subjective reflux symptom resolution less than 2 year* (1 observational study with 100 participants), absolute effect 136 more patients per 1000 (95% CI 25 more to 254 more) [146]

Harms and burdens

There were two outcomes with undesirable effects for RYGB as compared to fundoplication in patients with obesity. Overall, the panel felt that the effects were moderate.

1. *Objective reflux recurrence greater than 1 year,* assessed by mean postoperative DeMeester Score (1 observational study with 12 participants) mean difference 2.9 points higher (95% CI 1.6 higher to 4.3 higher) [147]

2. *Postoperative complications* (2 observational study with 112 participants), RYGB had a complication rate of 7.4% versus 0% with fundoplication. Because there were no events in the fundoplication arm, the absolute effects are not estimable [146, 147]

Certainty in the evidence of effects

The certainty of evidence of both desirable effects and patient harm was very low (*See evidence profile in the EtD framework, Supplement 6*)**.**

Decision criteria and additional considerations

Patient-reported GERD symptoms improved significantly after RYGB; however, these findings were not consistent with objective studies of GERD after these procedures which favored fundoplication. There were fewer complications after fundoplication as compared to RYGB.

These studies were uniformly observational with significant baseline differences (e.g., preoperative BMI and DeMeester scores) that could have impacted the study results. Studies did not evaluate objective findings such as pre- and post-operative antacids therapy. Results for complications were based on only two events in the RYGB group.

The panel recognized that because this guideline was focused on the treatment of GERD, there are many potential additional and relevant benefits with RYGB, such as weight loss and resolution of obesity-associated comorbidities. Of note, patients included in these studies had a mean BMI of 46.2 kg/m^2 in the RYGB group and 34.7 kg/m^2 in those that underwent fundoplication. Patients with a higher BMI may require additional multidisciplinary counseling before a surgical decision is made.

Bariatric consultation should be strongly considered in patients with morbid obesity for the treatment of associated metabolic comorbidities, not only GERD, before proceeding directly with fundoplication. However, there are many patients in this category who are suffering with both GERD symptoms and obesity complications and are willing to consider fundoplication, but not bariatric surgery. Insurance approval for bariatric procedures is also a big hurdle and thus important to maintain that either approach is acceptable.

It has been appreciated for many years that risk of reflux recurrence after fundoplication is increased in patients with morbid obesity [41, 161, 162], though there is contrary evidence [148, 163]. It is postulated that higher postoperative intraabdominal pressures can cause failure of the repair [164]. Based on this knowledge, it has been suggested that fundoplication may not be the preferred anti-reflux operation in the morbidly obese, and alternatives such as Roux-en-Y gastric bypass (RYGB) may be superior. Systematic review of comparative studies, as conducted above, do not yet support this view. Though subjectively results may be better, RYGB is a more complex operation, with two anastomoses and significant alteration to anatomy, and not unexpectedly perioperative morbidity is increased. Moreover, this increased risk in complication rate is not necessarily achieved with superior objective control of reflux disease. Numbers reviewed in our study are small, and there was a low certainty of evidence.

Conclusion and research needs

To date, no RCTs have been done comparing RYGB and fundoplication in patients with obesity and GERD. These studies could bring the much-needed certainty of evidence to this clinical question, especially if long-term follow-up is conducted. The feasibility of such a trial may present an obstacle. Furthermore, studies evaluating outcomes of patients with severe obesity may demonstrate more clarity for this surgical question. Current literature does not address outcomes after RYGB in patients who have pre-existing motility disorders and/or atypical GERD symptoms. High-quality comparative studies and RCTs addressing this patient population would be beneficial. As endoluminal treatments of GERD evolve, studies investigating their efficacy in patients with obesity is also a matter of importance.

4b. Should adult, candidate patients with obesity (BMI $\geq$ 35) and refractory GERD to best medical management undergo sleeve gastrectomy versus LNF?

Recommendation

While sleeve gastrectomy is the most commonly performed surgical procedure to treat obesity, it can be a refluxogenic operation. As such, the expert opinion of the consensus recommends that a sleeve gastrectomy should not be performed as an anti-reflux procedure (Expert Opinion, GRADE recommendation was unable to be determined due to lack of evidence).

Summary of the evidence

After systematic review of the literature, there were no comparative studies that evaluated the efficacy of fundoplication versus sleeve gastrectomy for the treatment of refractory GERD in morbidly obese patients. As such, single arm studies were reviewed, and data extracted for either the intervention or the comparator. Overall, these studies had very small sample sizes and were composed of heterogeneous populations and thus no direct comparisons can be made.

In two studies, the rate of symptom resolution in obese patients with GERD after fundoplication was 87.5% (range 81.4–97.8%) [148, 158]. There were nine studies which

averaged a symptom resolution rate of only 22.1% (range 7.0–51.8%) after sleeve gastrectomy [165–173]. There were similar rates of 30-day mortality between the two groups [148–150, 167–169, 172]. In four studies, fundoplication had a re-operative rate of 1.9% (range 1.2–3.1%) [149, 150, 158, 159]. Across nine studies, sleeve gastrectomy had a re-operative rate of 9.2% (range 4.1–19.8%) [171, 172, 174, 175]. Fundoplication had a hiatal hernia recurrence of 1.4% (range 0.4–4.7%) over three studies [148, 158, 159]. There was only one study that looked at hiatal hernia recurrence after sleeve gastrectomy (2.8%, range 1.1–7.3%) [168]. There was one study that showed 1.4% of obese patients required anti-reflux medication (ARM) after fundoplication [148]. There were five studies that reported an average of 26.4% (range 15.3%-41.6%) of patients required ARM after sleeve gastrectomy [165, 167, 171, 173, 175–177].

Two studies of obese patients after fundoplication showed that 7.0% (range 1.8–24%) of patients had dysphagia that required intervention [149, 158]. In contrast, in two studies after sleeve gastrectomy, only 1.4% (range 0.7–2.9%) of patients had dysphagia that required intervention [167, 168]. There were several outcomes for which only data on sleeve gastrectomy was available. Over five studies, there was an objectively established reflux recurrence in 43.7% (range 25.1–64.2%) after sleeve gastrectomy [169–172, 177]. Lastly, in two studies, 1.4% (range 0.02–52.8%) of patients were found to have Barrett's esophagus after sleeve gastrectomy [168, 169].

Decision criteria and additional considerations

Given the absence of studies directly comparing fundoplication to sleeve gastrectomy for the treatment of medically refractory reflux in patients with morbid obesity, the recommendations were made based on single-arms studies and consensus of the expert panel. The limited literature available also did not delineate between worsening of preoperative GERD or de novo GERD. Studies that demonstrated de novo GERD were not included in the systematic review since they did meet the inclusion criteria. With the current evidence and preoperative workup, there is no process to predict pre-operatively which patients without GERD will develop GERD post-sleeve gastrectomy, especially given the wide spectrum of practice in performing sleeve gastrectomy (pre-op workup, bougie size, distance from pylorus, exploration, and repair of concomitant hiatal hernias, etc.). While it is appreciated that sleeve gastrectomy has a variable and not easily predicted effect on reflux [178], sometimes worsening it [179, 180] and sometimes improving reflux [181], this is usually seen when performing the operation for the treatment of obesity. Because of the uncertainty, the panelists would always caution again sleeve gastrectomy in patients with severe reflux and would never recommend sleeve gastrectomy as a primary anti-reflux operation. Patients with preoperative dysmotility, regurgitation, high-grade esophagitis, and/or Barrett's esophagus should be counseled against sleeve gastrectomy due to the possibility of worsening GERD.

Conclusion and research needs

The use of sleeve gastrectomy for the primary treatment of GERD in the obese patient was not recommended by our expert panel. While there is a lack of comparative studies looking at outcomes for patients with morbid obesity and GERD undergoing sleeve gastrectomy or fundoplication, this dearth of data may be due to the current available data suggesting that sleeve gastrectomy is a refluxogenic operation and that better primary ARS options such as LNF or RYGB are available to treat patients with both obesity and medically refractory GERD. In other words, sleeve gastrectomy is a bariatric surgical procedure which may have beneficial effects on GERD, but sleeve gastrectomy is never to be considered a primary anti-reflux operation with beneficial effects on weight.

Opportunities for research specific to this population include outcomes for patients with hiatal hernia who undergo sleeve gastrectomy, information regarding LES integrity versus postoperative outcomes after sleeve gastrectomy, and the diameter of the sleeve affecting reflux outcomes and de novo GERD.

4c. After failed fundoplication should RYGB versus a redo fundoplication be performed for symptom control in adult candidate patients with GERD and concomitant obesity?

Recommendation

The panel suggests that adult patients with obesity and medically refractory GERD, who have failed previous fundoplication, may benefit from either RYGB or redo fundoplication based on surgeon and patient shared decision making. (conditional recommendation, very low certainty of evidence).

Summary of evidence

No large, RCTs were available for inclusion. Limited data was captured comparing redo fundoplication to RYGB in patients with a BMI $\geq$ 35, as such, the panel decided to increase the screening criteria to include patients with a BMI $\geq$ 30. Data from five observational, comparative studies from the systematic review were deemed critical or important for clinical decision making and thus were included in the EtD and informed decision making [182–186]. Across these studies, there was a mean BMI of 33.2 kg/m^2 in the patients who underwent RYGB and a mean BMI of 28.7 kg/

m^2 in those that underwent fundoplication. As the data from comparative studies was somewhat limited in this group of patients, we elected to review single arm series for both the comparator and intervention for this KQ. All patients included in the study by Antiporda et al. [182] had undergone ≥ 1 prior repeat fundoplication before either undergoing another fundoplication or RYGB. In the other included studies, majority of patients had only had the original fundoplication before study inclusion, however, a small proportion of patients had received multiple fundoplications before study inclusion. The study by Shao et al.[184] did not report on how many prior fundoplications patients received. Across the 4 studies reporting number of prior fundoplications, the Redo Fundoplication groups had a mean of 1.4 prior fundoplications and the RYGB groups had a mean of 1.9 prior fundoplications.

There were two outcomes where comparative data was lacking, objective reflux recurrence and progression to Barrett's esophagus. There was one single arm study which reported a 10.1% (range 5.2–19.0%) rate of objective reflux recurrence after RYGB in patients with obesity who had previously failed fundoplication [187]. Even in our query of single arm studies, there were no reports of progression to Barrett's esophagus in either redo fundoplication or RYGB after failed fundoplication.

Benefits of the Intervention

There were three outcomes with desirable effects for RYGB as compared to fundoplication in patients with obesity. Overall, the panel felt that the effects were small.

1. *Complete subjective reflux symptom resolution less than 2 year* (4 observational studies with 483 participants), absolute effect 0 more/fewer patients per 1000 (95% CI 65 fewer to 65 more) [182–185]
2. *Hiatal hernia recurrence* (1 observational study with 63 participants), absolute effect 43 fewer patients per 1000 (95% CI 110 fewer to 464 more) [182]
3. *Need for ARM* (1 observational study with 152 participants), absolute effect 15 fewer patients per 1,000 (95% CI 105 fewer to 184 more) [183]

The confidence interval for subjective reflux symptom resolution is compatible with clinically relevant, albeit small, benefits to clinically relevant, albeit small, harms for patient symptom resolution.

Harms and burdens

There were four outcomes with undesirable effects for RYGB as compared to fundoplication in patients with obesity. Overall, the panel felt that the effects were moderate.

1. *Patient reported symptom recurrence greater than 2 year* (1 observational study with 180 participants) absolute effect 42 more patients per 1000 (95% CI 46 fewer to 220 more) [184]
2. *Perioperative complications (*4 observational studies with 515 participants) absolute effect 52 more patients per 1000 (95% CI 13 fewer to 155 more) [182–185]
3. *Perioperative mortality* (5 observational studies, however only one contributed event data, with 698 total patients); RYGB had one death (0.4%) across all studies, whereas redo fundoplication had no postoperative mortality (0%) [182–186]
4. *Reoperation* (3 observational studies with 363 participants) absolute effect 96 more per 1000 (95% CI 19 more to 330 more) [182, 184, 185]

There were two observational studies which looked at dysphagia requiring intervention after either RYGB or redo fundoplication, however they observed vastly different findings. Weber et al. reported lower rates of dysphagia after redo fundoplication (6%) compared to RYGB (44.4%) [185]. However, Yamamoto et al. reported dysphagia rates of 18.5% after redo fundoplication compared to 0% after RYGB [186]. The reviewers could not discern meaningful differences in population, follow-up, or interventions to explain these differences, thus this outcome was excluded from decision making.

Certainty in the evidence of effects

The certainty of evidence was deemed to be very low based on the outcomes determined to be critical or important to decision making by the expert panel: patient-reported symptom improvement (critical), patient-reported symptom recurrence (critical), perioperative complications (important), perioperative mortality (important), and need for reoperation (important). The outcomes were primarily limited by unclear risks of bias and wide CI which increase the imprecision of the results. *(See evidence profile in the EtD framework, Supplement 6).*

Decision criteria and additional considerations

Due to the important variability in patient values, particularly the value of weight loss versus GERD resolution, the panelists felt that despite the balance of effects, that either RYGB or redo fundoplication may be chosen for patients with both GERD and obesity.

Experienced surgeons understand that revisional foregut surgery may be significantly more challenging than the primary operation[161], and the greater the tools available to the surgeon, the greater the chance for success. The anatomic derangements incurred in prior surgery, with interruptions

to vascularity, perhaps a non-viable fundus, alterations in hiatal anatomy and other changes may prevent re-fundoplication no matter the initial intent of the operating surgeon. It is of expert opinion that in patients who have previously undergone multiple revisions, more consideration should be given to conversion to a RYGB. In addition, this recommendation does not address the difference in outcomes in patients with obesity and a lower BMI to patients with a higher BMI. Patients with higher BMI and GERD should be strongly advised to undergo a RYGB since articles that evaluate anatomical findings in revisional procedures after failed fundoplication reported partially herniated, herniated, or slipped wraps [188]. The BMI threshold for this recommendation was not established by the expert panel. The evidence regarding delayed gastric emptying in these groups was not reviewed, however, it is of expert opinion that in patients with delayed gastric emptying, conversion to gastric bypass should be given more consideration.

Conclusion and research recommendations

The expert panel recommends that a large, RCT of revisional fundoplication versus conversion to RYGB would provide valuable insight. The feasibility of conducting such a trial is a likely obstacle. At minimum, a well-designed matched comparative study would improve the grade of evidence, especially those that evaluate patients with more severe obesity (BMI $\geq$ 35). The panel recommends including preoperative esophageal and gastric motility studies as well as gastric emptying studies after interventions for failed fundoplication. Finally, patients who have undergone multiple revisions should be a focus of future research.

Discussion

What is new in this guideline?

SAGES published a guideline in 2021 discussing the surgical treatment of GERD, which covered differing aspects than this current guideline [189]. The main difference in this guideline is the presence of multiple representatives from various societies bringing together different expertise to further enrich, engage, and drive the consensus discussions. Additionally, this guideline focuses on pre-operative testing, endoscopic approaches, and GERD associated with obesity, which the earlier guideline did not address.

Implementation

The consensus believes that it is feasible to successfully implement these recommendations into local practice and that the recommendations will be accepted by stakeholders. The main considerations regarding implementation of this guideline include costs and availability of the testing and treatment options. In addition, some of the recommended techniques require specialized knowledge and skills. Finally, to achieve the full benefit of these recommendations, standardizing aspects of GERD treatment is required, including LA grading, esophagograms, manometry, and the technical components of the fundoplication. The panel plans to survey physicians in the future to monitor and audit compliance with the recommendations put forth in this guideline.

Updating this guideline

SAGES plans to repeat a comprehensive literature review in three years to reevaluate and identify new evidence. Particular attention will be paid to any future studies that specifically address the research recommendations proposed in this guideline. A formal update will be generated when substantial literature is detected. The adoption and implementation of this guideline's recommendations will be assessed at an interval time in the future.

Limitations of this guideline

One of the main limitations of this guideline is the low certainty of evidence for most of the KQ, except for KQ 3. In addition, patient's values and preferences were not actually obtained and instead the panel's impression of their beliefs was used based on experiences with patients. While the recommendations in this guideline are based on the highest-level evidence meeting inclusion criteria, there may be certain areas globally with limited access to certain testing, such as pH-testing and HREM, as well as individual procedures or technologies. Insurance coverage and cost to society was not addressed in this guideline as it took a patient-centered perspective. In the development of the recommendations, we were not able to consider certain aspects of diversity, equity, and inclusion due to unavailability in the literature that was reviewed, thus may limit their generalizability. Specifically, various populations might have been underrepresented in the studies that were evaluated such as ethnic minorities or patients in lower socioeconomic areas. Additional research should be devoted to addressing these issues and as well as the effects of access to care as it relates to the treatment of GERD.

Conclusion

Through the development of these evidence-based recommendations, the consensus conference proposed a treatment algorithm for aid in the treatment of GERD (Fig. 1). Patients with typical symptoms should undergo EGD, manometry, and pH-testing; additional testing may be required for

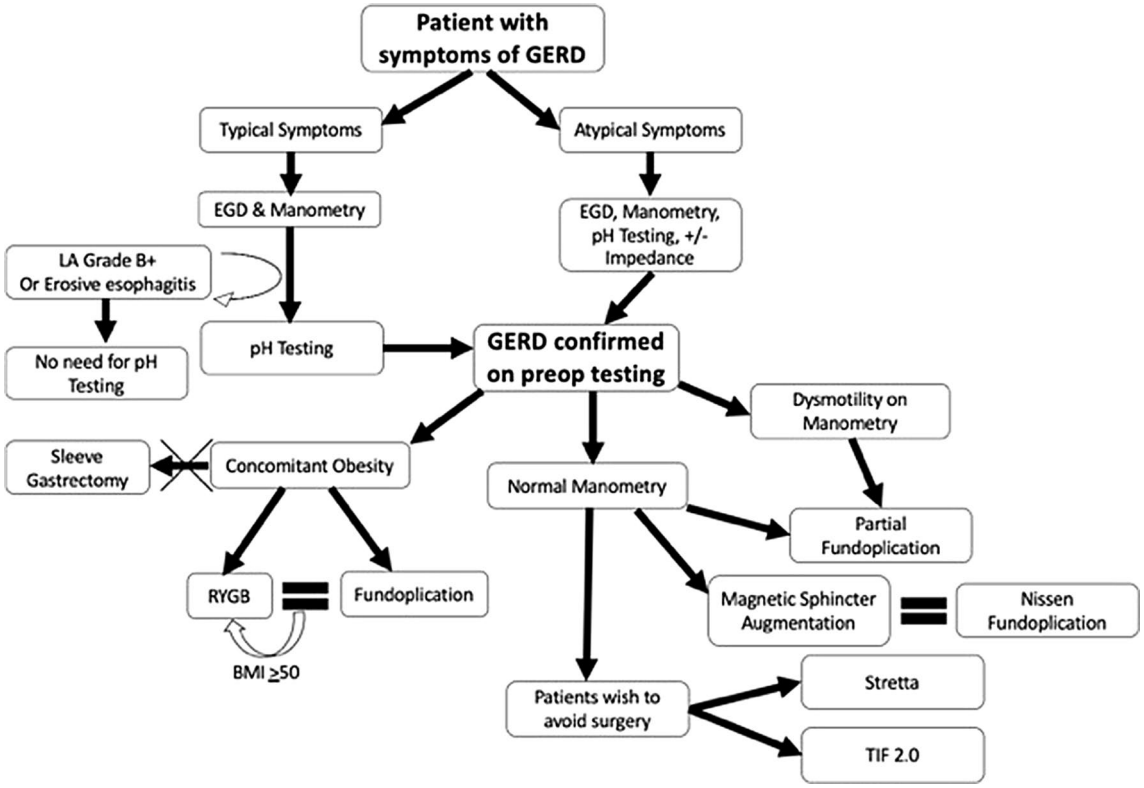

Fig. 1 Treatment Algorithm for adult patients with gastroesophageal reflux disease (GERD)

patients with atypical symptoms. MSA or fundoplication are both acceptable. MSA has better outcomes than PPI alone. Patients with normal or abnormal findings on manometry should undergo partial fundoplication. For patients that wish to avoid surgery, Stretta and TIF 2.0 were found to have better outcomes than PPI alone. Patients with concomitant obesity were recommended to undergo either RYGB or fundoplication, although patients with BMI > 50 should undergo RYGB for the additional benefits that follow weight loss and comorbidities resolution.

Using the recommendations and algorithm developed by this panel, physicians may better counsel their patients with GERD. Engaging in the identified research areas may improve future care for GERD patients.

Disclaimer

Clinical practice guidelines are intended to indicate the best available approach to medical conditions as established by a systematic review of available data and expert opinion. The approach suggested may not necessarily be the only acceptable approach given the complexity of the healthcare environment. This guideline is intended to be flexible, as the surgeon must always choose the approach best suited to the patient and to the variables at the moment of decision. This guideline is applicable to all physicians who are appropriately credentialed regardless of specialty and address the clinical situation in question. Some studies or treatment options may not be available in certain regions, and as such individual decision making must be used.

This guideline is developed under the auspices of SAGES, the guidelines committee, and approved by the Board of Governors. The recommendations of each guideline undergo multidisciplinary review and are considered valid at the time of production based on the data available.

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Authors and Affiliations

Bethany J. Slater[1] · Amelia Collings[2] · Rebecca Dirks[2] · Jon C. Gould[3] · Alia P. Qureshi[4] · Ryan Juza[5] · María Rita Rodríguez-Luna[6] · Claire Wunker[7] · Geoffrey P. Kohn[8] · Shanu Kothari[9] · Elizabeth Carslon[10] · Stephanie Worrell[11] · Ahmed M. Abou-Setta[12] · Mohammed T. Ansari[13] · Dimitrios I. Athanasiadis[2] · Shaun Daly[14] · Francesca Dimou[15] · Ivy N. Haskins[16] · Julie Hong[17] · Kumar Krishnan[18] · Anne Lidor[5] · Virginia Litle[19] · Donald Low[10] · Anthony Petrick[20] · Ian S. Soriano[21] · Nirav Thosani[22] · Amy Tyberg[23] · Vic Velanovich[24] · Ramon Vilallonga[25] · Jeffrey M. Marks[26]

1 University of Chicago Medicine, 5841 S. Maryland Avenue, MC 4062, Chicago, IL, USA

2 Department of Surgery, Indiana University School of Medicine, Indianapolis, IN, USA

3 Division of Minimally Invasive and Gastrointestinal Surgery, Department of Surgery, Medical College of Wisconsin, Milwaukee, WI, USA

4 Division of General & GI Surgery, Foregut Surgery, Oregon Health & Science University, Portland, OR, USA

5 Department of Surgery, University of Wisconsin, Madison, WI, USA

6 Research Institute Against Digestive Cancer (IRCAD) and ICube Laboratory, Photonics Instrumentation for Health, Strasbourg, France

7 Saint Louis University, St Louis, MO, USA

8 Department of Surgery, Monash University, Melbourne, VIC, Australia

9 Department of Surgery, Prisma Health, Greenville, SC, USA

10 Virginia Mason Medical Center, Seattle, WA, USA

11 University of Arizona Health Sciences, Tucson, AZ, USA

12 Department of Community Health Sciences, University of Manitoba, Winnipeg, Canada

13 School of Epidemiology and Public Health, University of Ottawa, Ottawa, Canada

14 Department of Surgery, University of California, Irvine, Orange, CA, USA

15 Washington University in St. Louis, St. Louis, MO, USA

16 Department of Surgery, University of Nebraska Medical Center, Omaha, USA

17 Department of Surgery, New York Presbyterian/Queens, Queens, USA

18 Massachusetts General Hospital, Boston, MA, USA

19 Section of Thoracic Surgery, Department of Cardiovascular Surgery, Intermountain Healthcare, Salt Lake City, UT, USA

20 Department of General Surgery, Geisinger School of Medicine, Geisinger Medical Center, Danville, PA, USA

21 Department of Surgery, University of California San Francisco School of Medicine, San Francisco, CA, USA

22 McGovern Medical School, Center for Interventional Gastroenterology at UTHealth, Houston, TX, USA

23 Rutgers Robert Wood Johnson Medical School, New Brunswick, NJ, USA

24 Division of Gastrointestinal Surgery, Tampa General, Tampa, FL, USA

25 Endocrine, Metabolic and Bariatric Unit, General Surgery Department, Vall d'Hebron University Hospital, Center of Excellence for the EAC-BC, Universitat Autònoma de Barcelona, Barcelona, Spain

26 Case Western Reserve University School of Medicine, University Hospitals Cleveland Medical Center, Cleveland, OH, USA