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SAGES GUIDELINES

SAGES guidelines for the surgical treatment of gastroesophageal reflux (GERD)

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Abstract

Background Gastroesophageal Reflux Disease (GERD) is an extremely common condition with several medical and surgical treatment options. A multidisciplinary expert panel was convened to develop evidence-based recommendations to support clinicians, patients, and others in decisions regarding the treatment of GERD with an emphasis on evaluating different surgical techniques.

Methods Literature reviews were conducted for 4 key questions regarding the surgical treatment of GERD in both adults and children: surgical vs. medical treatment, robotic vs. laparoscopic fundoplication, partial vs. complete fundoplication, and division vs. preservation of short gastric vessels in adults or maximal versus minimal dissection in pediatric patients. Evidence-based recommendations were formulated using the GRADE methodology by subject experts. Recommendations for future research were also proposed.

Results The panel provided seven recommendations for adults and children with GERD. All recommendations were conditional due to very low, low, or moderate certainty of evidence. The panel conditionally recommended surgical treatment over medical management for adults with chronic or chronic refractory GERD. There was insufficient evidence for the panel to make a recommendation regarding surgical versus medical treatment in children. The panel suggested that once the decision to pursue surgical therapy is made, adults and children with GERD may be treated with either a robotic or a laparoscopic approach, and either partial or complete fundoplication based on surgeon–patient shared decision-making and patient values. In adults, the panel suggested either division or non-division of the short gastric vessels is appropriate, and that children should undergo minimal dissection during fundoplication.

Conclusions These recommendations should provide guidance with regard to surgical decision-making in the treatment of GERD and highlight the importance of shared decision-making and patient values to optimize patient outcomes. Pursuing the identified research needs may improve future versions of guidelines for the treatment of GERD.

Keywords Antireflux surgery · Fundoplication · Gastroesophageal reflux · GERD · Partial fundoplication · Proton pump inhibitor

Abbreviations

EGD	Esophagogastroduodenoscopy
EtD	Evidence to decision tables
GERD	Gastroesophageal reflux disease
GRADE	Grading of recommendations assessment, development, and evaluation
PPI	Proton pump inhibitor
RCT	Randomized control trial

Executive summary

Background

Gastroesophageal Reflux Disease (GERD) is an extremely common condition with a number of both medical and surgical treatment options. A multidisciplinary expert panel

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was convened and developed evidence-based recommendations to help clinicians, patients, and others make decisions regarding the treatment of GERD, with an emphasis on evaluating different surgical techniques.

Methods

Literature reviews were conducted for 4 key questions, described below, regarding the surgical treatment of GERD in both adults and children. Evidence-based recommendations were formulated using the GRADE methodology by subject experts. Recommendations for future research were also documented.

Interpretation of strong and conditional recommendations

All guideline recommendations were assigned either a "strong" or "conditional" recommendation. These were based on the GRADE approach [1]. The words "the guideline panel recommends" are used for strong recommendations, and "the guideline panel suggests" for conditional recommendations, according to the GRADE approach.

How to use these guidelines

The aim of these guidelines is to assist all surgeons, gastroenterologists, and physicians who make decisions about management for their patients with GERD. They are also intended to provide education, inform advocacy, and describe future areas for research. The guidelines are meant to suggest the optimal, although not only, approach for management especially given the intricacies of both the overall healthcare environment as well as the individual patient needs and co-morbidities. Specific situations may require adjustment of treatment plans to suit the needs and prioritizations of the individual patient. Finally, due to the fact that the guidelines take a patient-centered approach, patients can use these guidelines as a source of information and for discussion with their physicians.

Key questions addressed by these guidelines

1. Should surgical (fundoplication) or medical (PPI) management be used in adult and pediatric patients with GERD?
2. Should robotic or laparoscopic fundoplication be used in adult and pediatric patients with GERD?
3. Should complete or partial fundoplication be used in adult and pediatric patients with GERD?
4. Should division of short gastric vessels or no division of short gastrics be performed in adult patients with GERD?
5. Should minimal dissection or maximal dissection* be used in adult and pediatric patients with GERD?

(*Minimal dissection was defined as minimal mobilization with no violation of the phrenoesophageal membrane, and maximal dissection was defined as circumferential division of the phrenoesophageal attachments).

Recommendations

1. Surgical (fundoplication) versus medical (PPI) management in adult and pediatric patients with chronic or refractory GERD

   1a The panel suggests managing adult patients with confirmed chronic or chronic refractory gastroesophageal reflux with surgical fundoplication rather than continued medical treatment (conditional recommendation based on very low certainty in the evidence of effects).
   1b No recommendation was made with regard to pediatric patients.

2. Robotic versus laparoscopic fundoplication in adult and pediatric patients with GERD requiring surgery

   2a The panel suggests that adult patients with gastroesophageal reflux who are candidates for surgery be treated with either robotic or laparoscopic fundoplication based on surgeon and patient's shared decision-making (conditional recommendation based on low certainty in the evidence of effects).
   2b The panel suggests that children with gastroesophageal reflux who are candidates for surgery be treated with either robotic or laparoscopic fundoplication based on surgeon and patient's shared decision-making and feasibility (conditional recommendation based on very low certainty in the evidence of effects).

3. Complete versus partial fundoplication in adult and pediatric patients with GERD who are candidates for surgery

   3a The panel suggests that adult patients with GERD who are candidates for surgery be treated with either partial or complete fundoplication based on patient values (conditional recommendations based on low certainty in the evidence of effects).

  - For patients who value improvement in reflux symptoms over the risk of dysphagia, complete fundoplication may be the preferred option.
  - For patients who value the minimization of dysphagia highly, partial fundoplication may be offered preferentially.

3b For pediatric patients without large hiatal hernia, the panel suggests either partial or complete fundoplication approaches guided by shared surgeon–patient decision-making (conditional recommendations based on low certainty in the evidence of effects).

4. Division of short gastric vessels or no division in adult patients with GERD undergoing fundoplication?

For adults undergoing fundoplication for GERD, the panel suggests either division or no division of short gastric vessels (conditional recommendations based on very low certainty in the evidence of effects).

- For patients who value reflux symptom relief more than the long-term risk of gas bloat or small risk of more procedural complications, division of short gastric vessels may be the preferred option.
- For patients who value long-term gas bloat, procedural complications, or both more than the improvement in their reflux symptoms, no division may be offered preferentially
- Minimal versus maximal dissection in pediatric patients with GERD undergoing fundoplication

In the pediatric GERD population without large hiatal hernias undergoing fundoplication, the panel suggests minimal rather than maximal dissection during fundoplication (conditional recommendations based on moderate certainty in the evidence of effects).

Aim of these guidelines and specific objectives

The purpose of these guidelines is to provide evidence-based recommendations from a surgeon and patient perspective regarding the surgical treatment of gastroesophageal reflux (GERD). This review assessed outcomes of antireflux surgery versus medical management of GERD in adults and children, robotic versus laparoscopic fundoplication, complete versus partial fundoplication, division or preservation of short gastric vessels in adults, and minimal versus maximal dissection in pediatric patients. The key target audience includes patients, surgeons, and gastroenterologists in a clinical setting. In addition, policy makers and insurance providers involved with healthcare services involving the treatment of GERD or evaluating benefits, harms, and costs associated with the procedures performed to treat the condition may also take these guidelines into consideration in their discussions and planning. Given that a patient–surgeon perspective was taken, and not a population perspective, considerations such as resources required, certainty of evidence of required resources, cost effectiveness, and equity were not evaluated.

Description of the health problem

Gastroesophageal reflux is defined as the passage of gastric contents from the stomach into the esophagus. Gastroesophageal reflux disease (GERD) refers to the pathological symptoms and complications that result from reflux. GERD is a very common condition and affects approximately 27% of adults and 7–20% of the pediatric population [2–4]. Medical treatment is frequently used as the initial treatment for GERD. Medical therapy usually consists of proton pump inhibitors (PPI), although H2 blockers are also a common medical therapy for GERD [5]. However, failure of medical treatment, side effects from medication, or complications from GERD are indications for surgical treatment. The decision as to which treatment modality should be recommended is difficult. In addition, there are a number of technical considerations that may affect the outcome of antireflux surgery that need to be considered. These include whether to perform partial versus total fundoplication, divide the short gastric vessels or not, whether to use a laparoscopic or robotic approach, or to provide minimal or maximal dissection in the pediatric population. These guidelines provide recommendations regarding the surgical treatment of GERD.

The statements included in this guideline are the product of a systematic review of published literature on the topic, and the recommendations are explicitly linked to the supporting evidence. The strengths and weaknesses of the available evidence are highlighted and expert opinion sought where the evidence is lacking. This is an update of previous guidelines on this topic (last revision 02/2010) as new information has accumulated.

Methods

A systematic review of the evidence informed the guideline recommendations. The guideline panel developed and graded the recommendations employing the *Grading of Recommendations Assessment, Development and Evaluation* (GRADE) approach [6–8] and using the GRADE guideline development tool [9]. Reporting of the guideline adheres

to the *Essential Reporting Items for Practice Guidelines in Healthcare* (RIGHT) checklist [10].

Guideline panel organization

Expert surgeons and gastroenterologists as guideline panelists developed evidence-based guideline recommendations. The panel primarily was composed of surgeons, both adult and pediatric, with gastroenterologist representation from the American Society of Gastrointestinal Endoscopy. A methodologist with guideline development expertise (M.T.A.), the SAGES Guidelines Committee Fellow (R.D.), and the first author of the systematic review (S.M.) facilitated guideline panel meetings as non-voting members of the panel. The panel used the GRADE methodology to review the systematic review evidence and judge the certainty of evidence and the strength of guideline recommendations [11].

After an introductory online conference reviewing the process and expectations, the panel convened during spring 2020 for a series of online video panel meetings. Panel members were provided with the articles and the methods and results of the systematic review pertinent to a key question 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 tables, and generated specific recommendations.

The guideline panelists formulated key questions and corresponding PICOs (patient—intervention—comparator—outcome) in consultation with the methodologist and Committee Chair (D.S). The systematic review of the evidence addressing the guideline questions has been published as a standalone manuscript [12].

Guideline funding and declaration and management of competing interests

SAGES provided funding for the librarians who assisted with the systematic review, for the methodologist, and for half the salary of the Guidelines Committee Fellow. No grants or other support came from industry, nor any input into the conception or development of this guideline. A SAGES standard conflict of interest form was collected from all guideline contributors by the guideline lead (B.S.). A full list of declarations is listed at the end of the manuscript.

Selection of questions and outcomes of interest

The use and techniques of operative treatment for GERD are the focus of this guideline. Given their longstanding experience with patients, panel members voted for outcomes that they considered most patient–surgeon dyads would consider important or critical for decision-making. The final set of question specific outcomes were selected by simple majority. Some outcomes, such as quality of life, were measures with multiple metrics, in which case a standardized effect was used. This is discussed in more detail in the separately published systematic review [12].

Evidence appraisal

GradePro evidence tables were populated with evidence from the SAGES systematic review and meta-analysis to facilitate evidence appraisal and panel decision-making. Comparative data alone was used for the tables and RCT data were kept separate from observational study evidence. Methods outlined in the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach handbook [13] were used to appraise the available evidence. In brief, the guidelines systematic review working group judged certainty of evidence using risk of bias across available studies, inconsistency, indirectness, and imprecision. When enough studies were available for an outcome to reasonably assess publication bias (> 10 studies), a forest plot was constructed. Otherwise, selective reporting within studies was part of individual study risk of bias assessment. When confidence intervals were not statistically significant it would be judged as imprecise evidence. This evidence was still considered in decision-making, but its poor quality was acknowledged and was reflected in the low or very low certainty for a recommendation.

The panel reviewed judgments on the certainty of available evidence and voted on the importance of outcomes for decision-making. Outcomes considered "not important" for decision-making were not used in the evidence-to-decision table, while "important" or "critical" outcomes formed the basis of guideline decisions. The clinical importance of each outcome was determined by each panel member while voting; no preset minimally clinical important difference (MCID) was assigned for outcomes. Because the individual patient–surgeon perspective was taken for this guideline, cost was only included as a desirable or undesirable effect as it applied to out-of-pocket expenses or was considered in feasibility as below.

Development of recommendations

Critical and important to decision-making outcomes were imported into GRADEPro Evidence to Decision tables (EtD) as desirable or undesirable effects for the intervention at hand. The panel then discussed the magnitude of desirable and undesirable effects, listed as absolute percent difference below unless stated otherwise, the certainty of evidence, variation in values that may be assigned to outcomes, and balance of these effects. Absolute percent differences were calculated by the GRADEPro software based on systematic

review data. After choosing whether the intervention, comparator, or combination was favored by the balance of these considerations, the panel discussed the acceptability and feasibility of this judgment. For each decision, both the available evidence was discussed as well as pertinent additional considerations taken either from panel expert experience or interpretation of evidence. Based on the balance of effects and the acceptability and feasibility of a favored option, the panel voted on the final recommendation for that key question. While serial voting was used to come to a consensus on individual components of the EtD, 80% panel agreement was mandatory for all final recommendations. Voting was done anonymously.

Subgroups, such as pediatric patients, were addressed in discussion for the justification for each recommendation and are specified for each key question below. Full evidence to decision tables are presented in Appendix 1–7 and summarized in the following recommendations.

Assumed values and preferences

The panel members used their collective patient experience to approximate judgments about patient values and preferences as well associated variability. Empiric evidence was not specifically searched as it was anticipated not to exist by subject matter experts.

Guideline document review

This guideline was reviewed and edited by all panel members. In accordance with SAGES Guidelines Committee policies, the revised draft was distributed to the committee for comments. 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.

Key questions

Key question 1 (KQ1): Should surgical (fundoplication) or medical (PPI) management be used in adult and pediatric patients with GERD?

Key question 2 (KQ2): Should robotic or laparoscopic fundoplication be used in adult and pediatric patients with GERD?

Key question 3 (KQ3): Should complete or partial fundoplication be used in adult and pediatric patients with GERD?

Key question 4 (KQ4): Should division of short gastric vessels or no division of short gastric vessels be performed in adult patients with GERD?

Key question 5 (KQ5): Should minimal dissection or maximal dissection be used in pediatric patients with GERD?

(KQ1) should surgical (fundoplication) or medical (PPI) management be used in adult and pediatric patients with GERD?

Recommendation

We suggest that adult patients with confirmed chronic or chronic refractory gastroesophageal reflux may benefit from surgical fundoplication over medical management. The panel judged there are moderate desirable effects of surgery over medical management which outweighed small undesirable effects. This balance favoring surgery would likely apply to most adult patients with GERD. However, due to very low certainty evidence, only a conditional recommendation could be made.

Summary of the evidence

Data from 15 RCTs from the systematic review were deemed critical or important to clinical decision-making for this question and were used to inform the panel's decision. The main limitation was that a large portion of studies ultimately included in panel decision-making were high risk of bias.

Benefits

There were four outcomes with desirable effects for surgery including percent time with abnormal pH, post-intervention PPI use, short-term quality of life, and long-term symptom control that were included for decision-making. In regard to percent time with abnormal pH, three RCTs with a total sample size of 572 patients were pooled to demonstrate a mean difference of 2.11% less time with abnormal pH (pH < 4) in surgical patients compared to patients only treated medically. For PPI use, there was 43.8% more PPI use in the medically treated arm in three RCTs with 671 patients. Of note, however, over 25% of patients in the operative arm still needed PPI during long-term follow-up (> 5-year follow-up), while 72% of patients in the medical group were still on PPI during long-term follow-up. The short-term quality of life was greater in the surgical arm by 0.51 standard deviations, when pooling quality of life metrics using different scales from four RCTs with 1169 total patients. Long-term symptom control also favored surgery with 16.6% more patients reporting symptom control compared to those treated with PPI in a pooled analysis of five RCTs with a total of 748 patients; specifically, 79.2% of surgical patients reported symptom control compared to 62.6% of medical patients.

The combined magnitude of these favorable effects was determined to be moderate by the panel.

Harms and burden

From the available outcomes that were critical or important for decision-making, there were three outcomes with undesirable effects for surgery. These included short-term complications (Clavien-Dindo ≥ 3) [14], gas bloat symptoms, and treatment failure. In five RCTs with 1129 total patients, the pooled complication rate was 2.9% less for the medical treatment arm (10.5% of surgical patients versus 7.5% of medical patients). Reoperation for symptom recurrence was not included in complications but was evaluated as a separate outcome. Two RCTs with a total of 485 patients were pooled for treatment failure rate, defined as reoperation or operation for symptom recurrence, and demonstrated a pooled rate of 2.4% less need for operation in the medical arm. Of note, 2.6% of medically treated patients still ended up receiving surgery. In a single RCT with 554 patients reporting on gas/bloat symptoms, 12% more surgical patients had gas/bloat symptoms. Overall, the panel felt the combined magnitude for these undesirable effects for surgery was small.

Certainty in the evidence of effects

The certainty of the above evidence was evaluated as very low based on the outcomes deemed critical to decision-making by the panel: complications, treatment failure, and long-term symptom control. These critical outcomes were primarily limited by imprecision and a large proportion of evidence from high risk of bias studies. (*see evidence profile in the EtD framework, Appendix 1*).

Decision criteria and additional considerations

This recommendation does not address pediatric patients due to a lack of comparative data. However, there is evidence that fundoplication is beneficial for pediatric patients with GERD in the long term (10-year follow-up) [15]. In addition, there is a growing body of literature that demonstrates PPI use may have additional drawbacks in the pediatric population, including increased risk of fracture from PPI-induced osteoporosis. Although there is no comparative data on this risk, a recent large single-arm registry-based cohort study that evaluated 115,933 children from Sweden [16], demonstrated an increased risk of fracture within the 2-year study follow-up period (HR 1.34; 95% CI 1.13–1.58). This could further reinforce the recommendation for surgical management of GERD in pediatric patients. The panel additionally acknowledged that PPI use as an outcome can be a poor proxy for objective reflux, given previously cited poor correlation between the two [17, 18].

Conclusions

The desirable anticipated effects for fundoplication compared to PPI were judged to be moderate and the undesirable effects for fundoplication were judged to be small. The panel agreed that the balance of effects favored surgical fundoplication over medical management in adults.

Research recommendations

Large, well-designed RCTs comparing medical treatment to surgical therapy are required. In addition to the lack of low risk of bias studies, the surgical procedures are not always well described in the studies. Finally, in these studies, the interventions are often performed by subspecialists in high volume centers thus limiting the generalizability to other centers. Comparative studies in pediatric populations are additionally needed.

(KQ2) Should robotic or laparoscopic fundoplication be used in adult and pediatric patients with GERD?

Recommendation

We suggest that adult patients with gastroesophageal reflux may be treated with either robotic or laparoscopic fundoplication based on surgeon and patient's shared decision-making. (Conditional recommendation based on low certainty in the evidence about effects) No evidence-based recommendation can be made for patients who are undergoing revisional fundoplication. Based on low certainty evidence available, the panel judged there are trivial differences in efficacy and safety between robotic and laparoscopic fundoplication. Patients' values and preferences for outcomes, overall certainty about the estimates of effect, and the feasibility of performing robotic fundoplication were considered in making recommendations. These data may not reflect the balance of effects for revisional cases, however. This population requires further research before a recommendation can be made.

The panel suggests that children with gastroesophageal reflux may be treated with either robotic or laparoscopic fundoplication based on surgeon and patients' shared decision-making and feasibility (Conditional recommendation based on very low certainty in the evidence about effects). No evidence-based recommendations can be made for patients who are undergoing revisional fundoplication.

Based on the limited and low certainty evidence available, the panel judged there are trivial differences in efficacy and safety between robotic and laparoscopic fundoplication. Each patient's values for other decision-making outcomes and the local feasibility of performing robotic fundoplication need to be discussed to make a final

decision. These data may not reflect balance of effects for revisional cases, however. This population requires further research before a recommendation can be made.

Summary of the evidence

In adults, four randomized control trials on robotic versus laparoscopic fundoplication were used from the systematic review to inform the panel's decision based. In children, four observational studies on robotic versus laparoscopic fundoplication were used from the systematic review to inform the panel's decision; three [19–21] used Nissen and one [22] used Thal fundoplication. There was no significant heterogeneity in the reported outcomes between these papers.

Benefits

In adults

The main desirable effect for robotic approach was decreased postoperative PPI use. The panel felt this outcome had varied importance for decision-making. A single RCT with 40 patients [23] demonstrated 12.9% fewer patients were using PPIs after robotic fundoplication compared to laparoscopic fundoplication. This study was particularly limited by small sample size and imprecision with a statistically non-significant CI for PPI use. The panel believed the degree of desirable effect ultimately varies based on the value taking a PPI post intervention has to a patient. The panelists varied in whether post-intervention PPI should even be included as a decision-making outcome as PPI use does not correlate with reflux symptoms. The panel further observed the inconsistency in the direction of effect between symptom control and PPI use. As such, an important proportion of informed patients would likely consider PPI use as of low importance for decision-making.

Notwithstanding, the panel acknowledged a subgroup of patients for whom PPI use would be an important or even critical decision-making outcome, particularly patients who opt for the procedure because of their concerns about long-term PPI use. For this subgroup of patients, PPI use would be an important outcome for decision-making, with small or even moderate magnitude of the observed desirable effect.

Short-term GI quality of life was deemed a critical outcome for decision-making which favored neither intervention nor comparator. Two RCTs with different scales for GI quality of life yielded a standardized mean difference of 0.01 standard deviations better in patients undergoing the robotic approach.

In children

The main desirable effect for the robotic approach in children was decreased complications (Clavien-Dindo score ≥ 3) and decreased patient-reported dysphagia, both considered important for decision-making. In four observational studies with a combined sample size of 182 patients, there were 1.1% fewer complications with the robotic approach. Regarding patient-reported dysphagia, a single observational study with 50 patients showed there were 2.7% fewer patients with dysphagia after the robotic approach.

There was additional evidence on patient-reported symptom control and reoperation for wrap failure, considered important and critical for decision-making, respectively, which did not favor either intervention or comparator. Three observational studies showed there was 0% difference in symptom control (82 total patients), and a single observational study showed 0% difference in reoperation for wrap failure due to no events in either arm (50 total patients). The panel believed the degree of the combined desirable effect was trivial.

Harms and burden

In adults

Short-term symptomatic reflux control, reoperation due to wrap failure, and complications were undesirable effects for robotic fundoplication relative to laparoscopic. Two RCTs with 90 total patients had a pooled absolute difference of 4.8% fewer patients with short-term symptomatic reflux control, with 3–6 and 12 months of follow-up. One of those RCTs with 40 patients showed no difference in reoperation due to wrap failure, with no wrap failures in either arm (absolute difference of 0%). In three RCTs with a total 140 patients, there was a pooled difference of 1% more complications. Complications were defined as Clavien-Dindo score ≥ 3 and the follow-up ranged from perioperative to 12 months. Overall, the panel voted the combined magnitude of these undesirable effects was trivial.

In children

There were no reported undesirable effects based on the available evidence.

Certainty in the evidence of effects

The certainty of the above evidence was evaluated as low for adults based on the outcomes deemed critical to decision-making by the panel: symptomatic reflux control < 5 years, complications, and GI quality of life. For some patient populations, long-term PPI use was also deemed critical,

however, this outcome was limited by its indirect representation for the clinically relevant outcome of recurrent reflux. The other critical outcomes were primarily limited by wide confidence intervals and small sample sizes. (*see evidence profile in the EtD framework, Appendix* 2*a*, *b*).

The certainty of the evidence was evaluated as very low for pediatrics on the critical outcome: reoperation for wrap failure mainly, due to the fact that there were no reported events and thus no effect could be estimated, as well as the limited number of studies.

Decision criteria and additional considerations

The panel felt there may be some stakeholders, including some hospitals and a minority of practicing surgeons, who would not find the robotic approach for fundoplication acceptable. While robotic surgery has become more common recently, the robotic approach still requires additional certification and an investment in a robot platform. The feasibility thus varies based on access to facilities who have made that investment and have surgeons certified in the robotic approach. The panel agreed that higher costs for robotic fundoplication could contribute to decreased feasibility [24], however, the panel did not do a dedicated cost analysis given these recommendations were from an individual patient perspective and not a societal perspective. The research evidence presented does not mean patient out-of-pocket cost is greater, but that due to expense of institutional acquisition, the robotic approach may be less feasible. To improve feasibility for robotic fundoplication, the panel opined that considerations for increased surgeon training are needed for both the adult and pediatric population. Additionally, for pediatric patients, robotic instruments are not currently sized for convenient use in small children. The development of smaller instruments may improve feasibility.

Conclusions

The panelists agreed that the evidence provided does not favor either robotic or laparoscopic approach for fundoplication in terms of safety or efficacy for both adults and children.

Research recommendations

Future studies on robotic versus laparoscopic fundoplication in adults with GERD include long-term effectiveness data, long-term cost- effectiveness studies, including cost of both operations (laparoscopic versus robotic) and long-term care (medications and reoperation), PPI use, potential benefits of the robotic techniques for reoperation, and additional studies comparing patient-reported pain in robotic versus laparoscopic surgery.

(KQ3): should complete or partial fundoplication used in adult and pediatric patients with GERD?

Recommendation

For adult patients with GERD, the panel suggests either partial or complete fundoplication approaches may be used guided by patient values (Conditional recommendations based on low certainty in the evidence about effects). For patients who value improvement in reflux symptoms over the risk of dysphagia, complete fundoplication may be the preferred option. However, for patients who value the minimization of dysphagia highly, partial fundoplication may be offered preferentially. There are mixed data to support both the intervention and the comparator. While the magnitude of overall effect is similar for desirable and undesirable effects, the values patients place on individual outcomes possibly vary such that these values can change the balance of effects.

Guided by shared surgeon–patient decision-making, we suggest either partial or complete fundoplication approaches be used for pediatric patients with GERD but without large hiatal hernia (Conditional recommendations based on low certainty in the evidence about effects). There is balanced evidence and the choice is likely influenced by surgeon practice patterns.

Training and familiarity with both partial and complete fundoplication is needed for this recommendation.

Summary of the evidence

From the recent systematic review, 22 randomized controlled studies on partial versus complete fundoplication in adults were used to inform the panel's decision. Two observational studies and a randomized controlled study on partial versus complete fundoplication in children were used to inform the panel's decision.

Benefits

In adults

Long-term dysphagia and short-term quality of life were outcomes which favored partial fundoplication from the systematic review. For long-term dysphagia (follow-up > 5 years), four RCTs with 400 total patients demonstrated a pooled difference of 7.4% fewer patients with dysphagia in partial fundoplication compared to total fundoplication (CI 13.2% fewer to 0.5% more). Five RCTs with a total of 754 patients provided evidence on short-term QoL (follow-up < 5 years), demonstrating a SMD of 0.12 standard deviations greater

QOL in partial fundoplication patients (CI 0.02 SD lower to 0.26 SD higher).

As noted in values below, some patients may place greater or less value on long-term dysphagia, influencing its estimated effect for them. Most panel members believed the size of the overall desirable effect, independent of value placed on different outcomes, however, was small. The overall desirable effect in adults was deemed small by the panel, while a minority felt that the effect magnitude could be moderate.

Given no difference in failure, defined as reoperation due to symptom recurrence, this outcome was seen as neither a desirable nor undesirable effect based on the available evidence. From 15 RCTs with a total of 1936 patients, there were 0.2% fewer failures with partial fundoplication (CI 2% fewer to 2.7% more).

In children

Long-term dysphagia, EGD with or without dilation and postoperative PPI use were desirable outcomes for partial fundoplication in children deemed critical or important for decision-making from the systematic review. Long-term dysphagia (follow-up > 5 years) was taken from a single observational study with 238 patients that demonstrated 2.2% fewer patients with dysphagia (CI 3.8% fewer to 4.9% more) with partial fundoplication. EGD with or without dilation was taken from a single RCT with 167 patients and was present in 9.3% fewer patients with partial fundoplication (CI 11.2 to 0.9% fewer). Post-operative PPI use was taken from the same RCT with 167 patients; there were 3.2% fewer patients with partial fundoplication taking PPI (CI 8.8% fewer to 10.1% more). The overall magnitude of these desirable effects was deemed moderate.

Harms and burden

In adults

From the original systematic review, increased postoperative PPI use and decreased long-term symptom control were undesirable outcomes for partial fundoplication. There was 5.6% more postoperative PPI use (CI 0.6% fewer to 15% more) in partial fundoplication in 5 RCTs with a total of 496 patients. For long-term symptom control (> 5-year follow-up), there were 5.1% fewer patients with symptom control (CI 12.8% fewer to 3.4% more) in partial fundoplication, pooled from 6 RCTs with a total of 865 patients. In adults, the magnitude of these statistically non-significant undesirable effects was deemed small.

In children

The only undesirable outcome for partial fundoplication considered a critical or important outcome for decision-making was wrap failure. This was taken from a single RCT with 167 patients, demonstrating 10% more failures (CI 0.1% more to 36.6% more) in partial fundoplication. The overall undesirable effect in adults was deemed moderate by the panel.

Certainty in the evidence of effects

The certainty of the above evidence was evaluated as low for adults and pediatric patients based on the outcomes deemed critical to decision-making by the panel: long-term dysphagia and wrap failure in both populations and need for dilation in the pediatric population. These critical outcomes were primarily limited by study small sample sizes and wide confidence intervals. *(see evidence profile in the EtD framework, Appendix 3a,b).*

Decision criteria and additional considerations

The need for postoperative dilation may vary in decision-making importance. Additionally, the indication for fundoplication and symptoms patients experience can influence the value they put on their symptoms for decision-making. Patients undergoing fundoplication for lung transplant protection, for example, may find risks for other symptoms (such as dysphagia and gas bloat) as overall not as important as reflux control. The panel additionally agreed there would possibly be patients who value dysphagia, post-intervention PPI use, and symptom control differently.

Some patient populations would favor minimizing reflux, and some would favor minimizing dysphagia. For the former as well as those patients who greatly value decreased PPI intake, the balance would probably favor the comparison (complete fundoplication) and for the latter, the balance would probably favor the intervention (partial fundoplication).

While the option of either intervention or comparator based on patient values is likely to be acceptable to stakeholders, the acceptability may be subject to the influence of individual training and local practice.

Conclusions

The panelists agreed that the evidence provided does not favor either partial or complete fundoplication for both adults and children.

Research recommendations

The panel made recommendations for future stratified studies including patients who failed PPI (medically refractory) versus those whose symptoms are controlled on PPI, patients facing reoperation (i.e., have already failed antireflux surgery), patients with a history of lung transplantation, or those with previous endoscopic reflux operations. In addition, future studies should focus on the use of a bougie as a subgroup analysis or as its own comparator, additional evidence on types of partial wrap as a subgroup analysis or as its own comparator, and studies with long-term effectiveness outcomes (reflux control and dysphagia and other side effects) in a larger sample of patients with limited attrition. The panel made multiple recommendations for future studies on robotic versus laparoscopic fundoplication in children with GERD, based on current lack of evidence, including neurologically impaired versus not neurologically impaired, effect of bougie on partial versus complete fundoplication outcomes, choice of partial wrap type, and additional studies stratifying by different pediatric age groups to determine if partial versus complete varies with age of patient for long-term outcome. For example, does a partial wrap in an infant last as well as a complete wrap long-term?

(KQ4): should division of short gastric vessels or no division be performed in adult patients with GERD?

Recommendation

For adults undergoing fundoplication for GERD, the panel suggests either division or no division of short gastric vessels may be used. (Conditional recommendations based on very low certainty in the evidence about effects). For patients who value reflux symptom relief more than the long-term risk of gas bloat or small risk of more procedural complications, division of short gastric vessels may be the preferred option. Patients who value long-term gas bloat, procedural complications, or both more than the improvement in their reflux symptoms, no division may be offered preferentially.

Summary of the evidence

From the systematic review, eight reports on randomized controlled trials on division versus no division of the short gastric vessels were used to inform the panel's decision. All trials used Nissen fundoplication. Three manuscripts pertained to the same randomized study [25–27], so these were never pooled to avoid duplicate counting of the same patients.

Benefits

From the original systematic review, long-term dysphagia, postoperative PPI use, and symptom control were included as critical or important decision-making outcomes that were a desirable effect for division of the short gastric vessels during Nissen fundoplication. Long-term dysphagia (follow-up 5–20 years) was pooled from RCTs with a total of 192 patients and there was 1% less dysphagia with division compared to no division (CI 11.1% fewer to 13.7% more). From 2 RCTs with 151 patients, there was 5.8% less PPI use (at 10–20-year follow-up) in division patients (CI 13.8% fewer to 10.1% more). Symptom control was taken from a single RCT with 10-year follow-up and 82 patients and demonstrated a difference 13.2% greater control with division of the short gastric vessels (3.1% fewer to 32.5% more).

Harms and burden

Complications and long-term gas bloat symptoms were undesirable effects considered during guideline decision-making. Complications, defined as Clavien-Dindo score ≥ 3, were taken from four RCTs with follow-up ranging from 6 month to 1 year and a total of 327 patients, demonstrating 1.8% more complications in patients with short gastric division (CI 0.7% fewer to 10.5% more). 2 RCTs with 10–20-year follow-up and 151 total patients demonstrated 21.8% more patients with gas bloat (CI from 12.2% fewer to 85.6% more).

The panel expressed concern for the high complication rate that could be due to the early learning curve and which does not seem congruous with recent complication rates for this procedure. The effect of a concurrent emptying procedure (pyloroplasty) or gastrostomy placement for prevention of gas bloat was contemplated. In these situations, gas bloat may be decreased but the certainty and degree of this effect is unknown.

Certainty in the evidence of effects

The certainty of the above evidence was evaluated as very low based on the outcomes deemed critical to decision-making by the panel: complications, long-term dysphagia, and long-term symptom control. These critical outcomes were primarily limited by small sample size and large confidence interval in most studies, and high risk of bias for varying reasons in many studies including attrition bias and lack of blinding. (*see evidence profile in the EtD framework, Appendix 4*).

Decision criteria and additional considerations

For those trained to do either division of the gastric vessels or no division, both options would be feasible based on training. Technically, the feasibility varies based on individual patient anatomy. Division may be necessary in situations where a tension-free wrap is not possible otherwise.

Conclusions

The panelists agreed that the evidence provided does not favor either division or no division of the short gastric vessels.

Research recommendations

The panel recommended that additional comparative studies using contemporary techniques would be beneficial.

(KQ5): should minimal dissection or maximal dissection be used in pediatric patients with GERD?

Recommendation

In the pediatric GERD population without large hiatal hernias undergoing surgery, the panel suggests minimal dissection rather than maximal dissection during fundoplication (Conditional recommendations based on moderate certainty in the evidence about effects). Given no comparative evidence in adults, no recommendation is given for adults.

Summary of the evidence

From the original systematic review, a single randomized controlled trial on minimal dissection versus maximal dissection during Nissen fundoplication was used to inform the panel's decision [28]. Minimal dissection was defined as minimal mobilization with no violation of the phrenoesophageal membrane, and maximal dissection was defined as circumferential division of the phrenoesophageal attachments.

Benefits

Outcomes that were critical or important for decision-making and which demonstrated desirable effect for minimal dissection included endoscopic dilation, reoperation for wrap failure, readmission for respiratory cause, and weight gain. Endoscopic dilation was 7.9% less common in minimal dissection patients (CI 8.6% fewer to 3.9% more), reoperation for wrap failure was 18.1% less common (CI 21.5% fewer to 7.5% fewer), readmission for respiratory cause was 5.0% less common (CI 11.2% fewer to 7.9% more), and weight gain was 6.9% more common (1.7% fewer to 17.2% more).

Harms and burden

There were no undesirable effects for minimal dissection based on the limited evidence available. Based on their experience and personal observations, the panel agreed there were trivial if any undesirable effects for minimal dissection.

Certainty in the evidence of effects

The certainty of the above evidence was evaluated as moderate based on the outcome deemed critical to decision-making by the panel: reoperation for wrap failure. This critical outcome was primarily limited by the small sample size of a single RCT. (*see evidence profile in the EtD framework, Appendix* 5).

Decision criteria and additional considerations

No evidence was found for adult patients and the panel did not think that pediatric findings would be generalizable to adult patients.

Conclusions

The panel was in agreement that the evidence clearly favors minimal dissection, though some minority of the panel members felt the degree of certainty in the evidence may warrant a less definitive recommendation.

Research recommendations

The panel made recommendations that research priorities include the need for studies in adults, additional studies with longer follow-up and minimal attrition to determine long-term failure rates, and additional research on the degree of mobilization appropriate in the setting of concomitant hiatal hernia.

Discussion

What is new in these SAGES guidelines?

Many guidelines have previously been published on gastroesophageal reflux disease since the 2010 SAGES guideline [29–49]. While surgery is often mentioned as an option for medically refractory GERD [37, 40, 42, 44, 46, 48, 49], only a handful of guidelines have focused in detail on surgical management of GERD. Most of these share the conclusion that fundoplication is an efficacious option compared to medical treatment [29, 34, 35, 41, 43, 45], and some systematic reviews even share similar conclusions that surgical treatment of GERD is more effective than medical treatment

for short- and medium-term outcomes in adults [5, 50]. Multiple guidelines also share the evaluation that partial fundoplication yields less dysphagia than complete fundoplication and they recommend either fundoplication can be used [34, 35, 41, 43, 45]. This guideline delves into additional technical considerations for laparoscopic fundoplication in its remaining key questions than other guidelines on GERD.

Another main difference between this guideline and others is the focus on outcomes critical to clinical decision-making and individualized recommendations based on a balance of clinical effects. This guideline emphasizes the values key stakeholders place on different outcomes and how this can affect individual recommendations. For example, while this guideline also recommends either a partial or a complete wrap can be performed, it specifies that this judgment should be based on the patient values and preferences, specifically regarding dysphagia.

Implementation and revision of these guidelines

Implementation

The panel believes that it is feasible to successfully implement these recommendations into local practice and that the recommendations will be accepted by stakeholders.

Updating these guidelines

After publication of these guidelines, SAGES will plan to perform repeat literature searches on a frequent interval to search for any new evidence. It is planned that a formal update will be generated when substantive literature is identified. A separate multi-society guideline group has also commenced that includes SAGES as well as multiple other societies. This multi-society GERD guidelines has taken a broader approach with key questions less focused on surgical technique. This guideline group was in the process of conducting their systematic review at the time of this publication and is expected to publish their guideline in the next couple of years.

Limitations of these guidelines

One of the main limitations of these guidelines is related to the low certainty of the evidence for all of the key questions. Due to this, recommendations were often supplemented by expert opinion when strong evidence was lacking or deemed insufficient for decision-making. In addition, there was limited long-term data without outcome bias. The lack of long-term data decrease the ability to advocate for one approach over another particularly if the durability of surgical repair is an important factor for the patient. In addition, the panel that created this guideline consisted predominantly of academic surgeons and endoscopists. Thus, the panel members may not be representative of the various opinions and practices of the Societies and other practitioners. In addition, the level of importance for the patient-centered outcomes were decided by the panel members rather than by patient advocates. As such, some individual patients might place more weight on different outcomes which could change the balance of effects. While not a true limitation, the data often portrayed a complex balance of effects and values such that no singular recommendations could be made for most of the key questions. However, a strength of this guideline is the careful consideration for patient values and preferences in view of individual critical outcomes.

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. These guidelines are 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. These guidelines are applicable to all physicians who are appropriately credentialed regardless of specialty and address the clinical situation in question.

These guidelines are 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. New developments in medical research and practice pertinent to each guideline are reviewed, and guidelines are periodically updated.

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Declarations

Disclosures Bethany J. Slater—Consultant for Bolder Surgical, not relevant for this manuscript. Rebecca C. Dirks—Equity in Johnson & Johnson, not relevant for this manuscript. Nirav Thosani—Consultant for Boston Scientific Corporation, and Pentax of America; Research Support Pentax of America, and Endogastric Solutions, Royalty—UpToDate, Advisory Board member—ColubrisMx Endoluminal Surgical System, Speaker—Abbvie, Endoluminal Surgical System, Speaker—Abbvie, Not relevant for this manuscript. Aurora D. Pryor—receives honoraria for speaking from Ethicon, Gore, Medtronic, Merck, and Stryker, not relevant for this manuscript. Dimitrios Stefanidis—Dr. Stefanidis is part of the PREVENT Trial with Becton Dickinson, and his institution receives compensation for participation. Dr. Stefanidis receives research support for ExplORer and Intuitive. Sophia K. McKinley, Mohammed T. Ansari, Geoffrey P. Kohn, Bashar Qumseya, Sarah Billmeier, Shaun Daly, Catherine Crawford, Anne P. Ehlers, Celeste Hollands, Francesco Palazzo, Noe Rodriguez, Arianne Train, Eelco Wassenaar, and Danielle Walsh declare that they have no disclosures.

Conflict of interest Bethany J. Slater, Rebecca C. Dirks, Sophia K. McKinley, Mohammed T. Ansari, Geoffrey P. Kohn, Nirav Thosani, Bashar Qumseya, Sarah Billmeier, Shaun Daly, Catherine Crawford, Anne P. Ehlers, Celeste Hollands and Francesco Palazzo declares that there is no relevant conflict of interest with the submitted work.

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