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SAGES guidelines for the surgical treatment of hiatal hernias

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Abstract

Background Hiatal hernia (HH) is a common condition. A multidisciplinary expert panel was convened to develop evidence-based recommendations to support clinicians, patients, and others in decisions regarding the treatment of HH.

Methods Systematic reviews were conducted for four key questions regarding the treatment of HH in adults: surgical treatment of asymptomatic HH versus surveillance; use of mesh versus no mesh; performing a fundoplication versus no fundoplication; and Roux-en-Y gastric bypass (RYGB) versus redo fundoplication for recurrent HH. Evidence-based recommendations were formulated using the Grading of Recommendations, Assessment, Development, and Evaluations methodology by subject experts. When the evidence was insufficient to base recommendations on, expert opinion was utilized instead. Recommendations for future research were also proposed.

Results The panel provided one conditional recommendation and two expert opinions for adults with HH. The panel suggested routinely performing a fundoplication in the repair of HH, though this was based on low certainty evidence. There was insufficient evidence to make evidence-based recommendations regarding surgical repair of asymptomatic HH or conversion to RYGB in recurrent HH, and therefore, only expert opinions were offered. The panel suggested that select asymptomatic patients may be offered surgical repair, with criteria outlined. Similarly, it suggested that conversion to RYGB for management of recurrent HH may be appropriate in certain patients and again described criteria. The evidence for the routine use of mesh in HH repair was equivocal and the panel deferred making a recommendation.

Conclusions These recommendations should provide guidance regarding surgical decision-making in the treatment of HH and highlight the importance of shared decision-making and consideration of patient values to optimize outcomes. Pursuing the identified research needs will improve the evidence base and may allow for stronger recommendations in future evidence-based guidelines for the treatment of HH.

Keywords Fundoplication · Hiatal hernia · Mesh · Roux-en-Y gastric bypass · Recurrent hiatal hernia · Redo fundoplication

Abbreviations

GERD	Gastroesophageal reflux disease
GEJ	Gastroesophageal junction
GEFV	Gastroesophageal flap valve
GI	Gastrointestinal
GRADE	Grading of recommendations, assessment, development, and evaluations
KQ	Key question
OR	Operating room
PICO	Population, intervention, comparison, outcome
RCT	Randomized controlled trial
RR	Relative risk
RYGB	Roux-en-Y gastric bypass

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 hiatal hernias. The guidelines are based on systematically reviewed evidence of benefits and harms associated with surgical management options of using mesh versus no mesh, repairing an asymptomatic hiatal hernia versus continued surveillance, performing a fundoplication versus no fundoplication, and conversion to RYGB versus redo fundoplication in patients without obesity and with recurrent hiatal hernia. The key target audience includes patients, surgeons, and gastroenterologists in a clinical setting. In addition,

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health care services policy makers and insurance providers involved with the treatment of hiatal hernias 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

Hiatal hernia is a condition in which the stomach protrudes through the diaphragm [1]. There are four types of hiatal hernias which are defined by what is herniated through the diaphragm. Type 1 hiatal hernias, referred to as a sliding hiatal hernia, occur when the gastroesophageal junction (GEJ) is located above the hiatus. Type 2 hiatal hernias occur when the gastric fundus protrudes superior to the hiatus with the GEJ in normal position. Type 3 hiatal hernias are a combination of the previous and occur when both the stomach and GEJ are located superior to the hiatus. Finally, type 4 hiatal hernias occur when any additional organ is herniated with the stomach above the hiatus. The presence of hiatal hernia is closely associated with the development of gastroesophageal reflux disease (GERD) and its long-term complications including Barrett's esophagus and esophageal adenocarcinoma. The lack of the "pinch" effect of the crural diaphragm is a significant contributor to the gastroesophageal reflux seen in hiatal hernias.

Management is complex and based on multiple factors including size and type of hiatal hernia, degree of symptoms, and associated failure of symptom control by non-surgical means. Deciding whether to proceed with surgical repair of an asymptomatic hiatal hernia can be difficult. Technical decisions that may affect the outcome of hiatal hernia repair need to be considered as well. These include whether or not to use mesh or perform a fundoplication in primary hiatal hernia repair and whether a conversion to RYGB or reattempting fundoplication in patients without obesity and with recurrent hiatal hernia is most appropriate. These guidelines aim to provide recommendations on the aforementioned dilemmas.

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 [2]. The strengths and weaknesses of the available evidence are highlighted, and expert opinion was sought where the evidence is lacking. This is a complement to the previous guidelines on this topic, last revised in 2013, as new publications have accumulated [3].

Methods

The guideline panel utilized the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) approach to determine the certainty of the underlying evidence and the strength and direction of recommendations [4, 5]. GRADE is a transparent framework used to develop practice guideline recommendations using the best available evidence. The reporting of this guideline adheres to the Essential Reporting Items for Practice Guidelines in Healthcare checklist [6].

Guideline panel organization

The guideline panel was composed of active members of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). All panel members are practicing surgeons who perform hiatal hernia repairs. The panel also included two non-voting members to facilitate the panel discussions: a methodologist with guideline development expertise (M.T.A.) and the SAGES Guidelines Committee Fellow (S.S.K.).

Guideline funding and declaration and management of competing interests

SAGES provided funding for the methodologist, the systematic review statistician, the librarian, and partial salary support for the guidelines committee fellow. Part of this funding came from a SAGES Education & Research Foundation grant. None of these members were voting members of the guideline panel.

All voting members of the panel participated voluntarily without monetary compensation. Industry did not provide any financial support for or input on the development of these guidelines. All guideline panel members completed SAGES standard conflict of interest forms. The guideline lead and committee chair evaluated these declarations for any pertinent conflicts. All disclosed potential conflicts of interest are listed at the end of the manuscript.

Selection of questions and outcomes of interest

The surgical management of type II, III, and IV hiatal hernias is the focus of this guideline. Panel members developed key questions (KQs) in consultation with the guideline methodologist according to the Population, Intervention, Comparison, Outcomes (PICO) format. Outcomes specific to each KQ were determined by panel members

based on what they thought most surgeons and patients would consider important to their decision-making.

Some papers recorded the outcome of hiatal hernia recurrence by size criteria as evaluated by radiologic or endoscopic means, while others recorded it by the presence or absence of symptoms. We have defined the outcome "recurrence (symptomatic or large)" as those which measured > 2 cm in any direction or were symptomatic.

Patients who had preoperative dysphagia were considered in the outcome of "unresolved dysphagia." Conversely, patients without preoperative dysphagia were eligible to inform the outcome of "new dysphagia." The "total dysphagia" outcome included both patients with and without preoperative dysphagia. Dysphagia outcomes were categorized as "early" (3 months to 1 year postoperatively) or "late" (greater than 1 year postoperatively).

Evidence reviews and synthesis

The recommendations in these guidelines are based on a systematic review of the evidence pertaining to each KQ according to the SAGES standard operating procedure [2, 7]. In brief, PubMed, Embase, Cochrane, Clinicaltrials.gov, and International Clinical Trials Platform databases were searched for each KQ. Search strategies and Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagrams can be found in Appendices B and C. The highest-level evidence available was utilized.

Two independent reviewers screened each study for eligibility at both the abstract and full-text level. Reviewers reached consensus on both data extraction and quality assessment for each study. The Cochrane Risk of Bias tool and Newcastle–Ottawa Scale were used to assess the quality of randomized and non-randomized studies, respectively [8, 9]. Estimates of effect were synthesized using random effects meta-analysis when appropriate.

Of note, the outcome of dysphagia was reported with variable granularity. Not all studies accurately identified which patient had dysphagia at baseline. Even in the studies which did identify these patients, the authors did not always intend to investigate these outcomes, thus baseline dysphagia may have been unbalanced between the two arms at baseline and unaccounted for in the analysis. This frequently introduced greater risk of bias for the outcomes of new, unresolved, and total dysphagia.

Determining the certainty of evidence

GRADEPro evidence tables for each KQ were populated with highest level of evidence available for each outcome [10]. For each outcome, certainty of evidence was determined by evaluating the risk of bias, inconsistency, indirectness, and imprecision of the included studies. Too few studies were available to assess publication bias. Certainty level was downgraded if there were concerns in any of these domains. These data were then imported into the Evidence to Decision (EtD) table for each KQ. The EtD table serves as the framework through which the recommendations are developed. EtD tables are available in Appendix D.

Assumed values and preferences

As no patients participated in the creation of this guideline, panel members used their own clinical experience to make judgements about patient values and preferences. The potential for variability in these values across patients was addressed for each KQ. The proposed target audience of these guidelines is physicians who care for patients with hiatal hernias. The patients themselves may also use this guideline as a reference point in discussion with their physicians.

Development of recommendations

The panel convened throughout the spring of 2023 via a series of online video conferences. The results of the systematic review and relevant articles for each KQ were available for review in advance of the meetings. Panel members reviewed the evidence and then completed the EtD tables to generate recommendations during the meetings. The panel voted on the following criteria to determine the overall directions and strength of recommendations for each KQ's intervention: magnitude of desirable and undesirable effects, overall certainty of evidence across the critical outcomes, variation in value assigned to outcomes, balance of these effects, acceptability, and feasibility. All recommendations were formulated by voting with 80% consensus. Due to the limited evidence across KQs, recommendations were made conditionally, requiring patient-physician shared decision-making and taking patient values and preferences into account. When evidence-based recommendations could not be made because of absent or inconclusive evidence, expert opinion was documented.

Guideline document review

This guideline was reviewed and edited by all panel members and then submitted to the SAGES Executive Board for approval. It was published online (https://www.sages.org) for 2 weeks of public comment for additional quality assurance prior to final publication.

Key questions

- *KQ1*: in adult patients with type II, III, or IV hiatal hernia who are candidates for mesh placement, should mesh versus no mesh be used during hiatal hernia repair?

- *KQ2:* in adult patients with asymptomatic type II, III, or IV hiatal hernia, should repair of the hiatal hernia be done versus continued surveillance?
- *KQ3:* in adult patients with type II, III, or IV hiatal hernia, should a fundoplication be performed during surgical repair?
- *KQ4*: in adult patients without obesity and with recurrent type II, III, or IV hiatal hernia, should conversion to RYGB be performed versus redo repair of the hiatal hernia?

Recommendations

KQ1: In adult patients with type II, III, or IV hiatal hernia who are candidates for mesh placement, should mesh versus no mesh be used during hiatal hernia repair?

Recommendation: The expert panel has decided not to make an evidence-based recommendation for or against the use of mesh in hiatal hernia repair.

Summary of evidence

Data from 10 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 [11–20]. The main limitation was that the studies were often underpowered, and therefore, the confidence intervals for estimates of effect size frequently crossed the threshold of significance.

Benefits

There were six total outcomes which favored the placement of mesh during hiatal hernia repair, five of which did not reach statistical significance. These five outcomes were hiatal hernia recurrence (symptomatic or large), return to OR, early unresolved dysphagia, late total dysphagia, and postoperative quality of life.

There was one outcome favoring the placement of mesh during hiatal hernia repair which did reach statistical significance, which was late total dysphagia.

Hiatal hernia recurrence (symptomatic or large) was evaluated in five RCTs with a total sample size of 410 pooled patients. The relative risk (RR) of recurrence was 0.98. This would translate to 4 fewer recurrences per 1000 patients with the routine use of mesh (95% CI 97 fewer to 186 more).

Return to the operating room, evaluated in six RCTs with a total sample size of 587 pooled patients. The RR for this outcome was 0.75. This would mean 14 fewer patients requiring reoperation per 1000 patients with the routine use of mesh (95% CI 38 fewer to 50 more).

Early unresolved dysphagia was evaluated in two RCTs with a total sample size of 38 pooled patients. The RR for this outcome was 0.86. This translates to 74 fewer patients with unresolved dysphagia in the early postoperative period with the routine use of mesh (95% CI 289 fewer to 337 more).

Postoperative patient quality of life was evaluated in four RCTs but the manner in which they were evaluated did not permit meta-analysis. Oor et al. utilized satisfaction scores and found that patients who received mesh were slightly more satisfied [12]. Ilyashenko et al. used the GERD health related quality of life survey and found a statistically significant difference favoring mesh [16]. Watson et al. also used satisfaction scores but did not find a meaningful difference [17]. Oelschlager et al. used the SF-36 and found no difference between the two groups.

Late total dysphagia was evaluated in three RCTs with a total sample size of 276 pooled patients. The RR for this outcome was 0.49. This translates to 108 fewer patients with dysphagia in the late postoperative period per 1000 patients with the routine use of mesh (95% CI 153 fewer to 30 fewer).

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

Harms and burdens

From the available outcomes that were deemed critical or important for decision-making, there were four outcomes where repair without mesh was favored over mesh placement, none of which reached statistical significance. These included Clavien-Dindo grade 3 or greater complications, early new dysphagia, early total dysphagia, and late unresolved dysphagia.

Four RCTs with a total sample size of 462 patients reported on Clavien-Dindo grade 3 or greater complications. The RR for these complications was 1.36. This would translate to 19 more such complications per 1000 patients with the routine use of mesh.

New onset dysphagia in the early postoperative period was reported by one RCT with 37 patients. The RR was 4.75 based on 2/19 patients developing new dysphagia in the mesh group, while 0/18 developed new dysphagia in the primary repair group. However, this new dysphagia resolved in all patients on longer-term follow-up.

One RCT with 100 patients reported on total dysphagia in the early postoperative period. The RR was 3.00, which would translate to 80 more patients with dysphagia in the early postoperative period per 1000 undergoing routine mesh repair (95% CI 14 fewer to 526 more). However, total dysphagia in the late postoperative period was less common in the mesh group and is noted in the Benefits section above.

Lastly, two RCTs with 38 pooled patients reported on unresolved dysphagia in the late postoperative period. The RR was 1.51 which would translate to 161 more patients

with unresolved dysphagia per 1000 patients undergoing routine mesh repair (95% CI 92 fewer to 698 more).

Across three RCTs with 270 patients, there were no episodes of mesh erosion.

Overall, the panel felt the combined magnitude for these undesirable effects for mesh placement was small.

Certainty of evidence

The certainty of the above evidence was evaluated as low based on the outcomes deemed critical to decision-making by the panel. These critical outcomes were primarily limited by imprecision and one high risk of bias study due to concerns over the randomization process (see evidence profile in the EtD framework, Appendix D).

Decision criteria and additional considerations

This recommendation does not address the difference in patient outcomes in cases in which the crura could be reapproximated during repair versus those cases where the mesh was utilized to bridge a crura that could not be closed. Other factors which could not be objectively taken into consideration in critically evaluating the evidence is the tension on the crural repair, the use and need for a relaxing incision, and the tissue quality of the crura. These were identified as subgroups that warrant additional consideration when deciding whether to use mesh in hiatal hernia repair.

Conclusions

After extensive discussion and debate, the guideline panel decided against making a recommendation; the necessary evidence is simply lacking. The panel considered conditionally recommending against routine mesh use, as the benefits and harms appear closely balanced; if it truly makes no difference, why add an extra step? However, the confidence intervals for each outcome are wide, which means that the truth may be anywhere from mesh being quite beneficial to being quite harmful. The wide confidence intervals mean it is possible there are different morbidity profiles with mesh use; e.g., perhaps there is more dysphagia but less recurrence. If so, the decision for mesh use would be heavily influenced by how the individual patient values these outcomes. The current evidence is not strong enough to say this association exists with certainty. The decision for the use of mesh must continue to be a joint decision between surgeon and patient.

Research recommendations

Large, well-designed RCTs comparing the type of mesh used and the orientation of the mesh are warranted. Long-term follow-up of these patients is especially important for the outcomes of recurrence and any potential mesh complications. Quality of life measurements must be emphasized as this is primarily a quality of life operation.

KQ2: In adult patients with asymptomatic type II, III, or IV hiatal hernia, should repair of the hiatal hernia be done versus continued surveillance?

Summary of evidence

There was no evidence identified in the literature of truly asymptomatic patients being managed operatively or with surveillance. Given there was no evidence on which to base a recommendation, the panel formulated a recommendation based on expert opinion. This expert opinion is additionally limited by the lack of patient input.

Expert opinion

The management of the patient with an asymptomatic type II, III, or IV hiatal hernia is challenging given the poor evidence base. The first step is to ensure the patient is truly asymptomatic; many patients referred for an "asymptomatic" hiatal hernia are suffering from non-gastrointestinal symptoms which could be secondary to the hiatal hernia, including but not limited to shortness of breath, exercise intolerance, or abnormal echocardiogram findings.

One study of 270 patients undergoing hiatal hernia repair demonstrated presenting symptoms to include anemia in 24–57% of patients, dyspnea in 21–67%, and chest pain in 40–60% [21]. In instances when these symptoms cannot be reasonably attributed to a comorbid disease process, such patients can be considered symptomatic and offered repair if medically fit.

In cases where the patient is confirmed to have a true asymptomatic hiatal hernia, it is important to discuss the potential benefits of further workup. There is often discordance between patient symptoms and objective evidence of reflux. The Lyon consensus noted that a history taken by a gastroenterologist has a sensitivity of 70% and a specificity of 67% for GERD when compared against GERD defined by pH monitoring or endoscopy [22, 23]. Surgical repair can potentially prevent progression and/or complications of their reflux disease and/or hiatal hernia**.** Micro-aspiration is another potential sequela of an untreated hiatal hernia. Endoscopy is a good diagnostic test for both. Patients with objective evidence of reflux or findings of micro-aspiration can be offered repair if medically fit. Certain patient populations are so high risk for complications of micro-aspiration that they can be offered repair even in the absence of objective findings, such as lung transplant patients.

The management of patients without any objective evidence of reflux or micro-aspiration is controversial and

unfortunately there are no strong data on which to base decision-making. A thorough discussion of the potential to develop an acute gastric volvulus is essential to allow the patient to make an informed decision. It is also important to have a frank discussion about our inability to predict which patients are high risk for gastric volvulus, though the panel does consider pre-existing organo-axial rotation a concerning feature.

Several studies have tried to model the risk for progression to gastric volvulus compared to the benefits and risks of an elective hernia repair in the minimally symptomatic patient population. Two studies found the overall benefits in favor of the watchful waiting arm, acknowledging that a certain number of patients will electively cross over into the operative arm, while the third study found quality of life favored operative intervention [24–26]. These studies did not weight significantly in our discussion because they are models, and they are based on a symptomatic patient population. However, if the models are accurate, the theoretical benefits of watchful waiting are likely even greater in an asymptomatic patient population.

If the diagnostic workup is unrevealing and the patient understands and accepts the risk of developing gastric volvulus, it is reasonable to pursue a strategy of watchful waiting. Shared decision-making and thorough discussion are essential at all decision points of the evaluation for optimal outcomes.

Research recommendations

The most important research questions to pursue are what is the risk of an asymptomatic hiatal hernia progressing to an acute presentation with gastric volvulus and what factors place certain patients at higher-than-average risk? Without compelling evidence for these two questions, it is difficult to give comprehensive recommendations to patients presenting to clinic with asymptomatic hiatal hernias.

KQ3: In adult patients with type II, III, or IV hiatal hernia, should a fundoplication be performed during surgical repair?

Recommendation: The panel suggests patients undergoing repair of a type II, III or IV hiatal hernia may benefit from surgical fundoplication compared to no fundoplication (conditional recommendation, low certainty evidence).

Summary of evidence

Data from two RCTs [27, 28] and 6 observational studies [29–34] from the systematic review reported outcomes which were deemed critical or important to clinical decision-making for this question and were used to inform the panel's decision. Given the reliance on observational studies, many of the effect estimates were subject to high risk of bias due to concerns over comparability of the two groups. In all the papers with direct comparative data, which were used to make this recommendation, a complete rather than partial fundoplication was performed.

Benefits

There were four outcomes with desirable effects for fundoplication in hiatal hernia repair including objective reflux, hiatal hernia recurrence (symptomatic or large), leak rates, and quality of life.

In regard to objective reflux, two RCTs with a total sample size of 147 patients demonstrated a RR of 0.31. This would mean 321 fewer patients with objective evidence of reflux per 1000 patients with the routine use of fundoplication (95% CI 386 fewer to 205 fewer).

Hiatal hernia recurrence (symptomatic or large) was evaluated in two RCTs with a total sample size of 148 pooled patients and demonstrated a RR 0.55. This would translate to 51 fewer recurrences per 1000 patient treated with fundoplication (95% CI 90 fewer to 57 more).

Postoperative leak rates were evaluated in one RCT with 40 patients and demonstrated a RR of 0.33. This would mean 33 fewer leaks per 1000 patients treated with fundoplication (95% CI 50 fewer to 336 more).

In one observational study with 58 patients, quality of life was improved by 1.5 on the GERD Health Related Quality of Life scale, but was not statistically significant.

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

Harms and burdens

There was one outcome with undesirable effects for adding a fundoplication to the hiatal hernia repair: total dysphagia (late). In two RCTs with 157 pooled patients, the RR for dysphagia in the late postoperative period was 2.94. This would translate to 25 more patients with dysphagia per 1000 treated with fundoplication (95% CI 7 fewer to 225 more).

Overall, the panel felt the magnitude for these undesirable effect for fundoplication was small.

Certainty of evidence

The certainty of the above evidence was low based on the outcomes deemed critical to decision-making by the panel. 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 D).

Decision criteria and additional considerations

This recommendation is based on data that was exclusively on patients receiving a complete fundoplication; our search criteria found no partial fundoplication data available for inclusion in our analysis. Based on indirect evidence from prior studies in patients with GERD without hiatal hernia, dysphagia rates are lower with partial fundoplication than complete fundoplication. This may be an important consideration depending on a patient's symptoms and values. Additional considerations are the patient's presenting complaint, the relative severity of the patient's heartburn and dysphagia, and the type of fundoplication to be performed.

Conclusions

The panel concluded that in patients undergoing type II, III, or IV hiatal hernia repair, the balance of the desirable effects, judged to be large, outweighed the balance of undesirable effects, judged to be small, which favored the intervention of fundoplication. Evidence from prior studies for surgical intervention for GERD suggest partial fundoplication may be a better option with regard to postoperative dysphagia. The expert panel had no high-level evidence regarding partial fundoplication in the hiatal hernia repair population but felt it was reasonable to apply this indirect evidence.

Research recommendations

Large, well-designed RCTs separating out complete fundoplication and partial fundoplication and/or separating out patients by complaint of heartburn versus dysphagia are warranted. The role of magnetic sphincter augmentation and how it compares to fundoplication must also continue to be investigated as the technique spreads. An analysis of patients undergoing emergency hiatal hernia repair for gastric volvulus and obstruction is also warranted to investigate outcomes of fundoplication compared to gastropexy in nonelective circumstances.

KQ4: In adult patients without obesity and with recurrent type II, III, or IV hiatal hernia, should conversion to RYGB be performed versus redo repair of the hiatal hernia?

Summary of evidence

The literature search completed for the systematic review only yielded two retrospective cohort studies and five single arm, observational studies [35–41]. Ultimately the panel decided that this evidence was too weak to utilize for an evidence-based recommendation for this question.

Expert opinion

Despite a paucity of high-quality comparative data, the panel of experts agreed that conversion to RYGB may be considered an appropriate treatment option in select patients without obesity and with recurrent type II, III, or IV hiatal hernia. In a patient with a recurrent hiatal hernia after a previous uncomplicated hiatal hernia repair with fundoplication, redo hiatal hernia repair and fundoplication is appropriate. Greater consideration for RYGB would be made in the following circumstances: patients with diabetes mellitus, severe esophageal dysmotility, short esophagus, or gastroparesis, patients with previous complicated hiatal hernia repair with fundoplication who now have poor quality tissue of the fundus, and lastly patients who have undergone multiple recurrent hiatal hernia failures by an expert. Such patients should be evaluated in a multidisciplinary fashion prior to proceeding with RYGB.

Research recommendations

Such patients should be followed long term in a prospective fashion to understand what operation will serve them best. Important outcomes include but are not limited to quality of life, reoperations, objective evidence of reflux, and malnutrition.

Discussion

Implementation

The panel believes that it is feasible to successfully implement these guidelines 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 every three years to search for any new evidence. It is planned that a formal update will be generated when substantive literature is identified.

Limitations of these guidelines

One of the main limitations of these guidelines is related to the low certainty of the evidence for all KQs. Due to this, evidence-based recommendations were replaced 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 decreases the ability to advocate for one approach over another. For two of the KQs, there were insufficient direct,

comparative data to make an evidence-based recommendation. No evidence-based recommendation could be made on an additional KQ due to seemingly equivocal evidence of lower certainty. 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 other societies and other physicians. In addition, the level of importance for the patient-centered outcomes was decided by the panel members rather than by patient advocates. As such, some individual patients value individual outcomes differently, 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 KQs. However, a strength of this guideline is the careful consideration for patient values and preferences in view of individual critical outcomes.

Health equity considerations

The prevalence of hiatal hernia increases alongside increasing age [42]. As discussed in KQ2, it is important that age alone not be used to disqualify patients from operative management. Instead, the decision to operate should be based on a nuanced consideration of their operative risk and the individual patient's values and preferences.

Obesity is a common comorbidity in patients with hiatal hernia and known to increase recurrence after hiatal hernia repair [43, 44]. With the proliferation of new medical weight loss therapies, future studies should investigate the BMI thresholds at which patients may benefit from lifestyle, medical, or surgical-based weight loss prior to hiatal hernia repair.

Research priorities summarized

Large, well-designed RCTs comparing the type of mesh used and the orientation of the mesh are warranted to further define the best role for mesh in hiatal hernia repair. In addition, large, well-designed RCTs that compare complete fundoplication and partial fundoplication for hiatal hernia repair and which separate outpatient cohorts by chief complaint, heartburn versus dysphagia, are necessary. The role of magnetic sphincter augmentation and how it compares to fundoplication should also continue to be investigated.

As described in the Health Equity section above, there should also be investigation into optimal weight loss strategies prior to hiatal hernia repair in patients with obesity.

Conclusion

The guideline committee could not make an evidence-based recommendation in adult patients with type II, III, or IV hiatal hernia who are candidates for mesh placement for the use or non-use of mesh in surgical repair. This statement is based on the equivocal outcome data and low certainty of evidence for the intervention compared to non-intervention. In patients with an asymptomatic type II, III, or IV hiatal hernia, the guideline committee relied on expert opinion to propose repair can be offered based on patient and surgeon discussion regarding future risk of complications and symptoms taking into consideration the hernia size and the condition of patient. The expert opinion emphasizes that patients with objective findings of GERD and patients with non-GI symptoms that may be secondary to the hiatal hernia such as shortness of breath or exercise intolerance should be offered repair in the appropriate setting. The guideline committee suggests patients undergoing repair of a type II, III, or IV hiatal hernia may benefit from surgical fundoplication compared to no fundoplication. Again, in adult patients without obesity, with recurrent type II, III, or IV hiatal hernia, the panel relied on expert opinion regarding performing a conversion to RYGB or performing a redo hiatal hernia repair. The expert opinion proposed that despite comparable data, conversion to RYGB can be considered. The expert opinion further suggests consideration for conversion in patients who have failed a prior attempt by an expert surgeon in the setting of previous complications, severe esophageal dysmotility, short esophagus, gastroparesis, or multiple failures. A patient with diabetes mellitus could be considered as a candidate for conversion to RYGB.

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.

Appendices

Appendix A: Authorship and roles.

Appendix B: Search strategies.

Appendix C: Preferred reporting items for systematic reviews and meta-analyses diagrams.

Appendix D: Evidence to decision tables.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00464-024-11092-3.

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Declarations

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