Guidelines for the Performance of Minimally Invasive Splenectomy

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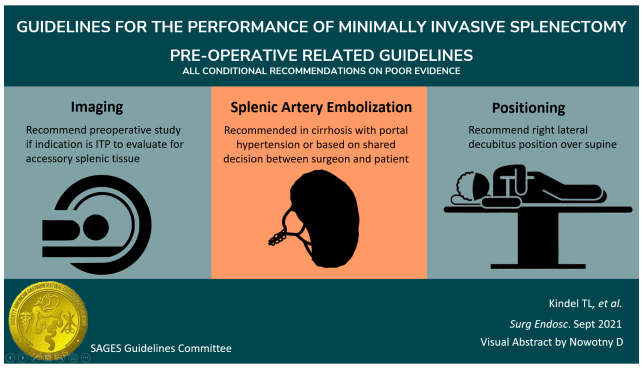

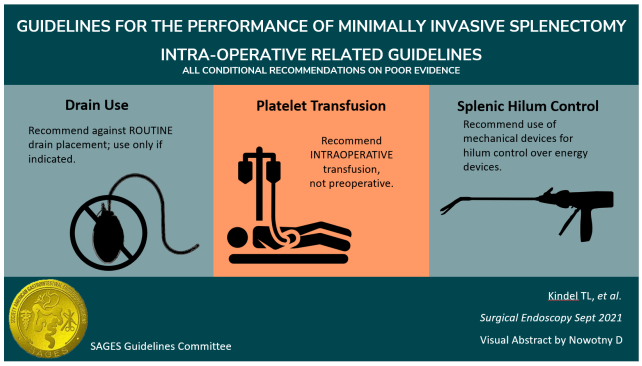

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Abstract

Background: Minimally invasive splenectomy (MIS) is increasingly favored for the treatment of benign and malignant diseases of the spleen, over open access approaches. While many studies cite the superiority of MIS in terms of decreased morbidity and length of stay over a traditional open approach, the comparative effectiveness of specific technical and peri-operative approaches to MIS is unclear.

Objective: To develop evidence-based guidelines that support clinicians, patients, and others in decisions on the peri-operative performance of MIS.

Methods: A guidelines committee panel of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) including methodologists used the Grading of Recommendations Assessment, Development and Evaluation to grade the quality of evidence and determine the strength of provided recommendations.

Results: Informed by a systematic review of the evidence, the panel agreed on eight recommendations for the peri-operative performance of MIS for adults and children in elective situations based on six key questions

Conclusions: Conditional recommendations were made in favor of lateral positioning for non-hematologic disease, intra-operative platelet administration for patients with idiopathic thrombocytopenic purpura instead of pre-operative administration, and the use

of mechanical devices to control the splenic hilum Further, a conditional recommendation was made against routine intraoperative drain placement.

Keywords: clinical practice guidelines, minimally invasive splenectomy, laparoscopic splenectomy, splenic artery embolization, surgical drain

Executive Summary

Background

Elective, minimally invasive splenectomy (MIS) is increasingly used for benign and malignant diseases of the spleen. While many studies cite the superiority of MIS in terms of decreased morbidity and length of stay compared to a traditional open approach [1-3], there is variability in technical and peri-operative aspects of the performance of MIS which is the focus of this guideline. Based on a systematic review of the evidence, these guidelines inform the surgeon regarding peri-operative care of patients undergoing splenectomy.

Interpretation of strong and conditional recommendations

The strength of these evidence-based recommendations is either “strong” or “conditional” as per the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach [4, 5]. The words “the guideline panel recommends” are used for strong recommendations, and “the guideline panel suggests” for conditional recommendations, according to the GRADE approach [5, 6]. Strong recommendations can be adopted as a policy in most situations. Conditional recommendations require shared decision-making between the surgeon and their patients. When insufficient evidence existed to inform recommendations, expert opinion consensus was sought.

How to use these guidelines

These guidelines are primarily intended to help surgeons make decisions about the peri-operative management of their patients undergoing MIS. Other purposes are to educate, inform policy and advocacy, and to define future research needs. Guidelines are applicable to all physicians facing patient management uncertainties addressed herein without regard to specialty, training, or interests. Due to the complexity of the healthcare environment, these guidelines are intended to indicate the preferred, but not necessarily the only, acceptable approach to management. Guidelines are intended to be flexible depending on individual circumstances. Given the wide range of specifics in any health care problem, the surgeon must always choose the course best suited to the individual patient and the variables in existence at the moment of decision. These guidelines can also be used by patients as a basis of discussion with their treating surgeon.

Key questions (KQ) addressed by these guidelines and recommendations

KQ 1. Should preoperative imaging versus no imaging be used for idiopathic thrombocytopenic purpura (ITP) patients undergoing elective minimally invasive splenectomy (MIS)?

Based on collective experience, the panel suggests that preoperative imaging may be beneficial for patients with ITP undergoing elective MIS (expert opinion due to lack of evidence).

KQ 2. Should pre-operative splenic artery embolization versus no embolization be used for elective MIS?

- **The panel suggests that patients scheduled for elective MIS may be managed with <u>either</u> preoperative splenic artery embolization or no embolization based on the surgeon and patient's shared decisions-making (conditional recommendation, very low certainty evidence).**
- **The panel suggests pre-operative splenic artery embolization before elective MIS in cirrhotic patients with portal hypertension and splenomegaly (conditional recommendation, very low certainty evidence).**

KQ 3. Should routine drain placement versus no drain placement be used for elective MIS?

The panel suggests that drains not be used routinely during MIS (conditional recommendation, very low certainty evidence).

KQ 4. Should patients be positioned supine versus lateral for elective MIS?

The panel suggests that lateral positioning be considered over supine positioning for elective, MIS (conditional recommendation, very low certainty evidence).

KQ 5. Should pre-operative versus intra-operative administration of platelets occur for patients with ITP during MIS?

The panel suggests that platelets be administered intra-operatively instead of pre-operatively during MIS for patients with ITP (conditional recommendation, very low certainty evidence).

KQ 6. Should endo-mechanical versus energy devices be used for control of the splenic hilum during minimally invasive splenectomy?

The panel suggests that mechanical devices be used to control the splenic hilum during elective, MIS instead of energy devices (conditional recommendation, very low certainty evidence)

Introduction

Aim of these guidelines and specific objectives. The aim of this evidence-based guideline by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) is to provide recommendations regarding the peri-operative performance of minimally invasive splenectomy (MIS). The key target audiences include surgeons and patients. Policy makers and insurance providers involved in delivering local, national and

international health care services aimed at the surgical treatment of splenic disease or involved in evaluating direct and indirect benefits, harms and costs related to the various procedures used in the peri-operative delivery of MIS may also consider these recommendations in their deliberations.

Description of the health problems. Over the past 30 years, there has been increasing utilization of MIS for benign, malignant and traumatic spleen-related diseases [1-3]. Compared to the traditional open approach, MIS is associated with decreased length of stay, operative blood loss, and total post-operative complications [1,3]. However, within the reported literature, there is variability in technical and peri-operative aspects of the performance of MIS, such as patient positioning, blood product resuscitation, and hilar control techniques with unclear comparative effectiveness prompting the development of this guideline. Guidelines can assist the surgeon in peri-operative care based on systematic synthesis of best available evidence.

Methods

The creation of this guideline followed SAGES policies and upon request and approval of members of the guidelines committee [5,7]. In brief, a systematic review was completed by a group of SAGES Guideline committee members. A broadened group of experts was included in the guideline panel which reviewed the evidence of the systematic review and formulated recommendations. The systematic review is reported briefly here, according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) checklist. The guideline panel used the GRADE Evidence to Decisions (EtD) approach to deliberate and formulate recommendations [8,9]. The Essential Reporting Items for Practice Guidelines in Healthcare (RIGHT) checklist was used to draft this guideline [10]. The overall methods and reporting expectations for SAGES Guidelines has been recently published [5]. General concepts are summarized here, including details specific to this guideline.

Guideline Panel Organization. The guideline panel was composed of volunteer members from the SAGES Guidelines committee and other experts who were surgeons and hematologists. Non-voting panel members included a systematic review methodologist (A.M.A), a guideline development methodologist (M.T.A), and two committee research fellows (R.D., A.C.). All contributors to the guideline and their roles are listed in Supplementary Material Appendix A.

Guideline funding and declaration and management of competing interests. All committee members and voting members of the guideline panel were volunteers and did not receive funding. Funding for the methodologists, the librarian, and partial salary support for the fellows were provided by SAGES. There was no monetary or other support from industry. All guideline panel members were required to fill out a conflict of interest form. The guideline lead and committee chair evaluated these declarations for any pertinent conflicts. All disclosed potential conflicts of interest are listed in Supplementary Material Appendix B.

Selection of questions and outcomes of interest. Under the guidance of the current committee chair and guideline methodologist, the systematic review group created a list of KQs relating to splenectomy using the PICO format: patient-intervention-comparator-outcome. Outcomes “critical” or “important” to decision-making for these KQs were defined and reviewed. Guided by their clinical experience, the guideline panel discussed and reached consensus regarding the importance and patient-centeredness of outcomes. The importance of these outcomes was re-visited by panel members during the formulation of recommendations after they had reviewed the systematic review evidence. Outcomes included pain, length of hospital stay/return to work, transfusions requirements/estimated blood loss, surgical site infection (SSI), organ injury, mortality, mesenteric venous thromboembolism, and conversion to open procedure. Cost to the patient was included as an additional consideration.

Evidence Synthesis and Grading the Certainty of Evidence

Standard systematic review approach using two independent reviewers (± third party arbitration) was adopted to synthesize the best available evidence for each KQ. A librarian searched multiple databases including PubMed, the Cochrane Library, and Embase, in August 2015. Systematic reviews and the bibliography of select included studies were hand searched for additional studies missed in the literature search. Given the potential paucity of data, both randomized controlled trials (RCTs) and observational studies addressing the KQs of interest were eligible for inclusion. Retrieved records were reviewed, duplicates removed and results screened for eligibility at two levels (title and abstract, and full-text review) against the eligibility criteria. Only peer-reviewed English language studies were included during study selection, which comprised the bulk of the existing literature. An updated literature search was performed in October 2020. Six additional articles relevant to the KQs were added to the systematic review.

Study data extraction included general study characteristics and PICO elements which was performed in *Covidence* digital software [12]. The Cochrane *Risk of Bias Tool* for RCTs and the *Newcastle Ottawa Scale* for non-RCTs were used to assess study risk of bias [13,14]. Meta-analysis was conducted in *Revman* using the Mantel-Haenszel random-effects model [15]. Heterogeneity between studies was quantified by the I^2 statistic and tested for statistical significance with the Chi^2 test. Study risk of bias and clinical covariates were used to explore important observed heterogeneity. Publication bias could not be assessed because of the general inadequacy of the evidence. When direct comparative evidence was lacking, evidence from non-comparative studies was used to make indirect comparisons (albeit with lower certainty). As the guideline took an individual patient-physician perspective, cost was considered from an individual patient perspective.

For each outcome, the certainty of evidence was graded as per the GRADE approach based on the overall risk of bias, inconsistency, indirectness, and imprecision and summarized in Evidence Tables in the online *GradePro* tool [16,17]. RCT evidence was preferred over non-RCT evidence with the intent of generating higher certainty.

Development of clinical recommendations

The panel took an individual perspective, using patient-based values to formulate recommendations for a target audience composed of practicing physicians as well as patients. We used the GRADE EtD framework in the GRADEPro tool [8,9]. The EtD framework requires panel members make deliberated judgments about the magnitude of desirable and undesirable effects across the important and critical outcomes. The values (and associated variability in values) patients place on those outcomes are taken into consideration. The balance of desirable and undesirable effects, the overall certainty of evidence across the critical outcomes, the potential for inequities in health, and acceptability and feasibility of the favored management option determine the recommendation and its strength. As we could not identify any literature that investigated the relative values and preferences patients assign to the various outcomes of interest, the panelists used their clinical experience as proxies for patient preferences.

Dissenting judgments and views were captured in a preliminary voting to foster further discussions and consensus development. Re-voting was used after the discussions. Final recommendation required ≥80% panel agreement.

All EtD tables are summarized in Supplementary Material Appendix C, including the evidence important to decision-making, the additional considerations, and judgements on each component of the guideline. These components are detailed in the recommendations that follow.

Guideline document review. After composition of the guideline, this manuscript was reviewed and appropriately revised as previously described [5] including panelists, the Guidelines Committee members, SAGES Executive Committee, SAGES Board, and SAGES membership before submission for publication.

Recommendations

KQ 1. Should preoperative imaging versus no imaging be used for idiopathic thrombocytopenic purpura (ITP) patients undergoing elective minimally invasive splenectomy (MIS)?

> **Based on collective experience, the panel suggests that preoperative imaging may be beneficial for patients with ITP undergoing elective, MIS (expert opinion due to lack of evidence).**

Summary of the evidence. Four non-randomized studies addressed the KQ of preoperative imaging in MIS for hematologic diseases, ITP alone, or a mixed disease but did not address the KQ outcomes [18-21]. We identified one additional systematic review on prevalence of accessory spleen, but it also does not address the KQ [22]. As there was no evidence to appropriately address any of the outcomes of interest for this KQ, the judgements were based on expert panel consensus opinion.

Benefits. The panel opined that there were expected small, desirable effects from preoperative imaging for patients with ITP. A small proportion of accessory spleens may be found by imaging which would otherwise not have been found during laparoscopy

alone [18]. The sensitivity is expected to be low given preoperative imaging has shown either worse sensitivity [18-20] or at best similar sensitivity to laparoscopy [21]. However, preoperative imaging likely prompts further intraoperative exploration and results in some degree of additional accessory spleen discovery. The frequency and success of additional spleen discovery is one of the outcomes for which additional evidence is needed. Any increase in the ability to detect accessory spleens pre-operatively is still beneficial considering that laparoscopy may not find all accessory spleens. Missing accessory spleens can lead to an inferior clinical outcome of splenectomy for ITP, specifically resulting in persistence and/or recurrence of disease [1, 23]. Additionally, preoperative imaging may inform anatomy of the spleen in select cases to aid operative planning and increase safety of the operation [21]..

Harms and burden. The panel opined that the expected undesirable effects from preoperative imaging would be small for patients with ITP. Undesirable effects include greater cost and potential radiation exposure from the preoperative imaging. In pediatric populations, the risk from radiation exposure may be greater if CT scans are used. These risks can become trivial if ultrasound or MRI is used but may be limited in specificity. If performed, pediatric CT scans should observe the ALARA principle, “as low as reasonably achievable” regarding radiation doses [24].

Certainty in the evidence of effects. No studies were included for determination of certainty.

Decision criteria and additional considerations. The panel used their own experiences with patients to gauge the true variation in how much people value the main outcomes that could be influenced by preoperative imaging before laparoscopic splenectomy. Expert opinion was that the desirable and undesirable effects would both be small for preoperative imaging before splenectomy in patients with ITP, but that the desirable effects would slightly outweigh the undesirable effects. In some populations, the undesirable effects may be greater, such as in pediatric patients with a diagnosis other than ITP, and the panel felt that the balance may favor no pre-operative imaging in this patient population.

Conclusion

There are both small desirable and undesirable effects according to expert opinion, though the desirable effects were felt to outweigh the undesirable effects except in children. Preoperative imaging may be helpful in surgical management of ITP if an accessory spleen is identified and may yield important information about splenic anatomy to aid in operative planning. However, the absence of accessory spleen(s) on preoperative imaging does not abdicate the need for minimally invasive exploration for accessory spleens intraoperatively.

Given that there is no available evidence informing the effectiveness of preoperative imaging compared to no imaging in this context, the panel provided their expert opinion. Therefore, the panel suggests that preoperative imaging may be beneficial for patients with ITP undergoing MIS. In pediatric populations, the concerns for additional radiation

exposure are greater. Modern imaging techniques may mitigate these negative effects and should be discussed with the patient and/or their parent/guardian(s). Regardless of intervention or comparison, patients with ITP should be monitored for recurrence of disease suggesting missed accessory spleen.

Recommendations for future studies. The panel made two recommendations for future studies on preoperative imaging in ITP patients undergoing splenectomy:

1. A comparative design study should be performed, such that post-surgical outcomes in a cohort of patients with preoperative imaging are compared with outcomes in a similar cohort of patients without preoperative imaging. Ideally, this design would also involve randomization and evaluate cost-effectiveness of these alternative management strategies.
2. The sensitivity and specificity of ultrasound, including contrast enhanced ultrasound, and other alternatives to CT for the preoperative identification of accessory spleens and their comparative effectiveness should be investigated, especially in children.

KQ 2. Should splenic artery embolization versus no embolization be used for elective MIS?

- **The panel suggests that patients scheduled for elective MIS may be managed with either preoperative splenic artery embolization or no embolization based on the surgeon and patient's shared decisions-making (conditional recommendation, very low certainty evidence).**
- **The panel suggests preoperative splenic artery embolization before elective, MIS in cirrhotic patients with portal hypertension and splenomegaly (conditional recommendation, very low certainty evidence).**

Summary of the evidence. Evidence from two observational studies of high quality, and an additional observational study of high quality which was analyzed as a separate subgroup population, all with small sample size, informed this KQ [25,26, 27].

Benefits. Splenic artery embolization was favored over no embolization in regard to [25,26]:

- Transfusion requirements (1 observational study of 36 participants; OR 0.24 [95% CI, 0.06-0.99], absolute difference 33.7% fewer [95% CI, 52.5 fewer to 0.2 fewer])
- Mean estimated blood loss (2 observational studies of 86 participants; MD -146.1 mL [-290.94 to -1.26])
- Conversion to open (2 observational studies of 86 participants; OR 0.30 [0.03-2.78], absolute difference 4.3% fewer [95% CI, 6.1 fewer to 9.4 more])
- Superficial site infection (2 observational studies of 86 participants; OR 0.32 [0.01-8.27], absolute difference 1.4% fewer (95% CI , 2.1 fewer to 12.9 more)].

The panel felt that different populations may experience a different degree of benefit. In pediatric patients, anemic patients, and patients with diminished blood loss, avoidance of transfusion is important, and the desirable effect may be moderate. Additionally, the size of the spleen and skill of the surgeon are important factors and could minimize desirable

effects of splenic artery embolization (trivial effects). Of note, specific subgroup analysis with splenomegaly (>18 cm) found the strongest benefit for reduced estimated blood loss [25].

A third small observational study (n=56) looked specifically at the subgroup of patients with cirrhotic portal hypertension and splenomegaly finding benefits of preoperative splenic artery embolization for the following outcomes [27]:

- Transfusion requirements [OR 0.24 (95% CI 0.07-0.85), absolute difference 28.5% fewer (39.6 fewer to 4 fewer)]
- Mean estimated blood loss [MD -114 mL (95% CI -184.6 to -43.5)]
- Conversion to open [OR 0.14 (95% CI 0.02-0.76), absolute difference 24.3% fewer (29.2 fewer to 5.4 fewer)]
- Massive bleeding [OR 0.27 (95% CI 0.06-1.29), absolute difference 16.7% fewer (23 fewer to 5.1 more)].

Harms and burden. None of the outcomes based on the identified evidence definitively favored the comparison. Increased mesenteric venous thrombo-embolic disease (MVTE) may be associated with splenic artery embolization (1 observation study of 50 participants; OR 8.24 [95% CI, 0.37-181.31]), but the actual risk is not known due to imprecise research evidence. This outcome can lead to lifelong increased risk of varices and need for further medical management or intervention.

Additional undesirable effects not reported are increased time required to perform embolization and increased cost. Further, there are additional procedural risks of severe adverse events (SAE) including contrast nephropathy, pleural effusions, and arterial access-site hematoma [28,29]. Together, the added cost, procedural risks, time delay, and the unknown potential for increased MVTE were deemed a small undesirable effect by the panel. Additionally, there may also be a burden to patients in the need to travel to facilities equipped to perform preoperative embolization. The panel felt the undesirable effects were small in magnitude.

Certainty in the evidence of effects. Only comparative evidence addressing the key question was used; albeit it was of very low certainty. Single cohort evidence was deemed inappropriate for inclusion given lack of a comparative group.

Decision criteria and additional considerations. Conversion to open is associated with additional risks that are important to patients, such as length of stay and return to work which were not reported in the two observational studies.

The population to whom this is applied, such as pediatric versus adult, may impact the value for different outcomes. Long term sequelae of MTVE and transfusions may make these outcomes of higher value to younger patient populations.

Not all hospitals have access to interventional radiology or interventional vascular capabilities, precluding the use of the intervention.

Conclusions

When performed for MIS, splenic artery embolization may be associated with less blood loss, transfusion, superficial wound infection, and conversion to open procedure, especially for patients with portal hypertension and splenomegaly, based on evidence with very low certainty. Evidence is too imprecise to establish whether there is no risk or greater risk of MTVE. For high risk patients, particularly those with splenomegaly or preoperative anemia, the increased safety of splenic artery embolization prior to splenectomy may outweigh the unknown risk of MVTE, as well as increase in cost, time, and procedure-related risks. In low risk patients, the long-term health implications of MVTE and added cost/time of splenic artery embolization may outweigh the short-term benefits. The panel suggests that splenic artery embolization be considered before laparoscopic splenectomy in cirrhotic patients with portal hypertension and splenomegaly.

The panel suggests that patients scheduled for MIS may be managed with either preoperative splenic artery embolization or no embolization. This decision should be based on the surgeon's and patient's shared decision-making and take into consideration the value and clinical sequelae of critical outcomes as well as the local feasibility and acceptability of splenic artery embolization.

Differences among affected patient populations influence the value of different outcomes as well as the feasibility and acceptability of splenic artery embolization. Long term sequelae of the procedure may influence decision making more in pediatric populations. Children may benefit more from decreased transfusions but also experience greater long-term detriment from a potentially higher MVTE risk. In addition, children may have less access to splenic artery embolization based on local acceptability and based on decreased feasibility due to small size and technical considerations. Patients with splenomegaly and arborized splenic arteries likely experience different outcomes from embolization that increase the desirable effects and decrease the undesirable effects. Patients with splenomegaly may place more value on decreased conversion to open and lower blood loss given a higher baseline risk for these outcomes.

Recommendations for future studies. The panel proposes multiple priorities for future research:

- Higher quality evidence on transfusion, blood loss, conversion, and MVTE risks after MIS with and without embolization may support stronger future recommendations. Randomized trials studying this comparison would be ideal. If not possible with randomization trials, large prospective studies should be sought to establish the risk of MVTE rate with splenic artery embolization.
- Studies with size-matched patients and size matched spleens would better elucidate risks of MIS after splenic artery embolization.
- More accurate and consistent measures of blood loss are needed for this outcome to have greater value in decision making.

KQ 3. Should routine drain placement versus no drain placement be used for elective MIS?

The panel suggests that drains not be used routinely during elective, MIS (conditional recommendation, very low certainty evidence).

Summary of the evidence. A single, small observational study of low quality and 54 participants yielded this research evidence [30].

Benefits. Routine drain placement was favored over no drain placement regarding operative time (MD -41.75 minutes (95% CI, -72.77 to -10.73). Reasons for placing a drain were not described in the paper. The panel felt that patients with clear indications for drain placement, such as infected fields or obvious injuries to the pancreas, experience greater desirable effects. For routine placement of drains, the effect was deemed trivial.

Harms and burden. Routine drain placement was possibly associated with small harm regarding:

- SSI (OR 2.97 [95% CI, 0.14 to 61.05], absolute difference is 1.2% more (0.6 fewer to 33.5 more).
- Length of stay (MD 1.46 [-0.32 to 3.24]).

The expert panel felt there could be an increased risk of SSI with routine drain placement based on duration of drainage [31], although not able to directly state due to lack of events in patients without drain placement [30]. There may also be increased costs to patients for increased length of stay.

Certainty in the evidence of effects. All evidence for each outcome was very low certainty.

Decision criteria and additional considerations. Based on panel expert opinion, the value and magnitude of decreased operative time on decision-making may vary. The trivial benefit from decreased operative time is outweighed by small undesirable effects from increased risk for SSI and increased length of stay. There was some distrust from the panel in any conclusions based on the evidence, specifically the benefit of drain placement on operative time, given the poor quality and limited nature of the available data, greatly tempering any judgement on overall balance [32].

Conclusions

Based on the limited and very low certainty evidence available, the panel judged there is trivial benefit to routine placement of a drain, and there may be a small detriment. The undesirable effects of increased SSI and possible increased length of stay outweigh any small benefit in operative time. A small proportion of the panel felt the evidence was limited such that no recommendation should be made.

The panel suggests that drain placement not be used routinely during MIS. Selective drain placement should be used instead of routine placement based on individual patient factors or operative considerations, such as infected fields, and obvious or suspected

injuries to the pancreas. In these situations, the desirable effects of drain placement such as control of a pancreatic leak, or source control for an infection, will outweigh the undesirable effects associated with drain placement.

Recommendations for future studies. Given the paucity of data available, the panel recommends additional research which address the following:

- Randomized studies that address this KQ would yield much more robust evidence. Such prospective studies should be conducted with comparable subgroups.
- The indication for drain placement, and specification of whether it is routine, is needed in future studies.

KQ 4. Should patients be positioned supine versus lateral for elective MIS?

> **The panel suggests that lateral positioning be considered over supine positioning for elective, MIS (conditional recommendation, very low certainty evidence).**

Summary of the evidence. One RCT with unclear risk of bias was used to address this KQ which included 80 adults with hematologic and malignant disorders [33].

Benefits. The use of supine positioning was variably favored regarding:

- MVTE (OR 0.19 [95% CI, 0.01-4.09], absolute difference 4.0% fewer [50 fewer to 152 more]).
- Organ injury (OR 0. 19 [95% CI, 0.01-4.09], absolute difference 4.0% fewer [50 fewer to 152 more]).

Harms and burden. The use of supine position was associated with moderate undesirable effects related to:

- Conversion to open (OR 2.25 [95% CI, 0.62-8.18], absolute difference 10.0% more [35 fewer to 511 more]).
- Mean estimated blood loss (MD 103.5 mL [30.46 to 176.54]).
- Transfusion requirement (OR 2.25 [95% CI, 0.62-8.18], absolute difference 10.0% more [35 fewer to 511 more]).

Certainty in the evidence of effects. The panel found the overall certainty of the evidence to be very low for the critical outcomes of conversion due to the small sample size and imprecision.

Decision criteria and additional considerations. The panel felt it was important to note that certain patients, who are unwilling to receive blood products, may value transfusion risk more than other individuals. The panel also considered whether the lateral approach may be technically easier than the supine approach, particularly in obese patients. A change in optimal positioning may occur due to other, concomitant procedures performed at the same time as the splenectomy.

Conclusions

The evidence suggests that lateral positioning be considered for MIS over supine positioning.

Recommendations for future studies. The panel felt future research should focus on:

- Surgeon-rated technical difficulty, learning curve, and ergonomics of lateral versus supine positioning.
- Studies which would identify any difference in accessory spleen identification rate for lateral versus supine positioning.
- Studies looking specifically at whether specific sub-populations, such as obese patients, low BMI patients, or pediatric patients benefit more from lateral versus supine positioning.

KQ 5. Should pre-operative versus intra-operative administration of platelets occur for patients with ITP during elective MIS?

> **The panel suggests that platelets be administered intra-operatively instead of pre-operatively during MIS for patients with ITP (conditional recommendation, very low certainty evidence).**

Summary of the evidence. A single, small observational study of high quality (n=30) yielded this research evidence [34]. There is very serious imprecision as a small sample size and wide confidence interval suggest both the potential for harm and benefit.

Benefits. There were no desirable effects seen for pre-operative platelet administration. There were no other desirable effects the panel knew of based on their experience.

Harms and burden. The administration of pre-operative platelets was associated with moderate harm and undesirable effects related to:

- Estimated blood loss (MD 150.5 mL [56.59 to 244.41]).
- Transfusion requirement (OR 1.50 [0.32-6.99], absolute difference 10.0% more [25.8 fewer to 37.5 more]).
- Conversion to open approach (OR 2.11 [0.12-37.72], absolute difference 5.0% more [4.4 fewer to 61.5 more]).
- Surgery time (MD 38 minutes (-22.77 to 98.77]).
- Length of stay (MD 1.1 days [-0.58 to 2.78]).
- 30-day spleen related disease remission (OR 0.47 [0.03-8.46], absolute difference 5.1% fewer [58.7 fewer to 4.4 more].

Certainty in the evidence of effects. The panel found the overall certainty of the evidence to be very low due to the retrospective nature of the study with small sample size.

Decision criteria and additional considerations. While all outcomes slightly favor intra-operative platelet administration over pre-operative, there is serious imprecision of the single study addressing this question due to small sample size and wide confidence intervals. The panel felt it important to note that while acceptable to most patients, certain patients may not be accepting of blood products, and may not favor either the intervention or comparator.

Existing treatment guidelines for ITP recommend platelet transfusion for life-threatening emergencies and major procedures only. However, perioperative timing of platelet transfusion is not addressed in the literature for pediatric patients.

Conclusions

Pre-operative platelet administration does not appear to have a benefit over intra-operative administration. There may be a slight disadvantage to pre-operative platelet transfusion according to the reviewed data. All outcomes slightly favor intra-operative platelet administration but there is serious imprecision of the single study addressing this question due to small sample size and wide confidence intervals. The panel suggests the use of intra-operative platelet transfusion during laparoscopic splenectomy for patients with ITP, as opposed to pre-operative administration. It is important to note, that many patients with ITP will not require any
platelet transfusion based on acceptable preoperative platelet counts.

Recommendations for future studies. The panel felt future research should focus on:

- Larger, prospective, possibly randomized studies addressing this KQ to increase the certainty of evidence.
- Studies that determine the minimum platelet count preoperatively for the safe conduct of major or minor surgical procedures without the need for platelet transfusion.

KQ 6. Should endo-mechanical versus energy devices be used for control of the splenic hilum during elective MIS??

> **The panel suggests that mechanical devices be used to control the splenic hilum during elective, MIS instead of energy devices (conditional recommendation, very low certainty evidence).**

Summary of the evidence. Two RCTs, one with unclear risk of bias [35] and high risk of bias [36], were used as evidence for this recommendation.

Benefits. There were moderate desirable effects for endo-mechanical control of the splenic hilum for minimally invasive splenectomy from two RCTs, 80 participants total.

- Estimated blood loss (MD -2.48 mL [95% CI, -66.35 to 61.38])
- Transfusion (OR 0.21 [95% CI, 0.02-2.03], absolute difference 6.2% fewer [7.8 fewer to 7 more])

- Conversion to open (OR 0.09 [95% CI, 0.00-1.77], absolute difference 7.2% fewer [8 fewer to 5.3 more]).

Limited operative technique description in the two studies leaves uncertainty on whether the effect was due to the hilar technique as described in the KQ, or a confounder such as dissection technique.

It was the view of the panel that the size of the vessel can play an important role in the choice of device. Larger vessels may be better occluded via mechanical devices. For example, energy devices have manufacturer recommended maximum vessel caliber for device application.

Harms and burden. The use of endo-mechanical devices for hilar control was associated with small harm and undesirable effects from 2 RCTs related to:

- Mesenteric venous thromboembolism (OR 6.11 [95% CI, 0.68-55.19], absolute difference 1.1% more [<0.1 fewer to 1.2 more]).
- Operative time (MD 14.45 minutes [95% CI, 5.17 to 23.74]).

Certainty in the evidence of effects. All critical outcomes for this KQ (transfusion rate, conversion to open, and mesenteric venous thromboembolism) have very low certainty of the evidence making the overall certainty very low.

Decision criteria and additional considerations. Surgeons will vary in whether they accept the balance of effects based on training and practice. The size of the vessel can play an important role in choice of device. Larger vessels may be better taken via endo-mechanical devices. For example, the manufacturer recommendations for some energy devices also do not recommend use above a certain size. Many surgeons would not accept using energy devices for larger vessels or vessels with substantial calcification.

While the low volume difference in blood loss is unlikely to be valued, the decrease in transfusions with mechanical devices is very likely to be valued by patients. Importance of transfusion ranged from important to critical, based on patient subpopulation, for example cancer patients.

Conclusions

The use of endomechanical devices for the control of the splenic hilum has slightly decreased risk of intraoperative blood loss, need for transfusion, and conversion to an open operation. The very low certainty in the evidence due to imprecision prevented the panel from giving a strong recommendation.

The panel conditionally suggests that endomechanical devices be used to control the hilum for most patients undergoing elective, MIS. The panel unanimously agreed that very large hilar vessels would be safer to take with endo-mechanical devices.

The panel felt future research should focus on:

- High quality studies that compare mechanical versus energy devices to control the splenic hilum during minimally invasive splenectomy using a randomized design, standardized surgical technique (besides the comparators), description of anatomic findings (specifically hilar vessel size and accessory spleen presence), and similar indications.
- Studies conducted in this area should report the following outcomes: blood loss, transfusion requirements, VTE rate, conversion to open, rate of pancreatic injury.

Limitation of these guidelines

The limitations of these guidelines are inherent to the very low certainty of the evidence we identified for all KQs. Multiple research priorities were made to try to improve the certainty and quality of the evidence for which recommendations were made.

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Authorship

T.K. was the panel Chair, wrote the first draft of the manuscript and revised the manuscript based on author's suggestions; R.D. and A.C. were the panel co-Chairs and non-voting members, contributed to drafting and critical revisions of the manuscript and contributed to further drafts, moderated the panel sessions, and checked the manuscript accuracy; A.M.A.S and M.T.A. provided methodological support; D.W., S.H., and D.S. provided supervision and guidance throughout the development process and critically revised this guideline. Guideline panel members (see Supplementary Material Appendix A) participated in the creation of the EtD tables (Supplementary Material Appendix C), critically reviewed the manuscript and provided suggestions for improvement. All authors approved the content.

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Appendices

Supplementary Materials

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