SAGES Guidelines Update to Laparoscopy in the Era of COVID-19

Appendix E: Evidence-to-Decision tables

QUESTION KQ1: ADULTS

Should nonoperative management vs. operative management be used for patients with disease processes amenable to either approach and active COVID infection?	
POPULATION:	patients with disease processes amenable to either approach and active COVID infection
INTERVENTION:	nonoperative management
COMPARISON:	operative management
MAIN OUTCOMES:	Conversion to operative management/ Return to OR; Mortality; ICU admission;
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem
Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o No o Probably no o Probably yes o Yes o Varies o Don't know		

Desirable Effects
How substantial are the desirable anticipated effects?

JUDGEMENT: o Trivial; o Small; o Moderate; o Large; o Varies; o Don't know

RESEARCH EVIDENCE:

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with operative management	Risk difference with nonoperative management
Mortality	35 (3 observational studies)	⨁◯◯◯ Very low[a,b,c]	**OR 0.02** (0.00 to 1.69)	Study population	
				45 per 1,000	**45 fewer per 1,000** (45 fewer to 29 more)

a. The studies utilized for this outcome were rated high risk of bias on the Newcastle Ottawa Scale.
b. The confidence interval for this outcome crosses the threshold of significance.
c. This outcome was underpowered.

ADDITIONAL CONSIDERATIONS:

Undesirable Effects
How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

o Trivial o Small o Moderate o Large o Varies o Don't know	<table><tr><th>Outcomes</th><th>№ of participants (studies) Follow-up</th><th>Certainty of the evidence (GRADE)</th><th>Relative effect (95% CI)</th><th colspan="2">Anticipated absolute effects* (95% CI)</th></tr><tr><th></th><th></th><th></th><th></th><th>Risk with operative management</th><th>Risk difference with nonoperative management</th></tr><tr><td>Conversion to operative management/ Return to OR</td><td>42 (1 observational study)</td><td>⨁◯◯◯ Very low[a,b,c]</td><td>OR 1.62 (0.08 to 34.72)</td><td colspan="2">Study population</td></tr><tr><td></td><td></td><td></td><td></td><td>0 per 1,000</td><td>0 fewer per 1,000 (0 fewer to 0 fewer)</td></tr></table> a. The studies utilized for this outcome were rated high risk of bias on the Newcastle Ottawa Scale. b. The confidence interval for this outcome crosses the threshold of significance. c. This outcome was underpowered.	

Certainty of evidence What is the overall certainty of the evidence of effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o Very low o Low o Moderate o High o No included studies	The panel judged this evidence too poor to be utilized for an evidence-based decision.	

QUESTION KQ1: PEDIATRIC

Should operative management vs. nonoperative management be used for patients with disease processes amenable to either approach and active COVID infection?	
POPULATION:	Pediatric patients with disease processes amenable to either approach and active COVID infection
INTERVENTION:	operative management
COMPARISON:	nonoperative management
MAIN OUTCOMES:	ICU admission;
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o No o Probably no o Probably yes o Yes o Varies o Don't know		

Desirable Effects How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	<table><tr><th rowspan="2">Outcomes</th><th rowspan="2">№ of participants (studies) Follow-up</th><th rowspan="2">Certainty of the evidence (GRADE)</th><th rowspan="2">Relative effect (95% CI)</th><th colspan="2">Anticipated absolute effects* (95% CI)</th></tr><tr><th>Risk with nonoperative management</th><th>Risk difference with operative management</th></tr><tr><td>ICU admission</td><td>581 (1 observational study)</td><td>⨁◯◯◯ Very low[a,b]</td><td>**OR 0.84** (0.22 to 3.13)</td><td colspan="2">Study population</td></tr><tr><td></td><td></td><td></td><td></td><td>22 per 1,000</td><td>**3 fewer per 1,000** (17 fewer to 43 more)</td></tr></table> a. The study utilized for this outcome was rated high risk of bias on the Newcastle Ottawa Scale. b. The confidence interval for this outcome crosses the threshold of significance.	

Undesirable Effects How substantial are the undesirable anticipated effects?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	N/A	

Certainty of evidence What is the overall certainty of the evidence of effects?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ Very low ○ Low ○ Moderate ○ High ○ No included studies	The panel judged this evidence too poor to be utilized for an evidence-based decision.	

QUESTION KQ 2: ADULT

Should a longer delay vs. shorter delay be used for elective cases in patients with recent COVID infection?	
POPULATION:	elective cases in patients with recent COVID infection
INTERVENTION:	a longer delay
COMPARISON:	shorter delay
MAIN OUTCOMES:	Mortality; MI; DVT/ PE;
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem Is the problem a priority?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**

o No o Probably no o Probably yes o Yes o Varies o Don't know		

Desirable Effects
How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o Trivial o Small o Moderate o Large o Varies o Don't know	See table below	Moderate effect size, mainly due to mortality.

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with shorter delay	Risk difference with a longer delay
Mortality	41015 (5 observational studies)	⨁⨁◯◯ Low[a]	**OR 0.32** (0.21 to 0.50)	Study population	
				38 per 1,000	**26 fewer per 1,000** (30 fewer to 19 fewer)
MI	37354 (1 observational study)	⨁⨁◯◯ Low	**OR 0.76** (0.67 to 0.86)	Study population	
				33 per 1,000	**8 fewer per 1,000** (11 fewer to 4 fewer)
DVT/ PE	40265 (3 observational studies)	⨁⨁◯◯ Low	**OR 0.73** (0.65 to 0.83)	Study population	
				34 per 1,000	**9 fewer per 1,000** (12 fewer to 6 fewer)

a. I2 value of 65.

Undesirable Effects
How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o Trivial o Small o Moderate o Large o Varies o Don't know	No undesirable effect outcomes in data.	

Certainty of evidence
What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o Very low o Low o Moderate o High o No included studies	The certainty of evidence was graded as it was all observational, retrospective studies.	

Values
Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o Important uncertainty or variability o Possibly important uncertainty or variability o Probably no important uncertainty or variability o No important uncertainty or variability		

Balance of effects
Does the balance between desirable and undesirable effects favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o Favors the comparison o Probably favors the comparison o Does not favor either the intervention or the comparison o Probably favors the intervention o Favors the intervention o Varies o Don't know	Only desirable effects with moderate effect size.	

Equity
What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o Reduced o Probably reduced o Probably no impact o Probably increased o Increased o Varies o Don't know	Disproportionate impact on racial and ethnic minority groups. The panel did not make a judgement on this domain; however, it is recognized that this could impact these groups. It is unclear in what direction.	

Acceptability
Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o No o Probably no o Probably yes o Yes o Varies o Don't know		

Feasibility
Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o No o Probably no o Probably yes o Yes o Varies o Don't know		

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	Conditional recommendation for either the intervention or the comparison	Conditional recommendation for the intervention	Strong recommendation for the intervention
o	o	o	o	o

CONCLUSIONS

Recommendation

The panel suggests delaying elective operations by greater than six weeks in patients with recent COVID infection.

Justification

Low certainty of evidence as all data was from observational studies, however, high number of patients and all outcomes favored the intervention. Considering the severity of the outcomes - mortality, MI, DVT/PE, and that all data is pointing in the same direction, the panel agreed it is best to schedule elective operations for at least 6 weeks following COVID infection.

Subgroup considerations

Race and ethnicity
Pediatric population

Implementation considerations

Outcomes in COVID-positive patients should continue to be monitored as these recommendations are implemented. This is particularly true in the case of any new outbreaks or surges of COVID.

Monitoring and evaluation

Research priorities

Research needs to include analysis of vaccinated versus unvaccinated patients and by specific COVID variants.

QUESTION KQ 2: PEDIATRIC

Should a longer delay vs. shorter delay be used for elective cases in pediatric patients with recent COVID infection?	
POPULATION:	elective cases in pediatric patients with recent COVID infection
INTERVENTION:	a longer delay
COMPARISON:	shorter delay
MAIN OUTCOMES:	Mortality; DVT/PE; Ventilation time;
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem
Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o No o Probably no o Probably yes o Yes o Varies o Don't know		

Desirable Effects
How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o Trivial o Small o Moderate o Large o Varies o Don't know	N/A	

Undesirable Effects
How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o Trivial o Small o Moderate o Large o Varies o Don't know		

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with shorter delay	Risk difference with a longer delay
Mortality	13 (1 observational study)	⨁◯◯◯ Very low[a,b,c]	**OR 23.00** (0.61 to 862.86)	Study population	
				0 per 1,000	**0 fewer per 1,000** (0 fewer to 0 fewer)
DVT/PE	13 (1 observational study)	⨁◯◯◯ Very low[a,b,c]	**OR 1.40** (0.04 to 45.68)	Study population	
				91 per 1,000	**32 more per 1,000** (87 fewer to 729 more)

Ventilation time	13 (1 observational study)	⊕◯◯◯ Very low[a,b,c]	-	The mean ventilation time was **0**	MD **6.68 higher** (8.12 lower to 21.48 higher)	

a. This out come is based on one study which was deemed to be at high risk of bias utilizing the Newcastle Ottawa Scale.
b. This study was underpowered.
c. The confidence interval for this outcome crosses the threshold of significance.

Certainty of evidence
What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o Very low o Low o Moderate o High o No included studies	The panel judged this evidence too poor to be utilized for an evidence-based decision.	