

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

## SUPPLEMENT 4: EVIDENCE TO DECISION TABLES FOR KEY QUESTION 2

2a. Should MSA vs. Fundoplication be used for patients with GERD?	
POPULATION:	patients with GERD
INTERVENTION:	MSA
COMPARISON:	Fundoplication
MAIN OUTCOMES:	Quality of life Scale - Long Term (>2yrs); Objective reflux (demeester, pH etc) ; Symptom RECURRENCE (patient reported) - Short term (<2yr); Complete Symptom Resolution (patient reported) - Short Term (<2yr); Perioperative complications (Clavien dindo ≥2) (<30 days); Reoperation (ANY); Need for PPI; Dysphagia requiring intervention; Dysphagia - patient reported - Long Term (>3mon); Patient satisfaction - yes; Cost (mean U.S. dollars);
SETTING:	
PERSPECTIVE:	PATIENT-CENTERED
BACKGROUND:	
CONFLICT OF INTERESTS:	

### ASSESSMENT

Problem												
Is the problem a priority?												
JUDGEMENT	RESEARCH EVIDENCE					ADDITIONAL CONSIDERATIONS						
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know												
Desirable Effects												
How substantial are the desirable anticipated effects?												
JUDGEMENT	RESEARCH EVIDENCE					ADDITIONAL CONSIDERATIONS						
<input type="radio"/> Trivial <input checked="" type="radio"/> Small <input type="radio"/> Moderate <input type="radio"/> Large <input type="radio"/> Varies <input type="radio"/> Don't know	<b>Outcomes</b>  Symptom RECURRENCE (patient reported) - Short term (<2yr)	<b>No of participants (studies) Follow up</b>  249 (1 observational study)	<b>Certainty of the evidence (GRADE)</b>  ⊕○○○ VERY LOW <sup>a</sup>	<b>Relative effect (95% CI)</b>  RR 0.23 (0.08 to 0.69)	<b>Anticipated absolute effects* (95% CI)</b> <table border="1"> <thead> <tr> <th>Risk with Fundoplication</th> <th>Risk difference with MSA</th> </tr> </thead> <tbody> <tr> <td>Study population</td> <td></td> </tr> <tr> <td>128 per 1,000</td> <td>98 fewer per 1,000 (117 fewer to 40 fewer)</td> </tr> </tbody> </table>	Risk with Fundoplication	Risk difference with MSA	Study population		128 per 1,000	98 fewer per 1,000 (117 fewer to 40 fewer)	Evidence based on short term, observational studies. Symptom recurrence is not an objective outcome and may not accurately reflect true reflux recurrence.
Risk with Fundoplication	Risk difference with MSA											
Study population												
128 per 1,000	98 fewer per 1,000 (117 fewer to 40 fewer)											

	Perioperative complications (Clavien dindo ≥2) (<30 days)	1211 (7 observational studies)	⊕○○○ VERY LOW <sup>b,c</sup>	<b>RR 0.41</b> (0.16 to 1.02)	Study population	
					27 per 1,000	<b>16 fewer per 1,000</b> (22 fewer to 1 more)
	Reoperation (ANY)	534 (4 observational studies)	⊕○○○ VERY LOW <sup>d</sup>	<b>RR 0.56</b> (0.17 to 1.86)	Study population	
					20 per 1,000	<b>9 fewer per 1,000</b> (17 fewer to 18 more)
	Dysphagia - patient reported - Long Term (>3mon)	450 (3 observational studies)	⊕○○○ VERY LOW <sup>a</sup>	<b>RR 0.80</b> (0.60 to 1.07)	Study population	
					386 per 1,000	<b>77 fewer per 1,000</b> (154 fewer to 27 more)
	Cost (mean U.S. dollars)	1610 (2 observational studies)	⊕○○○ VERY LOW <sup>e,f</sup>	-	The mean cost (mean U.S. dollars) was <b>0</b>	<b>MD 132 lower</b> (2512.81 lower to 2248.81 higher)
<p>a. There was a small sample size and very large confidence interval.</p> <p>b. Although there was a mix of low, high, and unclear ROB, the data across all studies was consistent with the low ROB studies</p> <p>c. Both the event size and the overall sample size were quite low, in addition to a very wide confidence interval.</p> <p>d. Although the overall sample size was large, the event size was quite small and the confidence interval was wide.</p> <p>e. Nearly all the included studies were found to have an unclear or high ROB.</p> <p>f. Although there was a large over all sample size, the confidence intervals were quite wide.</p>						

## Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE					ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <li>○ Large</li> <li>○ Moderate</li> <li>● <b>Small</b></li> <li>○ Trivial</li> <li>○ Varies</li> <li>○ Don't know</li> </ul>	<b>Outcomes</b>	<b>№ of participants (studies) Follow up</b>	<b>Certainty of the evidence (GRADE)</b>	<b>Relative effect (95% CI)</b>	<b>Anticipated absolute effects* (95% CI)</b>	
					<b>Risk with Fundoplication</b>	<b>Risk difference with MSA</b>
	Quality of life Scale - Long Term (>2yrs)	610 (3 observational studies)	⊕○○○ VERY LOW <sup>a,b</sup>	-	The mean quality of life Scale - Long Term (>2yrs) was <b>0</b> SD	<b>SMD 0.14 SD lower</b> (0.32 lower to 0.04 higher)
	Complete Symptom Resolution (patient reported) - Short Term (<2yr)	118 (2 observational studies)	⊕○○○ VERY LOW <sup>d,e</sup>	<b>RR 0.93</b> (0.70 to 1.24)	Study population	
				576 per 1,000	<b>40 fewer per 1,000</b> (173 fewer to 138 more)	
	Need for PPI	1445 (6 observational studies)	⊕○○○ VERY LOW <sup>a,f,g</sup>	<b>RR 1.02</b> (0.64 to 1.63)	Study population	
					137 per 1,000	<b>3 more per 1,000</b> (49 fewer to 86 more)

Dysphagia requiring intervention	297 (4 observational studies)	⊕○○○ VERY LOW <sup>a,e</sup>	RR 1.61 (0.85 to 3.03)	Study population	
				92 per 1,000	<b>56 more per 1,000</b> (14 fewer to 186 more)
Patient satisfaction - yes	846 (5 observational studies)	⊕○○○ VERY LOW <sup>h,i</sup>	RR 0.99 (0.93 to 1.05)	Study population	
				862 per 1,000	<b>9 fewer per 1,000</b> (60 fewer to 43 more)
<p>a. Nearly all the included studies were found to have an unclear or high ROB.</p> <p>b. There was a small sample size and very large confidence interval.</p> <p>c. The included study did not report the standard deviation for this outcome and so the effect is not estimable.</p> <p>d. Although one study had an unclear ROB, the findings were consistent with the low ROB study.</p> <p>e. Both the event size and the overall sample size were quite low, in addition to a very wide confidence interval.</p> <p>f. There was inconsistency across data with findings ranging from benefits from the intervention to harms from the intervention with an I2 of 57%.</p> <p>g. Although there was a large overall sample size, the confidence intervals were quite wide.</p> <p>h. Although there was a mix of low, high, and unclear ROB, the data across all studies was consistent with the low ROB studies.</p> <p>i. The optimal information size criteria was not met.</p>					

## Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE			ADDITIONAL CONSIDERATIONS
<p>● Very low</p> <p>○ Low</p> <p>○ Moderate</p> <p>○ High</p> <p>○ No included studies</p>	Outcomes	Importance	Certainty of the evidence (GRADE)	
	Quality of life Scale - Long Term (>2yrs)	CRITICAL	⊕○○○ VERY LOW <sup>a,b</sup>	
	Objective reflux (demeester, pH etc)	IMPORTANT	⊕○○○ VERY LOW <sup>a,c</sup>	
	Symptom RECURRENCE (patient reported) - Short term (<2yr)	CRITICAL	⊕○○○ VERY LOW <sup>b</sup>	
	Complete Symptom Resolution (patient reported) - Short Term (<2yr)	CRITICAL	⊕○○○ VERY LOW <sup>d,e</sup>	
	Perioperative complications (Clavien dindo ≥2) (<30 days)	IMPORTANT	⊕○○○ VERY LOW <sup>e,f</sup>	
	Reoperation (ANY)	NOT IMPORTANT	⊕○○○ VERY LOW <sup>g</sup>	

Need for PPI	CRITICAL	⊕○○○ VERY LOW <sup>a,h,i</sup>
Dysphagia requiring intervention	CRITICAL	⊕○○○ VERY LOW <sup>a,e</sup>
Dysphagia - patient reported - Long Term (>3mon)	IMPORTANT	⊕○○○ VERY LOW <sup>b</sup>
Patient satisfaction - yes	IMPORTANT	⊕○○○ VERY LOW <sup>f,j</sup>
Cost (mean U.S. dollars)	NOT IMPORTANT	⊕○○○ VERY LOW <sup>a,i</sup>
<p>a. Nearly all the included studies were found to have an unclear or high ROB.  b. There was a small sample size and very large confidence interval.  c. The included study did not report the standard deviation for this outcome and so the effect is not estimable.  d. Although one study had an unclear ROB, the findings were consistent with the low ROB study.  e. Both the event size and the overall sample size were quite low, in addition to a very wide confidence interval.  f. Although there was a mix of low, high, and unclear ROB, the data across all studies was consistent with the low ROB studies  g. Although the overall sample size was large, the event size was quite small and the confidence interval was wide.  h. There was inconsistency across data with findings ranging from benefits from the intervention to harms from the intervention with an I2 of 57%.  i. Although there was a large over all sample size, the confidence intervals were quite wide.  j. The optimal information size criteria was not met.</p>		

## Values

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

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input checked="" type="radio"/> <b>Probably no important uncertainty or variability</b> <input type="radio"/> No important uncertainty or variability		Patients with preoperative bloating

## Balance of effects

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

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Favors the comparison <input type="radio"/> Probably favors the comparison <input checked="" type="radio"/> <b>Does not favor either the intervention or the comparison</b> <input type="radio"/> Probably favors the intervention <input type="radio"/> Favors the intervention <input type="radio"/> Varies <input type="radio"/> Don't know		

Acceptability		
Is the intervention acceptable to key stakeholders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> <b>Yes</b> <input type="radio"/> Varies <input type="radio"/> Don't know		

Feasibility		
Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> <b>Yes</b> <input type="radio"/> Varies <input type="radio"/> Don't know		Skill set required to place is the same as foregut surgery. Nuance comes in sizing (learning curve). Less technical than fundoplication. Work up of GERD is same, with motility and BMI exceptions. Some cost (\$5500) and payers will reimburse less than fundoplication, but utilization of GERD surgery goes up.

## SUMMARY OF JUDGEMENTS

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

## TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	<b>Conditional recommendation for either the intervention or the comparison</b> ●	Conditional recommendation for the intervention ○	Strong recommendation for the intervention ○
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## CONCLUSIONS

### Recommendation

### Justification

### Subgroup considerations

Previous sleeve gastrectomy patients are unable to undergo fundoplication need to have other options available  
Currently, high BMI and poor dysmotility are contraindications for MSA  
Patients with preoperative bloating

### Implementation considerations

Device Training  
Fundoplication training and standardization  
Although approved for use, it has not been adopted globally

### Monitoring and evaluation

### Research priorities

Any RCT comparing MSA and fundoplication  
Objective postoperative reflux data from **comparative** observational or RCT studies  
Procedural standardization, especially with fundoplication  
Validated, disease specific patient centered outcomes long-term

## 2b. Should MSA vs. PPI be used for patients with GERD?

POPULATION:	patients with GERD
INTERVENTION:	MSA
COMPARISON:	PPI
MAIN OUTCOMES:	Patient reported complete symptom resolution - Short term (<2yrs); Need for PPI - at 6mon; Patient satisfaction - yes; Objective reflux recurrence – measured at 6mon with impedance-pH testing, average number of reflux events;
SETTING:	
PERSPECTIVE:	<b>PATIENT-CENTERED</b>
BACKGROUND:	
CONFLICT OF INTERESTS:	

### ASSESSMENT

Problem						
Is the problem a priority?						
JUDGEMENT	RESEARCH EVIDENCE					ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> <b>Yes</b> <input type="radio"/> Varies <input type="radio"/> Don't know						
Desirable Effects						
How substantial are the desirable anticipated effects?						
JUDGEMENT	RESEARCH EVIDENCE					ADDITIONAL CONSIDERATIONS
<input type="radio"/> Trivial <input type="radio"/> Small <input type="radio"/> Moderate <input checked="" type="radio"/> <b>Large</b> <input type="radio"/> Varies <input type="radio"/> Don't know	Outcomes	No of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
					Risk with PPI	Risk difference with MSA
	Patient reported complete symptom resolution - Short term (<2yrs)	148 (1 RCT)	⊕⊕⊕⊕ HIGH	<b>RR 9.03</b> (4.97 to 16.39)	Study population	
					99 per 1,000	<b>795 more per 1,000</b> (393 more to 1,524 more)
	Need for PPI - at 6mon	134 (1 RCT)	⊕⊕⊕○ MODERATE <sup>a</sup>	<b>RR 0.09</b> (0.04 to 0.23)	Study population	
					1,000 per 1,000	<b>910 fewer per 1,000</b> (960 fewer to 770 fewer)

Patient satisfaction - yes	134 (1 RCT)	⊕⊕⊕○ MODERATE <sup>a</sup>	RR 35.17 (8.88 to 139.37)	Study population	
				23 per 1,000	<b>786 more per 1,000</b> (181 more to 3,181 more)
Objective reflux recurrence – measured at 6mon with impedance-pH testing, average number of reflux events	158 (1 RCT)	⊕⊕○○ LOW <sup>b</sup>	RR 0.87 (0.52 to 1.45)	Study population	
				291 per 1,000	<b>38 fewer per 1,000</b> (140 fewer to 131 more)
<p>a. There was a small sample size and wide confidence interval.</p> <p>b. Small sample size and very wide confidence interval.</p>					

## Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <li>○ Large</li> <li>○ Moderate</li> <li>○ Small</li> <li>○ Trivial</li> <li>○ Varies</li> <li>● <b>Don't know</b></li> </ul>		

## Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE			ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <li>○ Very low</li> <li>○ Low</li> <li>● <b>Moderate</b></li> <li>○ High</li> <li>○ No included studies</li> </ul>	<b>Outcomes</b>	<b>Importance</b>	<b>Certainty of the evidence (GRADE)</b>	
	Patient reported complete symptom resolution - Short term (<2yrs)	CRITICAL	⊕⊕⊕⊕ HIGH	
	Need for PPI - at 6mon	CRITICAL	⊕⊕⊕○ MODERATE <sup>a</sup>	
	Patient satisfaction - yes	IMPORTANT	⊕⊕⊕○ MODERATE <sup>a</sup>	
	Objective reflux recurrence – measured at 6mon with impedance-pH testing, average number of reflux events	IMPORTANT	⊕⊕○○ LOW <sup>b</sup>	
<p>a. There was a small sample size and wide confidence interval.</p> <p>b. Small sample size and very wide confidence interval.</p>				





JUDGEMENT							
DESIRABLE EFFECTS	Trivial	Small	Moderate	<b>Large</b>		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	<b>Don't know</b>
CERTAINTY OF EVIDENCE	Very low	Low	<b>Moderate</b>	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	<b>Probably no important uncertainty or variability</b>	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	<b>Don't know</b>
ACCEPTABILITY	No	Probably no	Probably yes	<b>Yes</b>		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	<b>Yes</b>		Varies	Don't know

## TYPE OF RECOMMENDATION

Strong recommendation against the intervention <input type="radio"/>	Conditional recommendation against the intervention <input type="radio"/>	Conditional recommendation for either the intervention or the comparison <input type="radio"/>	<b>Conditional recommendation for the intervention</b> <input checked="" type="radio"/>	Strong recommendation for the intervention <input type="radio"/>
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## CONCLUSIONS

### Recommendation

### Justification

Evidence was based on one well-done RCT with only 6mon follow up.

### Subgroup considerations

People at risk for osteoporosis – (\*add in reference)  
 People who don't want to take daily meds  
 Currently, high BMI and poor dysmotility are contraindications for MSA  
 Patients with preoperative bloating

### Implementation considerations

Device Training  
 Although approved for use, it has not been adopted globally

### Monitoring and evaluation

## Research priorities

Long term data from RCTs comparing MSA and PPI  
 Objective postoperative reflux data from **comparative** observational or RCT studies  
 Validated, disease specific patient centered outcomes long-term

## 2d. Should TIF vs. PPI be used for patients with GERD?

POPULATION:	patients with GERD
INTERVENTION:	TIF
COMPARISON:	PPI
MAIN OUTCOMES:	Reflux Symptom Resolution scale - Short term (<2yrs); Patient reported symptom resolution - Short term (<2yrs); Perioperative complications (<30d) Clavien dindo $\geq 2$ ; Reoperation Required, anytime; Need for PPI at 6mon; Dysphagia - patient reported (>3mon); Patient satisfaction - yes; Objective reflux recurrence; Quality of Life Scale - Short term (<2yrs);
SETTING:	PATIENT-CENTERED
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

## ASSESSMENT

### Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> <b>Yes</b> <input type="radio"/> Varies <input type="radio"/> Don't know		

### Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE					ADDITIONAL CONSIDERATIONS														
<input type="radio"/> Trivial <input type="radio"/> Small <input checked="" type="radio"/> <b>Moderate</b> <input type="radio"/> Large <input type="radio"/> Varies <input type="radio"/> Don't know	<table border="1"> <thead> <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 PPI</th> <th>Risk difference with TIF</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Patient reported symptom resolution - Short term (&lt;2yrs)</td> <td rowspan="2">216 (3 RCTs)</td> <td rowspan="2">⊕⊕○○ LOW<sup>a,b</sup></td> <td rowspan="2">RR 1.50 (0.93 to 2.40)</td> <td colspan="2">Study population</td> </tr> <tr> <td>425 per 1,000</td> <td><b>213 more per 1,000</b> (30 fewer to 595 more)</td> </tr> </tbody> </table>	Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)		Risk with PPI	Risk difference with TIF	Patient reported symptom resolution - Short term (<2yrs)	216 (3 RCTs)	⊕⊕○○ LOW <sup>a,b</sup>	RR 1.50 (0.93 to 2.40)	Study population		425 per 1,000	<b>213 more per 1,000</b> (30 fewer to 595 more)			
Outcomes	№ of participants (studies) Follow up					Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)												
		Risk with PPI	Risk difference with TIF																	
Patient reported symptom resolution - Short term (<2yrs)	216 (3 RCTs)	⊕⊕○○ LOW <sup>a,b</sup>	RR 1.50 (0.93 to 2.40)	Study population																
				425 per 1,000	<b>213 more per 1,000</b> (30 fewer to 595 more)															

	Need for PPI at 6mon	233 (3 RCTs)	⊕⊕⊕⊕ HIGH <sup>c</sup>	<b>RR 0.27</b> (0.14 to 0.53)	Study population	
					953 per 1,000	<b>696 fewer per 1,000</b> (820 fewer to 448 fewer)
	Patient satisfaction - yes	57 (1 RCT)	⊕⊕⊕⊕ HIGH	<b>RR 21.55</b> (1.37 to 339.19)	Study population	
					0 per 1,000	<b>Not estimable</b>
	Objective reflux recurrence	33 (1 RCT)	⊕⊕⊕○ MODERATE <sup>d</sup>	<b>RR 0.16</b> (0.04 to 0.65)	Study population	
					615 per 1,000	<b>517 fewer per 1,000</b> (591 fewer to 215 fewer)
	Quality of Life Scale - Short term (<2yrs) assessed with: one used QOLRAD and other used GERD-HRQL	86 (2 RCTs)	⊕⊕⊕○ MODERATE <sup>b</sup>	-	The mean quality of Life Scale - Short term (<2yrs) was <b>0 SD</b>	<b>SMD 0.5 SD lower</b> (0.97 lower to 0.03 lower)
<p>a. There is some inconsistency demonstrated with an I2 of 58%.</p> <p>b. Small sample size and wide confidence intervals</p> <p>c. Although there is some statistical inconsistency, from a decision making perspective there is no clinically important inconsistency.</p> <p>d. Very small sample size with even smaller event sizes. Very wide confidence interval.</p>						

## Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE					ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <li>○ Large</li> <li>○ Moderate</li> <li>● <b>Small</b></li> <li>○ Trivial</li> <li>○ Varies</li> <li>○ Don't know</li> </ul>	<b>Outcomes</b>	<b>No of participants (studies) Follow up</b>	<b>Certainty of the evidence (GRADE)</b>	<b>Relative effect (95% CI)</b>	<b>Anticipated absolute effects* (95% CI)</b>	
					<b>Risk with PPI</b>	<b>Risk difference with TIF</b>
	Perioperative complications (<30d) Clavien dindo ≥ 2	173 (2 RCTs)	⊕⊕○○ LOW <sup>a</sup>	<b>RR 3.38</b> (0.43 to 26.58)	Study population	16 per 1,000
<p>a. Very small sample size, with only one trial contributing event data. Very wide confidence intervals.</p>						

## Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE			ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <li>○ Very low</li> <li>○ Low</li> <li>● <b>Moderate</b></li> <li>○ High</li> <li>○ No included studies</li> </ul>	<b>Outcomes</b>	<b>Importance</b>	<b>Certainty of the evidence (GRADE)</b>	
	Patient reported symptom resolution - Short term (<2yrs)	CRITICAL	⊕⊕○○ LOW <sup>a,b</sup>	

Perioperative complications (<30d) Clavien dindo ≥ 2	IMPORTANT	⊕⊕○○ LOW <sup>c</sup>
Reoperation Required, anytime	Non-informative outcome, not used in decision making	⊕⊕○○ LOW <sup>d</sup>
Need for PPI at 6mon	CRITICAL	⊕⊕⊕⊕ HIGH <sup>e</sup>
Dysphagia - patient reported (>3mon)	Non-informative outcome, not used in decision making	⊕⊕○○ LOW <sup>f</sup>
Patient satisfaction - yes	IMPORTANT	⊕⊕⊕⊕ HIGH
Objective reflux recurrence	IMPORTANT	⊕⊕⊕○ MODERATE <sup>g</sup>
Quality of Life Scale - Short term (<2yrs) assessed with: one used QOLRAD and other used GERD-HRQL	CRITICAL	⊕⊕⊕○ MODERATE <sup>g</sup>
<p>a. Small sample size and wide confidence intervals</p> <p>b. There is some inconsistency demonstrated with an I2 of 58% .</p> <p>c. Very small sample size, with only one trial contributing event data. Very wide confidence intervals.</p> <p>d. Neither trial had any events for either the intervention or comparator.</p> <p>e. Although there is some statistical inconsistency, from a decision making perspective there is no clinically important inconsistency.</p> <p>f. Very small sample size with only one patient in the TIF cohort reporting dysphagia. In addition there was a very wide confidence interval.</p> <p>g. Very small sample size with even smaller event sizes. Very wide confidence interval.</p>		

## Values

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

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input checked="" type="radio"/> <b>Probably no important uncertainty or variability</b> <input type="radio"/> No important uncertainty or variability		People who don't want to take meds nor undergo surgery

## Balance of effects

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

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Favors the comparison <input type="radio"/> Probably favors the comparison <input type="radio"/> Does not favor either the intervention or the comparison <input checked="" type="radio"/> <b>Probably favors the intervention</b> <input type="radio"/> Favors the intervention <input type="radio"/> Varies <input type="radio"/> Don't know		

## Acceptability

Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> <b>Probably yes</b> <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know		Alters their anatomy Has not been adopted globally

## Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> <b>Probably yes</b> <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know		Technically difficult learning curve Less reproducible techniques that need to be tailored to patient's anatomy

## SUMMARY OF JUDGEMENTS

PROBLEM	JUDGEMENT						
	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	<b>Moderate</b>	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	<b>Small</b>	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	<b>Moderate</b>	High			No included studies

JUDGEMENT							
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	<b>Probably no important uncertainty or variability</b>	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	<b>Probably favors the intervention</b>	Favors the intervention	Varies	Don't know
ACCEPTABILITY	No	Probably no	<b>Probably yes</b>	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	<b>Probably yes</b>	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 ○	<b>Conditional recommendation for the intervention</b> ●	Strong recommendation for the intervention ○
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### CONCLUSIONS

**Recommendation**

**Justification**

**Subgroup considerations**

Patients with small hiatal hernia vs. no hiatal hernia  
 People at risk for osteoporosis – (\*add in reference)  
 People who don't want to take daily meds

**Implementation considerations**

Contraindications for TIF – hiatal hernia >2-3cm, esophageal strictures, contraindications to endoscopy (i.e. neck extension restrictions)  
 Learning curve of device  
 TIF requires general anesthesia  
 Resource intensive compared to med management

**Monitoring and evaluation**

**Research priorities**

Long term, durability studies that include patients with heartburn, not just regurgitation  
 Examining strategy of C-TIF

## 2e. Should Stretta vs. Fundoplication be used for patients with GERD?

POPULATION:	patients with GERD
INTERVENTION:	Stretta
COMPARISON:	Fundoplication
MAIN OUTCOMES:	Quality of Life - Short Term; Objective Reflux Recurrence (Mean DeMeester Score @ 12mon); Subjective Reflux Symptom Recurrence - Long Term; Subjective Reflux Symptom Resolution - Long Term (>2yrs); Perioperative Complication (Clavien-Dindo >=2); Reoperation; Need for PPI; Dysphagia requiring intervention; Patient satisfaction ; Cost - mean hospital cost presented (\$1,808 Stretta vs. \$5,715 LNF);
SETTING:	<b>PATIENT-CENTERED</b>
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

## ASSESSMENT

### Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> <b>Yes</b> <input type="radio"/> Varies <input type="radio"/> Don't know		

### Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE					ADDITIONAL CONSIDERATIONS
<input type="radio"/> Trivial <input checked="" type="radio"/> <b>Small</b> <input type="radio"/> Moderate <input type="radio"/> Large <input type="radio"/> Varies <input type="radio"/> Don't know	<b>Outcomes</b>	<b>Nº of participants (studies) Follow-up</b>	<b>Certainty of the evidence (GRADE)</b>	<b>Relative effect (95% CI)</b>	<b>Anticipated absolute effects* (95% CI)</b>	
					<b>Risk with Fundoplication</b>	<b>Risk difference with Stretta</b>
	Perioperative Complication (Clavien-Dindo >=2)	283 (1 observational study) Ma 2020	⊕○○○ Very low <sup>a</sup>	<b>RR 0.54</b> (0.28 to 1.05)	Study population 173 per 1,000	<b>80 fewer per 1,000</b> (125 fewer to 9 more)
	Dysphagia requiring intervention	279 (2 observational studies) Liang 2014 Yan 2015	⊕⊕○○ Low	<b>RR 0.14</b> (0.02 to 1.08)	Study population 50 per 1,000	<b>43 fewer per 1,000</b> (49 fewer to 4 more)



Cost - mean hospital cost presented (\$1,808 Stretta vs. \$5,715 LNF)	140 (1 observational study) Richards 2003	⊕○○○ Very low <sup>b</sup>	-	The mean cost - mean hospital cost presented (\$1,808 Stretta vs. \$5,715 LNF) was <b>0</b>	<b>0</b> (0 to 0)
<p>a. Small sample sizes and very wide confidence interval.</p> <p>b. Small sample size increases the fragility of this outcome.</p>					

## Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE					ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <li>○ Large</li> <li>● <b>Moderate</b></li> <li>○ Small</li> <li>○ Trivial</li> <li>○ Varies</li> <li>○ Don't know</li> </ul>	<b>Outcomes</b>	<b>№ of participants (studies) Follow-up</b>	<b>Certainty of the evidence (GRADE)</b>	<b>Relative effect (95% CI)</b>	<b>Anticipated absolute effects* (95% CI)</b>	
					<b>Risk with Fundoplication</b>	<b>Risk difference with Stretta</b>
	Quality of Life - Short Term	140 (1 observational study) Richards 2003	⊕○○○ Very low <sup>a,b</sup>	-	The mean quality of Life - Short Term was <b>0</b> points	<b>MD 0.5 points lower</b> (0.94 lower to 0.06 lower)
	Objective Reflux Recurrence (Mean DeMeester Score @ 12mon)	226 (1 observational study) Ma 2020	⊕○○○ Very low <sup>c</sup>	-	The mean objective Reflux Recurrence (Mean DeMeester Score @ 12mon) was <b>0</b> points	<b>MD 1.5 points higher</b> (0.22 higher to 2.78 higher)
	Subjective Reflux Symptom Recurrence - Long Term	57 (1 observational study) Hu 2014	⊕○○○ Very low <sup>c,d</sup>	<b>RR 1.03</b> (0.25 to 4.19)	Study population 121 per 1,000	<b>4 more per 1,000</b> (91 fewer to 387 more)
	Subjective Reflux Symptom Resolution - Long Term (>2yrs)	57 (1 observational study) Hu 2014	⊕○○○ Very low <sup>c,d</sup>	<b>RR 0.63</b> (0.25 to 1.56)	Study population 333 per 1,000	<b>123 fewer per 1,000</b> (250 fewer to 187 more)
	Reoperation	191 (2 observational studies) Liang 2015 Zhang 2016	⊕○○○ Very low <sup>e</sup>	<b>RR 16.41</b> (2.21 to 121.68)	Study population 0 per 1,000	<b>0 fewer per 1,000</b> (0 fewer to 0 fewer)
	Need for PPI	345 (3 observational studies) Liang 2014 Yan 2015 Zhang 2016	⊕○○○ Very low <sup>c,f</sup>	<b>RR 1.81</b> (0.61 to 5.40)	Study population 206 per 1,000	<b>167 more per 1,000</b> (80 fewer to 905 more)
Patient satisfaction	123 (2 observational studies) Hu 2014 Zhang 2016	⊕○○○ Very low <sup>a,d</sup>	<b>RR 0.77</b> (0.60 to 0.98)	Study population 779 per 1,000	<b>179 fewer per 1,000</b> (312 fewer to 16 fewer)	
<p>a. Small sample size increases the fragility of this outcome</p> <p>b. The percent loss to follow up was not reported, which introduces possible bias.</p>						

- c. Small sample sizes and very wide confidence interval.
- d. This study was found to have an unclear ROB due to ambiguity regarding the patient selection for either intervention.
- e. Small sample sizes with even smaller event size. No events seen in one intervention making the estimated effects inestimable.
- f. Two studies found relatively no difference in PPI use between Stretta and fundoplication, whereas Liang 2014 demonstrated a much higher PPI use after Stretta, thus favoring Fundoplication. This difference could not be explained by study populations, length of follow up, nor risk of bias.

## Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE			ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <li>● Very low</li> <li>○ Low</li> <li>○ Moderate</li> <li>○ High</li> <li>○ No included studies</li> </ul>	<p style="text-align: center;"><b>Outcomes</b></p>	<p style="text-align: center;"><b>Importance</b></p>	<p style="text-align: center;"><b>Certainty of the evidence (GRADE)</b></p>	
	Quality of Life - Short Term	CRITICAL	⊕○○○ Very low <sup>a,b</sup>	
	Objective Reflux Recurrence (Mean DeMeester Score @ 12mon)	NOT IMPORTANT	⊕○○○ Very low <sup>c</sup>	
	Subjective Reflux Symptom Recurrence - Long Term	CRITICAL	⊕○○○ Very low <sup>c,d</sup>	
	Subjective Reflux Symptom Resolution - Long Term (>2yrs)	CRITICAL	⊕○○○ Very low <sup>c,d</sup>	
	Perioperative Complication (Clavien-Dindo >=2)	IMPORTANT	⊕○○○ Very low <sup>c</sup>	
	Reoperation	NOT IMPORTANT	⊕○○○ Very low <sup>e</sup>	
	Need for PPI	CRITICAL	⊕○○○ Very low <sup>c,f</sup>	
	Dysphagia requiring intervention	IMPORTANT	⊕⊕○○ Low	
	Patient satisfaction	IMPORTANT	⊕○○○ Very low <sup>a,d</sup>	
Cost - mean hospital cost presented (\$1,808 Stretta vs. \$5,715 LNF)	NOT IMPORTANT	⊕○○○ Very low <sup>a</sup>		
<ul style="list-style-type: none"> <li>a. Small sample size increases the fragility of this outcome</li> <li>b. The percent loss to follow up was not reported, which introduces possible bias.</li> <li>c. Small sample sizes and very wide confidence interval.</li> </ul>				

	<p>d. This study was found to have an unclear ROB due to ambiguity regarding the patient selection for either intervention.</p> <p>e. Small sample sizes with even smaller event size. No events seen in one intervention making the estimated effects inestimable.</p> <p>f. Two studies found relatively no difference in PPI use between Stretta and fundoplication, whereas Liang 2014 demonstrated a much higher PPI use after Stretta, thus favoring Fundoplication. This difference could not be explained by study populations, length of follow up, nor risk of bias.</p>	
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**Values**  
Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Important uncertainty or variability <input checked="" type="radio"/> <b>Possibly important uncertainty or variability</b> <input type="radio"/> Probably no important uncertainty or variability <input type="radio"/> 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
<input type="radio"/> Favors the comparison <input checked="" type="radio"/> <b>Probably favors the comparison</b> <input type="radio"/> Does not favor either the intervention or the comparison <input type="radio"/> Probably favors the intervention <input type="radio"/> Favors the intervention <input type="radio"/> Varies <input type="radio"/> Don't know		

**Acceptability**  
Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> <b>Probably yes</b> <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know		

**Feasibility**  
Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> <b>Probably yes</b> <input type="radio"/> Yes <input type="radio"/> Varies		

o Don't know		
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**SUMMARY OF JUDGEMENTS**

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

**TYPE OF RECOMMENDATION**

Strong recommendation against the intervention ○	<b>Conditional recommendation against the intervention</b> ●	Conditional recommendation for either the intervention or the comparison ○	Conditional recommendation for the intervention ○	Strong recommendation for the intervention ○
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**CONCLUSIONS**

- Recommendation
- Justification
- Subgroup considerations
- Implementation considerations
- Monitoring and evaluation

## Research priorities

Long term data from RCTs comparing Stretta and Fundoplication  
 Objective postoperative reflux data from **comparative** observational or RCT studies  
 Validated, disease specific patient centered outcomes long-term

### 2f. Should Stretta vs. PPI be used for patients with GERD?

POPULATION:	patients with GERD
INTERVENTION:	Stretta
COMPARISON:	PPI
MAIN OUTCOMES:	Quality of Life scale - Short term (<2yrs); Reflux symptom resolution - Short Term (<2yrs); Perioperative complications (<30d) Clavien dindo $\geq 2$ ; Need for PPI; Dysphagia - patient reported (<3mon); Requires additional procedures; Patient Satisfaction;
SETTING:	
PERSPECTIVE:	PATIENT-CENTERED
BACKGROUND:	
CONFLICT OF INTERESTS:	

## ASSESSMENT

### Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> <b>Yes</b> <input type="radio"/> Varies <input type="radio"/> Don't know		

### Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE					ADDITIONAL CONSIDERATIONS				
<input type="radio"/> Trivial <input type="radio"/> Small <input checked="" type="radio"/> <b>Moderate</b> <input type="radio"/> Large <input type="radio"/> Varies <input type="radio"/> Don't know	<b>Outcomes</b> Quality of Life scale - Short term (<2yrs)	<b>No of participants (studies) Follow-up</b> 89 (3 RCTs) Arts 2012 Aziz 2010 Coron 2008	<b>Certainty of the evidence (GRADE)</b> ⊕⊕⊕○ Moderate <sup>a</sup>	<b>Relative effect (95% CI)</b> -	<b>Anticipated absolute effects* (95% CI)</b> <table border="1"> <thead> <tr> <th>Risk with PPI</th> <th>Risk difference with Stretta</th> </tr> </thead> <tbody> <tr> <td>The mean quality of Life scale - Short term (&lt;2yrs) was 0 SD</td> <td>SMD 1.61 SD higher (1.12 higher to 2.1 higher)</td> </tr> </tbody> </table>		Risk with PPI	Risk difference with Stretta	The mean quality of Life scale - Short term (<2yrs) was 0 SD	SMD 1.61 SD higher (1.12 higher to 2.1 higher)
Risk with PPI	Risk difference with Stretta									
The mean quality of Life scale - Short term (<2yrs) was 0 SD	SMD 1.61 SD higher (1.12 higher to 2.1 higher)									

	Reflux symptom resolution - Short Term (<2yrs)	122 (3 RCTs) Aziz 2010 Coron 2008 Zerbib 2020	⊕⊕○○ Low <sup>b</sup>	<b>RR 1.32</b> (0.26 to 6.59)	Study population	180 per 1,000	<b>58 more per 1,000</b> (133 fewer to 1,008 more)
	Need for PPI	143 (4 RCTs) Aziz 2010 Coron 2008 Kalapala 2017 Zerbib 2020	⊕⊕○○ Low <sup>b</sup>	<b>RR 0.85</b> (0.69 to 1.04)	Study population	958 per 1,000	<b>144 fewer per 1,000</b> (297 fewer to 38 more)
	Patient Satisfaction	20 (1 RCT) Kalapala 2017	⊕⊕○○ Low <sup>b</sup>	<b>RR 2.67</b> (0.98 to 7.22)	Study population	300 per 1,000	<b>501 more per 1,000</b> (6 fewer to 1,866 more)
<p>a. Small sample size and wide confidence interval</p> <p>b. Very small sample size and very wide confidence intervals that crosses several clinically meaningful thresholds.</p>							

## Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE						ADDITIONAL CONSIDERATIONS	
<ul style="list-style-type: none"> <li>○ Large</li> <li>○ Moderate</li> <li>● <b>Small</b></li> <li>○ Trivial</li> <li>○ Varies</li> <li>○ Don't know</li> </ul>	<b>Outcomes</b>	<b>№ of participants (studies) Follow-up</b>	<b>Certainty of the evidence (GRADE)</b>	<b>Relative effect (95% CI)</b>	<b>Anticipated absolute effects* (95% CI)</b>			
					<b>Risk with PPI</b>	<b>Risk difference with Stretta</b>		
	Perioperative complications (<30d) Clavien dindo ≥ 2	86 (2 RCTs) Aziz 2010 Zerbib 2020	⊕⊕○○ Low <sup>a</sup>	<b>RR 3.27</b> (0.54 to 19.77)	Study population	22 per 1,000		<b>50 more per 1,000</b> (10 fewer to 417 more)
	Dysphagia - patient reported (<3mon)	24 (1 RCT) Aziz 2010S	⊕⊕○○ Low <sup>a</sup>	<b>RR 3.00</b> (0.13 to 67.06)	Study population	0 per 1,000		<b>0 fewer per 1,000</b> (0 fewer to 0 fewer)
	Requires additional procedures	62 (1 RCT) Zerbib 2020	⊕⊕○○ Low <sup>a</sup>	<b>RR 1.44</b> (1.03 to 2.01)	Study population	576 per 1,000	<b>253 more per 1,000</b> (17 more to 582 more)	
<p>a. Very small sample size and very wide confidence intervals that crosses several clinically meaningful thresholds.</p>								

## Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE			ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <li>○ Very low</li> <li>● <b>Low</b></li> <li>○ Moderate</li> <li>○ High</li> <li>○ No included studies</li> </ul>	<b>Outcomes</b>	<b>Importance</b>	<b>Certainty of the evidence (GRADE)</b>	
	Quality of Life scale - Short term (<2yrs)	CRITICAL	⊕⊕⊕○ Moderate <sup>a</sup>	

Reflux symptom resolution - Short Term (<2yrs)	CRITICAL	⊕⊕○○ Low <sup>b</sup>
Perioperative complications (<30d) Clavien dindo ≥ 2	IMPORTANT	⊕⊕○○ Low <sup>b</sup>
Need for PPI	CRITICAL	⊕⊕○○ Low <sup>b</sup>
Dysphagia - patient reported (<3mon)	IMPORTANT	⊕⊕○○ Low <sup>b</sup>
Requires additional procedures	NOT IMPORTANT	⊕⊕○○ Low <sup>b</sup>
Patient Satisfaction	IMPORTANT	⊕⊕○○ Low <sup>b</sup>

a. Small sample size and wide confidence interval  
b. Very small sample size and very wide confidence intervals that crosses several clinically meaningful thresholds.

### Values

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

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Important uncertainty or variability <input checked="" type="radio"/> <b>Possibly important uncertainty or variability</b> <input type="radio"/> Probably no important uncertainty or variability <input type="radio"/> 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
<input type="radio"/> Favors the comparison <input type="radio"/> Probably favors the comparison <input type="radio"/> Does not favor either the intervention or the comparison <input type="radio"/> Probably favors the intervention <input checked="" type="radio"/> <b>Favors the intervention</b> <input type="radio"/> Varies <input type="radio"/> Don't know		

### Acceptability

Is the intervention acceptable to key stakeholders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> <b>Probably yes</b> <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know		

Feasibility Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> <b>Probably yes</b> <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know		

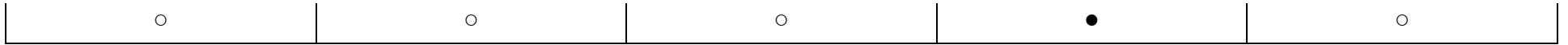
## SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	<b>Yes</b>		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	<b>Moderate</b>	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	<b>Small</b>	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	<b>Low</b>	Moderate	High			No included studies
VALUES	Important uncertainty or variability	<b>Possibly important uncertainty or variability</b>	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	<b>Favors the intervention</b>	Varies	Don't know
ACCEPTABILITY	No	Probably no	<b>Probably yes</b>	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	<b>Probably yes</b>	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	<b>Conditional recommendation for the intervention</b>	Strong recommendation for the intervention
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## CONCLUSIONS

Recommendation

Justification

Subgroup considerations

Implementation considerations

Monitoring and evaluation

Research priorities

Long term data from RCTs comparing Stretta and PPI  
Objective postoperative reflux data from **comparative** observational or RCT studies  
Validated, disease specific patient centered outcomes long-term