

**QUESTION 2**

Should POEM vs. Pneumatic Dilatation be used for achalasia in adults and children?	
POPULATION:	adults and children with achalasia
INTERVENTION:	POEM
COMPARISON:	Pneumatic Dilatation
MAIN OUTCOMES:	Short and longer-term control of symptom(s); patient reported short-term reflux; retreatment (with either PD or POEM); treatment-related serious adverse events; achalasia DS QoL; proton pump inhibitor (PPI) use
PERSPECTIVE:	Patient/surgeon perspective
SETTING:	International
CONFLICT OF INTERESTS:	No funding was provided for this Guideline. Individual authors all provided disclosures as listed in separate appendix within the guideline

**ASSESSMENT**

Desirable Effects																																											
How substantial are the desirable anticipated effects?																																											
JUDGEMENT	RESEARCH EVIDENCE																																										
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	<p>The panel unanimously agreed that the desirable effects of POEM as compared to PD were large.</p> <p>Most of the evidence was based on adults with type 1 or 2 achalasia, or on adults with unspecified achalasia type. Only one small observational study evaluated POEM versus PD in pediatric patients (n = 21 patients) and no study had predominantly type 3 achalasia. The panel felt that adult evidence could be generalized to pediatric patients and type 3 achalasia.</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
<ul style="list-style-type: none"> <li>○ Important uncertainty or variability</li> <li>● Possibly important uncertainty or variability</li> <li>○ Probably no important uncertainty or variability</li> <li>○ No important uncertainty or variability</li> </ul>		<p>The panelists agreed there would unlikely be any variability in how patients value the main outcomes involving efficacy or safety. Based on experience with this patient population, the panel was certain patients value dysphagia and procedure related adverse events as a critical decision-making outcomes.</p>

		However, there was extensive debate on the value post-intervention PPI use has for patient decision-making, suggesting there possibly may be variability in how this outcome is valued by patients. Given the magnitude of this outcome's effect, any such variability in values would be important to decision-making.
<b>Balance of effects</b>		
Does the balance between desirable and undesirable effects favor the intervention or the comparison?		
<b>JUDGEMENT</b>	<b>RESEARCH EVIDENCE</b>	<b>ADDITIONAL CONSIDERATIONS</b>
<ul style="list-style-type: none"> <li><input type="radio"/> Favors the comparison</li> <li><input type="radio"/> Probably favors the comparison</li> <li><input type="radio"/> Does not favor either the intervention or the comparison</li> <li><input type="radio"/> Probably favors the intervention</li> <li><input checked="" type="radio"/> Favors the intervention</li> <li><input type="radio"/> Varies</li> <li><input type="radio"/> Don't know</li> </ul>	As shown in desirable and undesirable effects, only one critical outcome and one outcome with variable importance for decision making favored PD, whereas all other important and all critical outcomes favored POEM with a large degree of effect.	<p>The panelists universally agreed that the evidence provided favored POEM over PD (10% probably favors, 90% favors).</p> <p>Esophagitis was still considered a critical outcome that likely favored PD based on expert opinion. However, the panelists agreed the unknown degree of effect from esophagitis was not enough to outweigh the large effect from evidence supporting POEM.</p>
<b>Acceptability</b>		
Is the intervention acceptable to key stakeholders?		
<b>JUDGEMENT</b>	<b>RESEARCH EVIDENCE</b>	<b>ADDITIONAL CONSIDERATIONS</b>
<ul style="list-style-type: none"> <li><input type="radio"/> No</li> <li><input type="radio"/> Probably no</li> <li><input type="radio"/> Probably yes</li> <li><input checked="" type="radio"/> Yes</li> <li><input type="radio"/> Varies</li> <li><input type="radio"/> Don't know</li> </ul>		<p>Panelists agreed that this intervention was acceptable or probably acceptable, with a simple majority (60%) favoring acceptable.</p> <p>Economic considerations for the patient were included in feasibility.</p>
<b>Feasibility</b>		
Is the intervention feasible to implement?		
<b>JUDGEMENT</b>	<b>RESEARCH EVIDENCE</b>	<b>ADDITIONAL CONSIDERATIONS</b>
<ul style="list-style-type: none"> <li><input type="radio"/> No</li> <li><input type="radio"/> Probably no</li> <li><input checked="" type="radio"/> Probably yes</li> <li><input type="radio"/> Yes</li> <li><input type="radio"/> Varies</li> <li><input type="radio"/> Don't know</li> </ul>		<p>There were a wide range of opinions on feasibility within the panel. Concerns for feasibility included the availability of endoscopists trained to perform POEM and the potential increased out of pocket cost for POEM in certain countries and health systems.</p> <p>Due to the variability and inequity in insurance markets, even within a single country such as the USA, the panel was unable to</p> <p>analyze the feasibility based on insurance coverage. However, they agreed that increased coverage by insurance would improve feasibility.</p> <p>The panel also considered the feasibility of the pneumatic dilatation and felt that accessibility of an endoscopist trained to perform esophageal dilatation with an achalasia balloon was also limited in certain regions and that concerns with feasibility were similar for POEM and PD.</p>

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
<b>DESIRABLE EFFECTS</b>	Trivial	Small	Moderate	<b>Large</b>		Varies	Don't know
<b>UNDESIRABLE EFFECTS</b>	Large	Moderate	Small	Trivial		<b>Varies</b>	Don't know
<b>CERTAINTY OF EVIDENCE</b>	Very low	Low	<b>Moderate</b>	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	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
<b>ACCEPTABILITY</b>	No	Probably no	Probably yes	<b>Yes</b>		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 <input type="radio"/>	Conditional recommendation against the intervention <input type="radio"/>	Conditional recommendation for either the intervention or the comparison <input type="radio"/>	Conditional recommendation for the intervention <input type="radio"/>	<b>Strong recommendation for the intervention</b> <input checked="" type="radio"/>
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## CONCLUSIONS

### Recommendation

The panel recommends peroral endoscopic myotomy over pneumatic dilatation in patients with achalasia who do not value PPI as a critical decision-making outcome, except when patient-specific factors suggest POEM is not feasible (strong recommendation, moderate certainty evidence)

### Justification

A recent RCT is in agreement with prior observational data that the desirable effects for POEM are large when compared to PD. There is variability in the magnitude of effect for the undesirable effect of post procedure PPI usage, and there is an unknown effect for esophagitis. The panel felt that these two variable and unknown effects, if established, would still not outweigh the greater number of critical outcomes favoring POEM, particularly the consistent superiority in efficacy displayed by POEM, and believed a majority of individuals would still want the intervention. Although there are concerns regarding feasibility, these are similar for both intervention and comparison and do not change the recommendation.

### Subgroup considerations

Specifically for patients who value PPI as a critical decision-making outcome, the panel suggests that either POEM or pneumatic dilatation can be used based on joint patient and surgeon decision-making (conditional recommendation, very low certainty evidence).

### Implementation considerations

In 2020 training is available for endoscopists for POEM. Increased teaching and training will be needed to improve the accessibility for patients and thus feasibility. In regions with poor insurance coverage for POEM and high out-of-pocket expense, improved insurance coverage would improve feasibility.

### Monitoring and evaluation

### Research priorities

The panel makes multiple suggestions for future research priorities:

- More research on achalasia treatment in pediatric populations. This can be achieved either with pediatric only studies, or studies with sample size large enough to perform adequately powered subgroup analysis based on pediatric versus adult population.
- More research on achalasia type 3 patients.
- Studies with long term follow-up measures to determine the incidence and severity of esophagitis after POEM, as well as incidence of sequelae of esophagitis.
- Further research on the role, patient acceptance, and efficacy of PPI use after POEM

**Acknowledgements** The authors thank Sarah Colon (SAGES) for administrative support

**Author contributions** GPK was the panel Chair, wrote the first draft of the manuscript and revised the manuscript based on author's suggestions; RCD was the panel co-Chair, contributed to drafting and critical revisions of the manuscript and contributed to further drafts, and moderated the panel sessions, and checked the manuscript accuracy; MA provided methodological support; Guideline panel members (GPK, JC, CD, LL, JM, DM, CR, PS, LS, RW, AP, DS) participated in the creation of the EtD tables, critically reviewed the manuscript and provided suggestions for improvement; All authors approved the content.

## References

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2. Andrews J, Guyatt G, Oxman AD, Alderson P, Dahm P, Falck-Ytter Y, Nasser M, Meerpohl J, Post PN, Kunz R, Brozek J, Vist G, Rind D, Akl EA, Schünemann HJ (2013) GRADE guidelines: 14. Going from evidence to recommendations: the significance and presentation of recommendations. *J Clin Epidemiol* 66:719–725
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