Discussion Summaries

Balloon up or balloon away? Examining the management of postoperative dysphagia following fundoplication

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Abstract

Dysphagia following laparoscopic fundoplication for medically refractory gastroesophageal reflux disease (GERD) is common. In patients without an anatomic defect, it has been hypothesized that the ant reflux wrap may be too tight. Therefore, pneumatic dilation may help relieve the obstruction. While retrospective data support this hypothesis, prospective data are lacking.

We summarize the @GIJournal discussion held on February 17, 2021 during which the article by Schuitemaker et al. “Pneumatic dilation for persistent dysphagia after ant reflux surgery, a multicentre single-blind randomized sham-controlled clinical trial” was critically reviewed by our expert Dr. John Pandolfino (JP), and moderated by Dr. Marianna Papademetriou (MP).

Introduction

Dysphagia is a common complaint following laparoscopic fundoplication for medically refractory gastroesophageal reflux disease (GERD), occurring in up to 25% of patients.¹ Surgical complications such as a slipped fundoplication can be managed operatively; however, there is no standard management for patients without an identifiable anatomic cause. In these patients, one hypothesis is that fundoplication is too tight, causing symptoms related to esophago-gastric junction outlet obstruction. As such, pneumatic dilation of the wrap at the esophagogastric junction should relieve symptoms. Indeed, prior retrospective data suggest that up to 64% of patients with postoperative dysphagia may derive benefit from dilation.¹

The recent article “Pneumatic dilation for persistent dysphagia after antireflux surgery, a multicentre single-blind randomised sham-controlled clinical trial” is the first prospective randomized trial to evaluate dilation for postoperative dysphagia following laparoscopic fundoplication for refractory GERD.¹ In the study, 42 adults from four centers with persistent dysphagia three months following laparoscopic fundoplication were randomized to dilation with a 35mm balloon (fully inflated to 35 mm for 1 min at 5 PSI and 1 minute at 8 PSI) or a sham dilation under deep sedation, where patients underwent EGD with the endoscope left in the stomach for an additional five minutes. Patients underwent high resolution esophageal manometry (HRM) and timed barium esophagram before and 30 days after the intervention. The Eckardt score, the Brief Esophageal Dysphagia Questionnaire (BEDQ), and the Short Form Health Survey (SFHS) were administered at baseline, 7 days after intervention, and 30 days after intervention. The primary outcome was treatment success, defined as an Eckardt score < 4 and a minimal reduction of 2 points in the Eckardt score after 30 days. Secondary outcomes included change in stasis on TBE, change in HRM parameters, and change in quality of life (QoL) measured by the BEDQ and SFHS.

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There was no difference in treatment success between the two groups (33% in the dilation group and 38% in the sham group per the intention-to-treat analysis and 45% vs 42% in the per protocol analysis). There was no difference in quality of life at 7 or 30 days between groups, nor was there change in either HRM or integrated relaxation pressure (IRP) from baseline. Stasis on TBE was higher in the dilation group at 1 minute, but not at 2 or 5 minutes. There were no adverse events in either group.

Pneumatic dilation was thus found to be no more effective than sham. Furthermore, a segment of patients in the sham group reported symptom improvement following intervention, suggesting a possible functional (as opposed to obstructive) physiology underlying the dysphagia.

Limitations of the study include possible selection bias toward patients with functional symptoms, limited number of patients with stasis on TBE, the inclusion of four patients with absent contractility, lack of information on body weight following treatment, and short follow up time.

Discussion

Q1. High resolution manometry, timed barium esophagram, and upper endoscopy were performed to exclude anatomical defects or achalasia as the cause of dysphagia. What work up algorithm do you follow for persistent postoperative dysphagia after fundoplication?

JP: The history helps direct my workup, but I tend to use both esophagram and esophagogastroduodenoscopy (EGD).

I will ask my radiologist to do a timed barium esophagram (TBE). If that empties, then I check a tablet and if it is stuck, I do a regular esophagram/upper endoscopy to assess anatomy. Most of the time I end up getting the esophagram as it helps me plan my endoscopy. But occasionally I will start with an EGD if I suspect that I will definitely be doing a dilation.

@AllonKahn: I've had cases where an initial esophagram did not show impaired outflow but a second one did. In that situation, I have also had some benefit from using a test meal with barium to characterize what consistencies are causing difficulty.

I tend to get an esophagram first to confirm outflow impairment and then EGD to investigate the wrap internally. I will say that timeframe is important. If there was no dysphagia ever before and then immediate dysphagia after surgery, it's not exactly a mystery.

@WalterChanMD: It depends on how long postoperatively they're presenting. If it is within the first 1-2 months and the symptoms are not causing significant complications such as dehydration, I would actually wait to do anything. Otherwise, I'd likely start with TBE +/- tablets followed by EGD.

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@BMoshiree Is the dilation always pneumatic or does TTS work too?

JP: I would try a TTS sometimes, especially if I think there is some peptic injury at play. However, it is very low yield outside of an overt stricture.

@AllonKahn: We almost always will do a conventional TTS balloon dilation first. I am curious as to how many are going straight to pneumatic. It is interesting that safety in this study was really not an issue though.

@WalterChanMD: We often do the same, although I suspect that those who "respond" to TTS balloon dilation may have more of a functional/hypersensitive etiology of their symptoms.

@EsophagusDoc: I agree with @AllonKahn! I always start with 20mm TTS +/- Savary. I only offer PD in patients in whom I have objective evidence of outflow obstruction (i.e., on TBE).

JP: The main thing I look at is where the wrap is located. If the wrap is below the diaphragm and I have evidence of obstruction on esophagram or FLIP, I tend to have better results. Anatomy is the key. I would never do a PD on someone without objective evidence of obstruction.

MP: Here's a review on what a Timed Barium Esophagram involves.² It can be helpful to make an otherwise subjective interpretation of esophageal emptying into a more objective, reproducible measurement.

Figure 1

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Figure 2

Q2. Eckardt score is a patient reported outcome score used widely to assess achalasia treatment success. Is it a good endpoint here?

JP: The ES has never really been critically evaluated outside of our recent paper and it is a poor PRO.³ I tend to use it only because everyone else does, but I also get the Brief Esophageal Dysphagia Questionnaire (BEDQ) and the Northwestern Esophageal Quality of Life (NEQOL) as they have been vetted appropriately.

@EsophagusDoc: Agree 100%. I am not a fan of the ES since it was never developed as a rigorous PRO, but it is unfortunately now widely used in studies due to history.

@WalterChanMD: I am not certain that Eckardt score is as ideal of an endpoint for these postoperative symptoms; for many of these post-surgical patients, the symptoms tend to be more mild-moderate. I'm not sure Eckardt gives as much stratification of symptom severity at the lower end of spectrum.

@SalihSamo: ES is not a good PRO. Per @JPandolfinoMD paper with @DrTiffTaft, it has fair reliability and validity, with a single factor structure mostly explained by dysphagia.³ Based on psychometric evaluation, chest pain and weight loss items may be decreasing ES reliability and validity.

Q3. What role does EndoFLIP have in helping to differentiate patients with post-fundoplication dysphagia?

JP: The normative data for FLIP does not exist– it barely exists for HRM. I think you work on the extremes: EGJ DI < 2.0 and a diameter < 10mm has a 95% chance of obstruction (data that will be published soon), and an EGJ DI > 2.0 with a maximum diameter of 16 mm 99% will be normal.

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The key with FLIP is to use both the EGJ DI and the maximum diameter so you don't run into the same problem as IRP. Also remember that DI and maximum diameter are different depending on whether they have RACs or absent contractility.

@WalterChanMD: I think while EndoFLIP may be helpful if the DI is substantially low or clearly in the normal range, I am afraid that the middle numbers will be harder to interpret, as it has not been fully validated, specifically in this postoperative population.

@SalihSamo: I don't think this has been looked at much. We published in Surgical Endoscopy about this.⁴ A DI of ≤ 2 was what we found to be abnormal. However, we did not have a control group.

Q4. It appears many patients included in the study had normal HRM and/or normal TBE. A small placebo effect was detected in this sham-controlled study. What does this tell us about the physiology of postoperative dysphagia?

JP: I think the negative result or strong placebo results once again argues for the interplay of functional symptoms and the role of hypervigilance and visceral anxiety in esophageal symptoms. The authors do a good job of explaining this issue and I love that they are advocating for behavioral interventions.

@WalterChanMD: My favorite part of the results is the 40% symptom response rate in the sham group. Many fundoplication patients with postoperative dysphagia improve just with time. I'm a fan of watchful waiting in these patients, especially in the early postoperative period.

@LindaNguyenMD: In patients with a normal TBE, do you recommend neuromodulator or behavioral therapy before more aggressive dilation?

@EsophagusDoc: I have used neuromodulators as a first step, but that is primarily because we don't have easy access to a truly GI-trained psychotherapist!

@WalterChanMD: For those with no obstructive physiology on testing, my order is watchful waiting, then neuromodulator, then behavioral therapy.

Q5: Are there any provocative maneuvers from the new Chicago Classification that would be especially helpful in post fundoplication dysphagia patients?

JP: The provocative swallows, especially the solid swallows and solid meal, are meant to find a mechanical obstruction. They can be helpful; however, I would still always get an esophagram or FLIP to document obstruction.

@WalterChanMD: Both multiple rapid swallow (MRS) and rapid drink challenge (RDC) may be useful during PRE-fundoplication manometry to identify patients at higher risk for postoperative dysphagia, as suggested by prior studies.

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Q6: Any final thoughts?

@EsophagusDoc: What I take away from this study is that empirically doing PD in everyone with post-fundoplication dysphagia is not effective!

@EsophagusDoc: It is great to see RCTs in esophagology. My main concern for the negative result is the study design. They randomized everyone with post-fundoplication dysphagia based on ES, and it looks like they only ended up enrolling people who didn't truly have an outflow obstruction based on TBE.

@SalihSamo: The conclusion that authors make is great, that not all postoperative dysphagia responds to PD. However, in carefully selected patients I do think it has a role, although long term effect is unlikely.

JP: In terms of the paper, it was a nice attempt by a great team at AMC. This is a hard topic to study and there is great value in the paper in terms of the negative result and the discussion.

Conclusion

Post-fundoplication dysphagia is very common, and the management depends on the etiology, which can be determined via history and selective studies. Those with anatomic defects that can be demonstrated on EGD or imaging studies (e.g., esophagram and computed tomography) require surgical revision. Timed barium esophagram and EGD are helpful in assessing for obstructive physiology. FLIP may also be useful in this respect, although normative data are lacking. While pneumatic dilation may be helpful in patients with objective evidence of obstruction, it is not recommended in those without obstruction. In these patients, esophageal hypersensitivity likely underlies their symptoms, and they may benefit instead from neuromodulator therapy and/or psychological therapies.

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