




# More beads, more peristaltic reserve, better outcomes: factors predicting postoperative dysphagia after magnetic sphincter augmentation

Rebeca Dominguez-Profeta<sup>1</sup> · Joslin N. Cheverie<sup>1</sup> · Rachel R. Blitzer<sup>1</sup>  · Arielle M. Lee<sup>1</sup> · Lauren McClain<sup>1</sup> · Ryan C. Broderick<sup>1</sup> · Bryan J. Sandler<sup>1</sup> · Garth R. Jacobsen<sup>1</sup> · Santiago Horgan<sup>1</sup> · David C. Kunkel<sup>2</sup>

Received: 19 May 2020 / Accepted: 16 September 2020 / Published online: 30 October 2020  
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## Abstract

**Introduction** Magnetic sphincter augmentation (MSA) offers a minimally invasive anti-reflux alternative to fundoplication for gastroesophageal reflux disease. The most common side effect of MSA is dysphagia, which may require dilation or even device removal. The incidence of dysphagia may be reduced by MSA sizing and preoperative motility studies. Multiple rapid swallows (MRS) is a provocative maneuver during high-resolution esophageal manometry (HRM) that assesses peristaltic reserve. We evaluated factors predicting development of dysphagia following MSA.

**Materials and methods** A retrospective review of a prospectively maintained database identified patients undergoing MSA. Preoperative work-up included barium swallow, esophagogastroduodenoscopy, and esophageal manometry. Peristaltic augmentation was defined as a ratio > 1 of the distal contractile integral (DCI) following MRS and the mean DCI of the 10 baseline wet swallows during manometry. Demographics, MSA implant size, and postoperative symptom data were gathered on all patients.

**Results** Sixty-eight patients underwent MSA. Mean age was 51.7 years, average BMI was 25.8 kg/m<sup>2</sup>. 15 (22.1%) of patients had severe dysphagia requiring endoscopic dilation. Peristaltic augmentation with MRS was significantly higher in patients without dysphagia (46.1% vs 6.3%  $p = 0.026$ ). 33.3% of patients requiring dilatation exhibited complete absence of smooth muscle contraction following MRS (DCI = 0). The ratio of the DCI of MRS/wet swallows predicting dysphagia following MSA was 0.56. Patients with a small (12–14 beads) versus a larger MSA implant (15–17 beads) had a significantly higher rate of postoperative dysphagia (58.5% vs 30.0%  $p = 0.026$ ).

**Conclusion** Adequate peristaltic reserve and larger device size correlate with decreased incidence of dysphagia following MSA implantation without compromising the anti-reflux barrier. Routine assessment of peristaltic reserve during preoperative HRM should be considered prior to MSA placement.

**Keywords** Gastroesophageal reflux disease (GERD) · Magnetic sphincter augmentation · Dysphagia · High-resolution manometry

Gastroesophageal reflux disease (GERD) is the most prevalent foregut pathology in the Western world, affecting nearly 25% of the adult population in the U.S. [1]. While

lifestyle modification and medical management with proton pump inhibitors (PPI) are considered first-line treatment for GERD, approximately 30–40% of patients have persistent or progressive symptoms despite maximal medical therapy [2]. Laparoscopic fundoplication is the gold standard in the surgical management of GERD with reported reduction of symptoms and PPI use up to 91% postoperatively [3, 4]. Magnetic sphincter augmentation (MSA) using the LINX<sup>TM</sup> Reflux Management System has emerged as an alternative to fundoplication. An implantable ring of magnetic beads placed at the distal aspect of the LES acts as a physiologic sphincter, with minimal disruption of native anatomy [5].

✉ Rachel R. Blitzer  
rrblitzer@gmail.com

<sup>1</sup> Division of Minimally Invasive Surgery, Department of Surgery, Center for the Future of Surgery, University of California, San Diego, CA, USA

<sup>2</sup> Division of Gastroenterology, Department of Medicine, University of California, San Diego, CA, USA

Following MSA placement, 84–92% of patients no longer require antisecretory therapy, with 75–88% reporting subjective resolution of preoperative heartburn [6, 7]. The side effect profile of MSA is favorable, with preserved ability to belch and vomit as well as decreased gas bloating [7–10].

While these techniques offer durable symptomatic relief of GERD, both have an established incidence of postoperative dysphagia [11]. Studies reviewing laparoscopic Nissen fundoplication have shown that postoperative dysphagia may be reduced by ensuring adequate preoperative esophageal motility and sufficient intraoperative wrap laxity [12–14]. Though the side effect profile of MSA is suggested to be superior to that of fundoplication, dysphagia remains the most frequently documented patient complaint following MSA placement [8]. MSA is associated with dysphagia in 47–83% of patients, with decreased rates over time [15, 16]. Increased MSA sizing to reduce the incidence of dysphagia and need for subsequent dilation has been proposed [17]. Regardless, refractory dysphagia remains the most common indication for MSA removal [6, 13, 17].

High-resolution manometry (HRM) is widely utilized for the clinical evaluation of esophageal motility. More recent application of supplemental provocative testing measures during high-resolution manometry may uncover subtle motor characteristics [18, 19]. Multiple rapid swallows (MRS) is a provocative maneuver in which five to ten swallows are administered in rapid sequence, resulting in profound inhibition of progression of esophageal peristalsis. In the setting of normal peristaltic reserve, a robust esophageal body contraction resulting in a high-amplitude peristaltic wave occurs after the final swallow, and LES tone is restored [19, 20]. Select patients demonstrate a weak final contraction following the last swallow, indicating impaired integrity of neural excitation and muscle function [19, 20]. The distal contractile integral (DCI) after MRS is a valuable indicator of esophageal peristaltic reserve and development of dysphagia with laparoscopic Nissen fundoplication [18]. Specifically, the ratio of DCI of MRS to routine wet swallows (ratio of the DCI of MRS/WS) has been shown to be a more reliable indicator of reserve than either measure alone. A ratio of the DCI of MRS/WS > 1 indicates adequate peristaltic reserve [21, 22]. This metric has yet to be examined in the context of MSA sizing and placement.

In this study, we hypothesized that impaired peristaltic reserve, as measured by the ratio of the DCI of MRS/WS, would predict which patients developed dysphagia following laparoscopic MSA, and that patients with zero peristaltic reserve as assessed by MRS would be the most likely to require postimplant endoscopic dilation.

## Materials and methods

### Subjects

A retrospective review of a prospectively maintained Institutional Review Board-approved database was performed to identify patients who had undergone laparoscopic MSA placement at a single institution. Consent was not required. Inclusion criteria were patients undergoing MSA at our institution from 2008 to 2019. Patient characteristics included sex, age, and body mass index (BMI). Presenting symptoms including heartburn, regurgitation, pharyngitis, water brash, cough, bloating/nausea, chest pain, and dysphagia. Perioperative anti-secretory therapy regimen was reviewed.

Preoperative work-up included esophagogastroduodenoscopy (EGD), barium esophagram, Bravo pH testing and/or 24-h pH impedance testing off medication, and esophageal manometry. Esophagitis was graded according to the Los Angeles (LA) classification and the size of any hiatal hernia was noted. Recorded parameters from pH testing included percentage of total acid exposure time, correlation to reflux episodes, and DeMeester scores.

A more recent subset received high-resolution esophageal manometry (HRM) as the technology became available.

### Esophageal HRM

Studies were performed with the Medtronic High-Resolution Esophageal Catheter with Impedance, 36-channel solid-state catheter system with circumferential sensors at 1cm intervals. After calibration, the catheter was advanced through the topically anesthetized nasal passage. A 30-s swallow-free baseline pressure was obtained to identify UES and LES (landmark period). HRM was then performed in the standard fashion, with a series of 10 swallows of 5mL room temperature normal saline with the subject in the supine position. Manometric analysis documented LES parameters including overall and intra-abdominal length, resting, and residual pressure. Additional esophageal contractile measurements were recorded including DCI and percent peristalsis. For patients undergoing provocative testing, included subjects on chart review had an adequately performed MRS sequence, with 4–6 swallows of water (2 mL volume) performed in rapid succession with a less than 4 second interval between swallows, performed in the both the supine and upright positions. A rebound response identified immediately after MRS indicated intact smooth muscle contraction; this was considered absent if no smooth muscle contraction was seen, or if contraction segments  $\leq 3$  cm were observed.

## Postoperative outcomes

Surgical data included operative time, absence or presence of hiatal hernia, whether a wide dissection was performed, and device size (number of beads). Postoperative outcomes included length of stay (LOS), duration of follow up, postoperative anti-secretory therapy requirement, and the nature of any postoperative symptoms. Patients exhibiting postoperative dysphagia were placed into descriptive categories: transient mild, persistent mild, and severe. Patients in the transient mild category recorded spontaneous symptom resolution within 3 months of the operation without intervention. Prior publications have shown that many patients report transient dysphagia 1 month postoperatively; this is not unexpected post-MSA [23]. Persistent mild dysphagia was defined as dysphagia adequately treated by lifestyle and diet modification without dilation. Severe dysphagia was defined as dysphagia that required endoscopic intervention or device removal, regardless of timeframe. Postoperative studies (i.e. barium swallow, Bravo pH testing, EGD, HRM) were selectively performed on symptomatic patients and/or at the surgeons' discretion. Continuous variables were analyzed using Student's *t* test. Pearson  $\chi^2$  test and Fisher's exact test were used for categorical variables. All analyses were performed using Prism 8 (GraphPad Prism, Version 8.4.0, La Jolla, CA). All statistical tests were two-sided with  $p < 0.05$  considered to be statistically significant.

## Results

Between 2009 and 2020, 68 patients were identified who underwent MSA. Patients were 61.3% female with an average BMI of  $25.8 \pm 4.3$  kg/m<sup>2</sup>. The most common preoperative symptom was heartburn, at 67.6% followed by regurgitation in 26.5%. 97.1% of patients were treated with PPI prior to MSA. Mean follow-up time was 26.6 months from the date of operation. Average preoperative DeMeester score was  $52.9 \pm 32.0$ . Hiatal hernia was diagnosed preoperatively in over half of patients with 45.6% measured as less than 3 cm on endoscopic evaluation (Table 1). Preoperative manometry demonstrated normal esophageal motor function in all patients, with no statistical difference in LES length or resting pressure (Table 2). While all 68 patients underwent manometric evaluation, a subset of 29 (42.6%) patients underwent HRM with MRS and WS provocative testing.

Following MSA, 32 patients (47.1%) experienced either transient mild, persistent mild, or severe dysphagia. There were no significant differences between the dysphagia and non-dysphagia groups with respect to preoperative traditional manometry values (Table 2). Of the 68 patients studied, 6 (7.3%) patients had transient mild dysphagia that resolved spontaneously, 8 (11.6%) had persistent mild

**Table 1:** Baseline patient characteristics

All patients ( $n = 68$ )	
Age (mean)	$51.7 \pm 15.2$ (19–79)
Sex (female)	41 (61.3%)
BMI (mean)	$25.8 \pm 4.3$
DeMeester score (mean)	$52.9 \pm 32.0$
TAE (mean)	12.6 (8.8)
Hiatal Hernia	45 (66.2%)
Small (< 3cm)	31 (45.6%)
Large ( $\geq 3$ cm)	14 (31.1%)
Esophagitis	23 (33.8%)
Preoperative PPI use	66 (97.1%)
Chicago classification 4	100%
Device size	
Small (12–14 beads)	41 (60.3%)
Large (15–17 beads)	27 (39.7%)

*BMI* body mass index, *TAE* total acid exposure, *PPI* proton pump inhibitor.

dysphagia, and 18 patients (26.5%) had severe dysphagia. 15 of the severe dysphagia group (22.1% of the entire cohort) required EGD with pneumatic dilation. Three patients with severe dysphagia (4.4% of the entire cohort) required device removal—one was due to refractory dysphagia. The second patient developed immediate postoperative device-induced achalasia, and the third requested removal due to persistent non-specific GI symptoms despite negative workup (Table 3).

In our subset of 29 patients who underwent HRM with provocative measures, all were classified as normal by the Chicago Classification (Table 2). Of the 13 patients undergoing HRM that did not develop dysphagia, peristaltic augmentation (as defined by the ratio of the DCI of MRS/WS > 1) was present in 46.2% compared to 6.3% of patients who developed dysphagia ( $p = 0.026$ ) (Table 4). Of the patients that underwent HRM with MRS, 33.3% of the patients requiring balloon dilatation exhibited complete absence of any smooth muscle contraction following MRS (DCI = 0). In addition, patients with postoperative dysphagia had a significantly lower ratio of the DCI of MRS/WS ( $0.56 \pm 0.62$  vs  $1.63 \pm 1.44$   $p = 0.015$ ) (Table 4) (Fig. 1). Patients with a ratio of DCI of MRS/WS < 1 were greater than seven times more likely to experience postoperative dysphagia. The ratio of the DCI of MRS/WS that predicted development of dysphagia following MSA was 0.56; if the ratio was smaller than this value, the patient was more likely to develop postoperative dysphagia.

When examining the entire cohort, patients with small versus large devices were significantly more likely to experience postoperative dysphagia (58.5% vs 30.0%  $p = 0.026$ ) (Table 5). Apart from dysphagia, there was no

**Table 2:** Preoperative manometry by postoperative dysphagia

	Dysphagia ( <i>n</i> = 32)	No dysphagia ( <i>n</i> = 36)	<i>p</i> value
LES length (cm) (mean)	2.98 ± 0.84	3.39 ± 0.78	0.06
Abdominal LES length (cm)	1.08 ± 0.90	1.48 ± 1.26	0.18
LES resting pressure	18.73 ± 10.1	15.72 ± 11.6	0.29
LES residual pressure	2.13 ± 4.72	3.27 ± 6.89	0.47
% Peristalsis (mean)	90.88	90.03	0.83
DCI (mean)	1494 ± 1315.2	1382 ± 1207.3	0.83
< 500	3 (9.4%)	2 (5.6%)	
Chicago classification: 4	100.0%	100.0%	1.0

LES lower esophageal sphincter, DCI distal contractile index

**Table 3:** Clinical outcomes

All patients ( <i>n</i> = 68)	
Symptoms	
Dysphagia	32 (47.1%)
Severe	18 (26.5%)
Dilation	15 (22.1%)
Removal	3 (4.4%)
Persistent mild	8 (11.6%)
Transient mild	6 (8.8%)
Chest pain	5 (7.4%)
Heartburn	3 (4.4%)
Regurgitation	6 (8.8%)
Bloating	10 (14.7%)
PPI use	
6 months	2 (5.7%)
1 year	2 (6.7%)
2 years	2 (13.3%)

PPI proton pump inhibitor

difference in postoperative symptoms between patients with large and small devices. Postoperative PPI use did not differ in the first 6 months, however, at 1 year, PPI use differed significantly between patients with small and large devices (0.0% vs 33.3%, *p* = 0.035) (Table 5). Overall, PPI use decreased from 97.1% preoperatively to 7.1% at 1-year follow-up (Fig. 2). Postoperative PPI requirements between the two groups were not significant.

**Table 4:** Patients undergoing high-resolution manometry with provocative measures (*n* = 29)

	Dysphagia ( <i>n</i> = 16)	No dysphagia ( <i>n</i> = 13)	<i>p</i> value
DCI: MRS (mean)	894.9 ± 1004.4	2217.2 ± 2288.9	0.055
DCI: MRS/WS (mean)	0.56 ± 0.62	1.63 ± 1.44	0.015
Peristaltic augmentation (ratio of DCI of MRS/WS > 1)	1 (6.3%)	6 (46.2%)	0.026

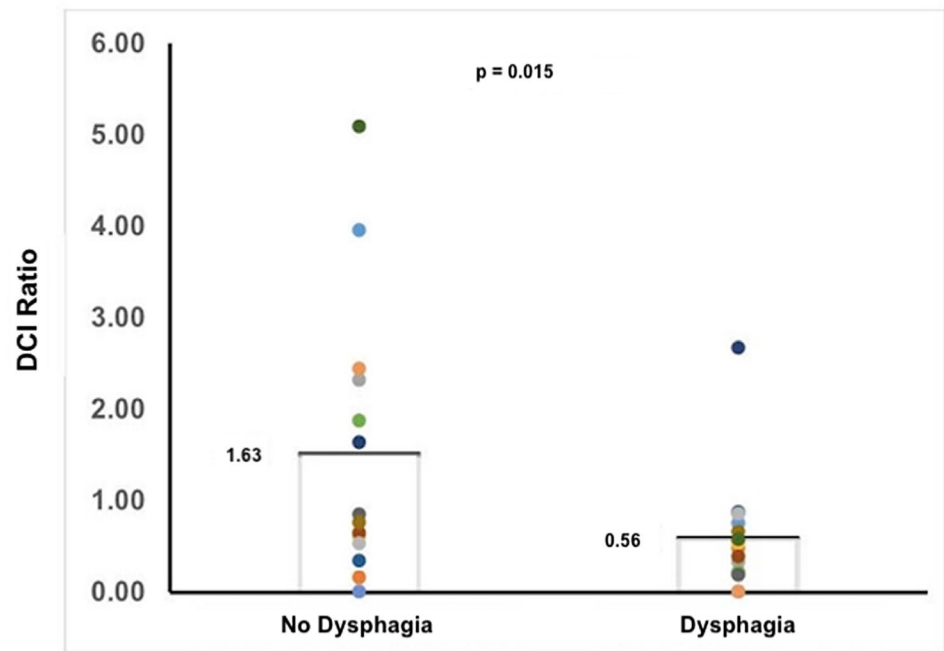
DCI distal contractile index, MRS multiple rapid swallows, WS wet swallows.

## Discussion

Preoperative manometry is currently standard of care in the preoperative work-up prior to fundoplication or MSA implantation. In recent years, HRM has become near ubiquitous with various studies evaluating factors contributing to esophageal dysphagia [20, 24, 25]. Despite normal esophageal motility by Chicago classification, assessment of peristaltic reserve using the ratio of the DCI of MRS/WS revealed that patients with augmented contraction were less likely to develop dysphagia. Moreover, patients with normal esophageal motor function but zero peristaltic reserve, i.e., no smooth muscle contractility following MRS, fared poorly in terms of dysphagia requiring additional interventions such as dilation. This is the first study demonstrating such a correlation. Similar to appropriate tailoring of a fundoplication to a patient's anatomy and motility, appropriate patient selection and device sizing using HRM provocative testing may improve MSA outcomes.

We confirmed that the ratio of the DCI of MRS/WS affects postoperative dysphagia. In addition, poor peristaltic reserve as measured by the ratio of the DCI of MRS/WS is a significant predictor of this symptom. While it has been previously shown that poor anti-reflux surgery outcomes are associated with reduced LES distensibility and elevated residual pressures [26], we are the first study to show a correlation of dysphagia specifically for peristaltic reserve (ratio of the DCI of MRS/WS) and sizing of the device. We believe that prior to MSA placement, peristaltic reserve should be evaluated in each patient; this is in addition to establishing

**Figure 1:** The ratios of DCI of MRS/wet swallow among patients who did and did not develop dysphagia following magnetic sphincter augmentation for GERD. *DCI* distal contractile index, *MRS* multiple rapid swallows, *WS* wet swallows.



**Table 5** Clinical outcomes by device size

	Small (12–14 beads) (n = 41)	Large (15–17 beads) (n = 27)	p value
Dysphagia	24 (58.5%)	8 (30.0%)	0.026
Chest pain	5 (12.9%)	0	0.149
Heartburn	3 (7.3%)	0	0.271
Regurgitation	4 (9.8%)	2 (7.4%)	1.0
Bloating	7 (17.1%)	3 (11.1%)	0.728
PPI use			
6 months	1 (4.2%)	1 (9.1%)	0.536
1 year	0 (0%)	2 (33.3%)	0.035

PPI proton pump inhibitor

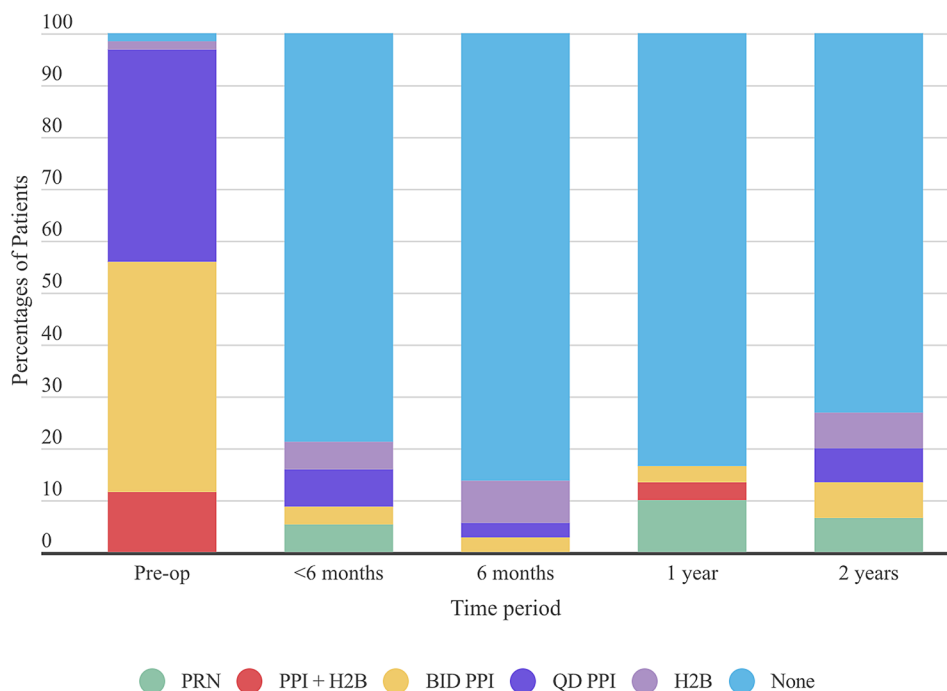
normal motility by standard esophageal manometric criteria (Chicago classification). Peristaltic reserve is best approximated by the DCI for MRS as well as MRS/WS ratio; these two measurements predict the ability of the esophagus to regain contractile tone after repeated neuromuscular inhibition. This allows maintenance of esophageal pressure to overcome LES pressure. Our study shows that low DCI and WS/MRS ratio < 1.0 are significantly associated with postoperative dysphagia requiring intervention.

Of note, postoperative diet management after MSA is distinctly different from a postfundoplication diet. After MSA, patients are placed on a regular diet on postoperative day 0 to encourage repeated opening and closing of the device during healing [23]. This prevents scar tissue from limiting the radial expansion of the device, which helps to maintain the required distensibility of the EGJ.

While up to 60% of patients report dysphagia in the first month after MSA implantation, the vast majority have spontaneous resolution in the first 8–12 weeks postprocedure [23]. However, some patients with persistent symptoms go on to require endoscopic dilatation, with reported rates ranging from 19 to 50 % following MSA [6, 11, 12, 27]. Our study demonstrated postoperative dysphagia requiring dilation in 22.1% of patients, in keeping with the literature. Discrepancies may be due to close symptom monitoring and a lower threshold for dilation compared to other institutions. Though the majority of patients did not require intervention, we believe it is important to assess the impact of preoperative testing on patient's outcomes in order to inform pre-operative discussions, mediate postoperative expectations, and address morbidity following MSA placement.

Our patients were significantly more likely to experience dysphagia after implantation of a smaller vs. larger MSA device, consistent with current literature [17]. A possible explanation for dysphagia with smaller device placement is that a smaller MSA mimics a tight wrap and elevated LES pressures, making it difficult for those with poor peristaltic reserve to pass liquids and solids through. This would be in keeping with fundoplication data showing that higher EGJ tone as reflected by increased integrated relaxation pressures in the esophagogastric junction independently predicted postoperative dysphagia [25, 28]. However, patients with a larger device were also more likely to require PPI therapy at 1 year postoperatively. This may be attributed to insufficient reinforcement of the GE-junction, as has been noted with less than 360° fundoplications [29].

**Figure 2:** Postoperative Antisecretory therapy by time period. *Pre-op* preoperative, *PRN* pro re nata (as needed), *H2B* H-2 receptor blocker, *BID* twice daily, *QD* once daily.



Limitations of our study include the retrospective nature of our data review, leaving us without a control group, small sample size, and lack of formal objective follow-up. Despite being the largest study evaluating device size and peristaltic reserve in MSA, more robust data could be accumulated with a larger patient population; however, as the use of provocative HRM increases, we anticipate more patients will be added to our cohort. Postoperative evaluation with objective studies such as endoscopy, pH monitoring, and HRM was performed only in patients with ongoing symptomatology. As such, we may not be identifying the normalization of objective measures of acid exposure in our satisfied patients. Much of the data compared post operatively is subjective and could be biased by each patient's different perception of normal postoperative recovery, particularly in the transient mild or persistent mild dysphagia subsets. In addition, the rate of postoperative follow-up varies by symptom; patients are more likely to return to clinic if they have issues to discuss, which could lead to a returning cohort that reflects a greater complication rate than the sample. As an example, in looking at PPI use at 1-year postprocedure, data was available on a limited number of patients, and may not reflect true rates of PPI use.

In addition, preoperative HRM was not widely in use at the start of this study in 2009; thus we were limited to analyzing newer MSA placements with provocative HRM. MSA technique has continued to develop, tending toward increased bead number. Lack of HRM measurements when

devices tended to be smaller may underestimate the effect of these maneuvers in predicting dysphagia depending on device size.

We believe that use of HRM to assess peristaltic reserve via multiple rapid swallows is essential prior to placement of an MSA device given the changes in our practice patterns over time. Further studies should be performed to identify additional ways in which preoperative HRM can inform anti-reflux procedure selection. Additional studies are required to validate these results in the setting of a multi-center prospective trial.

## Conclusion

Preoperative assessment of peristaltic reserve offers a comprehensive evaluation of esophageal function that can lead to improved patient selection and MSA device sizing. Patients with reflux under consideration for magnetic sphincter augmentation should undergo multiple rapid swallow provocation during high-resolution esophageal manometry as part of their routine workup. This data will help inform patient discussions and expectations, and can aid in surgical decision making. Adequate peristaltic reserve and larger MSA size may protect against development of dysphagia without compromising the anti-reflux barrier.

## Compliance with ethical standards

**Disclosures** Drs. Dominguez-Profeta, Cheverie, Blitzer, Lee, McClain, and Broderick have no relevant conflicts of interest or financial ties to disclose. Dr. Sandler receives is a consultant for Intuitive Surgical and Boston Scientific. Dr. Jacobsen receives a teaching honorarium from Gore Medical. Dr. Horgan is a consultant for Intuitive Surgical, Medtronic, Stryker Corporation, and Fortimedix Surgical. Dr. Kunkel is a consultant for Pallete Life Sciences, Allergan, Salix Pharmaceuticals, QOL Medical, Redhill Biopharma, Shire (Takeda), Arena Pharmaceuticals, and Portola Pharmaceuticals.

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