



First Experience with Banded Anti-reflux Mucosectomy (ARMS) for GERD: Feasibility, Safety, and Technique (with Video)

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Abstract

Background Anti-reflux mucosectomy (ARMS) is a relatively new endoscopic procedure for gastroesophageal reflux disease (GERD). A hemi-circumferential endoscopic mucosal resection (EMR) is performed around the gastroesophageal junction (GEJ), which then contracts and tightens during healing. The aim of this study was to assess the feasibility and safety of the procedure. A secondary aim was to assess short-term outcomes on PPI use and symptom resolution.

Methods IRB approval was obtained for retrospective review of a prospectively collected database including patients who underwent ARMS during a 2-year period. To be eligible for the procedure, patients required medically refractory GERD and a hiatal hernia no more than 2 cm. A 270-degree mucosal resection of the gastric cardia was performed in a retroflexed position using a multi-band EMR system. Demographics, preoperative workup, intraoperative factors, additional procedures, and other follow-up were collected by chart review. Voluntary validated surveys assessed symptomatic improvement over time.

Results There were 19 patients available for review. The procedure was technically completed in all cases. There was one muscle injury due to a deep resection that was repaired by endoscopic suturing. All patients were discharged on the day of the procedure. Early dysphagia was experienced by three patients (16%) which was addressed with endoscopic balloon dilation. GERD symptoms improved in 13 patients (68%) after discontinuing PPI therapy. Three of the six failures went on to have additional anti-reflux surgery. Among patients who did not have additional surgery, quality of life data showed significant symptomatic improvement by 6 months.

Conclusion In this ARMS case series, the procedure was technically successful in all patients with only one minor complication. Two thirds of patients showed symptomatic improvement and were able to discontinue their PPI. ARMS appears to be a safe procedure that does not hinder future laparoscopic anti-reflux surgery in case of failure. Additional tuning of technique and postoperative management may be able to reduce dysphagia rates and the need for dilation.

Keywords Anti-reflux · Mucosectomy · Endoscopic · Mucosal · Resection · Banding · ARMS · EMR

Introduction

Gastroesophageal reflux disease (GERD) is a common condition that carries significant economic burden.¹ The lower esophageal sphincter (LES) is the natural barrier to gastric reflux, and consists of a complex arrangement of esophageal, gastric, and diaphragmatic musculature, as well as an intragastric mucosal flap valve.^{2,3} Typical GERD is likely multifactorial, with contributions from increased intra-abdominal pressure (obesity), anatomic derangement (hiatal hernia), and LES dysfunction (transient relaxations). The mainstay of therapy consists of pharmacological gastric acid reduction, preferentially using proton pump inhibitors (PPIs). However, some patients do not find relief with medications, and long-term PPI therapy can have negative consequences.⁴

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For individuals who fail medical management, the gold standard surgical treatment is laparoscopic fundoplication. In recent years, endoscopic alternatives to transabdominal surgery have been described, including gastroesophageal (GE) junction plication, radiofrequency ablation, and transoral incisionless fundoplication. These techniques require proprietary equipment and are either ineffective long-term or are lacking substantial efficacy data.^{5,6} One technique that does not require specialized equipment is anti-reflux mucosectomy (ARMS), consisting of a hemi-circumferential endoscopic mucosal resection (EMR) of the gastric cardia around the GE junction. The resected area contracts as it heals (before and after endoscopic views of the GE junction are shown in Fig. 1). This procedure was incidentally discovered in 2003 when a patient who received GE junction EMR for Barrett's esophagus experienced improvement of GERD symptoms.⁷ The authors refined the technique and published a case series in 2014 demonstrating significantly improved symptoms and DeMeester scores.⁸ ARMS has been described utilizing cap EMR and endoscopic submucosal dissection. The following summarizes the first ARMS case series in the USA, as well as the first description of ARMS using a multi-band endoscopic banding system.

Methods

Retrospective review of a prospectively collected database was approved by the institutional review board. This database includes the following validated surveys for the purpose of quality improvement: GERD health-related quality of life (GERD-HRQL), reflux severity index (RSI), and dysphagia score. All patients who had ARMS were included for review; procedures were performed between December 2016 and April 2018. Collected data included demographics, preoperative symptoms and workup, intraoperative factors, postoperative symptoms and studies, and any additional procedures performed. Voluntary survey data was collected preoperatively, and postoperatively at 3 weeks and 6 months.

Preoperative workup consisted of upper endoscopy, esophageal manometry to rule out motility disorder, and pH testing. Significant hiatal hernia, defined as > 2 cm, disqualified patients from the procedure. Postoperatively, PPIs were discontinued, and patients were seen in clinic for follow-up about 2 weeks later. Patients without symptomatic improvement were offered additional anti-reflux surgery.

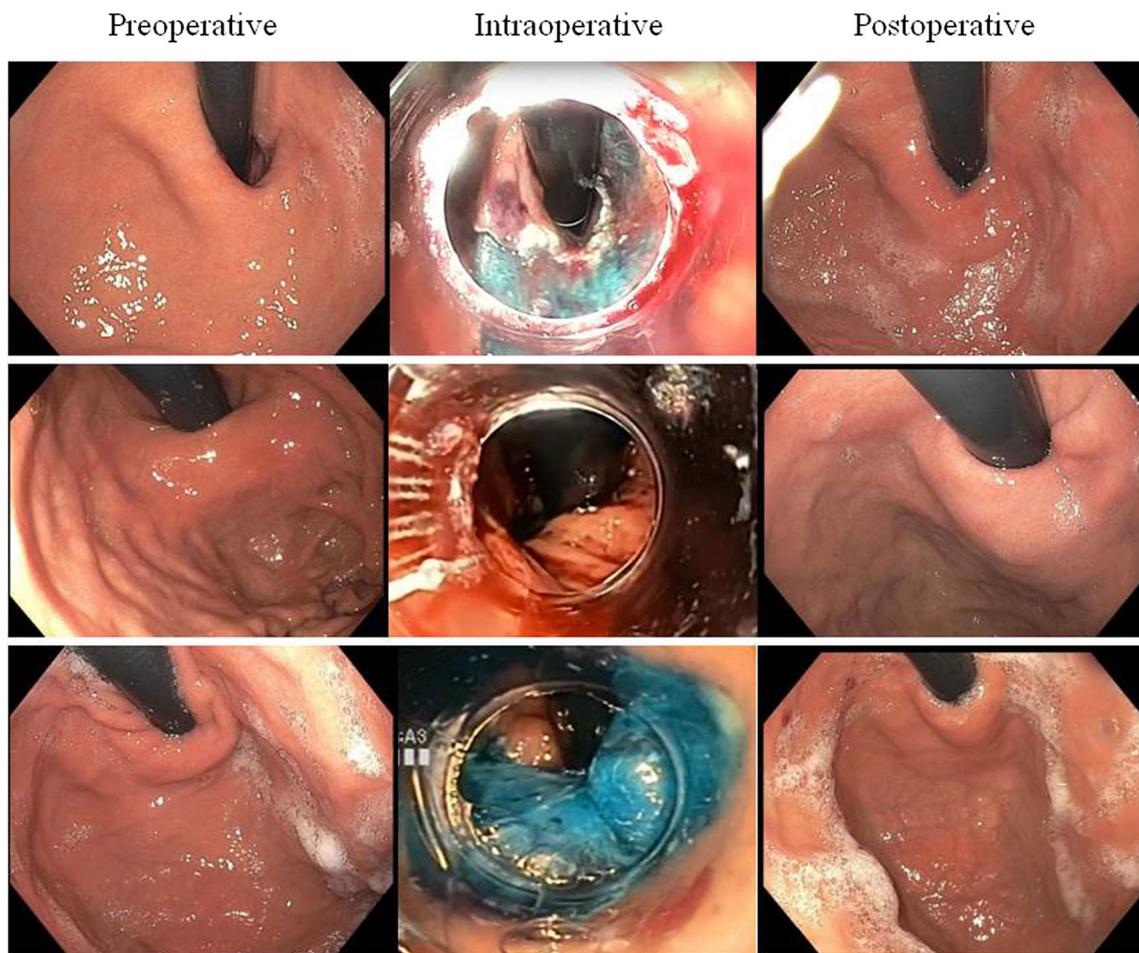


Fig. 1 Retroflexed view of the GE junction preoperatively, intraoperatively, and 2–6 months postoperatively

Table 1 Patient demographics and operative outcomes

Patient	Age	Gender	BMI	Balloon dilation?	Symptoms improved?	Additional procedures
1	44	F	24.1	N	N	Magnetic sphincter aug.
2	25	F	21.1	N	Y	
3	47	F	26.2	N	Y	
4	73	F	26.2	N	N	Toupet fundoplication
5	21	F	25.2	N	N	None
6	22	M	21.8	N	N	Magnetic sphincter aug.
7	68	F	28.2	N	Y	
8	60	F	21.7	Y	Y	
9	58	F	23.6	N	Y	
10	62	M	25.3	Y	Y	
11	74	M	33.1	N	Y	
12	50	F	29.8	N	Y	
13	63	M	34.7	N	Y	
14	80	F	19.4	N	Y	
15	57	M	24.7	Y	Y	
16	88	M	24.5	N	N	None
17	58	F	23.4	N	N	None
18	67	M	23.4	N	Y	
19	67	M	30.4	N	Y	
Average	57.1	42.1% male	25.8	15.8%	68.4%	

GERD-HRQL, RSI, and dysphagia survey scores over time were summarized with mean and standard deviation (SD). Patients who underwent additional anti-reflux surgery were excluded from this analysis. A figure graphically presents these data with mean and standard error. Due to the voluntary nature of the surveys, missing data resulted in limited sample size for paired analysis. Therefore, the independent samples *t* test was used to assess differences between preoperative and 3-week or 6-month responses. Statistical analysis was conducted using SAS 9.3 (Cary, NC). A *p* value of < 0.05 was considered statistically significant.

ARMS Description

The procedure can be summarized as an endoscopically performed, hemi-circumferential mucosectomy of the gastric cardia around the GE junction. The resection is performed in

retroflexed position, and includes 3 cm of mucosa 240–270° around the GE junction, sparing the gastric flap valve toward the greater curve of the stomach. The supplementary video demonstrates the procedure using submucosal injection and band-technique EMR (Video 1). A typical operative description for this case series is described in the following paragraph.

The patient was placed in a supine position and placed under general anesthesia. A Captivator™ EMR Device (Boston Scientific, Marlborough, MA) was fixed onto a GIF HQ190 upper endoscope (Olympus, Tokyo, Japan). The scope was advanced and thorough inspection of the esophagus, stomach, and duodenum was performed. In retroflexion, the mucosa was marked 270° around the gastroesophageal valve sparing the greater curvature side. The marking was performed with a snare on soft coagulation (effect 5, max W 80). The snare was then removed and an injector needle passed. The mucosa of the cardia was raised with a solution

Table 2 Analysis of GERD-related QOL scores

	Preoperative	3 weeks		6 months postoperative	
	Mean ± SD	Mean ± SD	<i>p</i>	Mean ± SD	<i>p</i>
RSI	22.4 ± 13.2	16.3 ± 7.1	0.2181	9.1 ± 3.9	0.0168
GERD-HRQL	21.6 ± 15.1	11.1 ± 9.4	0.0972	7.9 ± 5.1	0.0282
Dysphagia	1.4 ± 1.3	1.8 ± 1.0	0.4794	1.3 ± 0.7	0.7657

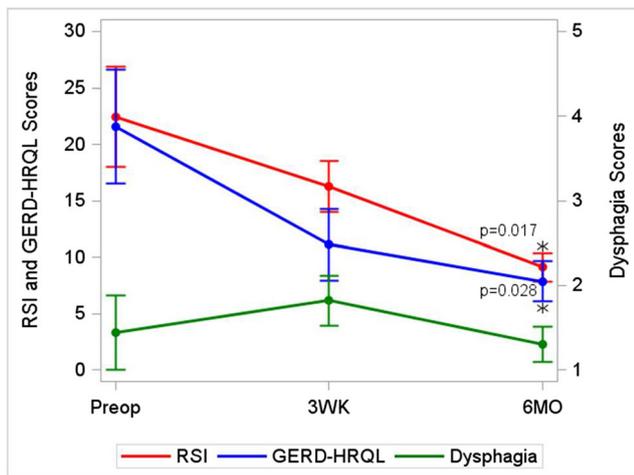


Fig. 2 GERD-related QOL scores over time. Significant improvement in GERD-HRQL and RSI was seen at 6 months

of saline, methylene blue (10 mg/ml), and epinephrine (1 mg/ml). Using the Captivator™ EMR kit, the raised mucosa was suctioned into the cap for a few seconds, and a band was fired. With the use of a snare, the banded tissue was transected using forced coagulation (effect 2, max W 40). The submucosa was noted and inspected for bleeding and injury to deeper layers. Going in a counterclockwise direction, this process was repeated until the previously marked area was completely resected (4–5 bands). With the use of the snare, visible vessels in the submucosa were coagulated on soft coagulation (effect 5, max W 80). The resection was inspected for hemostasis and deep tissue injury. The scope was removed, and the patient was extubated and discharged home after recovery.

Results

Nineteen patients underwent ARMS during the study period. The average procedure length was 40.7 min (17–64 min range), and all patients went home the same day. Two cases were performed with concurrent procedures—one a cholecystectomy, and the other an endoscopic pyloromyotomy (not included in above procedure time). There was one intraoperative complication and one postoperative complication. A deep-banded resection resulted in a partial-thickness muscle injury that was closed with an endoscopic stitch. Another patient with history of ischemic stroke on warfarin was bridged with low molecular weight heparin for the procedure, and was readmitted postoperative day three with melena and symptomatic anemia. He received one unit of packed red blood cells and bleeding was resolved without need for further intervention. Demographics and outcomes are shown in Table 1. Overall, 13 of the 19 patients (68%) showed significant symptomatic improvement and discontinued PPI use. Three of the

six patients who failed ARMS went on to have laparoscopic anti-reflux surgery. Those who did not preferred to remain on medical therapy and consider another procedure at a future date. Three patients (16%) experienced troubling dysphagia after the procedure which was addressed with balloon dilation. Two of these patients were satisfied after dilation and remained off their PPI. One patient had persistent GERD symptoms both before and after dilation, although dysphagia resolved after the procedure. Results from voluntary surveys are summarized in Table 2, and graphically represented in Fig. 2. Overall, the cohort showed significant improvement in GERD-HRQL and RSI scores by 6 months.

Discussion

ARMS was safely completed in all 19 cases. All cases but one was performed under general anesthesia. One patient was considered higher risk and the procedure was performed under conscious sedation. While the anti-reflux mechanism of ARMS has not been explicitly studied, contraction and scarring of the mucosectomy bed likely tightens the GE junction and augments the natural anti-reflux valve. This effect can be seen in the before and after images in Fig. 1. As of yet, ARMS technical descriptions have utilized endoscopic submucosal dissection or cap-technique EMR to perform the mucosectomy. The present series demonstrates band EMR as another viable technique.

Overall, two thirds of patients subjectively reported symptomatic improvement and discontinued PPIs. Results from survey data echo this improvement. The dysphagia score did increase from preoperatively to 3 weeks, but decreased again by 6 months. This may reflect the normal healing process or those patients who underwent balloon dilation for symptomatic dysphagia.

There was a 16% rate of dysphagia requiring intervention in this series. Although a simple dilation resolved this complication in all cases, the problem represents the significant scarification of the resected area. Individual anatomy likely dictates the ideal extent of resection to result in a favorable balance between reflux and dysphagia. Another variable that may influence the GE junction's remodeling after ARMS is the effect of gastric acid on the degree of scarification. In this study, PPI's were discontinued immediately after the procedure. This protocol has been changed for patients currently undergoing ARMS at our institution; patients are now kept on a PPI for 2 weeks after the procedure. This may reduce inflammation and scarring, and result in a lower dysphagia rate. Time will show the effect on symptomatic improvement when PPIs are discontinued after 1 month.

There are significant limitations to this case series. Ideally, consistent postoperative endoscopic evaluation and pH testing would be compared to preoperative workup to provide

objective evidence of improvement. Currently available post-operative data is skewed heavily toward those who did not symptomatically improve, given their ongoing workup and treatment. Additionally, the voluntary survey resulted in gaps in the data, necessitating an imperfect statistical method for analysis.

Conclusion

Although the majority of patients with GERD also have a hiatal hernia, ARMS is an attractive option for those who qualify. It is an incisionless procedure that does not hinder additional anti-reflux procedures should they be necessary. Risk of serious complication is very low, and in this series, two thirds of patients were able to discontinue their PPI. The rate of dysphagia may be addressed with alterations to operative technique and elucidating the role of postoperative PPIs. Short-term outcomes for ARMS seem encouraging, and long-term outcomes will be established with ongoing observation.

Authorship Statement All authors meet the criteria for Authorship as described in the guidelines of the International Committee of Medical Journal Editors (ICMJE).

Compliance with Ethical Standards

Conflict of Interest Dr. Hedberg and Ms. Kuchta have no conflicts of interest to disclose. Dr. Ujiki receives consulting fees from GORE, Boston Scientific, Apollo Endosurgery, Olympus, and Medtronic, none directly related to the submitted work.

Disclaimers The views expressed in the submitted article are the authors' own and not an official position of their respective institutions.

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