ISSN: 2837-4835

Research Article

International Internal Medicine Journal

GERD Symptoms Often Improve After Magnetic Sphincter Augmentation (MSA) Device Removal – an Observational Study

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Submitted: 2023, Dec 14 **Accepted**:2024, Jan 10 **Published**: 2024, Jan 16

Citation: Buniak, N., Buniak, B., Maini, A., Sivakumar, B., Sun, J., et al. (2023). GERD Symptoms Often Improve After Magnetic Sphincter Augmentation (MSA) Device Removal – an Observational Study. *Int Internal Med J, 2*(1), 01-06.

Keywords: Heartburn; GERD;Dysphagia; Magnetic Sphincter Augmentation Device.

Hypothesis: Extrinsic distal esophageal scaring after MSA device removal may improve symptoms of Gastroesophageal Reflux Disease (GERD) .

1. Introduction

Gastroesophageal reflux disease (GERD) affects over 60 million people, more than 20% of the United States population [1]. Treatments include dietary restrictions, behavior modifications, medications, endoscopic therapeutics or surgery. Long term, untreated reflux may lead toward Barrett's esophagus, esophageal cancer and benign intrinsic strictures resulting in varying degrees of dysphagia. Strictures of the distal esophagus, however, have also been artificially created in order to reduce reflux of gastric contents back into the esophagus. Procedures such as Stretta RFA, Enteryx bulking injections and HALO ablations have had mixed results in successfully managing GERD by way of generating fibrosis at the distal esophagus [2,3]. Magnetic Sphincter Augmentation device (MSA), or LINX, approved for use by the FDA in 2012, creates a functional improvement of the Lower Esophageal Sphincter similar to a previously utilized Angelchick prosthesis. This device is implanted around the distal esophagus at the level of the LES to prevent reflux of gastric content by way of extrinsic compression. This device is comprised of a series of magnetic titanium beads attached individually by a separate beveled wire, giving it an appearance of a bracelet, which wraps around the outside of the distal esophagus. It is surgically placed snugly around the lower esophagus, usually with laparoscopic or robotic technique. The magnetic attraction of this ring of beads is designed to maintain the LES in a closed position at rest. When enough pressure is generated during a swallow, the beads separate to create an opening for the passage of food, fluids or pills.

The MSA device comes in several different sizes. A sizing tool is used by the surgeon to determine the dimension appropriate for the patient. The device is subsequently robotically implanted around the distal esophagus, using the right or posterior vagus nerve to secure the implant. Majority of patients describe significant improvement in their GERD-Heartburn Related Quality of Life (HRQL) score after the procedure. However, 1-6% patients are intolerant of the device due to symptoms of dysphagia, chest pain or regurgitation and require surgical explantation. During surgery, significant scarring is encountered around the device making it a difficult dissection for removal. This remaining band of scar tissue, we suspect, may result in long term reduction of reflux by restricting relaxation of the esophageal outlet.

2. Methods

We completed a retrospective chart review of 118 patients who underwent LINX magnetic augmentation device placement at our institution for the treatment of GERD between 2017 and 2021. Prior to LINX insertion, all patients underwent esophageal pH monitoring, Esophageal Motility, Endoscopy and Barium Swallow to determine if they were candidates for the procedure. Criteria for inclusion included weak or normal LES sphincter pressure, adequate esophageal peristaltic pressures with normal propagation, hiatal hernia <3 cm and a DeMeester score of >14 on pH Monitoring. In addition GERD-HRQL and GAD-7 questionnaires were obtained before and after their surgery to assess severity of their symptoms [4-7]. In our cohort of patients, 8 needed to have their LINX removed due to side effects attributed to the LINX device. Patients with dysphagia were initially treated with pulse steroids and balloon dilation to help separate the magnetic beads which became adherent to each other caused by inflammatory adhesions. Surgical findings at time of explantation of the device

were documented. Patients' were brought back for follow-up to re-evaluate their GERD symptoms. GERD-Health Related Quality of Life Questionnaire (GERD-HRQL) and General Anxiety Disorder (GAD-7) questionnaires were administered to determine if additional surgery for correction of their symptoms were warranted. Endoscopy or Barium Swallow was used to assess the esophageal anatomy and motility post removal. None of the patients were agreeable to undergo another Esophageal Manometry to assess post-surgical functioning.

3. Results

Over five years, out of our 118 patients with MSA implants, eight (6.7%) required device removal due to symptom intolerance. Causes for removal included one with esophageal perforation, five with dysphagia and two as a result of anxiety with chest pressure. The mean time from MSA device placement to removal in patients with dysphagia was 170.6 days, for those with anxiety it was only 24 days. Despite balloon dilation, steroid treatments to reduce inflammation around the device, use of antacids and hyoscyamine, the five patients complaining of dysphagia did not notice an appreciable improvement in symptoms, requiring subsequent device removal. At time of surgery, extensive adhesions were encountered surrounding the beads. Once the device was removed, a band of adherent scar tissue remained on the outside of the distal esophagus. The longer the implants remained before removal, the more extensive the scar tissue encountered. The remaining 3 individuals had less scarring as their explanation was performed under 36 days after insertion. Of these latter three, the individual with an esophageal perforation had the implant removed on day three, but developed extensive scarring from inflammation, resulting in post-surgical dysphagia.

Of the 110 patients (Groups A) with a retained MSA device, 96.4% noted a significant improvement in their GERD-HRQL score. Ten patients (9%) in this group required esophageal dilation after LINX placement to alleviate symptoms of dysphagia. In comparison, in the post LINX removal cohort (Group B)l, five of eight patients (62%) described an improvement from their initial GERD-HRQL scores. Due to the small number of patients reviewed, a statistical analysis was difficult to determine. Three of eight patients required esophageal dilation after removal of the MSA device to alleviate symptoms of dysphagia. After dilation with non-guided bougies, one patient developed recurrence in heartburn. Overall, four patients experienced sustained improvement in symptoms up to two years after MSA device removal. One individual with history of anxiety and chest pain, PPI use successfully control his heartburn symptoms after LINX removal, and symptoms were significantly better than before his initial surgery. One patient described recurrence in heartburn severity to the same level as before surgery. None of the eight patients required or elected to undergo a fundoplication after implant removal.

Barium swallow after LINX removal noted a narrowing of the distal esophagus in three patients. This suggests that the consequence of scarring results in restricted movement of the distal esophagus and less regurgitation of gastric contents into the esophagus. In our experience, individuals with anxiety tolerated the LINX poorly, possibly as a result of a hypersensitive esophagus which retrospectively was suggested by their level of discomfort at time of BRAVO insertion

Descriptives	Group	N	Missing	Mean	Median
Age	A	109	1	51.02	52
	B	8	0	51.25	54.5
Pre-Score	A	100	10	21.71	22
	B	7	1	22.14	20
Post-Score	A	93	17	5.48	4
	B	7	1	13.71	7

Table 1: GERD-HRQL Score Comparison Between Group A (successful LINX) vs Group B (Explants)

Patient	Age	Sex	Implant Days	Dilations Post LINX	Steroids Rx	Symptoms	HRQL Scores Before/After	LES mm Hg	UGIS GEJ
1	62	F	271	2	Yes	Dysphagia	16/0	19.9	Narrow
2	57	F	134	2	Yes	Dysphagia	20/19	47	Narrow
3	52	F	36	1	Yes	Dysphagia	36/43	30.9	Normal
4	36	M	12	0	No	Chest pain	25/22	20.5	Normal
5	32	M	36	0	No	Chest pain	17/7	17.7	Narrow
6	51	F	250	2	Yes	Dysphagia	22/1	23.8	Normal

7	59	F	3	0	No	Perforation	NA	39.3	Narrow
8	61	M	162	1	Yes	Dysphagia	19/4	18	Normal

Table 2: Patient Details for LINX Removal (Group B)

4. Discussion

Long term medical management of GERD with Proton Pump Inhibitors (PPI's) has come under scrutiny. This class of medications may cause bone loss, Vitamin B12 and D deficiencies, increased risk of developing Clostridium difficile colitis or small intestinal bacterial overgrowth (SIBO), acute and chronic kidneys disease, dementia, pancreatitis pancreatic cancer, hypomagnesemia, and most recently may be related to an increased risk of developing severe clinical outcomes from COVID-19 infection [7-11]. H2RAs, a less effective acid-reducing medication in the treatment of GERD, may cause confusion, delirium or dizziness in the elderly [12,13]. Attempts at behavioral changes such as weight loss, smoking cessation, avoidance of trigger foods and late night snacks result in an inconsistent control of GERD symptoms [14,15]. Counseling patients to avoid smoking, alcohol, fatty foods, caffeine, large meals and spicy products are also not overly successful due to poor compliance or ineffective results. Endoscopic and surgical options, therefore, remain essential in providing adequate control of heartburn in patient refractory to medical management. As with most medical or surgical interventions, potential side effects often dissuade patients from pursuing invasive procedures.

As patients seek alternatives to medicinal therapies for GERD, a variety of surgical procedures have been developed to reduce the need of medications. Nissen fundoplication, initially performed in 1955, evolved into a laparoscopic technique in 1991 and has become the gold standard in managing GERD [16]. However, Toupet fundoplication has increasingly been used as an alternative for patients identified preoperatively with weak esophageal peristalsis [17]. Transoral Incisionless fundoplication (TIF) was introduced in 2006 as an endoscopic option to the Nissen Fundoplication but has not achieved acceptable clinical outcomes to replace conventional fundoplication [18,19]. Other options for managing GERD include placements of implants around the distal esophagus to reduce the luminal diameter which prevent regurgitation of gastric contents into the esophagus. Such devices include the Angelchik prosthesis introduced in 1979 and LINX which was approved by the FDA in 2012 [20]. The Angelchik prostheses, a C-shaped ring-like silicone prosthesis which wraps around the lower part of the esophagus to treat patients with GERD and a hiatal hernia, has fallen out of favor due to a variety of complications.. Its initial ease of placement and objective improvement comparable to the Nissen fundoplication was promising. However, side effects such as dysphagia and problems caused by migration of the device resulted in 15-24% removal and only a 66% favorable outcome [21,22]. At time of surgical removal, a dense fibrous capsule formed around the prosthesis making it difficult for removal [23]. Follow-up studies noted that most needed a fundoplication to help control reflux symptoms after removal of the prosthesis.

The LINX device is also easy to place but less bulky and more dynamic than the Angelchik prosthesis. Its safety and effectiveness makes it a good alternative for GERD management in a select patient population. To place the device, patients should have normal esophageal motility. and a hiatal hernia no more than 3 cm There is a relative contraindication to large paraesophageal hernias, but still possible if they could be repaired. GERD-HRQL (Table 3) scores improve dramatically after placement of the implant. In the event the device needs to be removed, the fibrous band that develops around the prosthesis seems to mitigate GERD symptoms by reducing LES relaxation. In our 7 patients who required implant removal, four noted less GERD after device removal possibly due to the inflammatory surgical adhesions that developed at the distal esophagus. We also suspect balloon dilation may have contributed toward the development of additional scar from the trauma of this intervention. The individual with perforation at time of LINX placement also developed adhesions at the distal esophagus due to the inflammatory response of esophageal content leakage. This area was stitched and patched with omentum. Subsequent inflammatory reaction created enough scarring to narrow the esophageal lumen and reduce episodes of regurgitation. Literature describes that the MSA beads may erode into the esophageal lumen at a very low incidence (0.1-0.15%) [24]. This complication causes a localized perforation, but leakage of contents into the peritoneum is prevented by the scar tissue surrounding the beads. The fibrous tissue offers the opportunity to remove the beads endoscopically without causing luminal content leakage into the mediastinum or peritoneum.

0 = No symptoms	**3 = Symptoms bothersome every day**
1 = Symptoms noticeable, not bothersome	**4 = Symptoms affect daily activities**
2 = Symptoms noticeable and bothersome	**5 = Symptoms incapacitating**

1. How bad is your heartburn?	
2. Heartburn when lying down?	
3. Heartburn when standing up?	

4. Heartburn after meals?	
5. Does heartburn change your diet?	
6. Does heartburn wake you from sleep?	
7. Do you have difficulty swallowing?	
8. Do you have bloating or gassy feelings?	
9. Do you have pain with swallowing?	
10. Heartburn total score	0-50 total score
If you take medication, does heartburn still affect you daily life?	Yes/No
How satisfied are you with your present condition?	Satisfied/Dissatisfied

Table 3: GERD-HRQL Questionnaire

Other techniques which cause scarring in the distal esophageal include the Stretta Procedure, Enteryx bulking injection and HALO RFA. Stretta procedure uses radiofrequency (RF) energy delivered to the tissues of the distal lower esophageal sphincter (LES) and gastric cardia, which decreases LES compliance, increases LES muscle mass, and limits the inappropriate transient LES relaxations responsible for GERD in many patients. This increased thickness of the distal esophagus reduces reflux in a select group of patients [25]. Enteryx bulking injections to the distal esophagus also creates thickening of the distal esophagus induced by chronic inflammation in response to the foreign body. This also leads to loss of sphincter compliance and distensibility of the esophagus which reduces GERD symptoms in a subset of patients which previously responded to PPI's. HALO RFA has been used to eradicate Barrett's esophagus, but only 5.6% (26) develop strictures of the treated esophagus and is therefore not a practical method of reducing GERD.

Generating fibrosis or thickening of the distal esophagus to control GERD symptoms has been extensively investigated. Thus far, creation of intrinsic esophageal fibrosis with Stretta, Enteryx and HALO ablations are less effective at managing reflux than mechanical compression of the LES as achieved by fundoplication or MSA. The latter procedures result in comparable reduction in regurgitation and improved GERD-HRLQ. The MSA device not only causes extrinsic compression of the distal esophagus, it also creates a dense fibrous band at this site (Fig 1)

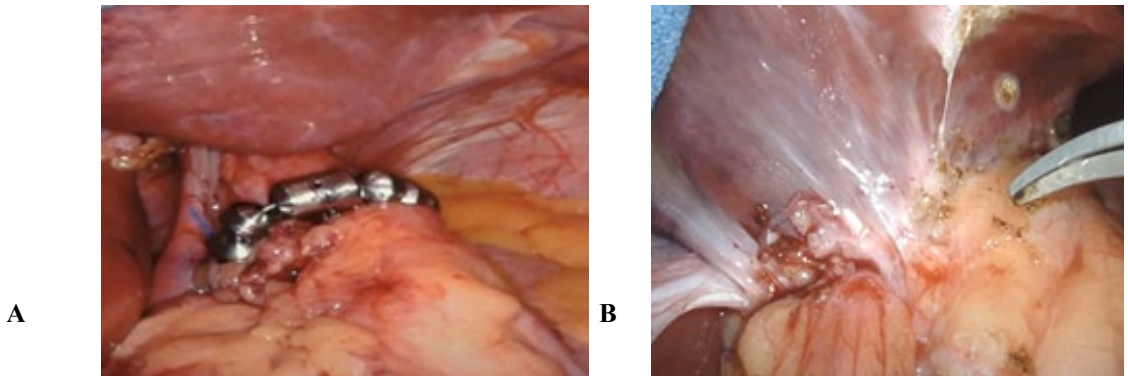

Figure 1: MSA Device Placed Around Distal Esophagus (A), Dense Fibrous Band at Site of MSA Placement at Distal Esophagus (B)

which contributes toward long term efficacy. It has been reported that up to 15.5% of patients complained of post-operative dysphagia after LINX placement. The overall response to dilation therapy was 67% but decreased with subsequent dilations possible due to progressing development of fibrous adhesions. In the event the magnetic properties of the device are lost, the scarring continues to provide adequate relief from reflux events. In a previous study of MSA removal, 77% of patients did not require surgery or medication to manage reflux [27,28]. The longer the device is implanted and subject to balloon dilation, the more scar tissue forms at the site of the implant. The compliance of the esophagus is apparently decreased by the combination of intrinsic and extrinsic effects. Barium swallow confirms that the esophageal lumen narrows after this procedure, and remains so even after LINX removal.

Further studies are needed on patients with LINX explantation to determine the long term efficacy of preventing gastroesophageal reflux. As patients were unwilling to undergo pH testing or Manometry after LINX removal, our clinical assumptions of improved LES function were based on endoscopy and radiologic findings. Endo flip, when more widely available, may provide us with more insight into LES functioning after LINX removal. Individuals with anxiety and sensitivity to BRAVO insertion did

not fare well with insertion of the MSA device. These individuals should be cautiously screened utilizing the GAD-7 scale, but are likely not appropriate candidates for the LINX device. In conclusion, we do not recommend a fundoplication at time of LINX removal as it appears the majority of patients appear to maintain adequate control of reflux symptoms if enough scar tissue develops at the distal esophagus to prevent regurgitation.

5. Conclusion

Fibrosis formed at the site of MSA device explantation improves heartburn symptoms in a majority of patients. This scarring causes decreased compliance and narrowing at the gastroesophageal junction resulting in observed clinical improvement. A fundoplication may not be necessary to prevent symptoms of reflux in patients who undergo MSA explantation for symptoms of dysphagia. Ongoing monitoring of symptoms, and possibly Endo Flip measurements of esophageal peristalsis and LES function, will further clarify our understanding of the physiologic changes post LINX placement and removal. Individuals with anxiety appear to be intolerant of foreign body implants in or around the esophagus, such as the BRAVO or LINX, and should carefully be screened prior to LINX consideration.

Acknowledgements

The authors received no financial support for the research and authorship of this article. The literature strategy was conducted in collaboration with an information specialist. This study was approved by our institutional Internal Review Board IRB # 21-1015-3

Funding

No funding received to conduct this review.

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