Laparoscopic Magnetic Sphincter Augmentation vs Laparoscopic Nissen Fundoplication: A Matched-Pair Analysis of 100 Patients

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BACKGROUND: The efficacy and safety of magnetic sphincter augmentation (MSA) with the LINX device (Torax Medical) has been reported in several short-and long-term studies, rivaling historic results of laparoscopic Nissen fundoplication (LNF), but with fewer side effects. However, there have been no studies comparing patients with similar disease to validate these results.

STUDY DESIGN: We conducted a retrospective analysis of 1-year outcomes of patients undergoing MSA and LNF from June 2010 to June 2013. Patients were matched using propensity scores incorporating multiple preoperative variables. Outcomes were measured by GERD Health Related Quality of Life scores, proton-pump inhibitor use, satisfaction, and complications.

RESULTS: One hundred and seventy-nine patients met inclusion criteria, 62 MSA and 117 LNF. Propensity score matching identified 50 patients in both groups using the "best-fit" model with a caliper of 0.5 SD. At 1 year after surgery, both groups had similar GERD Health Related Quality of Life scores (4.2 MSA and 4.3 LNF; $p = 0.897$) and proton-pump inhibitor use (17% of MSA and 8.5% of LNF; $p = 0.355$). Although there was no difference in the number of patients reporting mild gas and bloating (27.6% MSA and 27.6% LNF; $p = 1.000$), there were no patients with severe gas and bloating in the MSA group compared with 10.6% in the LNF group ($p = 0.022$). More LNF patients were unable to belch (8.5% of MSA and 25.5% of LNF; $p = 0.028$) or vomit (4.3% of MSA and 21.3% of LNF; $p = 0.004$). The incidence of postoperative dysphagia was similar between the groups (46.8% MSA and 44.7% LNF; $p = 0.766$).

CONCLUSIONS: Analogous GERD patients had similar control of reflux symptoms after both MSA and LNF. The inabilities to belch and vomit were significantly fewer with MSA, along with a significantly lower incidence of severe gas–bloat symptoms. These results support the use of MSA as first-line therapy in patients with mild to moderate GERD. (J Am Coll Surg 2015;221:123–128. © 2015 by the American College of Surgeons)

Laparoscopic Nissen fundoplication (LNF) is the gold-standard surgical treatment for GERD. Despite this, it is estimated that <1% of patients use or are offered this option.[1] Ninety-nine percent of patients with GERD are treated with acid-suppression therapy, the majority of which are proton-pump inhibitors (PPIs). These agents reduce the acidic symptoms of reflux by increasing the pH of the refluxed gastric juice without reducing the incidence of reflux episodes. Despite their ubiquitous use, it is estimated that approximately 60% of patients on PPIs continue to have symptoms or are unable to tolerate the medication.[2,3] Consequently, there is a considerable portion of GERD patients who remain poorly controlled on PPI therapy, and one-fourth have endoscopic evidence of progressive disease, such as esophagitis

Disclosure Information: Dr Lipham is a consultant for Torax Medical, the manufacturer of the LINX device. All other authors have nothing to disclose.

Support: Supported by the James & Pamela Muzzy Endowed Chair in GI Cancer.

Presented at the Western Surgical Association 122nd Scientific Session, Indian Wells, CA, November 2014.

Received December 1, 2014; Revised February 1, 2015; Accepted February 1, 2015.

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http://dx.doi.org/10.1016/j.jamcollsurg.2015.02.025
ISSN 1072-7515/15

Abbreviations and Acronyms

HRQL = Health Related Quality of Life survey
LES = lower esophageal sphincter
LNF = laparoscopic Nissen fundoplication
MSA = magnetic sphincter augmentation
PPI = proton pump inhibitor

or Barrett's esophagus.[4] Magnetic sphincter augmentation (MSA) was specifically designed for such patients.

Magnetic sphincter augmentation with the LINX device (Torax Medical) was approved by the FDA in 2012 for patients with mild to moderate GERD. Labeling of the device excludes patients with moderate dysphagia, severe esophagitis, and large hiatal hernias, exactly the population that often present for LNF. There have been several studies looking at the efficacy of MSA, and all find both short- and long-term efficacy to be similar to that reported for LNF.[5-9] However, these studies are likely reporting on a population with different disease severity than that undergoing LNF.

The aim of this study was to compare the outcomes of MSA with LNF in a group of patients matched by propensity scores calculated from disease-specific preoperative symptoms and endoscopic findings to evaluate the 2 procedures in patients with similar disease severity.

METHODS

All patients undergoing MSA or LNF between April 2007 and October 2013 were identified from a prospectively collected database. This range was chosen to include patients undergoing MSA and LNF during the same time period as the first MSA was performed at our institution in 2007 as part of the FDA Feasibility trial. Inclusion criteria included objective evidence of GERD, defined as an abnormal pH study, presence of biopsy-proven Barrett's esophagus, or esophagitis grade B or greater; documented history of PPI therapy for a minimum of 6 months; and normal esophageal motility documented by videoesophagram or esophageal manometry.

Surgical procedure

Magnetic sphincter augmentation was performed by 3 surgeons (JL, NB, and JZ) at 2 institutions according to a standard protocol (Table 1). The decision to repair unsuspected hiatal hernias was made intraoperatively by the operating surgeon. In general, crural closure was performed if a hiatal hernia was visible after a posterior dissection of the hiatus that kept the phrenoesophageal membrane intact anteriorly and laterally. Laparoscopic Nissen fundoplication was performed by the same 3 surgeons and at the same 2 institutions according to the standard protocol (Table 2).

Table 1. Magnetic Sphincter Augmentation Protocol

1.	Patient is placed in low lithotomy with the surgeon standing between the patient's legs.
2.	A 12-mm camera port is placed at the umbilicus. A 5-mm working port is placed in the right upper quadrant and a Nathanson liver retractor is placed in the right upper quadrant. An 8-mm working port in placed in the left upper quadrant to allow passage of the MSA device.
3.	The hepatic branch of the vagus nerve is identified and preserved. The right and left crura are identified and minimally dissected to create a tunnel behind the esophagus.
4.	If the posterior vagus nerve can be easily identified, it is dissected posterior. However, this step is often omitted in favor of keeping dissection to a minimum.
5.	Tissue on the anterior esophagus is removed so the MSA device can lie flush to the esophagus.
6.	The provided sizing device is used to determine the number of beads on the device.
7.	The MSA device is passed through the 8-mm port and pulled through the retro-esophageal tunnel. If the vagus nerve was dissected, it is placed anterior to the vagus.
8.	The MSA device is secured using the clasp on the device.
9.	Ports are removed and the abdomen desufflated.

MSA, magnetic sphincter augmentation.

At 1 year after surgery, patients were evaluated with a GERD-Health Related Quality of Life (HRQL) survey with questions about gas—bloat, their ability to belch, their

Table 2. Laparoscopic Nissen Fundoplication Protocol

1.	Patient is placed in low lithotomy with the surgeon standing between the patient's legs.
2.	A 12-mm camera port is placed above and to the left of the umbilicus. Two 12-mm working ports are placed at the bilateral subcostal margins in the mid-clavicular line. A Nathanson liver retractor is placed in the right upper quadrant. A 12-mm port in the left anterior axillary line at the level of the camera port is placed as an assistant port.
3.	The plane between the right crus and esophagus is developed and extended to the left crus until complete circumferential dissection of the esophagus is obtained with a large retro-esophageal window.
4.	Both vagus nerves are identified and preserved.
5.	The esophagus is encircled with a Penrose and the crura are closed.
6.	The short gastric vessels are divided to mobilize the fundus.
7.	A 52 to 56F esophageal bougie is passed and the fundus passed behind the esophagus creating a loose, floppy wrap.
8.	The fundus is sutured to itself to size the wrap and then the bougie is removed.
9.	Additional sutures are placed in the fundus, including the anterior esophageal wall to secure the wrap around the esophagus.
10.	Ports are removed and the abdomen desufflated.

ability to vomit, dysphagia, and overall satisfaction with surgical treatment. The GERD-HRQL is a validated disease-specific questionnaire consisting of 10 questions focused on heartburn, dysphagia, and gas–bloat, with each question rated 0 (least severe) to 5 (most severe), for a total score ranging from 0 to 50.[10] Dysphagia was recorded as mild if patients reported occasional food sticking less than once a week, moderate if they experienced symptoms more than once a week without regurgitation of undigested food or vomiting or made dietary modifications to accommodate symptoms, and severe if they experienced symptoms more than once a week that included regurgitation of undigested food or vomiting. Patients were also specifically asked if their preoperative symptoms improved, resolved, or did not change. The medical record was also searched for any complications or interventions that occurred within the first postoperative year.

Statistical analysis

Matching was performed by calculating propensity scores for MSA and LNF patients using the following predictors: age, sex, BMI, duration of GERD symptoms, esophagitis grade (Los Angeles classification) as described on endoscopy report, size of a hiatal hernia as measured on endoscopy, Hill valve grade, laryngeal–pharyngeal reflux symptoms, and dysphagia. Per inclusion criteria, all patients had objective evidence of pathologic reflux defined as an abnormal pH study, biopsy-proven Barrett's esophagus, or esophagitis grade B or greater. Also, all patients had normal motility assessed by videoesophagram or manometry and were on PPIs for at least 6 months before the procedure. Patients were matched using the "best-fit" model with a caliper of 0.5 SD and a limit of 100 cases.

Means were compared using independent *t*-test and categorical variables were compared using either Fisher's exact test for variables with 2 categories or Pearson's chi-square for variable with >2 categories. A p value <0.05 was considered significant.

All statistical analysis was performed with SPSS software, version 22 (IBM SPSS).

RESULTS

There were 179 patients that met the inclusion criteria for the study, 62 had MSA and 117 had a LNF. Propensity score matching with a 0.5-SD caliper identified 51 matches and the 50 best matches were included for analysis. Comparison of the preoperative characteristics between the patients who had MSA with those who had LNF showed no significant difference in any of the included variables (Tables 3 and 4). The presence of a hiatal hernia and the size of the hiatal hernia were distributed similarly in the MSA and LNF patients (Table 4). All LNF patients underwent crural closure as part of the standard LNF procedure (Table 2). In MSA patients, crural closure was performed if a hiatal hernia was visible after a posterior dissection of the hiatus that kept the phrenoesophageal membrane intact anteriorly and laterally. Twenty-two percent (11 of 50) of MSA patients underwent crural closure, including 33.3% (6 of 18) of patients with a 2-cm hernia, 44.4% (4 of 9) of patients with a 3-cm hernia, and 100% (1 of 1) of patients with a 4-cm hernia.

Table 3. Preoperative Demographics and GERD Charecteristics

Characteristics	MSA (n = 50)	LNF (n = 50)	p Value
Age, y	53.0	54.0	0.748
Sex, n			0.686
Male	30	27	
Female	20	23	
BMI, kg/m^2	26.4	26.7	0.741
GERD duration, mo	146.9	144.5	0.932
GERD-HRQL score	19.7	18.8	0.596
Esophagitis, n			0.711
None	35	36	
A	9	7	
B	5	4	
C	1	3	
D	0	0	
Hiatal hernia size, cm	1.5	1.6	0.735
Hill grade valve, n			0.482
1	1	0	
2	5	5	
3	17	12	
4	27	33	
LPR, n	20	20	1.000
Dysphagia, n	5	7	0.760
Barrett's esophagus, n	10	11	1.000

HRQL, Health Related Quality of Life survey; LNF, laparoscopic Nissen fundoplication; LPR, laryngeal–pharyngeal reflux; MSA, magnetic sphincter augmentation.

One-year follow-up data were available for 47 of 50 (94%) patients who had MSA and 47 of 50 (94%) LNF patients. Among MSA patients, 46 of 47 (97.8%) stated that their GERD symptoms had improved, and 24 of 47 (51.1%) reported complete resolution. Similarly, 46 of 47 (97.8%) LNF patients reported improvement of their GERD symptoms at 1 year, and 23 of 47 (48.9%) reporting complete resolution of symptoms (p = 0.978).

Mean GERD-HRQL scores at 1 year after surgery were similar, with 4.2 for the MSA patients and 4.3 for the LNF patients (p = 0.879). At 1 year after surgery, 39 of 47 (83.0%) MSA patients were off PPI therapy, compared with 43 of 47 (91.5%) LNF patients (p = 0.355).

Table 4. Hiatal Hernia Characteristics

Characteristics	LNF group (n = 50)	MSA group (n = 50)
Hiatal hernia size, n		
None	15	15
1 cm	4	7
2 cm	20	18
3 cm	9	9
4 cm	2	1
Any, n (%)	35 (70)	35 (70)

LNF, laparoscopic Nissen fundoplication; MSA, magnetic sphincter augmentation.

One year after surgery, 17 of 47 (36.2%) patients with MSA had mild dysphagia, characterized as food sticking less than once a week and 5 of 47 (10.6%) had moderate to severe dysphagia, characterized as symptoms more than once a week, regurgitation of undigested food, vomiting, or requiring dietary modifications. This was similar to patients who had LNF, with 15 of 47 (31.9%) reporting mild dysphagia and 6 of 47 (12.8%) reporting moderate to severe dysphagia ($p = 0.766$). Endoscopic dilation was performed for symptom of dysphagia in 8 of 50 (16%) patients who had MSA compared with 5 of 50 (10%) who had LNF ($p = 0.554$).

Of the patients who had MSA, 13 of 47 (27.7%) reported symptoms of gas–bloat, all characterized it as "mild." Eighteen of 47 (38.3%) patients reported gas–bloat after LNF and 5 (10.6%) characterized it as "severe" ($p = 0.067$). No MSA patients reported severe gas and bloating symptoms ($p = 0.022$). After MSA, 4 of 47 (8.5%) patients were unable to belch and 2 of 47 (4.3%) were unable to vomit when necessary. After LNF, 12 of 47 (25.5%) patients were unable to belch ($p = 0.028$) and 10 of 47 (21.3%) were unable to vomit when necessary ($p = 0.004$).

Overall, 42 of 47 (89.4%) MSA patients and 43 of 47 (92.5%) LNF patients were satisfied with the procedure ($p = 0.603$), and 44 of 47 (93.6%) MSA and 38 of 47 (80.9%) LNF patients would elect to have the procedure again ($p = 0.053$).

Complications within 30 days of surgery did not occur in patients who had MSA. In contrast, 2 patients who had an LNF had complications; 1 was readmitted for intractable nausea and oral intake intolerance on postoperative day 1, and another patient required an esophagogastroduodenoscopy for food impaction. One year after surgery, there were no MSA device removals or erosions and no LNF patients required reoperation. Endoscopic dilation for dysphagia during the first postoperative year occurred in 8 of 50 (16.0%) MSA patients and in 5 of 50 (10.0%) LNF patients ($p = 0.554$).

DISCUSSION

The era of minimally invasive surgical treatment of GERD began in the early 1990s with LNF. During the latter part of the intervening 25 years, several endoscopic procedures were developed to provide a less invasive surgical treatment of GERD. These included an attempt to form a fundoplication around the lower esophageal sphincter (LES) with a variety of endoscopic suturing devices, bulk and stiffen the LES with foreign materials, or decrease the compliance of the LES by producing escharotic lesions with radiofrequency ablation. However, none of these have been able to provide long-term control of acid reflux comparable with LNF with acceptable side effects.[11-13] The concept of sphincter augmentation was developed to prevent transient sphincter relaxation due to effacement and shortening of the sphincter's length secondary to postprandial gastric distention or gastric dilation caused by adaptive relaxation. In this way, MSA is fundamentally different from other anti-reflux procedures. It was designed specifically to augment a near-normal LES, the length of which is starting to shorten from reflux-induced inflammatory injury and to provide additional support during transient failures of the LES, such as during postprandial gastric distention or dilation. Magnetic sphincter augmentation provides a surgical alternative to patients with mild to moderate disease who have evidence of progressive disease, such as esophagitis on baseline endoscopy, failure of esophagitis to heal with acid-suppression therapy, the need to escalate the dose of acid-suppression therapy to achieve symptomatic relief, and a compulsive dependency on daily PPIs to control symptoms. The impetus to identify and counsel patients with progressive disease about the need for surgical therapy is critical if progression to inflammatory and metaplastic complications of the disease are to be prevented.

In this matched-pair analysis between MSA and LNF in patients with early disease, we found that those who had MSA obtained the same efficacy in symptomatic reflux control with less gas–bloat symptoms and less restriction in their ability to belch and vomit. Louie and colleagues[14] showed similar short-term results in a smaller group of patients controlled for hernia size and GERD symptoms.

A criticism of comparative studies to date is that the patients undergoing MSA have less severe disease than patients undergoing LNF. The current study is the first to test this criticism by matching patients for disease severity. By using propensity scores and matching on 9 variables known to affect disease severity, we were able to compare similar patients. Analysis of these characteristics confirms

that the majority of patients in both groups, those who had MSA and those who had LNF, had mild to early disease (ie, no Barrett's esophagus, no dysphagia, mild or no esophagitis, and small hiatal hernias). Analysis of 1-year outcomes confirmed that MSA is comparable with LNF in terms of efficacy, safety, and patient satisfaction. There was a significant difference favoring MSA in both severe gas–bloat symptoms and ability to belch and vomit, with twice as many LNF patients as MSA patients not being able to belch normally and 5 times as many being unable to vomit.

These results substantiate that MSA is as effective as LNF in controlling reflux, with the benefit of also having fewer side effects. Consequently, there is the potential that more patients with early evidence of progressive disease will be amenable to surgical therapy and potentially more gastroenterologists will be willing to refer patients with progressive disease earlier for MSA. This is particularly important because medical therapy with PPIs does not prevent reflux into the esophagus of the alkalized gastric juice, allowing the potential for progressive disease, despite silencing of the patient's symptoms. Treating such patients with MSA can prevent progressive disease and decrease the incidence of severe reflux complications and development of chronic inflammation, metaplasia, dysplasia, and esophageal adenocarcinoma.

The main shortcoming of this study is that it is a retrospective study and not a randomized controlled trial. Therefore, there is an inherent selection bias. We used propensity score analysis to limit the effect of this selection bias, but it does still exist. Early in the study, MSA was done as part of the FDA pre-approval trials and, therefore, was only available to a small subset of patients who met strict inclusion criteria and were willing to undergo the yearly invasive testing for 5 years, which was part of the study. Once MSA was approved by the FDA, the lack of insurance coverage for MSA was a considerable barrier for patients who wanted to undergo the procedure. Many of these patients elected to continue PPI therapy in lieu of undergoing LNF, however, some patients proceeded with LNF. Although infrequent, there were patients who were offered MSA but preferred to proceed with LNF for various personal reasons. The only way to remove all selection bias would be to perform a randomized controlled trial. However, given that current data already show that MSA is as effective as LNF and with a shorter operative time, shorter length of stay, and less-severe side effects, it seems unlikely that such a trial would be able to accrue the necessary number of patients.

CONCLUSIONS

Analogous GERD patients had similar control of reflux symptoms after both MSA and LNF. Annoying inabilities to belch and vomit and severe gas–bloat symptoms were significantly fewer with MSA. The more favorable side effect profile of MSA supports its use early in the course of GERD.

Author Contributions

Study conception and design: Reynolds, Zehetner, Bildzukewicz, Lipham
Acquisition of data: Reynolds, Wu, Shah
Analysis and interpretation of data: Reynolds, Zehetner, Lipham
Drafting of manuscript: Reynolds, Zehetner, Lipham
Critical revision: Reynolds, Zehetner, Lipham

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Discussion

DR MICHAEL UJIKI (Evanston, IL): Drs Reynolds, Lipham, and colleagues describe their experience with the magnetic sphincter augmentation through a matched pair analysis with patients who have undergone laparoscopic Nissen fundoplication, and correctly state one of the issues with the data to date, which is that patients having magnetic sphincter augmentation have been compared with groups of patients undergoing Nissen fundoplication who have more severe gastroesophageal reflux disease. They have analyzed 1-year outcomes in 100 patients who were identified through a propensity "best fit" analysis. Both groups reported improved or resolved symptoms of GERD, and most were off acid suppression. Dysphagia and satisfaction rates were similar. Complications and need for dilation were similar. Patients who underwent magnetic sphincter augmentation were more able to belch and vomit.

Up to what size hiatal hernia and body mass index are you currently willing to still perform magnetic sphincter augmentation? Or, in other words, have inclusion criteria expanded in your series of patients? This seems to be a limiting factor in the expansion of use with this device because most patients in whom surgery is indicated tend to have large hernias and are obese.

Has your group experienced any patients with Barrett's esophagus that progressed to dysplastic disease after sphincter augmentation? If so, how did you manage them? If not, how would you handle such a patient, as I would assume that ablation is contraindicated with these patients?

Given that magnetic sphincter augmentation tends to be aimed at a select group of thin patients with small hiatal hernias, mild reflux, and normal esophageal motility—a group that is not common in the surgeon's office—would it be more appropriate to compare magnetic sphincter augmentation with acid suppression rather than fundoplication? Does your group have any experience in comparing these 2 groups? And if so, can you share your results?

DR JOHN C LIPHAM (Los Angeles, CA): In regard to the question about Barrett's and progression, since the clinical trials, we have been placing the device in patients with short segment Barrett's. All patients come back yearly for an endoscopy, given the fact that it is a new procedure. And we have not seen progression of the Barrett's with patients now out 3 to 3½ years.

Specifically in regard to ablation, we have done it with the LINX in place using the HALO90 device. Ken Wang's group at the University of California-Irvine also did an animal study, looking at ablation with LINX in a pig model, and showed that the energy delivered by the ablation did not reach the level of the device, so there were no untoward effects of it. If we see a patient with dysplasia that develops afterwards, we will use the HALO90 to ablate that. So I do not think it precludes ablation in those. I would be a little nervous, however, using the 360, which is the balloon device, given the fact that the balloon there is quite large, and the diameter of the device runs from somewhere around 21 to 26 mm.

In regard to your question about hiatal hernia size, since the clinical trials, we have loosened our requirements in regard to hiatal hernias. We have operated on patients with hiatal hernia size up to 7 cm with seemingly similar results. Now, that is our own case series on those patients. We have recently started to enroll patients in a multicenter trial looking at patients with hiatal hernia size 4 to 7 cm. So hopefully within the next year, I will be able to give you an answer to that question.

Although BMI was an exclusion criterion within the clinical trials, since that time, we have really gone away from excluding patients solely based on their BMI. Even in this study, there were patients in that trial that got LINX with BMIs greater than 35 kg/m^2.

In regard to the MRI and erosion question or comment, initially, when the LINX came out, MRI was a contraindication to the device. Since that time, they have loosened their contraindications somewhat. Currently, a low powered MRI, or a 0.7-Tesla MRI, is allowable with the device in place. There has also been a redesign of the magnets that is currently at a level that seemingly can tolerate a 1.5-Tesla MRI, and the company expects approval from the FDA by January or February. The concern is not that the device will come shooting out like little BBs; the concern has been the repolarization of the magnetic beads, given the high power of the magnet.

In regard to erosion, there have been 5 erosions out of about 3,000 patients being operated on worldwide, giving it about a 0.2% erosion rate. Most of the erosions, at least 3 of the 5, seem to be infectious in origin, meaning the device, at the time of implant or shortly thereafter, got infected, and that seemed to be the reason for its erosion. In the 5 patients in whom it did erode, it was fairly easy to manage. They went down endoscopically. There were usually 2 or 3 or 4 little beads that were intraluminal. The link on each side of those beads was cut and those 3 or 4 beads were then removed endoscopically. Later, they went in laparoscopically and took the remaining part of the device out. No patients required esophagectomy, gastrectomy, or anything more major than that.

In regard to your last question, comparison with proton pump inhibitors (PPI), I agree. I think that is something that needs to be done. I think what we have shown, and others have shown here, is that the device is very effective for that gap population, which admittedly is the milder to moderate reflux patient. I think there are really 2 questions here. One is its comparison to PPI therapy alone, but I think we also need to look at a comparison with the more advanced degrees of reflux. The first step in that is going to be looking at the patients with the larger hiatal hernia size.

DR MARK A TALAMINI (Stony Brook, NY): The context or framework here, I think, is really fascinating, because there is the backdrop of the Angelchik prosthesis story, which is considered