Review Article

Is magnetic sphincter augmentation a reasonable surgical option for gastroesophageal reflux disease?

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Abstract: The magnetic sphincter augmentation (MSA) procedure is a highly standardized laparoscopic surgical option for patients with well-documented gastroesophageal reflux disease who do not fully respond to medical treatment with proton-pump inhibitors (PPIs), complain of volume regurgitation, or develop progressive/refractory symptoms despite escalation therapy. The effectiveness of the MSA procedure has been proven in patients with typical reflux symptoms and PPI dependent who show an increased esophageal acid exposure on prolonged pH monitoring. Observational studies have demonstrated that MSA compares well with Nissen and Toupet laparoscopic fundoplication (LF) in selected patients, and has an acceptable risk profile. Whenever necessary, the MSA device can be explanted via laparoscopy without complications or long-term consequences, and a standard fundoplication can be concomitantly performed. Combining formal crural repair with MSA appears to strengthen the antireflux effect and reduce the need of reoperation. MSA represents a reasonable therapeutic option in patients with gastroesophageal reflux disease (GERD) and perhaps an alternative to LF.

Keywords: Gastroesophageal reflux disease; Hiatus hernia; proton-pump inhibitors (PPIs); fundoplication; magnetic sphincter augmentation (MSA); Linx procedure; lower esophageal sphincter

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Introduction

The clinical outcomes of both medical and surgical treatment for gastroesophageal reflux disease (GERD) are still far from ideal. A significant proportion of patients do not respond completely to proton-pump inhibitor (PPI) therapy, and even dose escalation may be inadequate to treat individuals presenting with symptoms of volume regurgitation and a mechanically defective lower esophageal sphincter (1). Additionally, in the long run, acid suppression may have a negative impact on multiple physiologic pathways. Last but not least, patients with poorly controlled esophageal acid exposure may progress to severe complications such as erosive esophagitis, peptic stricture, aspiration pneumonia, exacerbations of chronic obstructive lung disease, lung fibrosis, Barrett's esophagus, and even esophageal adenocarcinoma (2,3).

Laparoscopic fundoplication (LF), the current surgical gold standard for GERD, is a safe, effective and long-lasting procedure when performed in high-volume centers (4,5). However, the Nissen fundoplication is generally underutilized due to perceived technical difficulties, side effects, and fear of long-term failure; furthermore, this procedure has been traditionally used for treating patients with severe disease and large hiatus hernia, i.e., those who are more prone to surgical failures.

The magnetic sphincter augmentation (MSA) procedure has been designed to augment the lower esophageal sphincter barrier using a standardized laparoscopic implant. The aim of this review is to describe the main features of this novel technology and summarize the currently available clinical studies.

Technology of MSA

The MSA device (Linx™ Reflux Management System, Torax Medical, Minneapolis, USA) consists of a collar of biologically compatible titanium beads incorporating magnetic cores. The beads, which are interlinked with independent titanium wires, can move independent of each other and form an expandable, ring-like dynamic implant that does not compress the esophageal wall. After implantation, the MSA is gradually encapsulated in a fibrous tissue sheath that surrounds the esophageal wall. The device, while augmenting the LES, allows for expansion to accommodate a swallowed bolus or the escape of peak gastric pressure associated with belching or vomiting. The device has recently received FDA approval for magnetic resonance imaging up 1.5 Tesla.

Procedure of MSA

The implant of MSA device requires a short laparoscopic procedure under general anesthesia. In patients with normal anatomy of the gastro-esophageal junction or small hiatus hernia, dissection should be minimal and the phrenoesophageal ligament should be preserved (6). The first step of the procedure consists of division of the peritoneum overlying the anterior surface of the gastroesophageal junction below the insertion of the inferior leaf of the phrenoesophageal ligament and above the hepatic branch of the anterior vagus. The posterior fundic wall is freed from the left crus without dividing any short gastric vessel. The lesser omentum is opened above and below the hepatic branch to the vagus in order to dissect the retro-esophageal window. Once the posterior vagus nerve is identified, a tunnel is created between the vagus and the esophageal wall, and the esophagus is encircled with a soft silicon drain. At this point of the procedure, the circumference of the esophagus is measured to determine the appropriate size of the MSA device to be implanted. A formal hiatus repair may not be required in most patients with a small and reducible hiatus hernia if the phrenoesophageal ligament and the lower mediastinum have not been violated. Patients are discharged the same day or on the first post-operative day after a chest film has been performed to check the correct placement of the device. Routine take-home recommendations for the patient include to chew well, take small volume meals, and discontinue the use of proton pump inhibitors.

Analysis of single-arm studies

Table 1 summarizes the single-arm clinical studies performed on patients treated with MSA. All studies are prospective and observational. Criteria for patient exclusion were history of dysphagia, previous upper abdominal surgery, previous endoluminal antireflux procedures, sliding hiatal hernia >3 cm, esophagitis > grade A, abnormal contractile amplitude and wave form in the esophageal body, and/or Barrett's esophagus. All MSA devices were implanted via laparoscopy. The median operative time was around 40 minutes and no intraoperative complications occurred. Maximum follow-up was 60 months. Mild postoperative dysphagia not requiring treatment was common. About 5% of patients rated dysphagia as severe and required endoscopic balloon dilation or surgical removal of device with complete resolution. The GERD-HRQL score significantly decreased compared to baseline in all studies, and between 80% and 90% of patients remained off PPI. Esophageal pH testing showed that 85% of patients achieved either normal esophageal acid exposure or had at least a 50% reduction from baseline. Most patients reported the ability to belch and vomit if needed. A few patients required laparoscopic device explant due to persistent dysphagia, the need to undergo magnetic resonance imaging, or persisting reflux symptoms (6-13).

A study comparing outcomes of MSA in patients with small (<3 cm) versus larger hiatus hernia found significantly reduced postoperative PPI requirements and mean postoperative GERD-HRQL scores in those with large hernia. The percent of patients requiring postoperative intervention for dysphagia and the incidence of symptom resolution or improvement was similar in the two groups (14). A subsequent study from the same group showed durable subjective reflux control and a 4.3% recurrent hernia rate at 1–2 years follow-up (20). Other authors have confirmed the feasibility and efficacy of MSA in patients with hiatus hernia and found that the clinical results were independent of hernia size (15,16).

Two studies investigated the effect of systematic, concomitant crura dissection and suture repair on the

Table 1 Analysis of single-arm clinical studies with magnetic sphincter augmentation

Author	No. patients	Age (yrs)	M/F	BMI (kg/m^2)	Mean FU (months)	GERD-HRQL score	Off PPI (%)	DeMeester score
Bonavina, 2008 (6)	38	42.8	23/15	24.5	6	2.5	89	4.2
Bonavina, 2010 (7)	44	42.3	26/18	25.7	24	2.4	86	9.4
Lipham, 2012 (8)	44	42.8	26/18	NR	45	3.3	80	14.7
Ganz, 2013 (9)	100	53	52/48	28	36	NR	87	13.5
Bonavina, 2013 (10)	100	44.5	74/26	24	36	2	85	11.2
Smith, 2014 (11)	66	53.7	28/38	26	6	6	81	nr
Saino, 2015 (12)	33	42.8	26/18	25.7	60	2.9	87.8	16.1
Ganz, 2016 (13)	84	53	NR	28	60	4	84.7	NR
Rona, 2017 (14)	192	56	103/89	25.9	20	5	NR	NR
Kuckelman, 2017 (15)	31	43.7	17/12	27.7	12	NR	NR	NR
Buckley, 2018 (16)	200	60	110/90	29	8	2	94	NR
Schwameis, 2018 (17)	68	45	46/22	25.5	13	2	87	NR
Tatum, 2018 (18)	182	63.1	93/89	27.3	15	NR	80	NR

PPI, proton-pump inhibitor; NR, not reported. Adapted from (19).

Table 2 Analysis of clinical studies comparing magnetic sphincter augmentation and fundoplication

Author	No. pts MSA/LF	Follow-up (months)	GERD-HRQL	Off PPI	Postoperative dilation	Ability to vomit	Ability to belch	Gas-bloat	Reoperation
Louie, 2014 (21)	34/32	8	MSA 5.0; LF 5.1	MSA 100%; LF 97%	MSA 3%; LF 0%	NR	MSA 67%; LF 0%	Less gas/bloat in MSA	MSA 0%; LF 0%
Reynolds, 2015 (22)	50/50	12	MSA 4.2; LF 4.3	MSA 83%; LF 91.5%	MSA 16%; LF 10%	MSA 97%, LF 79%	MSA 91.5%; LF 74%	MSA 28%; LF 38%	MSA 0%; LF 0%
Sheu, 2015 (23)	12/12	7	NR	NR	MSA 50%; LF 0%	NR	NR	Less gas/bloat in MSA	NR
Riegler, 2015 (24)	202/47	12	MSA 3.0; LF 3.5	MSA 82%; LF 63%	NR	MSA 91%, LF 44%	MSA 98%; LF 89%	MSA 10%; LF 32%	MSA 4%; LF 9%
Warren, 2016 (25)	201/214	12	MSA 3.0; LF 4.0	MSA 81%; LF 86%	NR	MSA 95%, LF 43%	MSA 96%; LF 69%	MSA 47%; LF 59%	MSA 1%; LF 2%
Reynolds, 2016 (26)	52/67	12	MSA 4.3; LF 5.1	MSA 85%; LF 92%	MSA 19%; LF 14%	MSA 96%, LF 81%	MSA 90%; LF 64%	MSA 23%; LF 53%	MSA 0%; LF 0%
Asti, 2016 (27)	135/103	12–84	MSA 3.0; LF 3.0	MSA 83%; LF 91%	MSA 2%; LF 4%	MSA 98%, LF 82%	MSA 98%; LF 90%	MSA 8%; LF 23%	MSA 1%; LF 2%

MSA, magnetic sphincter augmentation; LF, laparoscopic fundoplication; PPI, proton-pump inhibitor; NR, not reported. Adapted from (19).

outcomes of MSA, and found that formal cruroplasty improved reflux control and symptom relief without increasing the rate of dysphagia and recurrent hernia (17,18).

Analysis of studies comparing MSA and fundoplication

Table 2 summarizes the results of studies comparing the

outcomes of MSA and LF. All studies were observational, and the maximum follow-up was 84 months.

In the retrospective case-control study by Louie *et al.*, similar improvements in GERD-HRQL scores occurred and there were no significant differences in heartburn or regurgitation scores between the two patient groups. Acid exposure time significantly decreased in both groups, and there were no differences in dysphagia scores between groups at the 6-month follow-up, The MSA procedure allowed belching in 67% of patients compared with 0% in the LF group (21).

In the propensity-matched study by Reynolds *et al.*, similar GERD-HRQL scores and similar rates of PPI cessation at 1-year follow-up were noted in the two patient groups. Gas-bloat symptoms were significantly more frequent, and more patients were unable to belch or vomit in the LF group. The incidence of dysphagia and the number of patients requiring dilation was similar. Two postoperative complications occurred in the LF group and no complications, device migration or explants in the MSA group (22).

In the case-control matching study by Sheu *et al.*, complete GERD symptoms resolution was recorded over a mean follow-up of 7 months in 75% of MSA and 83% of LF patients, respectively. Incidence of dysphagia was similar, but persistent dysphagia requiring dilation was more common in the MSA group (23).

In a prospective multicenter study which collected data from the LINX European registry, elimination of PPI dependence was reported in 81.8% of MSA patients compared to 63% of LF patients. Moderate/severe regurgitation decreased in the MSA group to 3.1%, compared to 13.0% post-LF. Gas-bloating was significantly less, and ability to belch and vomit was significantly higher in the MSA group. Reoperation rates were similar in both groups (24).

In the propensity-matched analysis by Warren *et al.*, a significant improvement in GERD-HRQL scores and satisfaction rates compared to baseline was found in the two groups. Fewer MSA patients were completely free of PPI; however, more MSA patients reported they would undergo the procedure again. A greater ability to belch and significantly less gas-bloat symptoms were also noted in MSA patients. There was a higher prevalence of mild dysphagia in the MSA group, but the incidence of severe dysphagia was less. Two patients in the MSA group required reoperation; one had the device removed because of continued reflux symptoms and required a Nissen fundoplication, and the other had the device removed for erosion. In the LF group, two patients underwent reoperation for recurrent hiatus hernia and persistent reflux symptoms (25).

In an additional retrospective controlled study by Reynolds *et al.*, GERD-HRQL scores and PPI suspension rates were similar in MSA and LF patients at 1-year follow-up. There was significantly less gas-bloat, and greater ability to belch and vomit in the MSA group. Severe dysphagia occurred in 5% of LF patients compared to 0% in the MSA group. Two complications occurred in the MSA group; one patient had intractable vomit that resolved with conservative management, and a second patient had food impaction that required endoscopic removal (26).

Finally, a propensity-matched study by Asti *et al.* comparing MSA with Toupet fundoplication in 238 consecutive patients, found significant improvement in quality of life scores, comparable rates of PPI discontinuation, and comparable side effects and reoperation rates in both patient groups (27).

Safety risk profile and revisional surgery

A multicenter study including the first 1,000 MSA implants showed 1.3% hospital readmission rate, 5.6% need of postoperative endoscopic dilations, and 3.4% reoperation rate (28). There were no emergency operations for device explant. Dysphagia and recurrence of reflux symptoms were the most common complaints among the patients who had the device removed. Furthermore, 7% of patients enrolled in the prospective US pivotal trial had the device removed due to persistent dysphagia in 4, vomiting in one, chest pain in one, and reflux in one (13). A more recent study using the Manufacturer and User Facility Device Experience (MAUDE) database in the United States showed an overall explant rate of 2.7%. The majority of the explants (88%) occurred within 2 years and were managed electively, with no complications or long-term consequences (29).

The long-term results of one-stage laparoscopic MSA explant and LF were reported in a recent observational study. Among 11 explanted patients, the main presenting symptom requiring device removal was recurrence of heartburn or regurgitation, dysphagia, and chest pain. Full-thickness erosion of the esophageal wall with partial penetration of the device occurred in 1.2% of patients. Explant of the device was combined with Toupet or Dor LF in the majority of patients. The postoperative course was uneventful, and at 1–5 years after reoperation the GERD-

HRQL score was normal in all patients (30).

Comments

The LINX procedure offers the potential to replace both long-term PPI therapy and LF in patients presenting with normal anatomy of the gastroesophageal junction or small hiatus hernia. The procedure is effective in decreasing or eliminating the esophageal acid exposure, the typical reflux symptoms, and the drug dependence, and significantly improves health-related quality of life. Despite the lack of randomized clinical trials, the MSA procedure has gained a lot of interest among surgeons and even gastroenterologists because of the minimal invasiveness, the standardization, and the easy reversibility (19). The side-effect profile is quite similar to the Toupet fundoplication but more favorable compared to the Nissen. Device erosions or migrations have been rarely observed and have not been associated with mortality. Limitations of the MSA include the contraindication to MRI scanning >1.5 Tesla and the potential long-term consequences of a permanent foreign body implant. A BMI >35, a structurally defective LES, and a preoperative lower esophageal sphincter residual pressure appear to be independent negative predictors of success of the procedure (31).

A multicenter randomized controlled trial comparing MSA and maximal acid suppression medication found relief of volume regurgitation in 92.6% of MSA-treated and 8.6% of PPI-treated patients (32). Further, in a recent meta-analysis comparing MSA and fundoplication, MSA was associated with less gas-bloat symptoms and an increased ability to vomit and belch, while PPI suspension rate, dysphagia requiring endoscopic dilatation, and GERD-HRQL were similar in the two patient groups (33).

In patients with normal anatomy of the gastroesophageal junction, the MSA device can be implanted with minimal surgical dissection and preservation of the phrenoesophageal ligament and of the short gastric vessels. A formal posterior crural repair is obligatory only in the presence of hiatus hernia >3 cm, whereas it remains optional in patients with smaller hernias if the phrenoesophageal ligament and the lower mediastinum have not been surgically violated. The effectiveness of MSA in patients with very large hiatal hernia and/or Barrett's esophagus remains to be established in larger comparative studies with LF (19).

Based on the present review, MSA appears to be a reasonable therapeutic option for patients who are partially responders to pharmacological therapy and demonstrate evidence of progressive GERD. Further studies are needed to clarify which subgroup of GERD patients can benefit most from the MSA procedure.

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