Hiatal hernia recurrence following magnetic sphincter augmentation and posterior cruroplasty: intermediate-term outcomes

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Abstract

Background We have previously reported short-term outcomes after hiatal hernia repair (HHR) at the time of magnetic sphincter augmentation (MSA) for gastroesophageal reflux disease (GERD). Here we report intermediate-term outcomes and hernia recurrence rate after concomitant MSA and HHR.

Methods This is a retrospective cohort study of patients who underwent repair of a hiatal hernia 3 cm or larger at the time of MSA implantation between May 2009 and December 2015. The primary endpoint was hiatal hernia recurrence identified by routine postoperative videoesophagography or endoscopy. Recurrence was defined by a 2 cm or greater upward displacement of the stomach through the diaphragmatic esophageal hiatus. Secondary endpoints included cessation of proton-pump inhibitor (PPI), persistent dysphagia requiring intervention, and GERD health-related quality-of-life (HRQL) scores 1 year from surgery.

Results During the study period, 47 of 53 (89%) patients underwent concomitant MSA with HHR and complied with surveillance. Hiatal hernias ranged from 3 to 7 cm (mean 4 ± 1). Mean clinical follow-up time was 19 months (range 1–39). GERD-HRQL score decreased from 20.3 to 3.1 (p < .001), 89% of patients remained off PPIs, and 97% of patients reported improvement or resolution of symptoms. Two recurrent hiatal hernias were identified on surveillance imaging for a recurrence rate of 4.3% at a mean 18 (± 10) months after initial operation. Persistent dysphagia occurred in 13% (6/47) over the first year, which resolved after a single balloon dilation in 67% (4/6). Two patients elected for device removal due to dilation-refractory dysphagia and persistent reflux symptoms.

Conclusion Concomitant magnetic sphincter augmentation and hiatal hernia repair in patients with gastroesophageal reflux disease and a moderate-sized hiatal hernia demonstrates durable subjective reflux control and an acceptable hiatal hernia recurrence rate at 1- to 2-year follow-up.

Keywords GERD · LINX · MSA · Magnetic sphincter augmentation · Hiatal hernia · Hiatal hernia recurrence

Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tbody>
<tr>
<td>MSA</td>
<td>Magnetic sphincter augmentation</td>
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<tr>
<td>GERD</td>
<td>Gastroesophageal reflux disease</td>
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<tr>
<td>VEG</td>
<td>Videoesophagram</td>
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<tr>
<td>EGD</td>
<td>Esophagastroduodenoscopy</td>
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<tr>
<td>GERD-HRQL</td>
<td>GERD health-related quality-of-life</td>
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<tr>
<td>PPI</td>
<td>Proton-pump inhibitor</td>
</tr>
<tr>
<td>LES</td>
<td>Lower esophageal sphincter</td>
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<td>HHR</td>
<td>Hiatal hernia repair</td>
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An incompetent lower esophageal sphincter (LES) allowing pathologic reflux of gastric fluid into the distal esophagus is the primary physiologic abnormality underlying gastroesophageal reflux disease (GERD) [1]. Gastric fundoplication is the traditional surgical treatment for medically refractory GERD; however, magnetic sphincter augmentation (MSA) is an alternative surgical therapy with comparable efficacy,
potentially longer durability, and a less burdensome side effect profile [2–5]. Magnetic sphincter augmentation normalizes LES resting pressure to physiologic levels by means of dynamic external compression. Studies to date have confirmed both safety and efficacy of MSA in patients with mild to moderate GERD [6–11]. Initial studies excluded patients with a hiatal hernia larger than 3 cm. We recently published the first study reporting outcomes of MSA with expanded indications—patients with hiatal hernias beyond 3 cm [12]. This study demonstrated excellent short-term outcomes in patients undergoing simultaneous MSA and hiatal hernia repair (HHR). Here we follow this cohort of patients through the intermediate-term postoperative period, assessing for recurrence of hiatal hernia and symptom control.

Materials and methods

Study population

The study included all patients who underwent MSA with the LINX® Reflux Management System (Torax® Medical, Inc, Shoreview, MN) and repair of a hiatal hernia at our two affiliated institutions, Keck Hospital of the University of Southern California (Los Angeles, CA USA) and Hoag Memorial Presbyterian (Newport Beach, CA USA) between May 2009 and December 2015 with follow-up through September 2017. The institutional review board approved the study. Inclusion criteria were medically refractory GERD patients aged 18 years or older who were suitable surgical candidates. Patients with a history of gastroesophageal or diaphragmatic surgery were excluded from the study. Of note, there was no preoperative body mass index (BMI) cutoff.

Preoperative assessment

All patients underwent 48-h esophageal pH testing and upper gastrointestinal endoscopy prior to operative intervention. A DeMeester score of > 14.72 was diagnostic of GERD [15]. Screening for hiatal hernia preoperatively was through review of videoesophagram and esophagogastroduodenoscopy findings. During the study period, we did not exclude patients from surgery based on preoperative assessment of hiatal hernia size. Size of hiatal hernia in this study is defined by an intraoperative measurement of 3 cm or larger, as detailed below. Baseline GERD Health-Related Quality-of-Life (GERD-HRQL) scores were obtained prior to surgery while patients remained on their usual pharmacologic therapy.

Surgical procedure

Details of the operative procedure can be reviewed in a previous publication [12]. Magnetic sphincter augmentation device implantation and hiatal hernia repairs were performed by authors JCL or NB. For the purposes of this study, hiatal hernia is defined based on intraoperative measurement of long-axial distraction of the gastroesophageal junction past a horizontal plane spanning the diaphragmatic crura. All measurements were obtained by authors JCL or NB at the time of operation under routine insufflation pressures using a laparoscopic tool marked for measurement. Measurement occurred prior to hernia reduction and after exposure of the crus through the opening of the pars flaccida. All patients underwent complete hiatal dissection with reduction and resection of the hernia sac from the mediastinum, mobilization of the thoracic esophagus to provide 2–3 cm of intra-abdominal esophageal length, and primary posterior cruroplasty. No patients underwent Collis gastroplasty. The crura were reapproximated with 2–3 synthetic non-absorbable sutures in a figure-of-eight fashion. A bougie is not used during crural closure; rather the crura are approximated such that only one closed laparoscopic grasper can easily pass through the hiatus alongside the esophagus. We do not use mesh or adhesives at the diaphragmatic hiatus. Once the hiatal repair was complete, the external circumference of the gastroesophageal junction was measured and an appropriately sized LINX® device placed. Proton-pump inhibitors (PPI) were weaned off as tolerated over the first postoperative month.

Postoperative assessment

Subjective outcomes were evaluated at the initial postoperative visit and again at 6 months and then yearly. Postoperative visits included administration of the GERD-HRQL tool at 1 year, assessment of PPI use, and assessment for symptoms of dysphagia at each visit. Patients with persistent dysphagia over the first year were seen more frequently on an as-needed basis. Balloon dilation was performed in patients with persistent or worsening dysphagia that altered the diet at greater than 30 days after operation. Patients undergoing dilation were dilated from 1-to-4 times to a goal balloon size of 18 mm. Adverse events (death, reoperation, intra-abdominal infection) were captured through medical record review, which was complete in all patients included in this analysis. Symptom resolution or improvement was based on patient response to verbal inquiry. Prospective attempts were made to obtain videoesophagram (VEG) and esophagogastroduodenoscopy (EGD) at around 1 year postoperatively to assess for
hiatal hernia recurrence, irrespective of patient symptoms. Studies ordered on an as-needed basis for symptoms are also included in the analysis if they show a recurrent hernia occurring at less than 1 year. When multiple studies were obtained, the first study demonstrating recurrence was used for statistical analysis. A recurrence was defined as cephalad displacement of the stomach above the level of the diaphragm measuring 2 cm or greater by any modality (EGD or VEG).

Statistical analysis

Demographic data, perioperative characteristics, and postoperative outcomes were recorded into a centralized database. Continuous variables were analyzed using descriptive statistics and categorical variables were summarized using frequency distributions. One-year versus pre-implantation GERD-HRQL score comparisons were evaluated using a two-tailed paired Student’s t test with patients serving as their own control. All statistical analyses were performed using SPSS® Statistics V. 22 (IBM®). Statistical significance was set at $p \leq .05$.

### Results

Fifty-three patients underwent MSA implantation and repair of a hiatal hernia measuring at least 3 cm. Of these, 47 (89%) patients complied with postoperative screening protocols for hiatal hernia recurrence and were included in the study. Patient demographics and preoperative characteristics are shown (Table 1). GERD-HRQL scores decreased significantly in the cohort following MSA and HHR (20.3 versus 3.1, $p < .001$). Cessation of PPI use occurred in 89% of patients with 97% of patients reporting an improvement or resolution of their chief preoperative GERD symptom at a mean follow-up time of 19 months.

Surveillance for a recurrent hiatal hernia was performed with EGD and VEG in 77 and 89% of patients, respectively. A combination of both imaging modalities was used in 67% of patients. Esophagogastroduodenoscopy was performed at a mean of 19 ($\pm$ 9) months after surgery, while VEG was performed at a mean 15 ($\pm$ 9) months after surgery. The majority of patients who underwent EGD had normal esophageal mucosa. There was evidence of mild (Grade A or B) esophagitis in 5.6% of patients. Four patients were found to have Barrett’s esophagus (BE), three of which had short-segment BE. Two recurrent hiatal hernias were identified on surveillance imaging for a recurrence rate of 4.3% at a mean of 18 ($\pm$ 10) months after initial operation (Table 2).

The first recurrence was identified in a patient with persistent upper abdominal pain following report of a tearing sensation immediately after lifting a 45 lbs. object 2 weeks postoperatively. The second patient reported mild chest and upper abdominal pain with rare dysphagia. Of note, neither patient with recurrence of their hiatal hernia was obese (BMI of 26.0 and 28.2).

Balloon dilation for persistent dysphagia was required in 13% (6/47) of patients. Symptoms improved or resolved after a single balloon dilatation in 4 of the 6 patients (67%). The remaining two patients required 4 balloon dilations each. Symptoms resolved after the fourth dilatation in one of these patients but persisted in the other. The MSA device was removed and conversion to a Toupet fundoplication was performed. There were a total of two explants with the second device removed for refractory reflux symptoms and

### Table 1 Preoperative patient characteristics

<table>
<thead>
<tr>
<th>Preoperative characteristics</th>
<th>Age, years (range)</th>
<th>Gender, F:M</th>
<th>BMI, kg/m$^2$ (SD)</th>
<th>GERD-HRQL score (SD)</th>
<th>GERD duration, years (SD)</th>
<th>DeMeester score (SD)</th>
<th>Preoperative dysphagia, % of patients</th>
<th>Hiatal hernia size, mean (SD) [range]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years (range)</td>
<td>62.8 (40–79)</td>
<td>1.84:1</td>
<td>25.6 ($\pm$ 7.5)</td>
<td>20.3 ($\pm$ 8.5)</td>
<td>14.2 ($\pm$ 11.4)</td>
<td>52.4 ($\pm$ 26.6)</td>
<td>28.3</td>
<td>4.0 ($\pm$ 1.1) [3–7] cm</td>
</tr>
</tbody>
</table>

BMI Body Mass Index, SD standard deviation, GERD gastroesophageal reflux disease, GERD-HRQL GERD health-related quality-of-life score

### Table 2 Preoperative and postoperative characteristics of patients with a recurrent hiatal hernia

<table>
<thead>
<tr>
<th>Preoperative HH size (cm)</th>
<th>Postoperative symptoms</th>
<th>Time to recurrence (months)</th>
<th>Diagnostic modality</th>
<th>Recurrent HH size (cm)</th>
<th>PPI requirement</th>
<th>GERD-HRQL score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient 1</td>
<td>6</td>
<td>Yes</td>
<td>11</td>
<td>EGD</td>
<td>2</td>
<td>none</td>
</tr>
<tr>
<td>Patient 2</td>
<td>5</td>
<td>Yes</td>
<td>24</td>
<td>EGD</td>
<td>2</td>
<td>none</td>
</tr>
</tbody>
</table>

HH hiatal hernia, EGD esophagogastroduodenoscopy, GERD gastroesophageal reflux disease, GERD-HRQL GERD health-related quality-of-life score, PPI proton-pump inhibitor
a 1-cm hiatal hernia observed on EGD only. The patient underwent repeat hiatal hernia repair with primary cruroplasty and replacement of the MSA device at the GEJ as it was found to lie distal on the stomach at the time of reoperation. Both patients had resolution of their symptoms postoperatively and reported satisfaction with their therapies. There were no major intraoperative or postoperative complications identified. Furthermore, there were no device erosions or infections.

Discussion

In this study, we report intermediate-term outcomes after implantation of the MSA device in patients with GERD at the time of hiatal hernia repair. We observed significant reduction in GERD-HRQL scores and excellent rates of PPI cessation with a 13% rate of initial dysphagia, and a 4% device removal rate. Hiatal hernia recurrence was observed in 4% of patients, being discovered in the setting of routine surveillance imaging at a mean of 18 (± 10) months.

The physiologic antireflux barrier is the effect of a complex interplay between several anatomic elements: the intra-abdominally positioned lower esophageal sphincter (LES); appropriately approximated diaphragmatic crura; and an acute angle of His [13]. Recent manometric studies in patients undergoing gastric fundoplication and hiatal hernia repair support a primary rather than supporting role of the crura in achieving a competent antireflux mechanism during surgical treatment of GERD [14]. We have hypothesized that through treatment of the hypotensive LES with the MSA device in conjunction with the tightening of the diaphragmatic crura by means of suture cruroplasty we will achieve comparable rates of long-term GERD resolution and hiatal hernia recurrence compared to reported rates of recurrence after surgical repair with fundoplication and hiatal hernia repair. This study reports intermediate-term outcomes and confirms safety as we continue to collect data in support of our hypothesis.

Historically high rates of hiatal hernia recurrence irrespective of repair technique generate some concern when placing the MSA device at the time of repair. Published literature reports recurrence rates up to 59%, depending on the size and type of the hiatal defect, method of repair, use of mesh, and duration of follow-up [15–20]. Short-term recurrence may be reduced with mesh reinforcement at the hiatus, although this appears to be limited by mesh-related complications and a comparable long-term durability to primary cruroplasty [17, 18, 21]. Recurrence rates specifically following primary cruroplasty with partial or total fundoplication ranges from 17 to 67% [18, 22–24]. This high rate of recurrence may be secondary to inclusion of patients with large paraesophageal hernias and inconsistent patient follow-up. The MSA device may provide the early benefits of synthetic mesh. After implantation, the MSA device appears to incite an inflammatory response based on our reoperative experience and the experience of others [25]. This inflammatory process creates adhesion not only around the device but also between the device, esophagus, and the diaphragmatic crura—reinforcing the crural closure in much the same as synthetic mesh. Whether this inflammatory response could eventually contribute to MSA device erosions, current and expanding clinical data have not shown increasing rates of erosion beyond 0.5% [8]. In a recent study by Buckley et al. of patients with hiatal hernias larger than 3 cm undergoing MSA and non-permanent mesh-reinforced cruroplasty, there were no recurrent hernias at 11 months in 51 of 80 patients following routine VEG [26]. A second mechanism likely contributing to low intermediate-term hernia recurrence is the preserved ability to belch after MSA surgery, an ability lost after a correctly performed complete gastric fundoplication. It has been shown that total gastric fundoplication causes elevation in gastric pressures and subsequently lower gastric compliance in comparison to the partial fundoplication [27]. Similar to a partial fundoplication, the MSA device preserves the ability to belch and decompress the stomach, likely reducing external force on the hiatus during the initial healing process.

The MSA device was explanted in two patients for persistent dysphagia and refractory reflux, respectively. The incidence of persistent dysphagia requiring dilation was higher in our cohort than that reported in the literature, which ranges from 3 to 6% [8, 25]. This is unlikely related to the MSA device as previous studies have demonstrated that it prevents LES effacement rather than affect resting or residual LES pressure [6, 11]. We believe that the higher rate of refractory dysphagia is likely multifactorial. In addition to the presence of a hiatal repair, our population of patients may have an underlying component of esophageal dysmotility given their large chronic hiatal hernias. Despite this, 83.3% of patients had resolution of dysphagia following one or more dilations. The second explant was for refractory reflux. The patient was found to have a malpositioned MSA device and a 1-cm hiatal defect. Following revision of the MSA device and redo hiatal repair, the patient had resolution of his reflux symptoms. In any patient with objective evidence of refractory GERD, it is imperative to ensure that the device is properly sized and positioned, appropriately functioning, and to rule out the presence of a recurrent hernia.

Based on our results, the cost-effectiveness of surveillance imaging following MSA and hiatal hernia repair is questionable. Recurrence appears to be rare, and when it occurs, it is followed by the onset of symptoms. Once a recurrence is identified, we perform pH monitoring to determine if there is objective evidence of recurrent reflux. Revisional hiatal hernia repair is recommended for those
Concomitant magnetic sphincter augmentation and hiatal hernia repair in patients with gastroesophageal reflux disease and a moderate-sized hiatal hernia demonstrates durable subjective reflux control and an acceptable hiatal hernia recurrence rate at 1- to 2-year follow-up.

Conclusion

Conclusions regarding the efficacy of the device in this patient population.

Compliance with ethical standards

Disclosures Drs. Lipham and Bildzukewicz are consultants for Torax® Medical, manufacturer of the LINX® reflux management system. Drs. Rona, Tatsum, Schwameiss, Zehetner, Chow, Samakar, Doborowsky, and Houghton have no relevant conflicts of interest or financial ties to disclose.

References