#### **2020 SAGES POSTER**





# Fundic gastropexy for high risk of recurrence laparoscopic hiatal hernia repair and esophageal sphincter augmentation (LINX) improves outcomes without altering perioperative course

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#### **Abstract**

**Background** The aim of this study is to show that the addition of a fundic gastropexy to a laparoscopic hiatal hernia repair (HHR) and magnetic sphincter augmentation (MSA) with LINX (Johnson and Johnson, New Brunswick, NJ) in patients with high risk for hiatal hernia recurrence improves outcomes without altering perioperative course.

**Methods** An IRB approved, single institution retrospective review of patient outcomes after hiatal hernia repair with magnetic sphincter augmentation was performed. Data were obtained from the electronic health record and stored in a REDCap database. Using statistical software, the patient data were analyzed and stratified to assess the specific variables of the perioperative and postoperative course focusing on the high risk of hiatal hernia recurrence group (HRHR) and low risk hiatal hernia of recurrence group (LRHR). The HRHR group received a gastropexy and were defined using the following variables: comorbid state increasing abdominal pressure, gastric herniation > 30%, maximum transverse crural diameter > 4 cm, age 70 years or older, previous hiatal or abdominal wall hernia repair, BMI > 34, heavy weight bearing job/hobby, and/or emergent repair.

**Results** Hiatal hernia repair with magnetic sphincter augmentation was performed on 137 patients. The HRHR group (N=86) and the LRHR group (N=51) were compared and there was a difference observed with acute hernia recurrence, dysphagia (p value = 0.008), and number of post-op EGDs (p value = 0.005) in favor of the HRHR group. Other postoperative variables observed (i.e., length of stay and PPI use) showed no significant difference between the two groups.

**Conclusions** Fundic gastropexy for individuals who are considered high risk for recurrence does not appear to alter the perioperative course in our sample of patients. The HRHR group has the same length of stay experience and improved postoperative outcomes with reference to postoperative EGD, dysphagia and a decreasing trend in hiatal hernia recurrence.

Keywords LINX · Gastropexy · Hiatal hernia · GERD

Gastroesophageal reflux disease (GERD) affects more patients in the Western hemisphere than any other disease of the foregut [1]. Though GERD can be successfully managed with Proton Pump inhibitors (PPIs), Magnetic Sphincter Augmentation (MSA) with the LINX<sup>TM</sup> (Johnson and Johnson, New Brunswick, NJ) device has been successfully employed on patients for management of mild to moderate

GERD who are resistant to medical therapy [2]. The device is designed to restore lower esophageal sphincter (LES) function while preserving normal physiologic function [3]. Approved by the FDA in 2012, MSA via the LINX device has been employed in more than 3000 patients in the United States [1, 4].

Gastropexy has been a technique used in the past for patients who have undergone foregut surgery to help prevent kinking and herniation of the gastric remnant [5–7]. Studies show that it has decreased postoperative PPI use in gastric sleeve patients [8, 9]. This surgical technique helps minimize the risk of increased dysphagia related to previous foregut surgery, as well as the risk of recurrence of large hiatal hernias [1, 9]. It has become our practice when

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performing HHR and LES with MSA, to perform a fundic gastropexy to the left anterior hemidiaphragm on patients who we deem high risk for hernia recurrence. Our goal for the fundic gastropexy is to restore the angle of His, preserve the intra-abdominal esophageal length in time, and maintain the anatomical of the position of the stomach, therefore improving postoperative dysphagia and reducing recurrence in this operative population.

Our study compares patients undergoing HHR and MSA with LES with or without fundic gastropexy depending on HRHR factors, focusing on comparing the postoperative outcomes of the two groups to demonstrate the safety of the fundic gastropexy technique. Our hypothesis is that there will be no difference in measured postoperative operative outcomes when comparing these two groups.

# **Materials and methods**

# Study design

After obtaining Institutional Review Board (IRB) approval, we performed a retrospective review of over 130 patients who underwent laparoscopic hiatal hernia repair and MSA with LES between January 2017 to August 2019 at the East Carolina Heart Institute at Vidant Medical Center in Greenville, North Carolina.

#### Inclusion criteria

The study consists of patients greater than the age of 18 who underwent laparoscopic hiatal hernia repair and LES with MSA. The patients were then separated into the high risk of hiatal hernia recurrence group (HRHR) and low risk hiatal hernia of recurrence group (LRHR). The HRHR group was defined by these criteria: comorbid state increasing abdominal pressure, gastric herniation > 30%, maximum transverse crural diameter > 4 cm, age 70 years or older, previous hiatal or abdominal wall hernia repair, BMI > 34, heavy weight bearing job/hobby, emergent repair, and other subjective situations in which the surgeon felt the patient was at high risk of recurrence (Table 1). The patients in the HRHR group received a fundic gastropexy in combination with the previously stated procedure and LRHR had no additional intervention.

Preoperative workup for each patient consisted of objective studies to establish a diagnosis of GERD. Efforts were taken to establish the severity of the disease and to rule out any esophageal motility disorder. These diagnostic studies include a preoperative esophagogastroduodenoscopy (EGD), esophageal 24-h pH monitoring and high-resolution manometry.

 Table 1 Criteria for high risk for hiatal hernia recurrence

High risk for hiatal hernia recurrence (HRHR) factor Frequency as indicator for gastropexy $n=86$	
Comorbid state increasing abdominal pressure	67.2%
Gastric herniation > 30%	40.3%
Maximum transverse crural diameter > 4 cm	31.3%
Previous hiatal or abdominal wall hernia repair	33.0%
Age 70 years or older	26.7%
BMI > 34	12.8%
Heavy Weight bearing job/hobby	4.5%
Emergent repair	2.3%

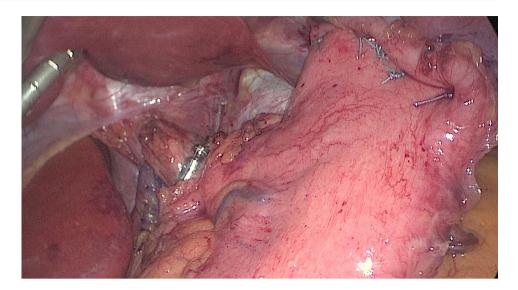
In the postoperative period, patients are monitored with a swallow study on postoperative day one and then assessed in clinic 2 weeks later at their postoperative visit. Each patient also receives a swallow at the one year mark to assess positioning of the MSA device and possible recurrence. Acute hiatal hernia recurrence was defined as a radiographically or endoscopically diagnosed hernia within 6 months of subsequent repair. Our hiatal hernia registry continues follow-up with yearly esophagrams till year 5.

## **Operative technique**

The procedure begins with laparoscopic access to the abdomen in the standard fashion. The esophageal hiatus is visualized with identification of the right and left crura of the diaphragm. Hiatal dissection is then carried out with preservation of the peritoneal lining of the crura. High mediastinal mobilization of the esophagus is performed to ensure 3-4 cm of intra-abdominal esophagus and complete hernia sac dissection. The crural opening is then measured and repaired with multiple interrupted sutures (0-0 Surgidac<sup>TM</sup> Covidien, Dublin, IE) followed by a second posterior crural running barbed layer (0-0 V-loc<sup>TM</sup> Covidien, Dublin, IE). Occasionally, anterior cruroplasty is performed in combination based on hiatal morphology and size thus preventing excessive angulation of the distal esophagus. A window is created between the posterior vagus nerve and the esophagus, just superior to the gastroesophageal junction (GEJ). Sizing is carried out and MSA device placed around the esophagus inside the posterior vagal nerve window, and outside of anterior vagal nerve. The patient is then selected for fundic gastropexy based on the HRHR inclusion criteria. Division of the more cephalad short gastric vessels with respect to the right gastroepiploic arcade is performed. Fundic gastropexy to the left anterior hemidiaphragm (Fig. 1) is performed in an interrupted manner (2-0 Surgidac<sup>TM</sup> Covidien, Dublin, IE) [10]. Attention is required to respect the GEJ angle and avoid overstretching of the LES area, as well as maintaining the lateral position of the greater curvature of stomach



**Fig. 1** Fundic gastropexy to the left anterior hemidiaphragm



without causing excessive leaning against the left crura. Left hemidiaphragm relaxation maneuvers such as controlled capnothorax induction or reduction of pneumoperitoneum are used to facilitate a tension free suture line. Intraoperative endoscopy is used for evaluation. If the patient is deemed LRHR case concludes after MSA is completed.

## Statistical analysis

Study data were collected and managed using Research Electronic Data Capture (REDCap) electronic data capture tools hosted at East Carolina University in *Greenville*, NC [11]. Statistical analysis including Pearson's Chi-square, Fisher exact test and independent *T*-test was performed using SPSS software, version 25 (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.)

# **Results**

137 patients underwent laparoscopic hiatal hernia repair and MSA. 86 of these patients met the HRHR group criteria and received a fundic gastropexy. 52 patients were categorized as LRHR and received no additional intervention. Demographic and preoperative data are shown in Table 2. The mean age of the HRHR group and LRHR group was 61.8 and 53.9, showing an increased age in the HRHR group (p value = 0.002). The majority of the patients in both groups were female, but there was a higher percentage of males in the LRHR group (39.2%) when compared to the HRHR group (27.9%) (p value = 0.171). The racial distribution was comparable between both groups, with white patients composing the majority of operative candidates in both the HRHR and LRHR groups. (77.7% and 82.1%, respectively).

Table 2 Preoperative characteristics

Characteristics	HRHR (N=86)	LRHR $(N=51)$	p value
(%)			
Age	61.8 (12.6)	53.9 (14.2)	0.002
Sex			0.171
Male	27.9	39.2	
Female	72.1	60.8	
Race			0.513
White	83.7	78.4	
Black	12.8	19.6	
Hispanic	3.5	2.0	
BMI	29.3(4.4)	28.3 (4.7)	0.221
Previous foregut surgery	20.9	7.8	0.044
Pre-op PPI use	89.5	96.1	0.173
DeMeester	40.9 (34.8)	40.3 (40.2)	0.679

When comparing the groups there was a higher prevalence of previous foregut surgery in the HRHR group when compared to the LRHR group (20.9%, 7.8% p value = 0.044). There was no significant difference between the groups for the variables of race, preoperative PPI use, and DeMeester score. The characteristics of the HRHR group were stratified and it was found that the majority of patients in this group had comorbid state increasing abdominal pressure (67.2%) and/or gastric herniation > 30% (40.2%). Other variables considered were maximum transverse crural diameter > 4 cm, previous foregut surgery, age greater than 70, BMI greater than 34, heavy weight bearing job and/or hobby, and urgency of the procedure (Table 2).

Perioperative and postoperative outcomes were compared within the two groups (Table 3). Postoperative dysphagia (p value = 0.008) and need for EGD dilations (p value = 0.005) were decreased in the HRHR when compared to the LRHR.



**Table 3** Postoperative outcomes

	HRHR (%) (N=86)	LRHR (%) (N=51)	p value
Resolved symptoms	100.0	98.0	0.422
Dysphagia	7.5	26.5	0.008
EGD dilations	2.9	18.4	0.005
Postoperative PPI use	4.4	10.2	0.229
Length of stay (hours)	44	53	0.145
Acute recurrence	0	4.3*	
Infection	0	0	

<sup>\*</sup>Two patients in this cohort experienced acute recurrence requiring operative intervention

There were two acute hiatal hernia recurrences within the LRHR group related to perioperative vomiting and retching. There was no observed difference in length of stay or postoperative PPI use when comparing HRHR and LRHR groups (*p* value = 0.145, 0.229).

#### Discussion

In this study we attempted to show that there is no difference in postoperative course when a fundic gastropexy is added to hiatal hernia repair and MSA in patients with a high risk of hernia recurrence, when compared to those with low risk of recurrence. The data presented confirm the hypothesis that there is no difference in postoperative course, and actually indicates that in several outcomes measures, the patients receiving gastropexy actually have improved outcomes in terms of lower rates of postoperative dysphagia, need for endoscopic dilation, and hernia recurrence. Not only does these data suggest that addition of fundic gastropexy to the standard operation is safe, but also that it should be considered in all patients in whom a high risk of hernia recurrence is present.

Laparoscopic hiatal hernia repair and LES with MSA has been utilized for a variety of patient populations. When first developed it was used for patients with GERD and/or a hiatal hernia less than 3 cm [2, 12]. It has since been shown that LES with MSA can be applied to patients with larger hernias and more complex anomalies of the foregut [13, 14]. As we begin to expand the use of this device in patients who were previously excluded, creativity in management will be key. Utilizing techniques like gastropexy that have been employed in foregut surgery must be considered for this new patient population [5, 8, 15]. It is important to identify the factors that lead to poor surgical outcomes in the complex foregut patient population [16–18]. Being able to recognize these patients in the preoperative time period will allow the surgeon to tailor his or her operation to fit the patient's need.

It is our practice to employ a fundic gastropexy with GEJ angle preservation to the left hemidiaphragm in response to patient populations who are in need of surgical options for management of sizeable paraesophageal hernias with mechanical predominant symptoms (i.e., early satiety, retrosternal pressure, GEJ angulation-related dysphagia, volvulusrelated ischemia, etc.) in populations older than 65 years old or 60 when extensive associated comorbidities. The addition of the technique when also undergoing LES MSA is employed if appropriate esophageal motility is confirmed preoperatively. Extensive scarring and encapsulation of the GEJ occurs in time as evidenced by reoperations on patients requiring explantation of MSA systems for various reasons. It has been proposed this serves as a secondary method of fixation in hernia repairs LES MSA, but also a cause of significant dysphagia, the Achilles heel of LES MSA [5]. The fundic gastropexy technique presented offers additional aid to preserve esophageal intra-abdominal length and layout with an appropriate GEJ angle in time. Interestingly this group showed a tendency to less dysphagia, and we wonder if it is a sample size artifact, or result of a more stable anatomy over time for the scarring to occur on and fixate. The investigation is hindered by a small patient population and the selection basis that is innate when sorting the patients into the HRHR and LRHR groups. For future investigation long-term follow-up and a defined criterion should be developed for applying fundic gastropexy to patients at risk for HHR. Although a randomized trial of fundic gastropexy versus no gastropexy in both HRHR and LRHR patients would be ideal, ethical considerations may prevent this from occurring, considering the results of this study. Despite its limitations, this study shows this technique can be employed in a safe manner with careful patient selection. Fundic gastropexy does not alter the patient's perioperative course, as evidenced by the length of stay data. This technique may lead to improved postoperative outcomes in meaningful variables such as dysphagia, EGD dilations, and recurrence of hiatal hernia. Further investigation is required and is in progress to assess improved postoperative outcomes to confirm the efficacy of fundic gastropexy in high risk populations.

In conclusion, continuous innovation in surgical technique will develop as technology advances the treatment of disease. The safe application of these innovations to improve outcomes in the appropriate patient populations is presented in this study. The data presented suggest that not only is this technique advancement safe, but also effective in preventing postoperative hernia recurrence along with improvements in several other known sequelae of hiatal hernia surgery. As a result of these data, we suggest considering fundic gastropexy in all hiatal hernia patients receiving MSA who are determined to have a high risk of recurrence. Application of fundic gastropexy to patients with a low risk of recurrence will also need to be considered and studied in the future.



## **Compliance with Ethical Standards**

**Disclosures** Dr. Anciano has a relationship with Johnson & Johnson as a Clinical Consultant/Preceptor with duty of evaluation and supervision of initial placements of an anti-reflux device. Drs. Allman, Rogers, Dali, Iannettoni, Oliver, Speicher, and Mr. Ledbetter have no conflicts of interest or financial ties to disclose.

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