

Laparoscopic Hiatal Hernia Repair in 221 Patients: Outcomes and Experience

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ABSTRACT

Background and Objectives: Hiatal hernia is a common condition often associated with symptomatic gastroesophageal reflux disease (GERD). The objectives of this study were to examine the efficacy and safety of laparoscopic hiatal hernia repair (LHHR) with biologic mesh to reduce and/or alleviate GERD symptoms and associated hiatal hernia recurrence.

Methods: We retrospectively reviewed consecutive LHHR procedures with biologic mesh performed by a single surgeon from July 2009 to October 2014. The primary efficacy outcome measures were relief from GERD symptoms, as measured according to the GERD–health-related quality-of-life (GERD-HRQL) scale and hiatal hernia recurrence. A secondary outcome measure was overall safety of the procedure.

Results: A total of 221 patients underwent LHHR with biologic mesh during the study period, and pre- and postoperative GERD-HRQL studies were available for 172 of them. At baseline (preoperative), the mean GERD-HRQL score for all procedures was 18.5 ± 14.4 . At follow-up (mean, 14.5 ± 11.0 months [range, 2.0–56.0]), the score showed a statistically significant decline to a mean of 4.4 ± 7.5 ($P < .0001$). To date, 8 patients (3.6%, 8/221) have had a documented anatomic hiatal hernia recurrence. However, a secondary hiatal hernia repair reoperation was necessary in only 1 patient. Most complications were minor (dysphagia, nausea and vomiting). However, there was 1 death caused by a hemorrhage that occurred 1 week after surgery.

Conclusions: Laparoscopic hiatal hernia repair using bi-

ologic mesh, both with and without a simultaneous bariatric or antireflux procedure, is an efficacious and safe therapeutic option for management of hiatal hernia, prevention of recurrence, and relief of symptomatic GERD.

Key Words: Cruroplasty, GERD, Incisionless fundoplication, Laparoscopic hiatal hernia repair, biologic mesh.

INTRODUCTION

Hiatal hernia is a common condition often associated with symptomatic gastroesophageal reflux disease (GERD). It is defined as a protrusion of any abdominal structure other than the esophagus into the thoracic cavity through a widening of the hiatus of the diaphragm.¹ Laparoscopic hiatal hernia repair (LHHR) is now an established operative approach for management and is associated with a reduced rate of perioperative morbidity and shorter hospital stay compared with outcomes of the open approach.^{1,2} However, in early studies of LHHR that evaluated recurrent hiatal hernia by x-ray or endoscopy, the recurrence rate was found to be between 12 and 42%.^{3–5} More recent studies indicate that the use of biologic mesh in laparoscopic paraesophageal hernia repair is clinically efficacious for symptomatic relief as well as short-term recurrence reduction. However, it may be associated with small anatomic recurrences in 50% of patients at long-term follow-up.^{6,7}

There are several reasons that primary closure of a hiatal hernia may not be adequate. First, in many patients, the hernia defect with an intrathoracic stomach is quite large, and a primary closure may then be under tension. Second, the pillars of the crus are often quite thin and composed of attenuated muscle rather than fascia. Finally, there are consistent and repeated episodes of stress on the diaphragm from breathing, coughing, and Valsalva maneuvers.⁶

To promote healing, tissues must be approximated with as little tension as possible. When tension is too great, failure of the hernia repair is inevitable.⁸ To that end, the use of an appropriate mesh as a buttress reinforcement may decrease tension on the repair, insulate the cruroplasty

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against the frequent mechanical turbulence in the diaphragm, and thus reduce the likelihood of recurrence.^{6,9,10}

Both GERD and hiatal hernia are well-recognized complications of obesity.^{11–14} Recent studies have indicated that a proactive approach to LHHR in obese patients who undergo bariatric surgery may be associated with a reduction in GERD symptoms, as well as anatomic hiatal hernia recurrence.^{15–18} The purpose of the present paper is to report the results of our study regarding the efficacy and safety of an LHHR reinforced with biologic mesh, to alleviate GERD symptoms and associated hiatal hernia recurrence in obese (body mass index [BMI] > 30 kg/m²) and nonobese patients.^{19–21}

METHODS

We conducted a retrospective study of patients who underwent LHHR with biologic mesh reinforcement (VERITAS Collagen Matrix, Baxter Healthcare Corp., Deerfield, Illinois, USA) from July 2009 through October 2014. The primary outcome measure was the overall efficacy of biologic-reinforced LHHR (with or without a simultaneous procedure) to alleviate symptomatic GERD, as well as associated anatomic hiatal hernia recurrence. The secondary outcome measure was the overall safety of the procedure. Demographic data and data related to morbidity and mortality were retrieved from a prospectively created database and in a retrospective review of the patients' records. Resolution of reflux was measured with a validated survey instrument, the GERD–Health-Related Quality-of-Life Scale (GERD-HRQL), a questionnaire specifically developed for use in patients with reflux disease (**Figure 1**).¹¹ The questionnaire consists of 10 items that return a score

Scale: No symptoms = 0; symptoms noticeable, but not bothersome = 1; symptoms noticeable and bothersome, but not every day = 2; symptoms are bothersome every day = 3; symptoms are bothersome and affect daily activities = 4; symptoms are incapacitating to perform daily activities = 5.

Questions	
1. How bad is your heartburn?	0 1 2 3 4 5
2. Heartburn when lying down?	0 1 2 3 4 5
3. Heartburn when standing up?	0 1 2 3 4 5
4. Heartburn after meals?	0 1 2 3 4 5
5. Does heartburn change your diet?	0 1 2 3 4 5
6. Does heartburn wake you from sleep?	0 1 2 3 4 5
7. Do you have difficulty swallowing?	0 1 2 3 4 5
8. Do you have pain with swallowing?	0 1 2 3 4 5
9. Do you have bloating or gassy feelings?	0 1 2 3 4 5
10. If you take medication, does this affect your daily life?	0 1 2 3 4 5

How satisfied are you with your present condition:
Satisfied__ Neutral__ Dissatisfied__

Figure 1. The GERD-HRQL instrument.

from 0 (best score, no symptoms) to 50 (worst score, severe symptoms).

In our practice, the GERD-HRQL questionnaire is routinely administered before and after surgery to patients who undergo a bariatric or antireflux procedure. For comparative purposes of GERD-HRQL outcomes in this study, 3 subgroups of patients were identified:

- 1) LHHR with a simultaneous bariatric procedure (gastric sleeve, gastric bypass)
- 2) LHHR with a simultaneous antireflux procedure (Nissen fundoplication, transoral incisionless fundoplication [TIF])
- 3) LHHR alone (without a simultaneous procedure).

Surgical Technique

The patient is placed in supine and is prepped and draped in the usual fashion for a minimally invasive surgical procedure. Ports are placed in the upper abdomen to facilitate exposure and repair of the hiatal hernia. The left lateral segment of the liver is elevated anteriorly with a stationary retractor or with a gallbladder grasper clamped to the diaphragm.

Initially, the diaphragm anterior to the esophagus is depressed with an instrument to detect the presence of a hiatal hernia. Deeply indented tissue indicates the hernia's presence. The gastrohepatic ligament is divided, exposing the right crus of the diaphragm. After exposing the hiatus, the herniated stomach is reduced into the abdomen. An instrument is passed from the right side posterior to the stomach up to the angle of His, to place a quarter-inch Penrose drain around the esophagus. The Penrose drain is invaluable for the remainder of the mediastinal dissection.

The entire sac should be removed from the hernia cavity. Parts of the sac may be left in proximity to the vagus nerves to avoid injury. In most cases, the esophagus can be dissected 5–10 cm into the mediastinum, to allow the surgeon to gain a long segment of intra-abdominal esophagus (ideally, 6 cm).

After exposure of the hernia, the crura are approximated posteriorly with figure-of-eight braided polyester sutures, beginning at the bottom of the defect. A calibration bougie is not used, as it inhibits a snug repair and carries an inherent risk of esophagogastric perforation. Oftentimes, at least 1 figure-of-eight suture is used to reapproximate the crura anteriorly.

The primary closure is then reinforced with biologic mesh to buttress the cruroplasty against the frequent mechanical

turbulence in the diaphragm and reduce the likelihood of recurrence without potential synthetic mesh-related complications.^{6,9,10} The biologic mesh is marked and cut in a “keyhole” fashion to facilitate circumferential placement over the cruroplasty, as an onlay graft to strengthen the repair, and is then sutured to the diaphragm at multiple points with interrupted 0 Vicryl sutures. The material handles well; it passes easily through a trocar. The mesh may also be tacked in place. The author prefers sutures, because they tend to be more precise and have a lower chance of visceral injury.

Statistical Analysis

Continuous data are summarized as the mean, standard deviation, and range, unless otherwise stated. Categorical data are summarized by frequencies and percentages. Changes in GERD-HRQL scores among patients were compared by 2-tailed paired *t* tests. Statistical significance was considered to be *P* < .05. All analyses were performed with SAS, version 9.3 (SAS Institute Inc., Cary, North Carolina, USA).

RESULTS

From July 2009 through October 2014, 221 patients (175 men and 46 women) underwent LHHR with biologic mesh reinforcement. The mean age was 51.1 ± 12.7 years (range, 17.0–80.0) and mean BMI was 36.1 ± 7.1 (range, 19.6–63.7). Most patients (79.4%) were obese, defined as BMI >30 kg/m². Most patients were also Caucasian (68.3%, 151/221) followed by Hispanic (28.1%, 62/221), African-American (3.2%, 7/221), and unspecified (0.5%, 1/221). In addition to demographic information, the medical/surgical history of the patients, including type of hiatal hernia, history of hiatal hernia repair, hiatal hernia diagnosis, type of surgical procedure with LHHR, and operating room time are also detailed in **Table 1**.

Greater than 95% of all hiatal hernias are type I.² In our study, 82.5% of patients had a type I hernia, 16.0% had type III, and 1.4% had type IV. No type II hernias were reported in the records.

GERD-HRQL questionnaires (**Figure 1**) were obtained from 172 patients at baseline (before LHHR) and after surgery, at a mean follow-up of 14.5 ± 11.0 months (range, 2.0–56.0). Unfortunately, we were unable to obtain both pre- and postoperative GERD-HRQL results on 49 patients, and they were therefore excluded from the calculations. The questionnaire consists of 10 items that return a score from 0 (best score, no symptoms) to 50

Characteristic	Summary*
Age†	51.1 ± 12.7 (221)
	52.0 [17.0, 80.0]
Weight (lb)†	217.1 ± 44.9 (220)
	212.0 [125.0, 385.0]
Height (inches)†	65.1 ± 3.6 (219)
	65.0 [55.0, 76.0]
(BMI)†	36.1 ± 7.1 (218)
	36.4 [19.6, 63.7]
Obesity	
Not obese	20.6 (45/218)
Obese	79.4 (173/218)
Gender	
Female	79.2 (175/221)
Male	20.8 (46/221)
Race/ethnicity	
Hispanic or Latino	28.1 (62/221)
White/Caucasian	68.3 (151/221)
Black/African American	3.2 (7/221)
Other	0.5 (1/221)
Type of hiatal hernia	
I	82.5 (175/212)
III	16.0 (34/212)
IV	1.4 (3/212)
Prior HHR	
No	97.3 (215/221)
Yes	2.7 (6/221)
Hiatal hernia diagnosis	
Intraoperative	48.9 (108/221)
Preoperative	51.1 (113/221)
Type of surgical procedure	
Gastric sleeve	53.4 (118/221)
Gastric bypass	1.8 (4/221)
TIF	20.8 (46/221)
Nissen fundoplication	4.5 (10/221)
Other	4.5 (10/221)
HHR alone	14.9 (33/221)
Operating room time (minutes)	148.5 ± 44.2 (220)
	143.0 [68.0, 365.0]

*Continuous data summarized as the mean ± SD (n); median [range]. Categorical data are expressed as % (n/N).

Table 2.
GERD-HRQL Questionnaire Comparative Data Summary

Surgical Group	Baseline	Follow-up	Change	<i>P</i>
All Groups: Laparoscopic Hiatal Hernia Repair (LHHR)*	18.5 ± 14.4 (172)	4.4 ± 7.5 (172)	-14.0 ± 14.7 (172)	<0.0001
	18.0 [0.0, 50.0]	1.0 [0.0, 50.0]	-14.0 [-50.0, 22.0]	
Bariatric procedure (GS/GB) and simultaneous LHHR	12.6 ± 12.3 (94)	2.7 ± 4.3 (94)	-9.9 ± 13.4 (94)	<0.0001
	8.0 [0.0, 38.0]	0.0 [0.0, 23.0]	-6.0 [-38.0, 19.0]	
Anti-reflux procedure (Nissen/TIF) and simultaneous LHHR	26.4 ± 12.2 (47)	5.9 ± 8.7 (47)	-20.5 ± 13.4 (47)	<0.0001
	27.0 [0.0, 50.0]	1.0 [0.0, 37.0]	-23.0 [-45.0, 22.0]	
LHHR alone	25.3 ± 16.4 (24)	8.0 ± 12.3 (24)	-17.2 ± 17.7 (24)	<0.0001
	30.5 [0.0, 50.0]	3.0 [0.0, 50.0]	-14.0 [-50.0, 17.0]	

Data summarized as the mean ± SD (N); median [range]. *P* by paired *t* test presented for the change from baseline. GS: gastric sleeve GB: gastric bypass, TIF: transoral incisionless fundoplication.

*There were 7 LHHR patients with GERD-HRQL data available that did not fall into the 3 defined subgroups.

Table 3.

GERD-HRQL Questionnaire Postoperative Outcomes Summary

	Frequency (n)	Rate (%)
Excellent	133	73.1
Good	21	11.5
Fair	13	7.1
Poor	15	8.2

(worst score, severe symptoms). The comparative pre- and postoperative GERD-HRQL scoring results are summarized in **Table 2** and include scores for the study group, as well as those for the specific subgroups previously identified.

The overall GERD-HRQL scores after LHHR decreased significantly (average, 14.0 ± 14.7 points; *P* < .0001). All 3 subgroups showed a statistically significant reduction in GERD-HRQL scores. The greatest GERD-HRQL score decrease (20.5 ± 13.4) was observed in patients who underwent LHHR with a fundoplication procedure (Nissen/TIF).

A secondary analysis of the postoperative GERD-HRQL scores alone, available for 182 patients (10 did not have a baseline scores available and were therefore excluded from other analyses described), was undertaken to determine the distribution of outcomes based on the total score. Using a classification system similar to that defined by Pierre et al,²² we reported results as excellent if the GERD-HRQL score was 0–5, good if the score was 6–10, fair if the score was 11–15, and poor if the score was >15

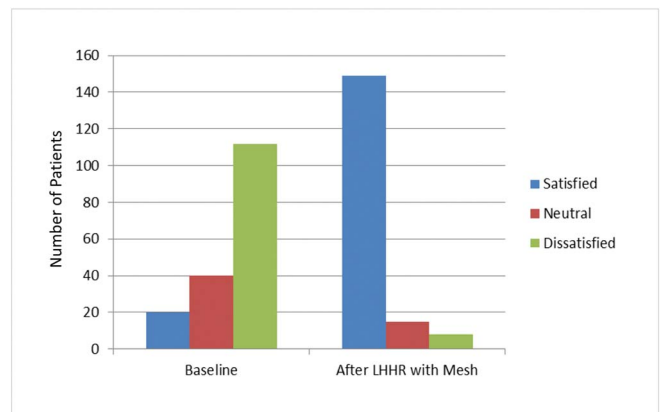


Figure 2. GERD-HRQL: satisfaction with present condition.

or the patient underwent reoperation. The breakdown of postoperative outcomes is shown in **Table 3**.

The responses to the final question on the GERD-HRQL questionnaire (“How satisfied are you with your present condition?”), at baseline and after LHHR, are summarized in **Figure 2**. At baseline, only 11.6% of patients (20/172) were “satisfied” with their present condition, whereas 65.1% (112/172) were “dissatisfied”. After LHHR, 86.6% of patients (149/172) were satisfied, and only 4.7% (8/172) were dissatisfied. The number of patients who rated their present condition as “neutral” decreased from 23.3% (40/172) at baseline to 8.7%, (15/172) after LHHR.

All patients with persistent symptomatic GERD after surgery were further evaluated with an upper gastrointestinal (GI) series to determine whether there has been a hiatal hernia recurrence. To date, in our sample, there have

been 8 patients (3.6%, 8/221) with a documented anatomic hiatal hernia recurrence. However, only 1 has needed reoperation. Initially, this patient underwent a hiatal hernia repair with bridge-the-gap mesh placement. Early on in our practice, biologic mesh was placed with this onlay technique without the benefit of an underlying cruroplasty. Biologic mesh is ill suited to this application. In 2010, we changed our technique and now use biologic mesh exclusively as an onlay after posterior/anterior cruroplasty, as described earlier. The other recurrences were small sliding hiatal hernias (< 2 cm). These patients had very subtle findings on fluoroscopy.

Most the complications were minor (dysphagia, nausea and vomiting) (Table 4). However, there was 1 death from hemorrhage in a 48-year-old man with a BMI of 38.5. He underwent LHHR and a simultaneous sleeve gastrectomy. This patient initially presented to an outside hospital in extremis. His abdomen was distended, and his blood work suggested hemorrhage. A postmortem study was not conducted. It is our suspicion that the patient bled from the sleeve portion of his surgery, not the hiatal hernia repair.

DISCUSSION

The goal of laparoscopic hiatal hernia repair is to close the hernia defect and prevent recurrence. The expected outcome is alleviation or prevention of reflux symptoms. Secondarily, we hope to prevent complications related to the hiatal hernia, such as gastric volvulus and incarceration.

The number of patients with excellent, good, fair, and poor symptom control after their laparoscopic hiatal hernia repair with biologic mesh is shown in Table 3. We were able to identify only 8 patients who had any evidence of a hernia recurrence. All but 2 of these patients had small, sliding hiatal hernias that were <2 cm in diameter. However, it is important to note that many of our patients had relatively small hiatal hernias at the time of the repair, and the hernias were often found incidentally during bariatric surgery. Per the current guidelines from the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), all hernias detected during the course of a bariatric operation should be repaired.² Bariatric surgery also mitigates obesity, one of the primary risk factors for recurrence.¹¹⁻¹⁴

Eight patients had a documented recurrent anatomical hiatal hernia. Because postoperative upper GI evaluations were not a requirement of this study, it is possible that there may be additional patients with recurrent hiatal hernias that remain symptom free. Based on the 2011 study by Oeschlager et al,⁷ symptom recurrence may not correlate with hiatal hernia recurrence after repair with a biologic mesh. Their 5-year data showed a 59% recurrence rate of the hiatal hernia when mesh was not used and a 54% recurrence rate of hiatal hernia repair when a biologic mesh was used. However, there was a large and statistically significant reduction in the severity of most symptoms when preoperative symptoms were compared with long-term follow-up results. It is also important to differentiate our results in mostly type I hiatal hernias <5 cm from the large, type II paraesophageal hernias reported by Oeschlager et al.

In our opinion, the use of mesh is essential during hiatal hernia repair. The diaphragm is constantly moving, and the crural repair is often under some tension. In addition, the diaphragmatic hiatus is composed primarily of muscle with very little fascia. There is a layer of the peritoneum overlying the crura that must be preserved for cruroplasty to be optimal. The biologic mesh we currently use incorporates into the diaphragm and adds an additional layer of strength to the repair. The use of a biologic mesh reduces the likelihood of recurrence without the potential synthetic mesh-related adverse effects, such as mesh erosion, ulceration, and long-term dysphagia.^{6,9,10} Furthermore, we have found that biologic mesh is best suited to an onlay approach versus a bridge-the-gap approach. One patient who had an obvious hernia recurrence underwent LHHR with the bridge-the-gap placement of mesh. The mesh was sutured to the edge of the hiatus, to create a tension-free repair. When this patient underwent reoperation,

Table 4.
Complications Summary

Complication	Subjects with Complication % (n/N)
Dysphagia	25.3 (56/221)
Nausea/vomiting	12.7 (28/221)
Abdominal pain	4.1 (9/221)
Wound infections	1.8 (4/221)
Leaks	1.4 (3/221)
Pneumonia	0.9 (2/221)
Readmission	0.5 (1/221)
Atrial fibrillation	0.5 (1/221)
Death	0.5 (1/221)
Other	14.0 (31/221)
Overall	45.7 (101/221)

there was no evidence of mesh placement. Preclinical studies suggest that biologic mesh is incorporated into the underlying tissues.²³ In this patient, the mesh was not placed on a suitable substrate.

Some of the most noteworthy findings from the study included dramatic reflux symptom improvement in all groups of patients. The greatest GERD-HRQL score decrease (20.5 ± 13.4) was observed in patients who underwent LHHR with a fundoplication procedure (Nissen/TIF). Of note, the postoperative reflux scores were also very low in the bariatric patients. Most of these patients underwent sleeve gastrectomy. Although the data are equivocal, multiple studies suggest a high rate of recurrent reflux and de novo reflux after sleeve gastrectomy.^{16,24–26} Experience has taught us that LHHR with sleeve gastrectomy prevents and treats reflux very effectively.

This study constitutes one of the largest single-institution/-surgeon series of LHHR with biologic mesh. The technique is challenging. The mesh is sutured to the diaphragm, which is concave and high in the abdomen. We liken this to sewing inside a thimble. In addition, the hiatus is surrounded by major structures. The aorta is routinely visualized posteriorly. The heart is anterior and superior, and the vena cava is right and posterior. Securing mesh with tacks is imprecise and dangerous.²⁷ Therefore, the surgeon must be proficient at laparoscopic suturing. We feel that a curved needle and good laparoscopic needle drivers provide the best combination for safety and multiple angles and degrees of freedom.

The initial study by Oelschlager et al⁶ cited a pneumothorax rate in 16 of 108 procedures (15%). Our experience has taught us that a pneumothorax that occurs during laparoscopy is most often clinically insignificant. An exception included a patient who developed some transient hypotension and required placement of a small-bore right-side chest tube for 24 hours.

Another noteworthy finding of our study is the lack of long-term dysphagia. Although 25% of our patients reported early dysphagia after LHHR, in all cases it resolved over time. We believe that we see a moderate amount of dysphagia early on after LHHR, because we reapproximate the crura fairly snugly around the esophagus and do not use a calibration bougie. If a bougie is placed in the esophagus during crural closure, the closure is more difficult to perform because of the rigidity of the esophagus and bougie. When the bougie is removed, the crural closure then appears loose. We have not used a bougie during a hiatal hernia repair since 2010. When the mesh is

placed over the cruroplasty, it is generally loose around the esophagus. Our experience suggests that the dysphagia tends to resolve over time. We think the cruroplasty loosens somewhat over time. Therefore, we accept a higher early dysphagia rate, with the expectation that it will improve. The higher early dysphagia rate also contributes to weight loss after bariatric surgery.

We have seen no cases of mesh erosion or infectious complications associated with mesh. However, the severity of symptoms generally has not warranted recurrent upper endoscopy to search for mesh erosion. We have had 3 leaks after sleeve gastrectomy with simultaneous LHHR, but mesh removal was not necessary. The sleeve leaks were treated with esophageal stents and percutaneous drainage and resolved uneventfully in all 3 patients.

The examination of results in a single-surgeon series has the advantage of consistency in preoperative evaluation, surgical technique, and postoperative patient management. The limitations of this study include the inherent drawbacks of a retrospective chart review, the subjectivity of GERD-HRQL data, as well as the lack of a control group and randomization. It is important to note that due to the positive, yet subjective, findings obtained from our analysis of the GERD-HRQL questionnaires, we now routinely obtain perioperative pH studies to collect additional physiologic data for verification of our results. Going forward, we believe this change in our practice will provide additional objective data that show the clinical benefits of LHHR.

Laparoscopic hiatal hernia repair with biologic mesh, both with and without a simultaneous bariatric or antireflux procedure, is an efficacious and safe therapeutic option for management of hiatal hernia, prevention of recurrence and relief of symptomatic GERD. The results are durable and the complication rate is very low in experienced hands. Prospective studies with standardized surgical techniques are needed. Reflux rates and symptom scores should be evaluated within these prospective studies.

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