Original Investigation

Long-term Quality of Life and Risk Factors for Recurrence After Laparoscopic Repair of Paraesophageal Hernia

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IMPORTANCE Laparoscopic repair of paraesophageal hernia (PEH) has been shown to result in excellent relief of symptoms and improved quality of life (QOL) despite a relatively high radiographically identified recurrence rate.

OBJECTIVE To assess potential risk factors for recurrence and long-term change in QOL after laparoscopic repair of PEH.

DESIGN, SETTING, AND PARTICIPANTS This was a prospective study of 111 patients who underwent elective laparoscopic repair of type III PEH with biological mesh buttressed over a primary cruroplasty from April 3, 2009, through July 31, 2014, at the Department of Surgery, Johns Hopkins University of Medicine. We administered a modified version of a validated gastroesophageal reflux disease–specific QOL tool to patients before and at 2, 12, and 36 months after the procedure. Higher QOL scores represent greater severity of symptoms. An upper gastrointestinal tract barium-contrast radiographic examination was performed at 1 year to assess for recurrence. Demographic factors, comorbidities, and preoperative radiographic findings were analyzed as possible indicators for recurrence using logistic regression.

MAIN OUTCOMES AND MEASURES Quality of life, measured by the gastroesophageal reflux disease–specific QOL tool, and recurrence, defined as a PEH of greater than 2 cm.

RESULTS Median patient age was 61 years, 63.1% of patients were women, and 81.1% of patients were white. Four patients required reoperation, of which only 1 was for symptomatic recurrent PEH. The mean follow-up time for the 36-month QOL assessment was 43.5 months. The overall preoperative and 2-, 12-, and 36-month QOL scores were 28.50, 10.18, 9.74, and 10.58, respectively ($P < .001$). Recurrences were found in 19 of the 70 patients (27%) who completed the 1-year radiographic examination. Compared with baseline, all individual symptoms improved significantly except for early satiety (mean [SD] score, 3.18 [1.88] at baseline vs 2.07 [1.70] at the 36-month follow-up; $P = .07$), nausea (1.69 [1.63] vs 0.77 [1.25]; $P = .08$), pain with swallowing (1.06 [1.50] vs 0.53 [0.90]; $P = .73$), and bloating/gas (3.28 [1.71] vs 2.23 [1.72]; $P = .05$) at the 36-month QOL assessment. Although not statistically significant, preoperative hernias containing most of the stomach were more likely to recur after repair when compared with those involving gastric cardia and fundus (odds ratio, 3.74 [95% CI, 0.93-15.14]; $P = .06$).

CONCLUSIONS AND RELEVANCE Overall, laparoscopic repair of PEH with biological mesh results in excellent long-term QOL. The cause of recurrence is likely multifactorial and individualized to each patient. Further evaluation of novel techniques and unidentified patient factors is needed.

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JAMA Surg. 2015;150(5):424-431. doi:10.1001/jamasurg.2015.25
Published online March 18, 2015.

Paraesophageal hernias (PEHs) account for 5% to 10% of all hiatal hernias and have become increasingly common with the aging of the population. Approximately 90% of PEHs are type III hernias, in which the stomach is herniated alongside the esophagus and the gastroesophageal junction is displaced above the diaphragm. Although the precise sequence of events leading to PEH development is not completely understood, the process likely involves progressive weakening and stretching of the phrenoesophageal membrane associated with enlargement of the diaphragmatic hiatus. Repair of a PEH can be technically challenging, and operative intervention is usually reserved for patients with symptomatic PEH,[1] particularly those with serious or life-threatening complications.[2,3] Although multiple studies have demonstrated that PEHs can be repaired safely and with minimal perioperative risk,[4,5] most of these reports are limited to short-term follow-up. Most noteworthy is the paucity of data regarding long-term functional and quality-of-life (QOL) outcomes—the most clinically relevant yardsticks by which the success of PEH repair should be judged.

Although PEH is most commonly repaired via a laparoscopic approach, no consensus has been achieved regarding the specific technique, and reviews of laparoscopic series have reported disappointingly high recurrence rates of greater than 50%.[6,7] The pathogenesis of PEH recurrence after repair is thought to be caused by the repetitive movement of the diaphragm and esophagus and crural tension created by primary closure; however, no studies have been able to identify specific risk factors for recurrence, nor has any intraoperative technique been identified that might reduce recurrence rates. Patient characteristics, such as body mass index (BMI) (calculated as weight in kilograms divided by height in meters squared) and presence of pulmonary disease,[8,9] as well as technical factors, such as esophageal lengthening, gastropexy, and mesh reinforcement,[10,11] have not been shown to be associated with decreased recurrence rates. A common thread among published studies, however, has been identification of PEH recurrence as an asymptomatic radiographic finding that bears no correlation with the symptomatic improvement conferred by PEH repair.[12] Moreover, this clinical efficacy appears to endure even in the face of radiographic hernia recurrence.

In this study, we analyzed data from an ongoing prospective study of patients undergoing laparoscopic repair of PEH at our institution. We aimed to identify potential risk factors for PEH recurrence and to evaluate long-term (>3.5 years) symptomatic response and postoperative change in QOL. Our study provides further clinical support to the limited data in the literature suggesting that, although recurrence rates may be high, most patients maintain an excellent and durable QOL after laparoscopic repair of PEH.

Methods

Data Source and Study Population

Data for analysis were derived from an ongoing prospective study. From April 3, 2009, through July 31, 2014, we enrolled 111 adults who underwent elective laparoscopic repair of PEH with biological mesh (Veritas collagen matrix; Synovis) buttressed over a primary cruroplasty. The study population included 70 patients who reached the 1-year milestone for the barium-contrast radiographic interval examination of the upper gastrointestinal tract (UGI examination). All patients underwent Nissen fundoplication with or without anterior gastropexy. The PEH cohort has been described in detail previously.[12] All data were prospectively collected on a standardized collection form and maintained in an electronic database. Patient demographics, surgical history, baseline comorbidities and symptoms (BMI, smoking status, diabetes mellitus, pulmonary disease, preoperative dysphasia, heartburn, and pain), operative details, postoperative course of care (reoperation and length of hospital stay), and postoperative clinic visits, including radiographic studies, were collected. This study was approved by the Johns Hopkins Medicine Institutional Review Board. All patients provided written informed consent.

Symptom Assessment and Radiographic Methods

A modified version of a validated gastroesophageal reflux disease–specific QOL tool was administered in person or by telephone before and at 2, 12, and approximately 36 months after the procedure.[13] All questions were rated on a scale of 0 to 5, with higher scores representing greater severity of symptoms.

Preoperative radiographic hernia characteristics were identified as potential risk factors for recurrence. *Vertical/horizontal hernia size* was the extent of gastric mucosa above the level of the hiatus, measured at its greatest length in both dimensions. *Anatomy* referred to the percentage of stomach extending above the diaphragm. This measurement was further delineated as type I (involving the gastric cardia and fundus) or type II (involving the body or any portion of the stomach distal to the body). We defined *rotation* as the degree of twisting of the herniated stomach, including none, partial (≤180°), or complete organoaxial malrotation. We defined *motility* as the finding of esophageal dysmotility during a live fluoroscopic study. *Shortening of the esophagus* denoted the absence of laxity of the esophagus despite location of the gastroesophageal junction above the diaphragm.

We performed the UGI examination at 1 year after the surgery and defined *hernia recurrence* as greater than a 2-cm vertical extension of gastric mucosa measured from the level of the diaphragm. This definition was derived from a previous analysis of this population.[12] A single radiologist blinded to patient information (R.M.F.) read all studies.

Statistical Analysis

We compared baseline comorbidities and preoperative radiographic findings between the patients with recurrent and nonrecurrent hernia. Categorical variables were expressed as frequencies and percentages and were compared using the Pearson χ^2 test or the Fisher exact test when appropriate. Continuous variables were expressed as mean (SD) and were compared using the Wilcoxon rank sum test. Overall and individual symptom scores from the QOL tool were compared at baseline and 2, 12, and 36 months postoperatively using the

Table 1. Baseline Demographic and Clinical Characteristics of Study Patients With PEH

Characteristic	Data (N = 111)
Age, mean (SD) [median], y	61.5 (13.5) [61]
Female sex, No. (%)	70 (63.1)
Race, No. (%)	
White	90 (81.1)
Black	17 (15.3)
Other	4 (3.6)
QOL score, mean (SD)[a]	
Preoperative	28.50 (11.13)
Postoperative	
2 mo	10.18 (7.39)
12 mo	9.74 (8.69)
36 mo	10.58 (9.14)
Follow-up, mean (SD), mo	19.9 (16.4)
LOS, mean (SD) [median], d	3.5 (4.8) [2]
Reoperation, No. (%)	4 (3.6)
Time to reoperation, median, d	314.5

Abbreviations: LOS, length of stay; PEH, paraesophageal hernia; QOL, quality of life.

[a] All questions on a validated gastroesophageal reflux disease–specific QOL tool were rated on a scale of 0 to 5, with higher scores representing greater severity of symptoms.

Wilcoxon signed rank test. In addition, we used univariate logistic regression analysis to identify independent clinical and radiographic factors as predictors of radiographic recurrence. $P < .05$ was chosen to indicate statistical significance. All statistical analyses were performed using commercially available software (STATA/MP, version 12.0; StataCorp).

Results

Baseline Demographic and Clinical Characteristics

A total of 111 patients have been enrolled in this ongoing study according to established inclusion criteria. Of these patients, 22 were unavailable for follow-up, including 16 patients who voluntarily withdrew from the study or were lost to follow-up and 6 patients who died of unrelated causes. None of the patients died during the hospitalization for the procedure. The median patient age was 61 (range, 24-89) years, and most of the population consisted of white women. Overall, patients experienced significant symptom improvement at postoperative months 2 (mean QOL score, 10.18 [7.39]), 12 (mean QOL score, 9.74 [8.69]), and 36 (mean QOL score, 10.58 [9.14]) compared with baseline (mean QOL score, 28.50 [11.13]) ($P < .001$) (**Table 1**). Four patients (3.6%) required reoperation, of which only 1 was for symptomatic recurrent PEH manifested by obstructive symptoms at postoperative month 9. One patient underwent reoperation on postoperative day 2 for intrathoracic wrap migration. Two additional patients underwent reoperation (at approximately 13 postoperative months) for chest pain and dysphagia with presumed stricture but without recurrent PEH being identified.

Of the 70 patients who completed their 1-year UGI examination, 19 (27%) were noted to have a radiographic hernia recurrence. We found no statistically significant difference between the nonrecurrent and recurrent groups with regard to age, sex, race, QOL scores, follow-up time, length of hospital stay, and reoperation. However, recurrent hernia size was significantly different between the 2 groups (0.37 vs 3.67 cm; $P < .001$), as expected (**Table 2**).

Postoperative Symptom Assessment

The mean follow-up time for the 36-month QOL was 43.5 months. Acid reflux, early satiety, bloating/gas, shortness of breath, and postprandial chest pain were the most bothersome preoperative symptoms. At postoperative month 12, significant improvement was reported in all symptoms and in overall satisfaction (**Table 3**). At postoperative month 36, patients continued to experience significant overall satisfaction; however, early satiety, nausea, pain with swallowing, and bloating/gas became comparable to those symptoms at baseline.

Assessment of Risk Factors for Recurrence

We found no significant difference between the recurrent and nonrecurrent groups with respect to clinical factors or preoperative radiographic findings. However, more patients had a preoperative type II anatomy in the recurrent group compared with the nonrecurrent group (81.3% vs 53.7%; $P = .06$) (**Table 4**). Moreover, univariate logistic regression revealed a trend toward increased odds of recurrence in patients with a preoperative anatomy type II (odds ratio, 3.74 [95% CI, 0.93-15.14]; $P = .06$), preoperative heartburn (odds ratio, 3.17 [95% CI, 0.81-12.31]; $P = .10$), and possibly preoperative vertical hernia size of 5.5 cm or greater (odds ratio, 2.32 [95% CI, 0.72-7.41]; $P = .16$) (**Table 5**). None of the remaining independent risk factors predicted development of recurrent hernia.

Discussion

In this study of prospectively collected data for 111 patients who underwent laparoscopic PEH repair during a 5-year period at our institution, careful analysis of multiple patient characteristics failed to identify any specific risk factors associated with PEH recurrence. Further investigation into variations of surgical technique and specific preoperative anatomic differences only demonstrated a trend toward significance for recurrence in patients with preoperative hernias that included most of the stomach. Long-term follow-up for this group demonstrated that, despite a 27% recurrence rate, overall QOL and patient satisfaction remained significantly improved compared with baseline.

The high recurrence rate after surgical repair of PEH remains an important challenge. Several factors have been thought to contribute to a reduced recurrence rate after laparoscopic repair of PEH, including complete excision of the hernia sac with extensive mobilization of the esophagus, performance of a cruroplasty, use of mesh, performance of a fundoplication, and gastropexy.[14,15] One of the key steps in a PEH repair is the closure of the hiatus or cruroplasty. Today, the most common primary repair includes a posterior approach of con-

tinuous or interrupted sutures of the crura (over a bougie) with or without mesh placement, followed by fundoplication. The cephalad force created with increased positive intra-abdominal pressure and negative intrathoracic pressure forces the stomach to migrate back into the chest, which can lead to recurrence. This result has been postulated to be prevented by anchoring the stomach to the anterior abdominal wall by way of gastropexy or gastrostomy. Poncet et al[10] reported a 50% recurrence rate without gastropexy vs 10.8% with gastropexy (P = .003). Similar findings were demonstrated by Ponsky et al.[16] All of our patients underwent complete esophageal mobilization and sac excision, but our study did not demonstrate any significant difference in recurrence rates between patients who did or did not undergo gastropexy (P = .21).

Table 2. Baseline Demographic and Clinical Characteristics for Patients With PEH at 1-Year Barium-Contrast UGI Radiographic Examination Stratified by Radiographic Recurrence

Characteristic	All Patients (n = 70)	Hiatal Hernia Group[a]		P Value[b]
		Nonrecurrent (n = 51)	Recurrent (n = 19)	
Age, mean (SD) [median], y	63.4 (13.2) [62.5]	63.4 (13.3) [63]	63.4 (13.1) [60]	.86
Age group, No. (%)				.73
<70 y	41 (59)	29 (57)	12 (63)	.63
≥70 y	29 (41)	22 (43)	7 (37)	
Female sex, No. (%)	49 (70)	36 (71)	13 (68)	.86
Race, No. (%)				
White	60 (86)	43 (84)	17 (89)	.99
Black	8 (11)	6 (12)	2 (11)	
Other	2 (3)	2 (4)	0	
QOL score, mean (SD)[c]				
Preoperative	27.18 (10.75)	27.45 (11.45)	26.53 (9.03)	.70
Postoperative				
2 mo	9.57 (6.45)	9.63 (6.11)	9.42 (7.39)	.70
1 y	8.72 (7.06)	8.26 (6.31)	9.83 (8.69)	.68
Score change, mean (SD)[d]	0.03 (6.46)	−0.43 (4.01)	1.11 (10.21)	.43
LOS, mean (SD) [median], d	3.2 (3.0) [2]	3.0 (2.4) [2]	3.7 (4.2) [2.5]	.86
Gastropexy, No. (%)	45 (64)	35 (69)	10 (53)	.21
Reoperation, No. (%)	3 (4)	2 (4)	1 (5)	.99
Recurrent hernia size, mean (SD), cm	1.27 (1.64)	0.37 (62.00)	3.67 (0.96)	<.001

Abbreviations: LOS, length of stay; PEH, paraesophageal hernia; QOL, quality of life; UGI, upper gastrointestinal tract.

[a] Nonrecurrent was defined as all hernias of 2 cm or less; recurrent, greater than 2 cm.

[b] Calculated using the Wilcoxon rank sum test for continuous variables and Pearson χ^2 test for categorical variables.

[c] All questions on a validated gastroesophageal reflux disease–specific QOL tool were rated on a scale of 0 to 5, with higher scores representing greater severity of symptoms.

[d] Calculated as the difference between the 1-year postoperative QOL score and the 2-month postoperative QOL score.

Table 3. Comparison of QOL Scores for Patients With PEH at 1-Year Barium-Contrast UGI Radiographic Examination

Symptom	QOL Score, Mean (SD)[a]						
	Preoperative (n = 104)	2-mo FU (n = 98)	P Value[b]	12-mo FU (n = 78)	P Value[c]	36-mo FU (n = 30)	P Value[d]
Follow-up time, mo		2.7 (0.9)	NA	13.2 (3.4)	NA	43.5 (4.9)	NA
Overall	28.50 (11.10)	10.18 (7.39)	<.001	9.74 (8.69)	<.001	12.13 (10.89)	<.001
Acid reflux[e]	6.88 (3.25)	1.35 (2.37)	<.001	1.42 (2.34)	<.001	2.13 (3.18)	.001
Postprandial chest pain	2.26 (1.82)	0.51 (1.02)	<.001	0.45 (1.08)	<.001	0.60 (1.19)	.001
Early satiety	3.18 (1.88)	1.98 (1.57)	<.001	1.86 (1.73)	<.001	2.07 (1.70)	.07
Nausea	1.69 (1.63)	0.73 (1.30)	<.001	0.74 (1.29)	<.001	0.77 (1.25)	.08
Vomiting	1.45 (1.71)	0.44 (1.19)	<.001	0.27 (0.82)	<.001	0.20 (0.61)	.001
Difficulty with swallowing	1.77 (1.74)	0.73 (1.10)	<.001	0.78 (1.31)	.001	0.67 (1.09)	.01
Pain with swallowing	1.06 (1.50)	0.22 (0.62)	<.001	0.27 (0.82)	<.001	0.53 (0.90)	.73
Bloating/gas	3.28 (1.71)	2.58 (1.66)	.001	2.13 (1.72)	<.001	2.23 (1.72)	.05
Shortness of breath	2.28 (1.71)	0.78 (1.28)	<.001	1.04 (1.60)	<.001	1.40 (1.48)	.01
Condition satisfaction	4.71 (1.04)	0.90 (1.66)	<.001	0.81 (1.60)	<.001	1.53 (2.01)	<.001

Abbreviations: FU, follow-up; NA, not applicable; PEH, paraesophageal hernia; QOL, quality of life; UGI, upper gastrointestinal tract.

[a] All questions on a validated gastroesophageal reflux disease–specific QOL tool were rated on a scale of 0 to 5, with higher scores representing greater severity of symptoms.

[b] Calculated as preoperative vs 2-month FU QOL score using Wilcoxon signed rank test.

[c] Calculated as preoperative vs 12-month FU QOL score using Wilcoxon signed rank test.

[d] Calculated as preoperative vs 36-month FU QOL score using Wilcoxon signed rank test.

[e] Indicates acid reflux after meals and its severity (2 questions combined into one).

Table 4. Comorbidities and Radiographic Findings for Patients With PEH at 1-Year Barium-Contrast UGI Radiographic Examination Stratified by Hernia Recurrence[a]

Characteristic	All Patients (n = 70)	Hiatal Hernia Group[b]		*P* Value[c]
		Nonrecurrent (n = 51)	Recurrent (n = 19)	
Comorbidities				
BMI, mean (SD)	30.06 (6.74)	30.06 (7.12)	30.13 (5.76)	.99
BMI group				
<25	6 (9)	5 (10)	1 (5)	.81
25-29	30 (43)	22 (43)	8 (42)	
≥30	34 (49)	24 (47)	10 (53)	
Diabetes mellitus				
No	63 (90)	47 (92)	16 (84)	.38
Yes	7 (10)	4 (8)	3 (16)	
Previous smoker				
No	47 (67)	32 (63)	15 (79)	.20
Yes	23 (33)	19 (37)	4 (21)	
Current smoker				
No	67 (96)	49 (96)	18 (95)	.99
Yes	3 (4)	2 (4)	1 (5)	
Previous abdominal surgery				
No	28 (40)	21 (41)	7 (37)	.74
Yes	42 (60)	30 (59)	12 (63)	
History of pulmonary disease				
No	41 (59)	31 (61)	10 (53)	.54
Yes	29 (41)	20 (39)	9 (47)	
Preoperative dysphagia				
No	46 (66)	31 (61)	15 (79)	.16
Yes	24 (34)	20 (39)	4 (21)	
Preoperative heartburn				
No	22 (31)	19 (37)	3 (16)	.09
Yes	48 (69)	32 (63)	16 (84)	
Preoperative pain				
No	36 (51)	28 (55)	8 (42)	.34
Yes	34 (49)	23 (45)	11 (58)	
Radiographic				
Hernia size, mean (SD), cm				
Vertical	6.28 (3.31)	6.27 (3.67)	6.33 (2.24)	.95
Horizontal	6.98 (4.21)	6.93 (4.00)	7.07 (4.86)	.93
Vertical, cm[d]				
<5.5	30 (50)	24 (56)	6 (35)	.15
≥5.5	30 (50)	19 (44)	11 (65)	
Horizontal, cm[d]				
<6.5	15 (48)	11 (52)	4 (40)	.70
≥6.5	16 (52)	10 (48)	6 (60)	
Anatomy[d,e]				
Type I	22 (39)	19 (46)	3 (19)	.06
Type II	35 (61)	22 (54)	13 (81)	
Rotation[d]				
Organoaxial rotation	16 (28)	12 (29)	4 (25)	.45
Partial	20 (35)	12 (29)	8 (50)	
None	21 (37)	17 (41)	4 (25)	
Mobility[d]				
Normal	12 (33)	9 (33)	3 (33)	.99
Abnormal	24 (67)	18 (67)	6 (67)	
Shortening of esophagus[d]				
No	36 (77)	25 (74)	11 (85)	.70
Yes	11 (23)	9 (26)	2 (15)	

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); PEH, paraesophageal hernia; UGI, upper gastrointestinal tract.

[a] Unless otherwise indicated, data are expressed as number (percentage) of patients.

[b] Nonrecurrent was defined as all hernias of 2 cm or less; recurrent, greater than 2 cm.

[c] Calculated using the Pearson χ^2 test or the Fisher exact test (when appropriate) for categorical variables and Wilcoxon rank sum test for continuous variables.

[d] Denominator used to compute percentages excluded cases with unknown information on radiographic findings.

[e] Type I preoperative hernia includes cardia and fundus of stomach; type II, at least the body or any portion of the stomach distal to the body.

All patients in our study underwent cruroplasty, fundoplication, and a posterior onlay of a biological mesh. Koch et al[17] evaluated 54 patients who underwent PEH repair with fundoplication, cruroplasty, and posterior onlay of a polyester mesh (Parietex; Covidien) if a hiatus with a surface area of 5.60 cm^2 or greater was present. The authors reported no significant complications with the use of mesh and concluded that recurrence was more likely with increased hiatal surface area. Although mesh use is now widely accepted, especially in the face of a large hiatus, substantial controversy remains surrounding the choice of mesh (prosthetic vs biological). This controversy mainly stems from lack of evidence from well-designed studies using long-term functional outcomes. Many studies have evaluated short-term outcomes from small series of patients using various mesh materials of different shapes, sizes, and techniques. Two earlier randomized clinical trials[18,19] compared prosthetic mesh placement with primary suture repair and demonstrated a significantly reduced recurrence rate in the mesh group. Unfortunately, use of prosthetic materials has been complicated by erosion, migration, and fistualization of the mesh into neighboring viscera or vessels and by dysphagia and esophageal dilation.[20-22] These complications have led surgeons to consider the use of biological mesh. Although biological mesh can be more costly compared with prosthetic materials or with not using any mesh, many biological options are currently available that are reasonably priced. Our choice of mesh for this study was based on ease of use and availability in our institution and a cost of approximately $1100 (a small fraction of the total hospital costs). A randomized trial by Oelschlager et al[23] compared primary repair with the use of a biological porcine submucosa mesh. Recurrence rates at 6 months were lower in the mesh group; however, in follow-up at 5 years, the recurrence rates did not differ between the biological mesh and primary repair groups.[11] Similarly, Dallemagne et al[24] reported a 66% recurrence rate at a median follow-up of 99 months, although their retrospective study had a fairly high loss to follow-up.

To date, our cohort has experienced a recurrence rate of 27% at approximately 1 year of follow-up, well within the reported ranges of previously published studies. In their original landmark report in 1967, Skinner and Belsey[25] suggested that most recurrences occur within 1 year. However, decades later, Luketich et al[26] reported a 15.7% recurrence rate at a median of 22 months. More recently, Jones et al[27] reported increased recurrence rates over time (40% by 5 years), which is similar to findings by Oelschlager et al[9] and Dallemagne et al.[24] Based on these studies, a propensity for recurrence over time is suggested, which ultimately may be demonstrated in our cohort as we continue to accrue and analyze our data.

Preexisting medical conditions have been implicated as risk factors for postoperative recurrence of PEH. Other investigators have suggested that obesity, smoking, and diabetes mellitus may play a role. The clinical factors that we investigated, including BMI, smoking, diabetes mellitus, pulmonary disease, previous abdominal surgery, preoperative dysphagia, heartburn, and pain, were not significantly associated with radiographically recurrent hernias. Nason et al[8] examined many of these same patient factors and found only a trend toward an increased risk for radiographic recurrence in patients with documented pulmonary disease but not based on BMI or preoperative hernia size. We may conclude intuitively that the bigger the hernia, the more likely it will be to recur. Among patients in our series who had most of

Table 5. Risk Factors for PEH Radiographic Recurrence Based on Preoperative Clinical Characteristics and Preoperative Radiographic Findings[a]

Risk Factor	OR (95% CI)	*P* Value[b]
Clinical		
Age, y		
<70	1 [Reference]	NA
≥70	0.77 (0.26-2.27)	.64
Female sex	0.91 (0.29-2.82)	.86
BMI		
<25	1 [Reference]	NA
25-29	1.82 (0.18-18.03)	.61
≥30	2.08 (0.22-20.17)	.53
Gastropexy	0.51 (0.17-1.49)	.22
Diabetes mellitus	2.20 (0.44-10.92)	.33
Smoker		
Previous	0.45 (0.13-1.55)	.21
Current	1.36 (0.12-15.94)	.81
Previous abdominal surgery	1.20 (0.40-3.56)	.74
History of pulmonary disease	1.40 (0.48-4.03)	.54
Preoperative symptom		
Dysphagia	0.41 (0.12-1.43)	.16
Heartburn	3.17 (0.81-12.31)	.10
Pain	1.67 (0.58-4.85)	.34
Radiographic		
Vertical hernia size, cm		
<5.5	1 [Reference]	NA
≥5.5	2.32 (0.72-7.41)	.16
Horizontal hernia size, cm		
<6.5	1 [Reference]	NA
≥6.5	1.65 (0.36-7.60)	.52
Anatomy[c]		
Type I	1 [Reference]	NA
Type II	3.74 (0.93-15.14)	.06
Rotation		
None	1 [Reference]	NA
Organoaxial rotation	2.83 (0.69-11.60)	.15
Partial	1.41 (0.29-6.81)	.66
Motility		
Normal	1 [Reference]	NA
Abnormal	1.00 (0.20-4.95)	.99
Shortening of esophagus		
No	1 [Reference]	NA
Yes	0.51 (0.09-2.73)	.43

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); NA, not applicable; OR, odds ratio; PEH, paraesophageal hernia.

[a] Data were analyzed using univariate logistic regression analysis.

[b] Calculated using univariate logistic regression analysis.

[c] Type I preoperative hernia includes the cardia and fundus of the stomach; type II, at least the body of the stomach or any portion of the stomach distal to the body.

the stomach herniated into the mediastinum preoperatively, a disproportionate number developed recurrence, although this finding was not statistically significant ($P = .06$).

Anecdotally, many surgeons are reluctant to offer hiatal hernia surgery to obese patients because of concerns regarding recurrence; however, surprisingly few studies support this concern. Obesity is a known risk factor for the development of hiatal hernia; on this basis, expecting an increased risk for PEH recurrence after repair in obese patients seems reasonable. Morgenthal et al[28] demonstrated that patients with morbid obesity (BMI >35) were more likely to experience treatment failure after laparoscopic Nissen fundoplication, although their series did not include patients with PEH. Other authors[29,30] have shown differing results, and more surgeons currently are offering morbidly obese patients concurrent bariatric surgery (sleeve gastrectomy or Roux-en-Y gastric bypass) at the time of PEH repair. The proponents of this approach[31] imply that the weight reduction that accompanies bariatric surgery will lower the recurrence rate of PEH in these patients in addition to providing the benefit that inheres as a result of the well-documented improvement of obesity-related comorbidities.

Although we found attrition of the initial improvement reported by some patients with regard to several individual symptoms (early satiety, nausea, and pain with swallowing), our patients sustained significant long-term improvement in their overall gastroesophageal reflux disease–specific QOL scores and condition satisfaction. A paucity of published studies address long-term outcomes after PEH. Soricelli et al[32] demonstrated that QOL evaluation after laparoscopic repair of hiatal hernia remained stable at a mean follow-up of 95.1 months. Although this study did not consist solely of patients with PEH, other authors have shown similar results. Mittal et al[33] and Oelschlager et al[9] demonstrated high levels of patient satisfaction and long-term maintenance of improvement in gastroesophageal reflux disease symptoms at 5 years after laparoscopic repair of PEH. Targarona et al[34] recently reported clinical efficacy after laparoscopic PEH repair at very long-term follow-up (≤160 months) despite almost 50% of patients having small anatomic recurrences. As in our study, these groups reported sustained symptom relief in most of the patients despite frequent radiographic recurrences, and the need for reoperation was very low.

This study has several limitations. Because our study is ongoing, we have yet to acquire a large cohort of patients with longer-term (ie, 3-year) follow-up. However, in view of the consistency of the analysis so far, we anticipate that these findings will be maintained as we continue to accrue more data. This study is prospective, and we have a dedicated team administering the QOL tool and scheduling clinical follow-up. Nevertheless, patients were lost to follow-up owing to unrelated deaths and other factors (eg, patient relocation). Because our institution is a tertiary referral center, a substantial proportion of our patients are referred to us from distant sources, frequently precluding us from consistently performing UGI examinations at the 3-year period. Conversely, these patients were able to respond to the QOL studies by telephone even when unable to travel to undergo the UGI examination. Finally, this study did not randomize patients into different treatment arms using various repair techniques, and other issues surrounding recurrent PEHs were not addressed, including type of recurrence or anatomic pattern and time to recurrence.

Conclusions

Our analysis of difference in QOL scores after laparoscopic repair of PEH with biological mesh suggests that, despite a high recurrence rate identified with the UGI examinations, overall, patients experience excellent long-term symptom resolution. We were unable to identify significant factors that increase the risk for recurrence, although the largest preoperative hernias (containing most of the stomach) were more likely to recur after repair. We believe that the cause may be multifactorial and individualized to each patient. As technical advancements and surgical equipment continue to develop, possible therapies may emerge that would help to alleviate the consistently high recurrence rates associated with PEH repair in the long term. Further evaluation of novel techniques and unidentified patient factors is needed.

ARTICLE INFORMATION

Accepted for Publication: September 3, 2014.

Published Online: March 18, 2015. doi:10.1001/jamasurg.2015.25.

Author Contributions: Dr Lidor and Ms Stem had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Lidor, Schweitzer, Marohn.
Acquisition, analysis, or interpretation of data: Lidor, Steele, Stem, Fleming, Marohn.
Drafting of the manuscript: All authors.
Critical revision of the manuscript for important intellectual content: Lidor, Steele, Schweitzer, Marohn.
Statistical analysis: Stem, Fleming.
Administrative, technical, or material support: Schweitzer, Marohn.
Study supervision: Lidor, Schweitzer, Marohn.

Conflict of Interest Disclosures: None reported.

Funding/Support: This study was supported by the Department of Surgery Research Fund from Mr Edwin Lewis and by the Morton K. and Jane Blaustein Foundation.

Role of the Funder/Sponsor: The funding sources had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Additional Contributions: Qingwen Kawaji, ScM, and Benjamin Pollock, MSPH, Department of Surgery, Johns Hopkins University School of Medicine, contacted patients and administered the QOL questionnaire as part of our clinical staff team. Both were compensated as research assistants to Dr Lidor.

REFERENCES

1. Stylopoulos N, Gazelle GS, Rattner DW. Paraesophageal hernias: operation or observation? *Ann Surg*. 2002;236(4):492-501.

2. Polomsky M, Hu R, Sepesi B, et al. A population-based analysis of emergent vs elective hospital admissions for an intrathoracic stomach. *Surg Endosc*. 2010;24(6):1250-1255.

3. Bawahab M, Mitchell P, Church N, Debru E. Management of acute paraesophageal hernia. *Surg Endosc*. 2009;23(2):255-259.

4. Lidor AO, Chang DC, Feinberg RL, Steele KE, Schweitzer MA, Franco MM. Morbidity and mortality associated with antireflux surgery with or without paraesophogeal hernia: a large ACS NSQIP analysis. *Surg Endosc*. 2011;25(9):3101-3108.

5. Yano F, Stadlhuber RJ, Tsuboi K, Gerhardt J, Filipi CJ, Mittal SK. Outcomes of surgical treatment of intrathoracic stomach. *Dis Esophagus*. 2009;22(3):284-288.

6. Furnée E, Hazebroek E. Mesh in laparoscopic large hiatal hernia repair: a systematic review of the literature. *Surg Endosc*. 2013;27(11):3998-4008.

7. Draaisma WA, Gooszen HG, Tournoij E, Broeders IA. Controversies in paraesophageal hernia repair: a review of literature. *Surg Endosc*. 2005;19(10):1300-1308.

8. Nason KS, Luketich JD, Qureshi I, et al. Laparoscopic repair of giant paraesophageal hernia results in long-term patient satisfaction and a durable repair. *J Gastrointest Surg*. 2008;12(12):2066-2077.

9. Oelschlager BK, Petersen RP, Brunt LM, et al. Laparoscopic paraesophageal hernia repair: defining long-term clinical and anatomic outcomes. *J Gastrointest Surg*. 2012;16(3):453-459.

10. Poncet G, Robert M, Roman S, Boulez JC. Laparoscopic repair of large hiatal hernia without prosthetic reinforcement: late results and relevance of anterior gastropexy. *J Gastrointest Surg*. 2010;14(12):1910-1916.

11. Oelschlager BK, Pellegrini CA, Hunter JG, et al. Biologic prosthesis to prevent recurrence after laparoscopic paraesophageal hernia repair: long-term follow-up from a multicenter, prospective, randomized trial. *J Am Coll Surg*. 2011;213(4):461-468.

12. Lidor AO, Kawaji Q, Stem M, et al. Defining recurrence after paraesophageal hernia repair: correlating symptoms and radiographic findings. *Surgery*. 2013;154(2):171-178.

13. Velanovich V. The development of the GERD-HRQL symptom severity instrument. *Dis Esophagus*. 2007;20(2):130-134.

14. Edye M, Salky B, Posner A, Fierer A. Sac excision is essential to adequate laparoscopic repair of paraesophageal hernia. *Surg Endosc*. 1998;12(10):1259-1263.

15. Wiechmann RJ, Ferguson MK, Naunheim KS, et al. Laparoscopic management of giant paraesophageal herniation. *Ann Thorac Surg*. 2001;71(4):1080-1086.

16. Ponsky J, Rosen M, Fanning A, Malm J. Anterior gastropexy may reduce the recurrence rate after laparoscopic paraesophageal hernia repair. *Surg Endosc*. 2003;17(7):1036-1041.

17. Koch OO, Asche KU, Berger J, Weber E, Granderath FA, Pointner R. Influence of the size of the hiatus on the rate of reherniation after laparoscopic fundoplication and refundoplication with mesh hiatoplasty. *Surg Endosc*. 2011;25(4):1024-1030.

18. Frantzides CT, Madan AK, Carlson MA, Stavropoulos GP. A prospective, randomized trial of laparoscopic polytetrafluoroethylene (PTFE) patch repair vs simple cruroplasty for large hiatal hernia. *Arch Surg*. 2002;137(6):649-652.

19. Granderath FA, Schweiger UM, Kamolz T, Asche KU, Pointner R. Laparoscopic Nissen fundoplication with prosthetic hiatal closure reduces postoperative intrathoracic wrap herniation: preliminary results of a prospective randomized functional and clinical study. *Arch Surg*. 2005;140(1):40-48.

20. Nandipati K, Bye M, Yamamoto SR, Pallati P, Lee T, Mittal SK. Reoperative intervention in patients with mesh at the hiatus is associated with high incidence of esophageal resection: a single-center experience. *J Gastrointest Surg*. 2013;17(12):2039-2044.

21. Stadlhuber RJ, Sherif AE, Mittal SK, et al. Mesh complications after prosthetic reinforcement of hiatal closure: a 28-case series. *Surg Endosc*. 2009;23(6):1219-1226.

22. De Moor V, Zalcman M, Delhaye M, El Nakadi I. Complications of mesh repair in hiatal surgery: about 3 cases and review of the literature. *Surg Laparosc Endosc Percutan Tech*. 2012;22(4):e222-e225.

23. Oelschlager BK, Pellegrini CA, Hunter J, et al. Biologic prosthesis reduces recurrence after laparoscopic paraesophageal hernia repair: a multicenter, prospective, randomized trial. *Ann Surg*. 2006;244(4):481-490.

24. Dallemagne B, Kohnen L, Perretta S, Weerts J, Markiewicz S, Jehaes C. Laparoscopic repair of paraesophageal hernia: long-term follow-up reveals good clinical outcome despite high radiological recurrence rate. *Ann Surg*. 2011;253(2):291-296.

25. Skinner DB, Belsey RH. Surgical management of esophageal reflux and hiatus hernia: long-term results with 1,030 patients. *J Thorac Cardiovasc Surg*. 1967;53(1):33-54.

26. Luketich JD, Nason KS, Christie NA, et al. Outcomes after a decade of laparoscopic giant paraesophageal hernia repair. *J Thorac Cardiovasc Surg*. 2010;139(2):395-404.e1. doi:10.1016/j.jtcvs.2009.10.005.

27. Jones R, Simorov A, Lomelin D, Tadaki C, Oleynikov D. Long-term outcomes of radiologic recurrence after paraesophageal hernia repair with mesh. *Surg Endosc*. 2015;29(2):425-430.

28. Morgenthal CB, Lin E, Shane MD, Hunter JG, Smith CD. Who will fail laparoscopic Nissen fundoplication? preoperative prediction of long-term outcomes. *Surg Endosc*. 2007;21(11):1978-1984.

29. Chaudhry UI, Marr BM, Osayi SN, et al. Laparoscopic Roux-en-Y gastric bypass for treatment of symptomatic paraesophageal hernia in the morbidly obese: medium-term results. *Surg Obes Relat Dis*. 2014;10(6):1063-1067.

30. Pham DV, Protyniak B, Binenbaum SJ, Squillaro A, Borao FJ. Simultaneous laparoscopic paraesophageal hernia repair and sleeve gastrectomy in the morbidly obese. *Surg Obes Relat Dis*. 2014;10(2):257-261.

31. Rodriguez JH, Kroh M, El-Hayek K, Timratana P, Chand B. Combined paraesophageal hernia repair and partial longitudinal gastrectomy in obese patients with symptomatic paraesophageal hernias. *Surg Endosc*. 2012;26(12):3382-3390.

32. Soricelli E, Basso N, Genco A, Cipriano M. Long-term results of hiatal hernia mesh repair and antireflux laparoscopic surgery. *Surg Endosc*. 2009;23(11):2499-2504.

33. Mittal SK, Bikhchandani J, Gurney O, Yano F, Lee T. Outcomes after repair of the intrathoracic stomach: objective follow-up of up to 5 years. *Surg Endosc*. 2011;25(2):556-566.

34. Targarona EM, Grisales S, Uyanik O, Balague C, Pernas JC, Trias M. Long-term outcome and quality of life after laparoscopic treatment of large paraesophageal hernia. *World J Surg*. 2013;37(8):1878-1882.

Invited Commentary

Outcomes of Paraesophageal Hernia Repair

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The treatment of paraesophageal hernias (PEHs) is challenging. They tend to occur in patients in their seventh and eighth decades of life with multiple medical problems and a variety of associated symptoms. Detailed preoperative evaluation is crucial to determining a safe and effective strategy for repair in the operating room. Laparoscopic repair has been shown to be advantageous compared with conventional open repair with regard to hospital stay, recovery time, and decreased complications.[1] Although some results indicate that higher recurrence rates occur in laparoscopic PEH repair (LPEHR), the clinical significance of these recurrences has not yet been determined.

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Studies looking at repair of hiatal hernia with mesh are by their very nature controversial. Results of long-term studies of symptomatic and radiographic outcomes in these patients are limited. In this issue of *JAMA Surgery*, Lidor et al[2] address this important topic by prospectively following up 111 patients who underwent LPEHR with posterior cruroplasty and biological mesh followed by a Nissen fundoplication with or without gastropexy. They used a modified gastroesophageal