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Outcomes after a Decade of Laparoscopic Giant Paraesophageal Hernia Repair

James D. Luketich, MD[1], **Katie S. Nason, MD, MPH**[1], **Neil A. Christie, MD**[1], **Arjun Pennathur, MD**[1], **Blair A. Jobe, MD**[1], **Rodney J. Landreneau, MD**[1], and **Matthew J. Schuchert, MD**[1]

[1] University of Pittsburgh, Division of Thoracic Surgery, Pittsburgh, PA

Abstract

OBJECTIVE—Laparoscopic repair of giant paraesophageal hernia (GPEH) is a complex operation requiring significant laparoscopic expertise. Our objective was to compare our current approach and outcomes with LRGPEH to our previous experience.

METHODS—A retrospective review of patients undergoing non-emergent LRGPEH, stratified by early and current era (1/1997–6/2003 and 7/2003–6/2008) was performed. Surgeon credentialing required a minimally invasive surgical fellowship and/or careful proctoring prior to independent LRGPEH. We evaluated clinical outcomes, barium esophagram and quality-of-life (QoL).

RESULTS—LRGPEH was performed in 662 patients (median age 70, range 19–92); median percent of herniated stomach 70% (range 30–100%). Over time, use of Collis gastroplasty decreased (86% to 53%) as did crural mesh reinforcement (17% to 12%). Current era patients were 50% more likely to have a Charlson comorbidity index score >3. Common complications included pleural effusion (56/652; 9%) and pneumonia (29/653; 4%). Thirty-day mortality was 1.7% (11/662). Mortality and complication rates were stable over time, despite increasing comorbid disease in the current patient cohort. Post-operative GERD-health-related QoL scores were available for 489 patients (30-month median follow-up) with “Good” to “Excellent” results in 90% (438/489). Radiographic recurrence (15.7%) was not associated with symptom recurrence. Reoperation occurred in 3.2% (21/662).

CONCLUSIONS—Over time, we have obtained significant minimally invasive experience and refined our approach to LRGPEH. Perioperative morbidity and mortality remain low, despite increased comorbid disease in the current patient cohort. LRGPEH provided excellent patient satisfaction and symptom improvement, even with small radiographic recurrences. Reoperation rates were comparable to the best open series.

Corresponding author: Katie S. Nason, MD, MPH, 5200 Centre Ave, Suite 715, Shadyside Medical Building, Pittsburgh, PA 15232, Phone: (412) 623-2025, Fax: (412) 623-0329, nasonks@upmc.edu.

Authorship and Scientific Responsibility: Conception and design: James D. Luketich, Katie S. Nason, Matthew J. Schuchert, Blair A. Jobe
Acquisition of data: Katie S. Nason
Analysis and interpretation of data: James D. Luketich, Katie S. Nason, Matthew J. Schuchert, Blair A. Jobe
Drafting and manuscript revision: James D. Luketich, Katie S. Nason, Neil A. Christie, Arjun Pennathur, Blair A. Jobe, Rodney J. Landreneau, Matthew J. Schuchert
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Keywords

Laparoscopy; hernia; hiatal; outcome assessment (health care); recurrence; gastroesophageal reflux; mesh; surgical

Background

Surgical repair of giant paraesophageal hernia (GPEH) is a complex operation and the laparoscopic approach requires advanced laparoscopic expertise. Over time, the feasibility and safety of a laparoscopic approach to GPEH repair has been established.[1–3] However, there is still considerable debate regarding the optimal approach to operative repair, use of routine mesh-reinforcement of the hiatus, the need for an esophageal lengthening procedure and routine fundoplication. Attempts to address these questions have been limited by the small numbers of patients reported in most series.

Over the past decade, we have refined the operation and acquired significant experience in advanced laparoscopic techniques. This study was designed to achieve the following aims: 1) describe the perioperative morbidity and mortality associated with the laparoscopic approach and determine whether these rates have changed over the period of study; 2) evaluate patient and operative factors contributing to an increased risk for perioperative adverse outcomes; 3) assess symptom relief, quality of life, radiographic and symptomatic recurrence and the need for reoperation for symptomatic recurrent hernia during follow-up; and 4) identify potential risk factors for radiographic recurrence and the need for reoperation.

Methods

Patient Selection and Stratification

Patients undergoing elective or urgent laparoscopic repair of GPEH (defined as more than 30% of the stomach herniated into the mediastinum) from January 1, 1997 to June 30, 2008 were included. During this time period, 739 consecutive patients underwent operative repair of GPEH. For this analysis, patients were excluded if they required emergency surgery (n=13), a planned open operation (n=13), or had prior anti-reflux surgery (n=51). Patients requiring hospitalization for hernia-associated symptoms and repaired urgently during the same admission were included in this analysis (n=106; 16%). This retrospective study was approved by our Institutional Review Board.

Patient Demographics and Operative Techniques

Attempted elective or urgent laparoscopic repair of GPEH was performed in 662 consecutive patients. Conversion to an open procedure was necessary in 10 patients (1.5%) for bleeding (n=3), gastric perforation or serosal tear (n=2), adhesions (n=3) or inability to laparoscopically reduce the hernia (n=2). The majority of patients were female (75%; median age 70 years (IQR 19-92)). Body mass index (BMI) ≥35 was documented in 15% of patients. Preoperative history of anemia and/or hematocrit <37 was identified in 41% of patients (271/654). Age-adjusted Charlson comorbidity index (CCI) score was ≥3 for 49% of patients.

Operative Approach

The operative approach to laparoscopic GPEH repair continues to be a “work in progress.” (Details online in Appendix E1.) In this series, esophageal lengthening (Collis gastroplasty) was used in 63%, mesh cruraplasty in 13% and fundoplication (floppy Nissen or partial fundoplasty) in 98%. (Table 1) Operations were performed by 13 thoracic surgeons at the University of Pittsburgh Medical Center. Two senior surgeons (JDL and RJL) performed

56% (n=372) and 17% (n=114) respectively. Under senior supervision, junior surgeons with advanced minimally invasive foregut surgical training (minimum of 25 laparoscopic GPEH repairs) performed the remaining operations. Independent operating required a minimum of 10 successful proctored cases.

Database

Using a standardized outcome protocol, data on patients undergoing repair of GPEH were collected retrospectively by trained research personnel and entered into a computerized surgical outcomes database. Data included standard observer-recorded measures, preoperative symptoms, laboratory and radiographic studies, operative details, length of stay (LOS), perioperative mortality, and post-operative adverse outcomes (in-hospital and 30-day).

Symptom assessment questionnaire, barium esophagram, the Gastroesophageal Reflux Disease Health Related Quality of Life (GERD-HRQoL)4, 5 instrument, and the Medical Outcomes Study Short Form-36 (SF-36) Health Survey6 were obtained as described previously.7 The GERD-HRQoL and SF-36 questionnaires were administered in the clinic by trained clinic personnel. Raw GERD-HRQoL scores were converted to categorical variables as follows: excellent: 0 to 5; good: 6 to 10; fair: 11 to 15; and poor: 16 or greater.8 Radiographic recurrence was considered present if >10%, or 2 cm of the stomach was located above the level of the diaphragm on barium esophagram.7, [9] All subsequent esophageal operations were recorded, including reoperation for recurrence (n=21), conversion to Roux-en-Y for obesity (n=3), and esophagectomy for cancer (n=3).

Statistical Analysis

Statistical analysis was performed using STATA SE 10.0 Corp software. Primary outcome variables were 1) perioperative mortality (in-hospital and/or 30-day); and 2) major morbidity (including pneumonia, perioperative hernia recurrence, post-operative leak, pulmonary embolism, need for reoperation and hospital readmission) and LOS. Secondary outcome measures were 1) reoperation for recurrent hernia; 2) radiographic recurrence by barium swallow; and 3) patient-reported outcomes.

Perioperative Morbidity and Mortality Associated with the Laparoscopic Approach

Data were summarized with frequencies and percentages for categorical variables and median with inter-quartile range (IQR) for continuous variables for the entire cohort and then stratified by date of surgery (Early=January 1, 1997–June 30, 2003; Current=July 1, 2003–June 30, 2008). Chi-square, Fischer's exact, and Student's t-tests, accounting for unequal variance, were used to describe differences between groups. To determine factors associated with an increased risk for death or major adverse outcomes, crude and adjusted analyses were performed using univariate and multivariate logistic regression. Preoperative and current (most recent) patient-reported outcomes measures were compared using McNemar's chi-square test for differences in proportions of paired outcomes. Using logistic regression, the odds ratios for radiographic recurrence, reoperation for recurrence and recurrent symptoms associated with the finding of recurrent hiatal hernia on barium esophagram, were determined. Two-sample Wilcoxon rank-sum (Mann-Whitney) test for differences between means was used to calculate the differences in SF-36 summary scores and GERD-HRQoL composite score, stratified by radiographic hernia recurrence.

Missing Data

When clear documentation of the presence or absence of a symptom was not found in retrospective chart review, the data were considered missing. Recognizing that missing data

may introduce bias into the analysis, patient factors associated with the probability of data missingness were evaluated using Fisher's exact test and univariate logistic regression.

Results

Perioperative Morbidity and Mortality after Laparoscopic GPEH Repair

Major adverse outcomes included pneumonia (n=29/653; 4%), congestive heart failure (n=17/654; 2.6%), pulmonary embolism (n=22/653; 3.4%), post-operative leak (n=16/653; 2.5%), perioperative hernia recurrence (n=5/652; 0.8%), need for re-intubation (n=17/655; 2.6%), acute renal failure (n=6/656; 0.9%), cerebral vascular accident (n=4/653; 0.6%), and myocardial infarction (n=6/653; 0.9%). The majority of post-operative leaks occurred in patients who received Collis gastroplasty (14/16; 88%). There were 11 post-operative deaths (11/662; 1.7%). Reoperation within 30-days was performed in 32 patients (32/650; 4.9%) for post-operative leak (n=11), recurrent hernia (n=3), visceral injury (n=2), wound infection requiring incision and drainage (n=2), bleeding (n=2), enteral access for nutrition (n=6), obstructing fundoplication (n=1), small bowel obstruction (n=1), empyema (n=1), retained foreign body(n=1), periesophageal hematoma (n=1), and incisional hernia(n=1).

Laparoscopic Repair of Giant Paraesophageal Hernia in the Current Era—Over the study period, significant shifts in the patient cohort undergoing non-emergent laparoscopic repair, the approach to operation and operative details have occurred. (Table 1) Adverse outcomes in the post-operative period did not differ significantly between the two eras, despite the increased comorbid disease burden in the current cohort. (Data not shown) Current era patients were 60% less likely to undergo reoperation in the immediate postoperative period (OR 0.4, 95% CI 0.2, 0.9) but were 2.3 times more likely to require admission to the ICU than in the early era (OR 2.3, 95% CI 1.5, 3.4). This finding reflects the increased prevalence of comorbid diseases in the current patient population. Median post-operative LOS was 3 days (IQR 2-5) and did not differ significantly between the two eras (early era LOS=3; IQR 2-5 versus current era LOS=4; IQR 2-5, p-value=0.62). Need for hospital readmission after discharge (15/201 (7.5%) in the early era versus 37/458 (8%) in the current era; p= 0.9) and rates of postoperative mortality were similar between the two eras (2/202 (1%) versus 9/460 (2%); p=0.52). The most common reason for readmission was thromboembolic complications (6/52; 11.5%).

Factors that May Contribute to an Increased Odds of Adverse Outcome

Post-operative Mortality—All post-operative deaths occurred in patients with one or more of the following characteristics: age ≥ 70 years, BMI ≥35 and age-adjusted CCI≥3. Mortality at 30-days increased significantly with age (age <60 and 60–69 (0%); age 70–79 (0.9%); age 80 and older (7.8%; p<0.001). Post-operative mortality was also associated with urgency of operation. Patients admitted electively for operative repair had a post-operative mortality rate of 0.5% (3/556) compared to 7.5% for patients undergoing urgent repair (8/106).

Major Non-fatal Adverse Outcomes—In multivariate analysis, patients ≥70 years had a 67% increase (OR 1.67; 95% CI 1.1, 2.7) in the odds of major non-fatal adverse outcomes compared to those <70 years of age. Those with age-adjusted CCI ≥3 had a 66% increase (OR 1.66; 95% CI 1.1, 2.6) in odds of major non-fatal adverse outcome. Odds of post-operative leak were increased 3.8 times (OR 3.82; 95% CI 1.2, 12.7) in patients with BMI ≥35.

Post-operative Length of Stay—Patients with CCI ≥3 had a 2.7 times increased odds of a long hospital stay (defined as ≥5 days: OR=2.7; 95% CI 1.9, 3.8) compared to patients with a CCI <3. There was a trend toward an increased odds of a long hospital stay in the current era (OR 1.4; 95% CI 0.96, 2.0, p-value 0.08) compared to the early era which disappeared when

controlled for comorbidities (OR=1.3 for length of stay ≥5 days in the current era; 95% CI 0.86, 1.8, p=0.24).

Symptom Relief and Quality of Life

Recent symptom follow-up was available for 74% of patients (492/662). Median time to follow-up was 30 months (IQR 17-56). There were 170 patients without symptom follow-up (74 are deceased and the remaining 96 declined or were lost to follow-up). Symptom follow-up, validated GERD-HRQoL and SF-36 were more likely to be missing if patients were ≥80 years (p=0.02, p<0.001 and p<0.001, respectively) or had a CCI score of 3 or greater (p=0.01, p=0.01 and p=0.001, respectively). Early era of surgery was significantly associated with missing GERD-HRQoL (p=0.001) and SF-36 (p=0.002) measures.

Symptomatic Relief after Laparoscopic Giant Paraesophageal Hernia Repair— Overall, patients had significant relief of preoperative complaints. (Table 2) The proportion of patients complaining of dysphagia, heartburn, regurgitation, chest and/or abdominal pain, shortness of breath, and aspiration was significantly reduced at current follow-up compared to preoperatively. The proportion of patients complaining of postprandial bloating, however, was unchanged. Of patients complaining of postprandial bloating preoperatively, 33% had persistent symptoms (47/144). In addition, 29% of patients without preoperative bloating (97/337) reported this symptom at their most recent follow-up.

Symptoms and the Association with Radiographic Recurrence—There was no difference in rates of symptomatic complaints between patients with a radiographic recurrence and those without radiographic recurrence. A radiographic recurrence was not associated with increased odds of recurrent symptoms. (Table 3)

Quality of Life: Patient Satisfaction, GERD-HRQoL and SF-36—GERD-HRQoL questionnaires were completed by 489 of 662 patients (74%) at a median time of 30 months from initial operation (IQR 17–56 months). Using the GERD-HRQoL satisfaction scale, patient satisfaction with surgery and current symptoms was high. (Table 4) Radiographic recurrences did not have a significant impact on patient-reported satisfaction (p=0.79) or patient-reported reflux-related quality of life and did not require reoperation in the majority of cases.

Finally, overall patient satisfaction was assessed using the SF-36 instrument. A complete SF-36 was available for analysis in 476 of 662 patients at a median time from initial operation of 30 months (Table 4; IQR 17-56).

Radiographic and Symptomatic recurrence and the Need for Reoperation

Long-term Radiographic Recurrence and Need for Reoperation—Post-operative barium esophagram was available for 92% of patients (607/662). In 67% (445/662) of patients, the esophagram was obtained 3 months or more after operation. Lack of a barium esophagram obtained 3 months or more after operation was significantly associated with age ≥80 years at time of operation (p=0.04) but not with sex, CCI, BMI, or era of operation. Median time to most recent esophagram was 25 months (IQR 12–46 months). Recurrent hiatal hernia was identified in 70 of 445 patients (15.7%) at a median time of 22 months (IQR 11–39 months). Most radiographic recurrences were small (between 11 and 20% re-herniation of the stomach and/or wrap). Radiographic recurrence and significant symptoms leading to a decision to re-operate occurred in 3.2% of patients (21/662) at a median follow-up of 25 months (IQR 17–43 months), driven primarily by the degree of clinical symptoms.

Risk Factors for Radiographic Recurrence and Need for Reoperation for Recurrence—Age <70 at initial operation was associated with significantly increased odds

of radiographic recurrence. Age <70 at initial operation, BMI ≥35, and mesh cruraplasty at initial operation were associated with an increased odds of need for reoperation in crude and adjusted analysis. (Table 5)

Discussion

In this single institution, decade-long series of 662 patients, we demonstrate that laparoscopic GPEH repair is feasible, safe, and provides excellent patient satisfaction and symptom resolution despite an increase in patient comorbid conditions over the study period. Laparoscopic repair of GPEH was successfully accomplished in 98.5% of patients with a post-operative mortality rate of 1.7% and major morbidity of 19%. Thromboembolic complications were a significant source of post-operative morbidity, despite routine use of anti-thrombotic compression stockings and subcutaneous heparin. Patient factors that were predictive of increased risk of post-operative death and significant major adverse events were age ≥70 years, BMI ≥35, and CCI score ≥3 and urgent operation. Symptom relief after laparoscopic repair was excellent, with 89% of patients expressing satisfaction with the surgical result at 30 months median clinical follow-up. Importantly, patients with a limited radiographic recurrence compared to those with no radiographic recurrence were equally satisfied with surgery and reported similar GERD-HRQoL outcomes.

When the current era of operation (July 1, 2003–June 30, 2008) was compared to the early era (January 1, 1997 to June 30, 2003), patients were 50% more likely to have significant age-adjusted comorbidities and 60% more likely to have an underlying pulmonary disease. Despite this, the risk of adverse outcome in the current era was the same as in the early era. Operative time and need for reoperation in the immediate post-operative period were significantly less in the current era, reflecting the experience of the surgical team, on-going efforts to refine the operative approach and perioperative patient care.

The only patient characteristic which was associated with a risk for radiographic recurrence and reoperation on multivariate analysis was age younger than 70 years at initial operation. This association with younger age has not been previously described, but one possible hypothesis for this observation is that younger patients are healthier and more active, thereby exerting greater stress on the hiatal repair. This may be a subpopulation where routine crural reinforcement with mesh can lead to improved long-term durability of the repair. Further studies are needed to confirm this association and test this hypothesis.

Laparoscopic Giant Paraesophageal Hernia is comparable to Open Repair

The operative outcomes, long-term symptomatic relief and freedom from radiographic recurrence after laparoscopic repair of GPEH reported here are similar to the outcomes for open repair as reported in the literature. Our operative mortality of 1.7% compares quite well to mortality rates of 0–3.7% that have been reported by Hashemi, Low and others.[10–12] Interestingly, we found that the operative mortality for elective repair was significantly lower than urgent repair (0.5% versus 7.5%), which contradicts recent studies[13] suggesting that mortality for elective and emergent repairs are not substantially different. In our series, elective repair in the hands of experienced surgeons has significantly better outcomes than urgent repair by the same surgeons. This observation warrants further study to more clearly describe this association.

Our radiographic recurrence and symptom outcomes also compared favorably to the outcomes reported for open repair and contrast with the very high rates of radiographic recurrence published in some series of laparoscopic repair.[7, 10, 14–16]. Hashemi and colleagues, in 2000,[10] were among the first to publish a high-rate of radiographic recurrence in patients undergoing laparoscopic repair (42% radiographic recurrence rate in 27 patients; median time

to barium esophagram 17 months). This sharply contrasted with the 15% radiographic recurrence rate in the open group (median time to barium esophagram 35 months). Symptomatic relief was also worse in the laparoscopic group; 77% of patients reported a good to excellent outcome compared to 88% in their open group. These results should emphasize the need for surgeons to assess their ongoing clinical outcomes and strive for superior outcomes using the surgical approach that works best for their group. In our center, extensive minimally invasive surgical experience and good to excellent results in close to 90% of our patients undergoing laparoscopic repair of their GPEH led to our adoption of this approach in preference over the open approach.

The On-going Debate Regarding Mesh Cruraplasty and Esophageal Lengthening

The use of esophageal lengthening and mesh cruraplasty in repair of GPEH continues to be debated among surgeons and a clear answer does not exist.[7, 17–21] Hiatal herniation is associated with two distinct processes: axial tension caused by proximal migration of the GEJ in the setting of acquired short esophagus; and radial tension exerted on the hiatal orifice as the hernia enlarges.[22] The goal of esophageal lengthening is to eliminate the axial tension exerted on the hiatus by creating an adequate length of intra-abdominal neoesophagus. The goal of mesh cruraplasty is to strengthen the ability of the hiatus to resist radial tension created by the pressure differential between the abdomen and thorax. As such, use of esophageal lengthening and/or mesh cruraplasty is an intraoperative decision and should be made after optimal surgical mobilization of the esophagus and diaphragm. The surgeon then determines the best repair for the patient. The optimal repair may require esophageal lengthening and mesh cruraplasty, one but not the other, or neither.

In our series, use of mesh cruraplasty was not necessary in the opinion of the surgeon in the majority of cases. We believe that two factors are critical to the success of primary crural re-approximation: 1) maintenance of the peritoneal lining over the crura; and 2) complete division of all attachments from the diaphragm to the stomach and spleen. This allows free mobility of the left limb of the crus and facilitates re-approximation without tension. In our experience, we accomplished these the majority of the time and mesh was only required in 13% of cases when the overlying peritoneum had been compromised, leading to exposed muscle fibers of poor integrity or the hiatal opening was unable to be closed without undue tension. The finding in our series that mesh cruroplasty is associated with a significantly increased odds of reoperation for recurrence over time and is not protective against radiographic recurrence reflects the fact that mesh, in our hands, is only used when the crural closure is compromised. Similarly, it may also indicate that the type of mesh and the technical aspects of the cruroplasty are still in evolution and the ideal approach has not been determined.

Conversely, Collis gastroplasty for esophageal lengthening was used in 63% of patients in this series. The majority of our patients had a Type III paraesophageal hernia. Restoring adequate length to the intraabdominal esophagus returns the GEJ to the abdomen and releases the axial tension created by the shortened esophagus, thereby minimizing the axial forces exerted on the hiatal repair. While the use of esophageal lengthening has decreased over time in our series, in our opinion, this is due to the increased experience and success of extended mediastinal mobilization. Extended mobilization may obviate the need for an esophageal lengthening procedure in some patients with mild to moderate shortening or, at least limit the length of the Collis gastroplasty to a shorter segment. This is clearly an important component of the repair and every effort should be made to strive for adequate esophageal length using laparoscopic esophageal mobilization to the maximal degree prior to determining if a Collis gastroplasty is indicated.

Discussion of Study Limitations

This study has several strengths and limitations. Long-term follow-up on this patient population can be difficult to obtain due to the extremes of age and also to the costs of maintaining a clinical outcomes research team. We present mid-term validated patient-reported outcomes in 74% of patients at a median follow-up of 30 months. Radiographic follow-up at least 3 months after operation was available for 67% of patients at a median follow-up of 25 months. While these numbers are comparable to other series,[10, 14, 15, 23, 24] a concerted effort has been made over the past two years to improve our longitudinal care for these patients and clinical pathways, have been instituted at our center to provide routine and standardized follow-up. In spite of these measures, serial time-points were not available for most patients, limiting assessment of the time course for radiographic and/or symptom recurrence.

The degree of missing data for the outcomes measured in this study is also a limitation of the study. When factors associated with missing data were analyzed, we found that patients of who were 80 years or older at the time of operation, those with significant comorbid illness and early era of operation were more likely to be missing follow-up symptom questionnaires and validated quality of life studies. Octogenarians were also more likely to be missing a barium esophagram obtained at least 3 months after operation. This degree of missing data introduces bias into the analysis that must be taken into consideration. For example, the percentage of patients complaining of postoperative dysphagia may be under-estimated by the findings of study given that elderly patients are more likely to experience dysphagia than are younger patients. It is also possible that the increased rate of radiographic recurrence in younger patients is reflective of the higher rate of availability of follow-up barium esophagram in this group rather than a true association with increased risk of radiographic recurrence.

Analysis of preoperative symptoms was also limited by the fact that the majority of these data were derived from retrospective review of existing medical records. While most patients had clear prospective documentation of the presence or absence of symptoms such as reflux, regurgitation, dysphagia, and shortness of breath, other symptoms, such as cough and hoarseness were less well-documented. Important post-operative complaints, such as early satiety, diarrhea and excessive flatulence, were rarely assessed preoperatively. These symptoms can be the source of long-term patient dissatisfaction and warrant further study.

Summary

In the largest series to date, we found that laparoscopic repair of GPEH is technically feasible, associated with good to excellent outcomes in close to 90% of patients, and has a low morbidity and mortality in the hands of experienced surgeons. Patients who are obese, older and who have more comorbid illness are at higher risk for adverse post-operative outcomes, but the majority of such cases can still be accomplished laparoscopically with good results. Decisions regarding esophageal lengthening and mesh cruraplasty are best made at the time of operation related to the specific anatomic considerations of the individual patient. Laparoscopic repair of paraesophageal hernia provides excellent patient satisfaction and symptom resolution, with reoperation rates that are comparable to the best open series.[10, 25]

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Laparoscopic Repair of Giant Paraesophageal Experience: Cohort analysis of early (January 1, 1997 to June 30, 2003) versus current (July 1, 2003–June 30, 2008) experience.

	Overall n=662	Early n=202	Current n=460	Crude OR[a] (95% CI)	p-value
Patient Demographics:	**n (%)**	**n (%)**	**n (%)**		
Male sex	167 (25)	57 (28)	110 24)	0.8 (0.5, 1.2)	0.24
Age ≥70 years	336 (51)	101 (50)	235 (51)	1.0 (0.8, 1.5)[b]	0.8
Obese (BMI ≥35) (n=620)	92 (15)	25 (13)	67 (15)	1.2 (0.7, 1.9)	0.6
Charlson Comorbidity Index ≥3[b] (n=660)	326 (49)	85 (42)	241 (53)	**1.5 (1.1, 2.1)**	**0.01**
Preoperative Hernia Size (%)[c]					
30–49%	280 (42)	78 (39)	202 (44)	referent	0.12
50–74%	87 (13)	23 (11)	64 (14)	1.1 (0.6, 1.9)	
75–99%	148 (22)	52 (26)	96 (21)	0.7 (0.5, 1.1)	
Intrathoracic Stomach	147 (22)	49 (24)	98 (21)	0.8 (0.5, 1.2)	
Preoperative Pulmonary Disease	163 (25)	38 (19)	125 (27)	**1.6 (1.1, 2.4)**	**0.02**
History of Ever Smoking (n=650)	251 (39)	70 (36)	181 (40)	1.2 (0.8, 1.7)	0.32
Preoperative Symptoms					
Chest and/or Abdominal pain (n=655)	353 (54)	102 (51)	251 (55)	1.2 (0.8, 1.7)	0.33
Heartburn (n=650)	431 (66)	118 (59)	313 (70)	**1.6 (1.1, 2.3)**	**0.007**
Dysphagia (n=648)	280 (43)	76 (38)	204 (45)	**1.3 (0.96, 1.9)**	**0.09**
Difficulty Swallowing: (n=637)					
Hard Solids	204 (32)	54 (28)	150 (34)	1.4 (0.9, 2.0)[e]	0.29
Soft Solids	42 (7)	10 (5)	32 (7)	1.6 (0.8, 3.4)[e]	
Liquids	21 (3)	8 (4)	13 (3)	0.8 (0.3, 2.0)	
Regurgitation (n=655)	388 (59)	110 (55)	278 (61)	1.3 (0.9, 1.8)	0.12
Dyspnea (n=650)	273 (42)	72 (36)	201 (45)	**1.4 (1.0, 2.0)**	**0.03**
Bloating (n=634)	195 (31)	57 (29)	138 (32)	1.2 (0.8, 1.7)	0.4
Details of the Operation					
Esophageal Lengthening Procedure (n=647)	408 (63)	171 (86)	237 (53)	**0.2 (0.1, 0.3)**	**<0.0001**
Fundoplication	647 (98)	198 (98)	449 (98)	0.8 (0.3, 2.6)	0.74

	Overall n=662	Early n=202	Current n=460	Crude OR[a] (95% CI)	p-value
Mesh Reinforcement of Crura	88 (13)	35 (17)	53 (12)	**0.6 (0.4, 0.99)**	**0.04**
Conversion to open operation	10 (1.5)	2 (1)	8 (1.7)	1.8 (0.4, 8.4)	0.47
Operative Time >260 minutes[d] (n=630)	182 (29)	85 (42)	97 (21)	**0.4 (0.3, 0.5)**	**<0.0001**

[a] Odds ratio (OR) represents the odds of each variable in the current cohort compared to the early cohort.

[b] Charlson comorbidity index (CCI) adjusted for age.

[c] Percent of stomach within the mediastinum by barium esophagram, preoperative endoscopy or by intraoperative description. Complete intrathoracic stomach was defined as the entire stomach, including the antrum, herniated into the mediastinum

[d] Operation time greater than 260 minutes represents the 75th percentile for operation time for the entire cohort

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Table 2

Paired analysis of the relationship between preoperative complaints and current symptoms

Symptom	Currently present?	Symptom present preoperatively? yes	Symptom present preoperatively? no	Difference in proportion (95% CI)	OR (95% CI)[a]	p-value[b]
Dysphagia						
	yes	76	55	−0.20 (−0.25, −0.14)	0.34 (0.25, 0.47)	<0.0001
	no	160	246			
Heartburn						
	yes	100	27	−0.44 (−0.49, −0.39)	0.1 (0.07, 0.15)	<0.0001
	no	261	138			
Regurgitation						
	yes	28	20	−0.48 (−0.53, −0.43)	0.08 (0.05, 0.12)	<0.0001
	no	261	193			
Chest/Abdominal Pain						
	yes	34	30	−0.42 (−0.47, −0.36)	0.13 (0.09, 0.19)	<0.0001
	no	228	183			
Postprandial Bloating						
	yes	47	97	−0.02 (−0.08, 0.04)	0.92 (0.69, 1.2)	0.53
	no	106	240			
Aspiration						
	yes	2	12	−0.09 (−0.12, −0.05)	0.24 (0.11, 0.45)	<0.0001
	no	51	387			
Shortness of Breath						
	yes	31	29	−0.29 (−0.34, −0.23)	0.18 (0.12, 0.27)	<0.0001
	no	163	243			
Proton Pump Inhibitors						
	yes	161	31	−0.41 (−0.46, −0.36)	0.12 (0.08, 0.18)	<0.0001
	no	249	89			

[a] Odds ratio (OR) and 95% confidence interval (CI) for having a symptom currently if it was present preoperatively

[b] McNemar's chi-square for analysis of paired variables

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Table 3

Comparison of current symptoms between patients with recurrent hernia by barium esophagram and those without recurrent hernia

		Radiographic recurrence?[b]			
Symptom	**Currently present?[a] (n, %)**	**yes**	**no**	**p-value[c]**	**Crude OR (95% CI)**
Dysphagia (n=380)					
	Yes (94, 25%)	15	79	0.13	1.75 (0.89, 3.5)
	No (286, 75%)	28	258		
Heartburn (n=373)					
	Yes (101, 27%)	11	90	1.00	0.92 (0.44, 1.9)
	No (272, 73%)	32	240		
Regurgitation (n=350)					
	Yes (36, 10%)	6	30	0.28	1.65 (0.64, 4.3)
	No (314, 90%)	34	280		
Chest/Abdominal Pain (n=330)					
	Yes (46, 14%)	7	39	0.31	1.58 (0.65, 3.9)
	No (284, 86%)	29	255		
Postprandial Bloating (n=408)					
	Yes (122, 30%)	16	106	0.50	1.24 (0.65, 2.67)
	No (286, 70%)	31	255		
Aspiration (n=318)					
	Yes (11, 4%)	1	10	1.00	0.92 (0.11, 7.5)
	No (307, 96%)	30	277		
Shortness of Breath (n=326)					
	Yes (48, 15%)	7	41	0.31	1.59 (0.65, 3.9)
	No (278, 85%)	27	251		
Proton Pump Inhibitors (n=369)					
	Yes (145, 39%)	16	129	1.00	0.99 (0.51, 1.9)
	No (224, 61%)	25	199		

[a] n=number of patients with current symptom assessment

[b] Analysis includes only those patients with a barium swallow at least 3 months after initial operation and current symptom complaints. If patients required reoperation (including recurrent hernia, treatment of obesity or esophageal cancer), symptom follow-up was censored to the most recent symptoms prior to reoperation

[c]Fischer's exact test for differences in symptoms between patients with and without radiographic recurrence

Table 4

Analysis of the impact of radiographic recurrence on GERD-related and overall patient health status at current clinical follow-up

		Radiographic Recurrence[a]		
	All patients	**Yes**	**No**	
Satisfied with Surgery and Current Symptoms	**n=493**			
yes	**440 (89)**	**37 (90)**	**284 (91)**	**0.79[e]**
no	**53 (11)**	**4 (10)**	**30 (9)**	
	n=489	**n=41**	**n=312**	**p-value**
GERD-HRQoL[b]	1 (0–4)	1 (0–4)	2 (0–6)	0.33[d]
Excellent to Good[c]	438 (90)	36 (88)	279 (89)	0.79[e]
Fair to Poor[c]	51 (10)	5 (12)	33 (11)	
Short-form 36 Health Survey[b]	**n=476**	**n=40**	**n=304**	**p-value**
Physical Component Summary (PCS)	51 (40–57)	54 (48–57)	51 (40–57)	0.12[d]
Mental Component Summary (MCS)	53 (47–56)	53 (49–56)	53 (49–56)	0.62[d]

[a] Includes only patients with current barium esophagram and SF-36 score. Results for patients requiring reoperation were censored at the date of reoperation

[b] Results presented as median (IQR)

[c] GERD-HRQoL scale: excellent (score 0–5), good (score 6–10), fair (score 11–15), poor (score >15); Results presented as n(%)

[d] Two-sample Wilcoxon rank-sum (Mann-Whitney) test

[e] Fisher's exact test for independence

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Table 5

Analysis of preoperative risk factors and operative techniques and the risk of reoperation and radiographic recurrence at any time after operation

	Recurrent hernia by barium esophagram (n= 445)[b]			Reoperation for recurrent hernia or symptoms		
	n (%)	Crude OR (95% CI)	p-value	n (%)	Crude OR (95% CI)	p-value
Overall[a]	70/445 (15.7)			21/662 (3.2)		
Age at initial operation (years)						
Less than 70	44/235 (19)	referent	**0.07**	16/326 (4.9)	referent	**0.01**
70 years or greater	26/210 (12)	**0.61 (0.36, 1.04)**		5/336 (1.5)	**0.29 (0.11, 0.81)**	
Age-Adjusted Charlson Comorbidity Index						
Less than 3 (n=334)	42/239 (18)	referent	0.25	12/334 (3.6)	referent	0.53
3 or greater (n=328)	28/206 (14)	0.74 (0.44, 1.24)		9/326 (2.7)	0.76 (0.3, 1.8)	
Body Mass Index						
BMI less than 35	50/351 (14)	referent	**0.09**	15/528 (2.8)	referent	**0.07**
BMI 35 or greater	15/67 (22)	**1.74 (0.91, 3.3)**		6/92 (6.5)	**2.4 (0.9, 6.3)**	
Preoperative Pulmonary Disease						
None (n=499)	51/337 (15)	referent	0.54	13/499 (2.6)	referent	0.15
Present (n=163)	19/108 (18)	1.2 (0.67, 2.13)		8/163 (4.9)	1.93 (0.78, 4.75)	
Preoperative Hernia Size (%)[c]						
30 up to 50%	28/189(15)	referent	0.60[d]	12/280 (4.3)	referent	0.1
50% up to 75%	10/67 (15)	1.0 (0.46, 2.2)		4/87 (4.6)	1.1 (0.3, 3.4)	
75% up to 99%	17/99 (17)	1.2 (0.6, 2.3)		2/148 (1.4)	0.3 (0.1, 1.4)	
Complete Intrathoracic Stomach	15/90 (17)	1.2 (0.58, 2.3)		3/147 (2.0)	0.5 (0.1, 1.7)	
Type of Fundoplication[e]						
Partial	16/100 (16)	referent	0.89	6/135 (4.4)	referent	0.37
Circumferential	52/337 (15)	0.96 (0.52, 1.77)		15/512 (2.9)	0.65 (0.25, 1.7)	

	Recurrent hernia by barium esophagram (n= 445)[b]			Reoperation for recurrent hernia or symptoms		
	n (%)	Crude OR (95% CI)	p-value	n (%)	Crude OR (95% CI)	p-value
Esophageal Lengthening						
None (n=212)	24/165 (15)	referent	0.65	10/239 (4.2)	referent	0.3
Collis gastroplasty (n=383)	44/272 (16)	1.13 (0.66, 1.94)		11/408 (2.7)	0.63 (0.27, 1.5)	
Mesh Cruraplasty						
None (n=574)	58/387 (15)	referent	0.27	13/574 (2.3)	referent	**0.0007**
Mesh (n=88)	12/58 (21)	1.48 (0.74, 2.97)		8/88 (9.1)	**4.3 (1.7, 10.8)**	
Operation Time						
Time <260 minutes	46/331 (14)	referent	**0.07**	14/480 (2.9)	referent	0.54
Time 260 minutes or more	24/114 (21)	**1.65 (0.95, 2.86)**		7/182 (3.9)	1.3 (0.5, 3.4)	

[a] Analysis was also performed for operative time, preoperative pulmonary function testing, history of peptic ulcer disease or diabetes, post-operative complications (leak, pneumonia, acute renal failure, perioperative hernia recurrence, any need for reoperation in the perioperative period) and no association with risk for reoperation and radiographic recurrence was identified.

[b] Analysis includes only those patients with barium esophagogram. OR=crude odds ratio for reoperation and radiographic recurrence for each confounding variable.

[c] Percentage of stomach within the mediastinum determined by barium esophagography, preoperative endoscopy, or intraoperative description. Complete intrathoracic stomach was defined as the entire stomach, including the antrum, herniated into the mediastinum.

[d] p-value for score test for trend of odds

[e] Two patients with recurrence did not receive a fundoplication at the initial operation (one gastropexy and one Rouxen-Y gastric bypass)