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Outcomes of laparoscopic fundoplication for gastroesophageal reflux disease and paraesophageal hernia

Experience with 1,000 consecutive cases

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Abstract
Background: Laparoscopic fundoplication has become the standard for operative treatment of gastroesophageal reflux disease (GERD).
Methods: We reviewed our experience with 1,000 consecutive patients receiving laparoscopic fundoplication for GERD ($n = 882$) or paraesophageal hernia ($n = 118$) between October 1991 and July 1999. Patients with achalasia and failed fundoplication were excluded from analysis. All the patients were evaluated preoperatively by upper endoscopy, esophageal manometry, and barium swallow. After 1994, 24-h pH monitoring was performed selectively in patients with extraesophageal symptoms and/or those without erosive esophagitis. There were 490 men 510 women in this review. Their mean age was 49 years. Procedures performed were 360° floppy fundoplication ($n = 879$), 360° fundoplication without fundus mobilization (Rossetti) ($n = 22$), 270° posterior fundoplication ($n = 96$), and anterior fundoplication ($n = 2$). Esophageal lengthening procedure (Collis gastroplasty) was performed in combination with fundoplication in 15 patients. In seven patients the treatment was converted to open fundoplication.
Outcomes: The average length of hospitalization was 2.2 days, and 136 patients stayed longer than 2 days. Major complications occurred in 21 patients: esophageal perforation ($n = 10$), acute paraesophageal herniation ($n = 4$), splenic bleeding ($n = 2$), cardiac arrest ($n = 1$), pneumonia ($n = 3$), and testicular abscess ($n = 1$). Additional operations were required to manage the complications in 14 patients (70%): Four of these procedures were performed emergently, and 10 patients underwent reoperation between 6 h and 10 days. There were three deaths, all of which involved elderly patients with paraesophageal hernia. There were 35 late failures requiring reoperation for recurrence of GERD or development of new symptoms: The treatment of 32 patients was revised laparoscopically, and 4 patients required laparotomy. Beyond 1 year (median follow-up period, 27 months), 94% of the reviewed patients were satisfied with their surgical outcome.

Key words: GERD — Laparoscopic surgery — Nissen fundoplication — Paraesophageal hernia

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Gastroesophageal, reflux disease (GERD) is a chronic condition with progressive symptoms. An estimated 35% to 50% of patients with GERD require lifelong medical treatment. Cessation of medication frequently leads to recurrence of symptoms and/or injury to the esophagus, larynx, or tracheobronchial tree [1, 11, 13]. Whereas medical therapy generally is effective at controlling heartburn, it does not correct the mechanical and functional abnormalities that cause reflux. There also are concerns regarding the expense, effectiveness, and side-effect profiles of medications prescribed for the treatment of GERD. Given the choice, many patients prefer surgical correction of the defective antireflux mechanism over pursuing a lifetime of medical therapy [1].

Paraesophageal hernias represent a different clinical problem. These large hiatal hernias constitute less than 5% of all hiatal hernias, but account for most of the hiatal hernia complications. Traditionally, the presence of types 2, 3, and 4 paraesophageal hernias has been an indication for elective surgical repair [4, 5] because the complications may be insidious (e.g., anemia) or immediately life threatening (e.g., strangulation).

Sutured hiatal hernia closure and laparoscopic floppy 360° fundoplication (Nissen) have become the surgical standard for patients with GERD and paraesophageal hernia in the United States. This minimally invasive approach to GERD and paraesophageal hernia has vastly increased the

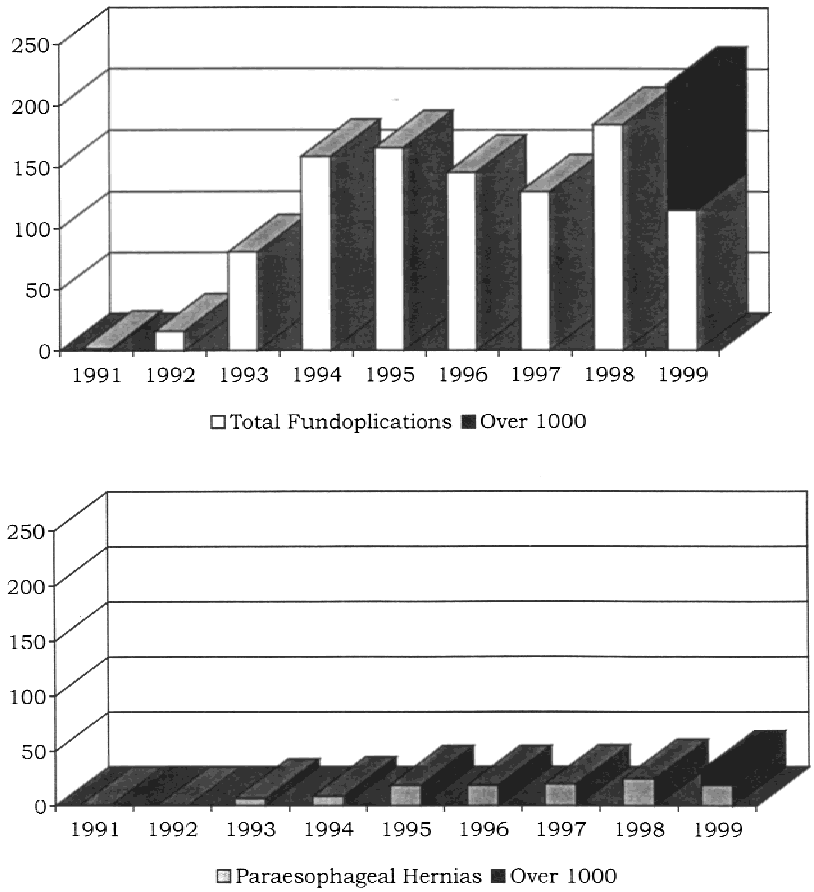

Fig. 1. One thousand laparoscopic fundoplications.

Table 1. Age and gender of patient population (n = 1,000)

	Women n (%)	Mean age (years)	Men n (%)	Mean age (years)
GERD	428 (49)	49 ± 13	454 (51)	45 ± 13
Paraesophageal hernia	82 (69)	65 ± 13	36 (31)	63 ± 13
Total	510 (51)	52 ± 15	490 (49)	46 ± 14

GERD, gastroesophageal reflux disease

popularity of surgical repair, leading to a fourfold increase in the use of this procedure over the past decade. The aim of this study was to review the outcomes of 1,000 consecutive primary laparoscopic fundoplications for GERD and paraesophageal hernia at a university swallowing center.

Patients and methods

Between October 1991 and July 1999, 1,000 consecutive patients underwent primary laparoscopic fundoplication for GERD (n = 882) or paraesophageal hiatal hernia (n = 118) at the University of Utah Hospital (n = 13 patients) or the Emory University Hospital and Crawford Long Hospital (n = 987 patients). Patients with a diagnosis of achalasia or failed fundoplication were excluded from this analysis. There has been a steady increase in the number of laparoscopic antireflux procedures performed at our institutions over the past 8 years (Fig. 1). Paraesophageal hernia repair has grown similarly but at a lower rate.

There were 510 women and 490 men in this study. The mean age was 52 ± 15 years for the women and 46 ± 14 years for the men (Table 1). In patients with GERD, there was an equal gender distribution, and age was normally distributed about a mean in the fifth decade (Fig. 2). In contrast, the mean age of patients with the diagnosis of paraesophageal hernia was 65 ± 13 years, and nearly two-thirds of these patients were women.

Most of the patients with GERD were referred by gastroenterologists for the management of typical reflux symptoms (heartburn, regurgitation, and dysphagia) and/or atypical symptoms (chest pain, cough, hoarseness, and asthma) that were completely or incompletely eliminated with aggressive medical therapy.

Esophagogastroduodenoscopy (EGD) was performed on all patients preoperatively. Patients with Barrett's esophagus had extensive preoperative biopsy (four-quadrant biopsy for each 2 cm of Barrett's esophagus). All histology from other institutions was reviewed at Emory University Hospital when the diagnosis was in doubt, or when a diagnosis of dysplasia had been assigned. Barium swallow was performed on all the patients to assess the size of the hiatal hernia, to determine esophageal length, to identify strictures and diverticula, and to help characterize esophageal motility disorders. Patients with an esophageal stricture were treated with intensive medical therapy and dilated each 1 to 2 weeks preoperatively until a dilator 46 Fr or larger passed easily.

Esophageal motility testing was used on all patients to assess esophageal body and lower esophageal sphincter function. In general, if distal esophageal body peak amplitude was lower than 30 mmHg or if less than 70% of wet swallows induced peristalsis, a partial (Toupet) fundoplication was performed. All other patients received complete (Nissen) fundoplication.

Whereas 24-h ambulatory pH monitoring was performed in all patients before 1994, it was used selectively after 1994 only in patients with supraesophageal reflux symptoms and/or patients without EGD findings of esophageal injury (Savary-Miller class 0-1). The rationale for this approach was reported previously [21].

Gastric emptying studies were used liberally to evaluate reflux patients with normal lower esophageal sphincter manometrics, vomiting, diabetes, prominent gastric symptoms, retained food or bezoar on EGD, or a history of peptic ulcers. Patients with a gastric emptying half-time, that was twice the upper limit of normal, were considered candidates for pyloroplasty or pyloromyotomy at the time of laparoscopic fundoplication.

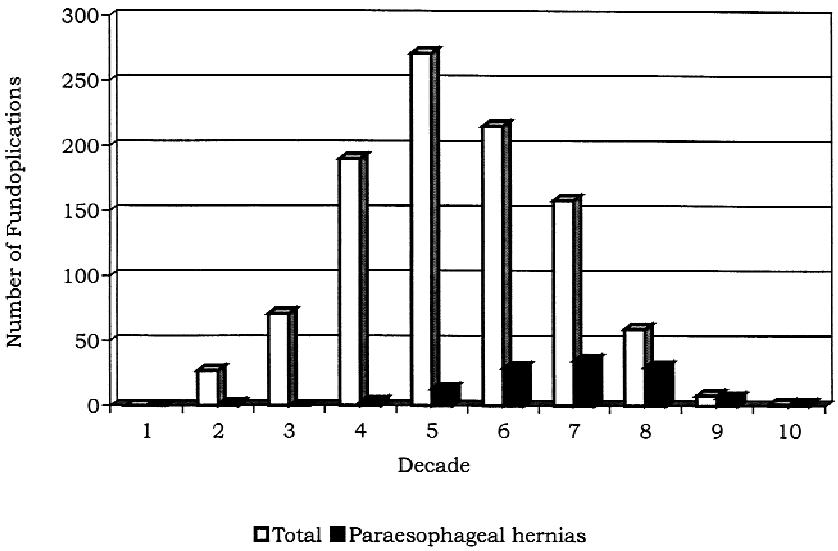

Fig. 2. Age of population ($n = 1000$).

Table 2. Barrett's esophagus and esophageal stricture

	GERD ($n = 882$)	PEH ($n = 118$)	Total ($n = 1000$)
Barrett's esophagus	110	9	119
Stricture	87	3	90
Barrett's esophagus and stricture	13	2	15
Total (%)	210 (23.8%)	14 (11.9%)	224 (22.4%)

GERD, gastroesophageal reflux disease; PEH, paraesophageal hernia

The indications for fundoplication were (a) gastroesophageal reflux incompletely controlled or refractory to standard doses of H_2-blockers, proton pump inhibitors, and prokinetic agents; (b) gastroesophageal reflux controlled with these agents in patients who did not wish to take medications chronically because of young age, medication expense, medication dependence, medication side effects, or quality of life issues; (c) complications of GERD such as Barrett's esophagus, esophageal stricture, or laryngotracheal aspiration; and (d) presence of symptomatic paraesophageal hernia.

Contraindications to laparoscopic fundoplication included severe cardiopulmonary disease, inability to tolerate general anesthesia, uncorrectable coagulopathy, and pregnancy. Patients with previous open procedures about the gastroesophageal junction (e.g., vagotomy and antrectomy) were approached through a laparotomy, but other abdominal operations (e.g., prior cholecystectomy, splenectomy, colectomy) were not considered contraindications to laparoscopic fundoplication.

Surgical procedure

Laparoscopic fundoplication has remained a five-trocar technique, which evolved over 9 years at our institutions [15]. Common to all such operations was complete dissection of the crural diaphragm, mobilization of the gastric fundus away from the spleen and left hemidiaphragm, division of the posterior gastric vessels, mobilization of 2 to 3 cm of the distal esophagus from the mediastinum, sutured closure of the diaphragm (with 1 cm^2 Teflon pledgets after 1995), and performance of a short (<2 cm), floppy (loose around a 56- to 60-Fr dilator), 360° fundoplication. Three interrupted 2-0 silk or braided nylon sutures were used to form the fundoplication, and after 1998, an additional suture was placed between the posterior esophagus and the fundoplication. No sutures were placed between the stomach and the diaphragm after 1996. The 360° fundoplication without mobilization of the fundus (Rossetti-Nissen) was discontinued early in this study when a complication study associated it with excessive dysphagia [7].

A 270° posterior fundoplication (Toupet) was used liberally early in this study in patients with no hiatal hernia. Subsequently (after 1993), it was performed only in patients with impaired esophageal motility, as described earlier. Partial anterior fundoplication (Dor) was performed rarely, and Collis gastroplasty was performed when thorough mobilization of the distal esophagus from the mediastinum did not achieve a 2-cm length of intra-abdominal esophagus without tension.

Pyloroplasty was performed when gastric half-emptying time exceeded 150 min, and cholecystectomy was added for symptomatic cholelithiasis. Highly selective vagotomy was used extremely sparingly, and only after peptic ulcers were documented in a helicobacter-negative, salicylate-negative, gastric acid hypersecretor.

Data acquisition and management

All data were gathered prospectively and entered into a Microsoft Access (Microsoft Corporation, Seattle, WA, USA) database. Preoperative data included patient demographics, barium swallow findings, EGD findings, esophageal motility study, 24-h ambulatory pH monitoring, and gastric-emptying study. Subjective symptom score (SSS) assessment was performed until 1997 with a 5-point Likert scale from 0 to 4: 0, (no symptoms), 1 (infrequent symptoms), 2 (occasional symptoms, sometimes bothersome), 3 (frequent symptoms, often bothersome), and 4 (incapacitating symptoms). This grading system was changed in 1997 to a range of scores from 0 to 3: 0 (no symptoms), 1 (mild symptoms), 2 (moderate symptoms), and 3 (severe symptoms). For purposes of this analysis, pre-1997 scores of 3 and 4 were grouped together because they both represented severe symptoms.

Operative data, length of stay, complications, and follow-up testing results also were recorded in the database. Postoperative questionnaires included additional questions about the patients' overall satisfaction with surgical result, need for medication, and further problems requiring physician assessment and/or intervention. Postoperative scores were obtained in the clinic by the nursing staff 4 to 6 weeks after surgery. All the forms were completed by patients without staff assistance or intervention. Identical symptom assessment forms were mailed to each patient annually, thereafter. From 1994 to 1996, quality-of-life assessment was performed before and after surgery, using the Short form 36 (SF-36). These results have been reported elsewhere [20].

Of the 1,000 patients, 824 completed preoperative symptom assessment questionnaires. The symptom score sheets of the remaining patients were incomplete, lost, or otherwise unusable. Of these 824 patients, 787 (96%) completed one or more postoperative symptom assessment questionnaires. The mean postoperative follow-up period was 26 months, and the longest follow-up assessment occurred at 76 months.

At the time this study was closed (7/1/99), 623 patients (operative date

Table 3. Operative procedures for gastroesophageal reflux disease and paraesophageal hernia

	360° Fundoplication (Floppy Nissen) *n* (%)	360° Fundoplication (Nissen–Rosetti) *n* (%)	270° Posterior fundoplication (Toupet) *n* (%)	180° Anterior fundoplication (Dor) *n* (%)	Addition of Collis gastroplasty *n* (%)
GERD ($n = 882$)	779 (88)	17 (27)	86 (10)	0	9 (1.0)[a]
Paraesophageal hernia ($n = 118$)	100 (85)	5 (4)	10 (8)	3 (3)	6 (5.1)[a]
Total ($n = 1000$)	879 (88)	22 (2)	96 (10)	3 (0.3)	15 (1.5)

[a] $p < 0.01$
GERD, gastroesophageal reflux disease

Table 4. Additional procedures with laparoscopic fundoplication

Laparoscopic procedures	
Cholecystectomy	17
Highly selective vagotomy	2
Excision esophageal leiomyoma	3
Segmental liver resection	1
Pancreatic cyst drainage	1
Incisional herniorrhaphy	1
Preperitoneal inguinal herniorrhaphy	1
Laparoscopically assisted procedures	
Right colectomy	1
Take-down gastrostomy	1

Table 5. Major complications

	Morbidity	Mortality
Procedural		
Esophagogastric perforation	10	3
Acute paraesophageal herniation	4	0
Splenic bleeding	2	
Splenectomy	1	0
Splenorrhaphy	1	
Medical		
Cardiac arrest	1	0
Pneumonia	3	0
Testicular abscess	1	0
Total	21	3

Table 6. Esophagogastric perforations

	Morbidity	Mortality
Intraoperative recognition and repair via open approach	3	1
Injury from esophageal dilator	1	
Delayed recognition and repair	5	2
Injury from esophageal dilator	1	
Clinically occult	2	0
Total	10	3

before 7/1/1998) of the 824 patients with preoperative symptom scores had been followed for more than 1 year after their operation. Of these patients, 548 (80%) continued to return annual postoperative symptom assessment questionnaires.

Statistical analysis

Comparisons of preoperative and postoperative symptom scores used the Wilcoxon signed-rank test. Statistical significance was inferred with $p < 0.001$ for each symptom assessed. Continuous data was reported as the mean ± the standard deviation. Comparisons of continuous data were made with the Student's *t*-test.

Results

Preoperative assessment

In 210 of 882 patients (24%) with GERD, complications were present. Barrett's esophagus (intestinal metaplasia in the columnar esophagus) was present in 110 patients, esophageal stricture in 87 patients, and both conditions in 13 patients with GERD (Table 2). Of the 118 patients with a paraesophageal hernia, Barrett's esophagus was present in 9 patients, esophageal stricture in 3 patients, and both conditions in 2 patients.

Despite the nearly universal use of proton pump inhibitors by our patients, heartburn was experienced by 79% of the patients preoperatively, and scored as severe in 56% of the patients. Whereas one or more laryngopharyngeal reflux symptoms (cough, hoarseness) or reactive airway disease symptoms (e.g., wheezing) were present in 45% of the patients, laryngopharyngeal or asthma symptoms provided the only indication for fundoplication in 6% of the GERD patients.

Operative information

The operative procedure was tailored to preoperative motility findings and intraoperative anatomic assessment (Table 3). Most of the operations (879 patients) performed were floppy 360° (Nissen) fundoplications. A 360° fundoplication without fundus mobilization (Nissen-Rossetti) was performed in 22 patients. A 270° posterior fundoplication (Toupet) was performed in 96 patients and a 180° anterior fundoplication (Dor) in 3 patients. An esophageal lengthening procedure (Collis gastroplasty) was performed in combination with fundoplication in 15 patients. Pyloroplasty was performed in 13 patients and pyloromyotomy in 4 patients. Additional procedures performed at the time of fundoplication are listed in Table 4. Three of the authors performed the 1,000 fundoplications as follows: 778 operations (J.G.H.), 116 operations (G.B), and 106 operations (C.D.S.). The mean operative time was 177 min, (range, 55 min to 7 h and 6 min). The mean length of stay was 2.2 days (range, 1–127 days). Only 136 patients stayed for more than 2 days.

There were seven conversions to laparotomy. Conversion occurred in patients 50, 86, 98, 236, 363, 535, and 633. Five of the seven conversions occurred in the surgeon's first 100 laparoscopic fundoplications. The reasons for conversion were adhesions from prior upper abdominal operations in three patients, esophageal perforation in two patients, and hepatomegaly in two patients.

Table 7. Laparoscopic fundoplication mortality ($n = 1{,}000$)

	Patient 298	Patient 363	Patient 883
Diagnosis	Paraesophageal hernia	Paraesophageal hernia	Paraesophageal hernia
Age (years)	73	68	75
Gender	F	F	F
Complication	Gastric necrosis perforation	Esophageal perforation	Esophageal perforation
Intervention	Postoperative swallow (negative) Reoperation POD 3	Intraoperative repair	Postoperative Swallow (negative) Reoperation POD 10

POD, postoperative day

Table 8. Outcome comparison between gastroesophageal reflux disease and paraesophageal hernia ($n = 1{,}000$)

	No. of patients	Operative duration (min)	Length of stay (days)	Major complications	Mortality
GERD	882	72[a]	2.0[a]	9 (1.0%)[a]	0 (0%)[a]
Paraesophageal hernia	118	217[a]	3.9[a]	12 (10%)[a]	3 (2.5%)[a]
Total	1000	177	2.2	21 (2.1%)	3 (0.3%)

[a] $p < 0.001$
GERD, Gastroesophageal reflux disease

Complications

Major complications occurred in 21 patients (Table 5). Ten patients experienced esophagogastric perforation (Table 6). Two of these perforations were caused by esophageal dilators, and both perforations occurred in the cervical esophagus. One patient underwent immediate neck exploration and repair. The other patient required neck and chest exploration for drainage 24 h later. Two perforations were recognized during esophageal dissection, and both procedures were converted to laparotomy. In another patient, the perforation was recognized with a routine contrast swallow on postoperative day 1. Three patients had a further delay in diagnosis after a normal contrast swallow on postoperative day 1. All three patients were explored within 12 h of diagnosis. The last two patients had radiographic findings of a contained perforation, but no symptoms or signs of perforation. They were successfully treated nonoperatively.

Acute paraesophageal herniation occurred in four patients after episodes of coughing and retching. These patients received immediate reoperation after confirmation of the diagnosis with a contrast swallow. Splenic injury with bleeding that exceeded 200 ml occurred in two patients. In one patient, a retractor caused splenic capsular injury after the operation had been converted to laparotomy for hepatomegaly. This injury required splenectomy. The second splenic injury was a capsular tear found on reexploration. Bleeding from this injury was controlled with Avitene. One patient had a cardiac arrest from an intraoperative arrhythmia and was successfully resuscitated without further event. A testicular abscess developed in one neurologically impaired patient secondarily to prolonged urethral catheterization. Three patients had a protracted hospital stay because of pneumonia. Additional operations were required to manage complications in 14 patients (70%): 4 performed emergently and 10 performed 6 h to 14 days later.

Mortality

The three deaths in this series occurred in cases 298, 363 and 883 (Table 7). All three patients were elderly female patients (ages 68, 73, and 75 years, respectively) with paraesophageal hernias. Two patients had esophageal perforation, and one had gastric perforation. In the first patient, the esophageal perforation was recognized intraoperatively, so laparotomy and esophageal repair were performed at the first procedure. This patient had a protracted hospital course, with a 127-day hospitalization and subsequent discharge to a nursing home where she died.

The second patient who died had an uneventful postoperative hospital course, including a contrast-swallowing study before discharge, which showed no evidence of a leak. On postoperative day 9, she began to have chest pain after strenuous physical activity. She was brought to the emergency room on postoperative day 10 in septic shock. A chest computed tomography (CT) scan followed by endoscopy established the diagnosis of distal esophageal perforation. Despite immediate thoracotomy and repair, she succumbed to sepsis in the next 24 h.

The third patient who died developed an acute abdomen on postoperative day 3 after eating a large meal. Exploratory laparotomy showed a perforation in the greater curvature of the stomach, which was caused by either operative trauma or perforation of a Cameron's ulcer in her previously incarcerated stomach. Despite repair of the stomach, she died on postoperative day 11 from multiple system organ failure.

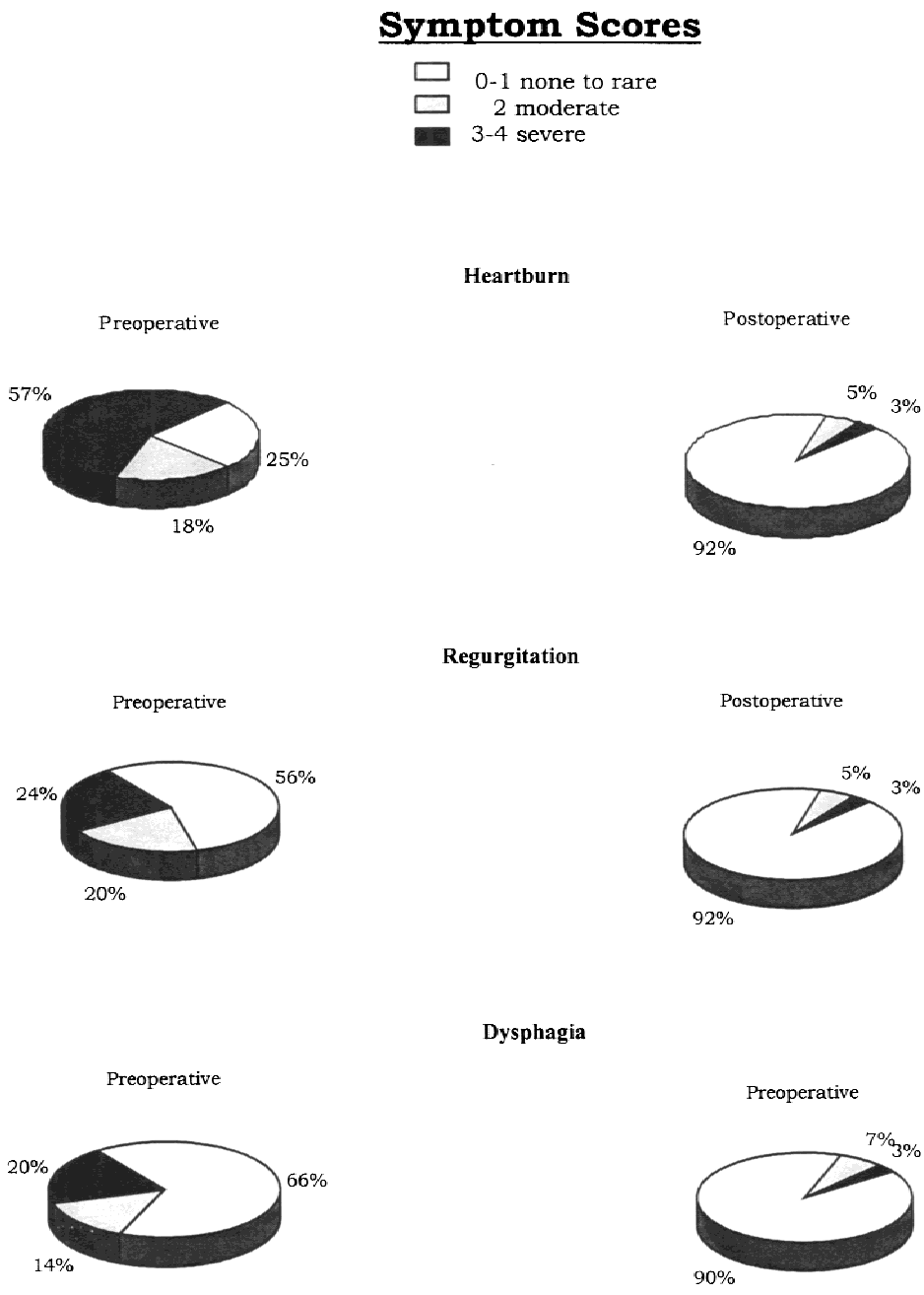

Fig. 3. Symptomatic outcomes after laparoscopic fundoplication (minimum follow-up period, 1 year).

Comparison of operative result as functions of preoperative diagnoses

Paraesophageal hernia repairs were significantly more difficult than fundoplication in patients with GERD. The duration of the operation was 217 min in individuals with paraesophageal hernia and 172 min in patients with GERD ($p < 0.001$). Collis gastroplasty was necessary more frequently in patients with paraesophageal hernia than in patients with GERD (5.1% vs 1.0%; $p < 0.01$) (Table 3). The length of hospitalization was greater for patients with paraesophageal hernia than for patients with GERD (3.9 vs 2.0 days; $p < 0.001$). Complication and mortality rates also were significantly higher in patients with paraesophageal hernia (10% and 2.5%, respectively) than in patients with GERD (1.0% and 0%, respectively) ($p < 0.001$) (Table 8). Reoperation for fundoplication failure was more frequently required after laparoscopic fundoplication for GERD than for paraesophageal hernia (4.2% vs 1.7%; $p < 0.01$).

Outcome assessment

Subjective assessment of symptoms, quality-of-life assessment (using the SF-36), and global satisfaction were the three principal measures of outcome assessment in this study. Early in our experience, as a quality control measure, effectiveness of fundoplication was determined by comparing pre- and postoperative 24-h pH studies [19]. These studies demonstrated the elimination of excessive reflux by 24-h

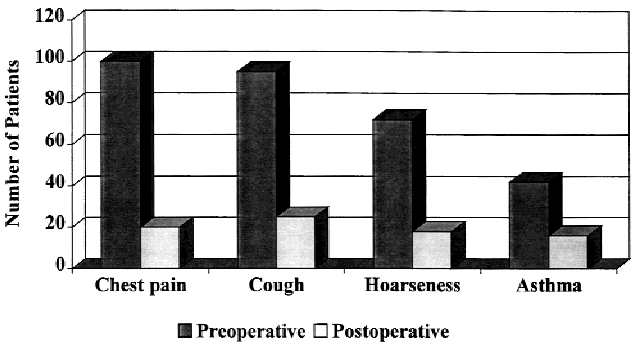

Fig. 4. Frequency of severe extraesophageal symptoms.

ph probe evaluation in 94% of patients after fundoplication, with similar symptomatic success using SSS assessment.

Of all patients with Subjective Symptom Scores (SSS) grouped together and followed for more than one year, 92% reported elimination of heartburn or rare symptoms (SSS 0-1). A similar number reported freedom from dysphagia and regurgitation (Fig. 3). Most of the patients with severe extraesophageal symptoms obtained symptom relief, but not all symptoms were equivalently responsive (Fig. 4). Although it appears that asthmatics had the poorest response to fundoplication, symptom improvement was significant, and more than 70% of those previously steroid dependent were able to discontinue the use of steroids postoperatively [17].

When the subjective symptom scores of individual patients were compared before and one year or greater after operation (Table 10), heartburn was shown to be improved or cured in 94% of patients and unchanged or worsened in 6% of patients. A similar success rate was seen with regurgitation, with improvement or cure in 95% of patients and unchanged or worsening symptoms in 5% of patients. Dysphagia was improved or cured in only 81% of patients, unchanged in 14% of patients and worsened in 4% of patients. Comparing extraesophageal symptoms revealed a less satisfactory outcome with improvement or cure rates.

More than 1 year after surgery, 85 (16%) of the patients reported the use of antacids. H_2-blockers, or proton pump inhibitors. Dyspeptic symptoms were the indication for medical therapy in most of the patients , and the response to medical therapy was rarely complete.

In terms of satisfaction with surgical outcome, 97% of the patients were satisfied 6 weeks postoperatively, surgical outcome, and 96% of patients were satisfied after 1 year. Beyond 2 years, 94% of the patients were satisfied with their decision to have a laparoscopic fundoplication (median follow-up period, 27 months).

Fundoplication failure requiring reoperation

Fundoplication revision for anatomic failure was performed in 39 patients [6]. Four of these operations were performed during the initial hospitalization, all for acute recurrence of hiatal hernia. Diaphragmatic stressors (retching, −3; straining to urinate, −1) caused all the acute recurrences. All four acute recurrences were approached laparoscopically, and one was converted to laparotomy because of gastric incarceration.

Table 9. Reoperation for fundoplication failure

Causes of failure	Laparoscopic fundoplication $n = 39$ (%)
Transdiaphragmatic fundoplication herniation	29 (74)
Slipped/twisted fundoplication	4 (10)
Fundoplication too tight	3 (8)
Esophageal motility disorder	2 (5)
Fundoplication disruption	1 (3)

Reoperation for recurrence of GERD symptoms or development of new symptoms was required in 35 patients between 6 weeks and 4 years after laparoscopic fundoplication. Evaluation of all symptomatic patients included barium swallow and EGD. Gastric-emptying studies were performed liberally, and esophageal motility was performed in all patients before reoperation. Of these reoperations, 32 were performed laparoscopically, with three patients requiring laparotomy. The anatomy of failure in 25 patients (71%) was herniation of the intact fundoplication through the hiatus. In four patients, the Nissen fundoplication slipped onto the stomach, one with associated herniation of the fundoplication. Three fundoplications were judged to be too tight because postoperative dysphagia and fundoplication narrowing observed on barium swallow did not resolve after 3 to 6 months. These patients were revised to a posterior 270° (Toupet) fundoplication. One fundoplication was found to be completely disrupted, and another was partially disrupted and slipped. In two patients, ineffective esophageal peristalsis developed postoperatively, associated with severe dysphagia in both cases. This problem was addressed with laparoscopic cardiomyotomy (Heller) and posterior partial (Toupet) fundoplication (Table 9). Dysphagia resolved in both patients, but one developed moderate gastroesophageal reflux postoperatively. In addition to these 39 procedures, one patient with severe medically refractory dumping syndrome was treated with antrectomy and Roux-en-Y gastrojejunostomy 2 years after fundoplication.

Discussion

Laparoscopic fundoplication has become the most common operation performed currently for GERD and paraesophageal hernia. The outcomes from these procedures have been equivalent or better than those from open fundoplication for these conditions [2, 8, 9, 12, 19, 22] with rare exception [3]. To date, this study represents one of the largest experiences with laparoscopic fundoplication.

In this study, outcome assessment was performed primarily with subjective symptom assessment and patient satisfaction assessment. It has been said that symptomatic assessment may not accurately reflect the status of the antireflux valve and hiatal hernia repair because patients with damaged repairs may be asymptomatic, and symptomatic patients may have intact repairs. Although postoperative anatomic and physiologic assessment may provide the best assessment of the antireflux valve, it is impractical, inconvenient, and costly to perform these studies routinely in such a large population. Furthermore, it is unlikely that any

Table 10. Comparison of pre- and postoperative symptoms in individual patients

Symptom	Preoperative (*n*)	Improved or cured *n* (%)	unchanged *n* (%)	worsened *n* (%)
Heartburn	480	452 (94)	14 (3)	14 (3)
Regurgitation	304	289 (95)	12 (4)	3 (1)
Dysphagia	308	248 (81)	47 (15)	13 (4)[a]
Chest pain	312	235 (76)	51 (16)	26 (8)
Cough	300	231 (77)	53 (18)	16 (5)
Hoarseness	256	205 (80)	39 (15)	12 (5)
Asthma	111	71 (64)	33 (30)	7 (6)

[a] New onset postoperative dysphagia remained in 3.3% of patients at 1 year or greater follow-up

intervention, medical or surgical, will be indicated in the asymptomatic, satisfied patient with fundoplication disruption. Only in patients with Barrett's esophagus or those who have ulcers or anemia associated with a hiatal hernia recurrence would one be tempted to recommend reoperation in the absence of symptoms. Nevertheless, the performance of postoperative 24-h pH may be justified as a quality assurance mechanism in research trials and as a means of assessing postoperative reflux symptoms, especially if anatomic failure is not demonstrated with EGD or barium swallow. Anatomic assessment of the postoperative esophagus with an EGD is mandatory in patients with Barrett's esophagus. It is complemented by a barium swallow in patients with recurrent or new postoperative foregut symptoms.

In this study, laparoscopic fundoplication improved or cured typical symptoms of heartburn in 94% of the patients, regurgitation in 95% of the patients, and dysphagia in 81% of the patients. New onset dysphagia lasting more than 1 year postoperatively was reported in 3.3% of the patients. Laparoscopic fundoplication improved or cured the atypical symptoms of hoarseness in 80% of the patients, cough in 77% of the patients, chest pain in 76% of the patients, and asthma in 64% of the patients up to 6 years postoperatively. Because the improvement of atypical symptoms is less than uniform, one must be extremely honest in preoperative discussions with patients who have primarily atypical symptoms. As demonstrated elsewhere, a preoperative response to proton pump inhibitors was the only effective means of predicting improvement or elimination of atypical symptoms with laparoscopic fundoplication in patients who had an abnormal 24-h pH study [16].

Despite less than uniform control of atypical symptoms, 94% of all the patients were satisfied with their surgical outcome 2 to 5 years postoperatively. This high rate of satisfaction is similar to that reported by others [3]. High satisfaction levels may be reflected best in studies that have looked at objective measures of life quality before and after laparoscopic fundoplication. Two recent studies, using the SF-36 have demonstrated normalization of many parameters of poor life quality after successful laparoscopic fundoplication [14, 19].

This study represents an update of our experience with 300 consecutive laparoscopic fundoplication patients reported several years ago [8]. The outcomes reported here are not dramatically different from those reported earlier. It appears that the number of patients with severe heartburn preoperatively has decreased, but this merely reflects a different method of symptom reporting. Previously, we asked patients to score their symptoms as they were before proton pump inhibitors were started. After 1996, however, we asked patients to score their symptoms as they were at the time of the initial clinic visit. As might be expected, a greater proportion of patients in this study reported no heartburn while on proton pump inhibitors, as compared with the earlier report. Those who believe that fundoplications lose their effectiveness over time might expect to see a return of preoperative symptoms with longer follow-up periods, but postoperative symptom scores and satisfaction rating decreased very little between these two reports. Also, the failure rate might be expected to grow with time, but the percentage of patients requiring a revision has grown very modestly from 3.3% to 3.9% over the interim between studies.

A review of 3,070 laparoscopic fundoplications for GERD from 22 centers was published recently [22]. In this review, mean or median operating times were 30 to 186 min, and conversion rates were 0% to 15%. Our operating time was at the long end of this range, and our conversion rate was at the low end, reflecting complete meticulous dissection and the participation of surgical trainees in most of the procedures. The complication rate in the large review ranged from 2.3% to 26%, depending on the definition and classification of complications. Three mortalities were reported in these 3,070 patients. In this analysis, patients with paraesophageal hernia were largely excluded, accounting for the low morbidity and mortality rate reported. In contrast, the inclusion of elderly patients with paraesophageal hernia in any study will increase the rate of complications [18, 23].

For the 1,000 patients reported in this study, most of the complications occurred in patients with paraesophageal hernia, as compared with GERD (10% vs 1%, respectively) and all three mortalities occurred in patients with paraesophageal hernia. This difference reflects significant differences between patients with GERD and patients with paraesophageal hernia as well as the increased complexity of laparoscopic paraesophageal hernia repair. The mean age of patients with paraesophageal hernia was 15 years greater than the mean age of patients with GERD, and the number of comorbities was greater. In addition, the mean operative duration was 45 min longer for paraesophageal hernia repair and hospitalization was 1.9 days longer than for GERD. Because of these differences, a number of experts have questioned the application of laparoscopy to paraesophageal hernia. As we have achieved more experience with this technique, complications have decreased significantly. In addition, the failure rate of laparoscopic fundoplication for paraesophageal hernia has been no higher than that seen for

GERD [6]. Once considerable experience is gained with laparoscopic fundoplication for GERD, we believe that laparoscopic paraesophageal hernia repair is a reasonable next step.

Although the long-term durability of laparoscopic antireflux procedures has yet to be determined fully, the midterm data (2 to 5 years) suggest that the success of laparoscopic fundoplication is equivalent to that reported with open fundoplication or better [2, 9, 10, 22]. Follow-up evaluation of this 1,000-patient cohort for 10 to 20 years is planned.

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