

Long-Term Outcomes After Laparoscopic Antireflux Surgery

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OBJECTIVES: We studied the long-term outcomes of laparoscopic antireflux surgery (LARS) and the factors that determine it, as neither has been previously well established.

METHODS: From September 1993 (start of our program) to September 1999, 441 patients underwent LARS. Preoperative symptoms and the results of esophageal functional studies as well as details of the operation and follow-up were recorded prospectively in our database. In 2004, with the help of a private investigator, we were able to contact 288 (65%). There were no differences in presentation profiles of those patients contacted and those we could not.

RESULTS: At a median follow-up of 69 months, individual symptoms, among those who had it preoperatively, were as follows: heartburn (N = 282) improved in 254 (90%) and resolved in 188 (67%); regurgitation (N = 258) improved in 238 (92%) and resolved 199 (70%); dysphagia (N = 123) improved in 96 (78%) and resolved in 76 (62%); cough (N = 119) improved in 82 (69%) and resolved in 48 (40%); and hoarseness (N = 106) improved in 73 (69%) and resolved in 50 (47%). Univariate regression analysis showed that the presence of heartburn ($P = 0.02$), male gender ($P = 0.03$), and younger age ($P = 0.04$) predicted symptom resolution, whereas preoperative dysphagia ($P = 0.03$), airway manifestations ($P = 0.03$), bloating ($P = 0.04$), and defective esophageal motility ($P = 0.08$) were negative predictive factors. By multivariate analysis, male gender, dysphagia, and age remained significant ($P < 0.05$). Seven patients (2%) developed a new onset of dysphagia; 32 patients (11%) developed new or increased diarrhea and 27 patients (9%) developed bloating postoperatively. One hundred nineteen patients (41%) were taking some form of antacid medication; 66 (23%) patients were using PPIs and 10 (3%) had undergone reoperation.

CONCLUSION: LARS provides effective long-term relief of GERD. Younger patients, men, and those without dysphagia are predictors of superior outcomes.

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INTRODUCTION

Gastroesophageal reflux disease (GERD) is one of the most common gastrointestinal disorders in the United States, with up to 10% of the population experiencing symptoms daily and 50% experiencing symptoms monthly (1, 2). In most instances, the symptoms are relatively easy to control with diet and/or changes in body position, quality of food ingested, and other modifications of daily living. When GERD's symptoms become troublesome or when complications develop, patients are often offered therapy. The mainstays of therapy today are proton pump inhibitors (PPIs) and/or an antireflux procedure. The latter has become more acceptable for patients since the introduction of laparoscopic antireflux surgery (LARS). The short-term outcomes of LARS are quite good, with 85–95% of patients experiencing excellent control of GERD symptoms (3, 4), but two recently conducted long-term studies

in unselected patients have suggested that these good early results erode with time (5, 6).

There are very few reports of long-term results of LARS, and none have analyzed factors that if used to select patients for operation may result in better long-term outcomes. We have been performing a high volume of LARS for more than a decade, and have thus acquired a large cohort of prospectively followed patients. Since the start of our program, our philosophy has been based on three principles: very thorough workup of every patient (which yielded a rich set of objective measures in these individuals); a careful selection of patients (based on our determination that in addition to objective demonstration of reflux these patients understand and accept the rationale and risks of an operation and are willing to undergo it); and the performance of a highly structured and standardized operation, which is meticulously performed. We sought to determine how the application of these

three principles influenced the long-term control of GERD after LARS in these selected patients. Our study was also designed to address two other issues that can potentially result from LARS. First, we determined who, among our patients, had developed new and different symptoms, a factor that has consistently been underestimated and/or reported in previous publications. Second, we sought to determine factors that may predict outcomes.

MATERIALS AND METHODS

Study Population

In 2003, we identified 441 patients who had a primary LARS for GERD performed at the University of Washington between September 1993 and September 1999. These dates were chosen to obtain long-term follow-up (at least 4 yr between their operation and date of contact) in each patient. Patients operated on because of a paraesophageal hernia or failed prior antireflux procedure were not included.

Method of Contact

We attempted to contact patients for this study in three different ways. First, a letter was sent to each patient inviting them to participate in this study (156 patients were contacted). Second, we attempted to contact by phone using an internal medical center database (77 patients contacted). Third, we hired a private investigator who attempted to determine the most recent whereabouts of each patient (55 patients contacted). In the end, 288 patients (65%) were contacted and comprise the study population.

Preoperative Assessment

Each patient was evaluated before surgery with a comprehensive workup to establish the diagnoses of GERD, its severity, and relevant anatomic features. This evaluation included a GERD symptom questionnaire (288 patients), upper endoscopy (288), upper gastrointestinal series (268 patients), manometry (266 patients), and 24-h pH monitoring (259 patients). These data were prospectively entered into a database.

Symptom Questionnaire

The questionnaire asked participants to indicate how often they experienced eight commonly reported GERD symptoms. These symptoms were heartburn, regurgitation, dysphagia for solids, chest pain, bloating, hoarseness, diarrhea, and coughing. The questionnaire also asked participants to indicate their primary GERD symptom, in other words the symptom that had the greatest severity and impact on quality of life.

Each symptom was scored in terms of their current frequency and severity. Frequency data were coded on the following scale (0–4): 0 = never, 1 = once a month, 2 = once a week, 3 = once a day, and 4 = several times per day. A reported symptom frequency between scores was rounded up

(*e.g.*, heartburn 3 times per week would be scored as a “3”). At the time of contact for this study, we administered a symptom questionnaire similar to the one administered preoperatively to each patient. Severity data were coded on a 10-point visual analog scale, with 1 meaning “mild” and 10 “most severe.” The severity scale was added to the postoperative questionnaire to better elucidate the impact of each symptom on the patient’s subjective quality of life. We asked several additional questions in the long-term follow-up questionnaire to better characterize the long-term outcome of LARS. Patients rated the success of the operation as excellent, good, fair, and poor. We determined which patients were currently taking antacid medications, and the reason for restarting them. We also investigated details about endoscopic procedures or reoperations performed after LARS.

MANOMETRY. Prior to 2002, a water-perfused 8-channel catheter (4 radial ports at the same level and 4 separated by 5 cm intervals; Medtronic, Shoreview, MN) was used to assess esophageal pressures with the patient in the supine position. The lower esophageal sphincter (LES) was examined with four radial ports. A station pull-through measurement of the LES pressure determined the characteristics of the sphincter. Postoperative studies since 2002 used a solid-state catheter with circumferential transducer (Sandhill Scientific Inc, Highlands Ranch, CO), with the same technique. The LES pressure was averaged over a series of three respiratory cycles. The peristaltic pump of the esophageal body was assessed over a minimum of 10 episodes of deglutition with 5 cc aliquots of water. The upper esophageal sphincter (UES) location, pressure, and relaxation were measured with the four radial ports before completion of the procedure.

TWENTY-FOUR-HOUR ESOPHAGEAL PH MONITORING. Ambulatory 24-h pH monitoring was performed using a dual probe catheter. The distal probe was located 5 cm above the manometrically determined LES. The proximal probe was located 10 cm above the distal probe. A portable digital data logger (Medtronic Medical Inc., Shoreview, MN) was used to record pH fluctuations, while the patient recorded symptoms in an event diary. All data were downloaded and analyzed by a computer program. Abnormal acid exposure was defined as a pH <4 more than 1% of the total time in the proximal channel and more than 4% in the distal channel, or a DeMeester composite score >14.7.

Procedure Selection

A laparoscopic Nissen fundoplication was the procedure of choice. In 19 patients with ineffective esophageal peristalsis, we chose to perform a partial posterior fundoplication (Toupet fundoplication). Our use of a partial fundoplication decreased throughout the study period, so that toward the end of it only those with severe impairments in motility (aperistalsis) received a partial fundoplication.

Definition of Operative Success

For the purposes of this study, we defined operative success in two ways. The first was complete resolution, meaning a complete absence of the presenting symptom at the time of our study. The second was symptom improvement, which was defined as a reduction in the symptom frequency score from preoperative values (*e.g.*, pre-op score of 3 and a follow-up score of 2) and the patient's confirmation that indeed the symptom was less severe than before operation.

Statistical Analysis

Specialized software was used for statistical analysis (SPSS version 13.0, SPSS Inc, Chicago, IL). Descriptive statistics are presented as percentages or mean \pm standard deviation (SD). The χ^2 or Fisher's exact test were used for comparing proportions. Logistic regression were used for univariate and multivariate analysis to identify factors associated with resolution of the primary presenting symptom. We take $P < 0.05$ as statistically significant.

The institutional review board at the University of Washington approved this study, HSD# 03-6767-E 01.

RESULTS

There were 288 patients (147 [51%] men and 141 [49%] women) with a median follow-up of 69 months (range 48–116 months). At the time of surgery, the median patient age was 47 yr (13–81 yr).

Initial Patient Presentation

The presenting symptoms before operation are shown in Table 1. Heartburn was the most common symptom, as well as the most common primary presenting symptom. One hundred fifty-two patients (53%) presented with some form of respiratory symptom (cough, hoarseness, wheezing, etc.). Objective presenting characteristics are included in Table 2. All 288 patients had either abnormal pH monitoring and/or esophagitis prior to surgery.

Table 1. Presenting and Primary Symptoms Among 288 Patients

	Presenting Symptom	Primary Presenting Symptom
Heartburn	260 (90%)	213 (74%)
Regurgitation	193 (67%)	20 (7%)
Dysphagia	123 (43%)	17 (6%)
Abdominal pain	64 (22%)	
Chest pain	86 (30%)	10 (3%)
Bloating	41 (14%)	
Nausea	17 (6%)	
Cough	88 (31%)	11 (4%)
Hoarseness	63 (22%)	10 (3%)
Aspiration	47 (16%)	2 (<1%)
Odynophagia	47 (16%)	
Sore throat	25 (9%)	4 (1%)
Laryngitis	22 (8%)	
Wheezing	13 (4%)	1 (<1%)

Table 2. Objective Presenting Characteristics

Condition	N Patients or Mean (% or \pm SD)
Esophagitis	168 (58%)
Barrett's esophagus	51 (18%)
Hiatal hernia	160 (56%)
DeMeester score	78.2 \pm 71.2
Distal exposure time	21.2 \pm 20.7
LES pressure (mmHg)	12.8 \pm 8.8
Ineffective esophageal motility	37 (13%)

Symptom Control

The individual symptom improvement and/or resolution at long-term follow-up is depicted in Figure 1. At 69 months, the majority of patients maintained improvement or resolution of heartburn (90%), regurgitation (92%), and dysphagia (75%) when compared to before LARS. The results were less satisfactory in patients with extraesophageal symptoms such as hoarseness (69%) and cough (69%). The average symptom severity of persistent GERD symptoms at long-term follow-up was 4.1 (on a 10-point scale). The mean symptom severities for individual persistent symptoms were as follows: heartburn 4.1 \pm S.D 2.2 (N = 94, 33%), regurgitation 4.3 \pm SD 2.6 (N = 59, 20%), dysphagia 4.7 \pm SD 2.7 (N = 67, 23%), cough 3.9 \pm SD 2.5 (N = 71, 25%), and hoarseness 4.3 \pm SD 4.9 (N = 56, 19%). Fifty-eight patients with recurrent heartburn had postoperative pH monitoring, and 13 (22%) had abnormal results.

When asked to rate the success of their operation, 174 patients (60%) rated it as "excellent," 65 patients (23%) rated as "good," 21 patients (7%) as "fair," and 28 patients (10%) rated as "poor." When asked if they were happy with their decision to have the operation, 260 patients (90%) said "yes" and 28 patients (10%) said "no."

Predictors of Primary Presenting Symptom Improvement

Using primary symptom improvement as our definition of "success" (see Methods), we found through univariate analysis that presentation with heartburn, and/or absence of respiratory symptoms were both significantly associated with improvement of the patient's primary presenting symptom (Table 3). In addition, there was a trend toward older patients (at the time of surgery) being less likely to have symptom improvement (OR 1.03, $P < 0.07$). Multivariate analysis revealed that only the presence of heartburn as the primary presenting symptom predicted primary symptom improvement ($P = 0.008$).

Predictors of Primary Presenting Symptom Resolution

Using primary symptom resolution (complete) as our definition of "success" (see Methods), we found through univariate analysis that male gender, presentation with heartburn, and/or absence of respiratory symptoms, bloating, and dysphagia on presentation were all significantly associated with complete resolution of the patient's primary presenting symptom

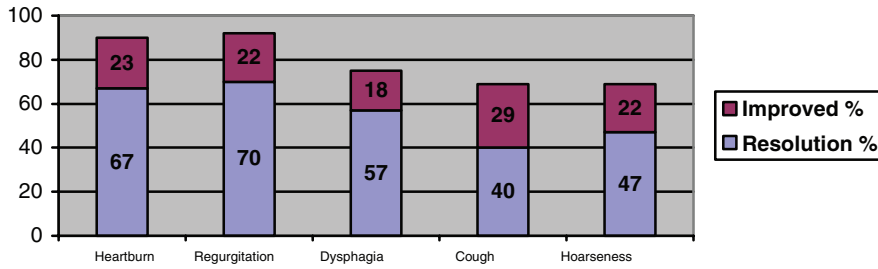


Figure 1. Symptoms improvement and resolution after LARS among those presenting with the symptom.

(Table 3). The older the patient at the time of surgery, the less likely (OR 1.05, $P < 0.05$) it was for the primary symptom to resolve. Also, the longer it had been since the operation was performed, the more likely that the presenting symptom remained resolved (OR 0.96, $P = 0.02$).

Multivariate analysis revealed that male gender remained a predictor of a successful operation. Dysphagia before operation, shorter time since operation, and advanced age were negative predictors of a successful operation (Table 4).

Recurrence

The majority of the patients interviewed for the study (59%) were not currently taking any antacid medications, whereas 23% were taking prescription antacids and 18% were taking nonprescription/over-the-counter (OTC) antacids. Of the patients taking some form of antacids at the time of follow-

up (41% of all patients interviewed), over two-thirds (71%) were taking the medication for GERD-related symptoms (this proportion was similar for those on antisecretory medications and OTC meds). Thus, 27% of all study participants were taking antacid medication (PPI or antacids, prescribed or not) for symptoms of GERD at long-term follow-up. In addition, of those patients who were on medications at the time of follow-up, 81% considered their symptoms under better control than before operation, whereas among those who were not taking medications at the time of follow-up, 95% considered their symptoms under better control than before operation.

Ten patients (3%) have required reoperations. Two were for acute complications: one for gastric perforation (postoperative day #3) and another for acute herniation of the fundoplication (postoperative day #3). The other eight patients with reoperation had a revision Nissen fundoplication for chronic

Table 3. Risk Factors for Symptom Improvement and Resolution

Risk Factor	Category	Primary Symptom Improvement (%)	P Value	Primary Symptom Resolution (%)	P Value
Operation	Nissen	88	0.6	68.8	0.6
	Toupet	84		63.2	
Gender	Male	91	0.11	74.1	0.03
	Female	85		62.4	
Esophagitis	Yes	86	0.3	67.8	0.9
	No	90		68.3	
Barrett's	Yes	88	1	68.6	0.97
	No	88		68.4	
Hiatal hernia	Yes	87	0.13	66.7	0.2
	No	94		74.6	
DeMeester score >50	Yes	89	0.9	66.9	0.8
	No	88		68.4	
Distal exposure time >4%	Yes	89	0.11	68.4	0.5
	No	79		62.1	
Ineffective esophageal motility	Yes	82	0.2	54.5	0.08
	No	89		69.8	
Heartburn	Yes	91	0.01	72.3	0.02
	No	80		57.3	
Dysphagia	Yes	89	0.8	60	0.03
	No	88		72.9	
Primary symptom: respiratory	Yes	75	0.02	50	0.03
	No	90		70.4	
Bloating	Yes	87	0.9	55	0.049
	No	88		70.6	
Abdominal pain	Yes	92	0.3	64.1	0.4
	No	87		69.6	

Table 4. Predictors of Primary Presenting Symptom Resolution, Multivariate Analysis

	Odds Ratio	95% CI	P Value
Dysphagia	2.17	1.18–3.98	0.01
Male	0.52	0.29–0.94	0.03
Age	1.03	1.01–1.05	0.04
Date of surgery	1.26	1.01–1.58	0.04

Variables included in analysis: type of surgery—Nissen versus Toupet; esophagitis; hiatal hernia; Barrett's esophagus; LES pressure; peristalsis >80%; manometry; ineffective esophageal motility; DeMeester score; DeMeester score >50; % exposure time; % exposure time upright; heartburn; bloating; abdominal pain; respiratory symptoms as primary presenting symptom; presence of respiratory symptoms.

problems: either dysphagia (N = 1) or recurrent GERD (N = 7). One patient subsequently underwent a gastrectomy for recurrent GERD after failure of the re-do Nissen. The median time from initial operation to reoperation was 35 months (range 4 days to 81 months).

Side Effects

The most commonly noted side effects after LARS in this study were bloating, diarrhea, and dysphagia. Fifty-two patients (18%) complained of bloating before LARS. Of these, 31 patients noted improvement, 10 remained the same, and 11 worsened. Twenty-seven patients (9%) developed a new onset of bloating after their antireflux procedure. Of the patients who developed new or increased bloating, the average VAS severity score for bloating was 5.5 (± 1.9). Thirty-two (11%) patients developed new or increased diarrhea after the operation; the average VAS severity score for diarrhea was 5.6 (± 2.8).

Dysphagia was reported by 123 patients before LARS. Of these, 96 (78%) had improvement (improved + resolved) and 76 (62%) had complete resolution of dysphagia after LARS when contacted. Seven patients (2%) developed new onset dysphagia after LARS. The mean VAS of the 7 patients was 6.2 (± 3.0). One patient has required revisional surgery for dysphagia.

Missing Patients

In order to determine if missing patients might have different outcomes than those who were contacted, we determined the correlation between the difficulty of contacting a patient and the resolution/nonresolution of the primary symptom. To this end, the three ordered "difficulty" categories used in this analysis (coded as 1, 2, 3) were: immediate patient response from a letter (least effort to contact), patient had to be telephoned (intermediate difficulty), and patient reached through private investigator (more difficult). The Spearman correlation coefficient between difficulty and resolution of the primary symptom was 0.03, suggesting that the most difficult to contact (*i.e.*, those not contacted at all) would have outcomes similar to those contacted and included in this study.

DISCUSSION

The advent of the laparoscopic approach, by decreasing the morbidity of the procedures, made antireflux surgery a more appealing option in the treatment of GERD. This was largely based on the belief that the 91% long-term success rate reported for the open approach (7, 8) would be reproduced with laparoscopy. Several initial reports on short-term results following LARS (9) suggested that that was the case and reinforced that belief. The first real challenge came in 2001 when Spechler *et al.* published the 10-yr follow-up of their prospective randomized trial of Nissen fundoplication versus medical treatment (5). Despite the fact that the patients who had undergone fundoplication had been operated on via the *open* approach and many of them by "low-volume" surgeons in today's standards, the realization that nearly two-thirds of those patients were taking antireflux medications cast doubt on the long-term result of operative treatment. A second report of a prospective trial, this time from Sweden, suggested that 5 yr after operation the results in terms of long-term relief of heartburn were slightly better among patients undergoing open operation in relatively low-volume centers when compared with patients allowed to take PPIs at whatever dosage was needed to quench the symptoms (6). These studies and other reports have brought skepticism about the long-term durability of antireflux operations.

Our study shows that in patients with severe GERD who are carefully selected for operative management, and are operated by a standardize approach, LARS provides durable relief of GERD symptoms. Furthermore, we have identified factors that seem to portend superior results, namely, men and those with typical reflux symptoms, like heartburn. Thus, our study provides further evidence that LARS should play a prominent role among the therapeutic options now available for the treatment of GERD.

Symptom Improvement/Resolution Following Operation

Improvement and, ideally, relief of GERD symptoms are the main goals of any treatment for GERD. The vast majority of patients in this series were operated because of substantial but incomplete relief of symptoms while on PPIs. Approximately 90% of patients with typical symptoms (heartburn and regurgitation) were improved, and remain so for more than 5 yr after operation. This is very similar to other reports of long-term heartburn relief after LARS (10).

Respiratory symptoms were more difficult to control. In our population, there was a 60–70% response rate for symptoms such as cough and hoarseness. Nearly half of the patients that we reported had airway manifestations or symptoms, though in only 10% was it the primary GERD symptom that initiated the patient's referral. Those in whom respiratory manifestations were the primary indication for operation had an inferior response to LARS. Other groups have also found pulmonary symptoms more difficult to control than typical

GERD symptoms (11, 12). For this reason, we are now very meticulous about our workup, in an attempt to match the disease with the symptoms using pharyngeal pH monitoring, laryngoscopy, and impedance, and evaluate these patients in a multidisciplinary setting with pulmonologists and otolaryngologists with an interest in this problem. The alternative, medical treatment, is quite ineffective for pulmonary disease. For example, there are randomized trials showing similar outcomes for antisecretory therapy and placebo for both laryngitis (13) and asthma (14). Therefore, LARS provides excellent long-term control of the spectrum of GERD symptoms.

Persistence or Recurrence of Symptoms After Operation

USE OF ANTISECRETORY MEDICATION. Some authors consider medication use as an outcome measure for antireflux surgery (5). In our study, 23% of patients were taking PPIs or H₂ blockers. Another 18% were taking occasional OTC antacid medications. This rate is similar to other reports of medication use after LARS (15). Nearly a third of the patients who were taking medication in our study were doing so for non-GERD symptoms. Moreover, 81% of patients on medications still considered their GERD symptoms under better control than before the operation. In the current medical environment, antacid medications, especially PPIs, are readily prescribed for many GI complaints. Furthermore, because their complication/side effect profile is so low, patients stay on these medications even if they have minimal or no effect on their complaints. The data from the study of Spechler *et al.* suggest just that. Indeed, in that study, the GRACI score (a measurement of the frequency and intensity of GERD symptoms) did not change significantly when patients in the surgical arm were asked to abstain from the use of medications over a 2-wk period (5). The best way to evaluate whether symptoms are due to GERD is with 24-h pH monitoring, perhaps with symptom association scales. While we asked patients to return for such monitoring with our long-term follow-up, almost all declined. Further support for the premise that medication use is not a good surrogate for surgical failure is the fact that when patients on medications are evaluated with 24-h pH monitoring, the majority do not have pathologic reflux. This finding has been confirmed by other studies as well (16). This strongly argues against using the fact that a patient uses antacid medications as the sole indicator of failure of surgical therapy. Instead, patient-centered views of the success of the operation should be given more emphasis. For example, nearly 7 yr after the operation, 90% of our patients were happy that they chose to have it and many of those taking PPIs found them more effective than before the operation.

REOPERATION. The other widely used outcome measure of antireflux surgery is the need for revisional surgery. Very few of our patients (3%) required a reoperation. This rate is similar to the 3.5% recurrence/reoperative rate reported by

Hunter *et al.* (17) and lower than the average reoperation rate of 8% cited by Valiati *et al.* in a literature review (18).

Predictors of Success

In order to determine which patients were most likely to have long-term relief of GERD symptoms, we analyzed the factors that were associated with improvement (and/or complete resolution) of the primary presenting GERD symptom. This confirmed our hypothesis that successful antireflux surgery depends heavily on patient selection. Factors that have been suggested to lead to superior outcomes include: the presence of typical GERD symptoms (heartburn, regurgitation), abnormal 24-h pH monitoring (19), good response to medical therapy, and absence of complicated disease (*e.g.*, Barrett's) (20). We found that patients who presented with heartburn were much more likely to experience symptom improvement than those presenting with other symptoms. When evaluating the likelihood of long-term primary symptom resolution, other predictors became evident: younger patients, men, and those without dysphagia were more likely to have complete long-term resolution of their main presenting symptom. Almost all of our patients have abnormal 24-h pH monitoring or objective signs of severe GERD (esophagitis, Barrett's) and respond to medical therapy (at least initially), thus we could not evaluate these as predictors.

We are not sure why men do better, though this has been shown in other series. O'Boyle and colleagues suggested that this may be due to a greater tolerance for side effects after intervention (19). This is merely speculation and we feel this needs further study. We showed that increasing age had a negative association with symptom control, although the odds ratio (OR 1.03) suggests that it may not be clinically significant. Older patients are more likely to have larger hiatal hernias and anatomic presentations that increase the difficulty of achieving a durable repair. Other authors have not demonstrated an association between age and control of GERD (19). Dysphagia before operation was a strong predictor of poor clinical response (OR 2.17). This was the case even though dysphagia improved after fundoplication in the majority of patients (87%). It may be that dysphagia is a surrogate for more complicated disease (HH, esophagitis, stricture), so that even though none of these specific anatomic findings associated with complicated GERD were predictive of negative outcome, the presence of dysphagia may have been an encompassing variable.

Finally, we also observed that patients with the longest follow-up had better results. While this may seem surprising since the general belief is that funduplications have a tendency to fail over time, it may be explained by the fact that when the program started we were more selective and the surgeon that performed most of these initial procedures (CAP) had had experience with LARS at another institution (which eliminated the potential ill-effect of the learning curve). On the other hand, with time we broadened the scope

of patients offered this option, and these are the patients with shorter follow-up in our series. For example, the percentage of patients referred with respiratory and atypical symptoms has increased over time. This analysis obviously raises the question: should the presence of these factors preclude the performance of LARS? The correlation is not strong enough to make these a contraindication for surgery. On the other hand, a surgeon's knowledge of these associations should be factored in when deciding the optimal treatment for individual patients.

Side Effects ("New Symptoms") Following Antireflux Surgery

To be a viable therapeutic option, LARS must relieve symptoms and have a low incidence of side effects. Because, by nature, a fundoplication restores integrity and resistance to the cardia, it has the possibility of causing dysphagia. While nearly 100% of patients have short-lived dysphagia after LARS, in our experience this does not usually persist. Furthermore, even in patients with so-called ineffective esophageal motility, LARS can be performed without the development of dysphagia. Despite the fact that the presence of dysphagia was associated with inferior resolution of other GERD symptoms, the majority of our patients experienced improvement of dysphagia (75%) after LARS. Moreover, only 7 (2%) patients developed dysphagia as a result of the operation that persisted at the time of contact for this study.

Bloating and diarrhea were the two most common symptoms to get worse after LARS. It is important to realize that these symptoms often exist in patients with GERD and are not necessarily the result of surgical intervention. Bloating was a common presenting symptom before LARS. In fact, bloating improved after operation in 31 of the 52 patients complaining of bloating before LARS, perhaps because a Nissen fundoplication improves gastric emptying (21). We do not recommend a gastric emptying procedure (e.g., pyloroplasty) at the time of LARS, and to date we have never had to do one postoperatively. In fact, our data suggest that for most patients with bloating after operation the problem is not severe. This study shows that side effects after LARS are relatively uncommon and are usually mild. Diarrhea is rarely assessed in outcome studies of antireflux surgery, but most people who treat GERD recognize its association (22). Therefore, we took the opportunity to assess it in this study and were surprised to find it occurred or worsened in 11% of our patients. We did not set objective parameters but instead left it to the patient to report if they had diarrhea; thus, in many this likely represents loose or frequent bowel movements. There are two likely possibilities for this finding. One, there may have been vagal nerve injury or irritation resulting in rapid intestinal transit. We think this is unlikely because we perform meticulous dissection and identify both nerves in all cases so that injury is avoided. The other possibility is associated gastrointestinal disorders, such as irritable bowel

syndrome. Indeed, in a recent review of the literature, Nas-taskin and colleagues point out a 50% prevalence of IBS in patients with GERD (23). So, it is unclear to us whether this is an association or cause and effect.

The major weakness of this study is that not all the patients were available for long-term follow-up. There is a possibility that those patients that we were unable to contact have inferior outcomes. However, we believe this to be highly unlikely. First, we went to substantial efforts to contact patients, even hiring a private investigator; and all patients for whom we had current contact information agreed to participate. Second, we analyzed patient presentation and outcome by the difficulty of contacting the patient, and found no significant difference. These reasons lead us to believe that our study group is likely to be representative of the entire cohort, and that the lack of 100% follow-up is simply a reflection of the transitory nature of the U.S. population today.

It may be that these results from a specialized, high-volume center are not representative of the results from the majority of laparoscopic antireflux procedures, which are currently done in low-volume centers. Although we believe that part of our success in these patients reflects our experience, not only with the technical aspect of the operation but also with GERD, esophageal physiology, and patient selection, superior outcomes in centers like ours have not been well studied or confirmed. Administrative data have demonstrated superior outcomes in high-volume centers for complex procedures such as esophagectomy, pancreatectomy, lung resections, and many cardiac procedures (24). Such administrative data from our institution would suggest that surgeon experience does indeed affect morbidity and mortality with antireflux surgery (25). However, administrative data can shed light on complications and mortality, but cannot assess symptomatic or quality of life outcomes. These outcomes generally come from single, high-volume institutions. Therefore, one must be careful in making universal conclusions about the results of LARS, but we feel our data make a compelling case for LARS in the treatment of GERD when performed in experienced hands.

CONCLUSION

Our study, taken in the context of emerging data on the long-term outcomes of LARS, suggests that LARS provides excellent control of GERD symptoms and this control is durable. Our study also identifies subgroups for which this operation is particularly effective and shows that LARS can be performed with a low rate of side effects. LARS should be considered as an excellent option in the armamentarium for treating severe GERD.

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STUDY HIGHLIGHTS**What Is Current Knowledge**

- Laparoscopic anti-reflux surgery (LARS) provides excellent short-term control of GERD.
- LARS is occasionally associated with short-term side effects such as dysphagia and bloating.
- There are conflicting reports of the long-term results from open anti-reflux surgery.

What Is New Here

- Presence of heartburn, absence of dysphagia, male gender, and younger age were positive predictors of symptomatic success with LARS.
- Complications and long-term side effect profile rates associated with LARS are low.
- In a specialized center, LARS provides durable relief of GERD symptoms.

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CONFLICT OF INTEREST

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