Long-term outcomes of endoluminal gastroplication: a U.S. multicenter trial

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Background: Endoluminal gastroplication has shown promise for the treatment of GERD in short-term studies. Until now, long-term outcome data have been lacking.

Methods: A prospective, multicenter trial enrolled 85 patients with GERD to be treated with endoluminal gastroplication. Inclusion criteria were 3 or more heartburn or regurgitation episodes per week, >4.2% time in 24 hours with esophageal pH < 4, and dependency on antisecretory medications. Exclusion criteria were the presence of varices, achalasia, aperistalsis, or previous gastric resection. Patients underwent manometry, 24-hour pH monitoring, and symptom severity scoring before and after the procedure. Patient diaries were used to assess medication use and to estimate annual medication cost.

Results: At 1- and 2-year follow-up, patients had significant reductions in median heartburn symptom scores (72 at baseline [interquartile range (IQR) 90-48] vs. 4 at 12 months [IQR 43-0] and 16 at 24 months [IQR 53-3.5]; \( p < 0.0001 \) vs. baseline) and median regurgitation symptoms (2 at baseline [IQR 3-1] vs. 0 at 12 months (IQR 1-0) and 1 at 24 months [IQR 1.0]; \( p < 0.0001 \) vs. baseline). Of all patients, 59% and 52% showed heartburn symptom resolution at 12 and 24 months, respectively (\( p < 0.0001 \) vs. baseline). Also, 83% and 77% had regurgitation symptom resolution at 12 and 24 months, respectively (\( p < 0.0001 \) vs. baseline). Proton pump inhibitor use also was significantly reduced at 12 and 24 months after the procedure. At 2-year follow-up, median annualized medication costs were reduced by 88% ($1381) (\( p < 0.0001 \)). Endoluminal gastroplication significantly reduced the duration and the number of episodes of esophageal acid exposure (\( p < 0.0001 \) vs. baseline). Only 7 patients experienced adverse events.

Conclusions: Endoscopic gastroplication is safe and effective, and is associated with symptom reductions in patients with GERD for at least 24 months. (Gastrointest Endosc 2005;61:659-67.)

GERD is the most common esophageal disorder. Epidemiological studies suggest that up to 44% of the U.S. population experiences heartburn symptoms at least once a month and about 20%, once per week.\(^1\) GERD also is among the most costly of digestive disorders. One study reported that GERD accounted for direct and indirect annual costs of over $10 billion (year 2000 dollars).\(^3\)

The underlying etiology of GERD in most patients is believed to be dysfunction of the lower esophageal sphincter (LES), resulting in symptoms of heartburn and regurgitation. Potential complications of GERD include erosive esophagitis, esophageal stricture, Barrett’s esophagitis, and even adenocarcinoma of the esophagus.\(^4\) The goals of treatment for patients with GERD are the relief of symptoms, and the prevention of the potential complications.\(^5\)

For many patients with GERD, lifestyle modifications, and medical management with proton pump inhibitors (PPI), H2 receptor antagonists (H2RA), antacids, and/or prokinetic agents may be adequate to maintain symptom control. However, relapse is common after cessation of medical treatment. Furthermore, PPIs and other medications are expensive with continuous use. Drug costs were estimated in one study to account for 63% of all direct costs for GERD in the United States, an annual burden of over $9 billion (year 1998 dollars).\(^5\)

Until recently, the only other treatment option for patients with GERD was open or laparoscopic fundoplication.\(^6\) Only a minority of patients choose this surgical
The aim of this study was to evaluate the long-term (24 month) safety and effectiveness of ELGP. The primary study objectives were improvement in heartburn and regurgitation symptom scores and elimination of, or >50% reduction in, PPI use at 12- and 24-month follow-up visits. The secondary study objective was improvement in esophageal acid exposure as assessed by 24-hour pH monitoring. A surrogate indicator for symptom improvement was the reduction in GERD-related drug costs over 24 months. It should be noted that this study included patients with less favorable clinical parameters (e.g., hiatal hernia, Barrett’s esophagus, pulmonary symptoms) reflective of the GERD patient population.

PATIENTS AND METHODS

This study was an open-label, prospective trial conducted at 5 centers in the United States. Eighty-five patients were enrolled in this study. Institutional review board approval was obtained by each participating institution, and written consent was obtained from each patient. Inclusion criteria were the following: (1) more than 3 episodes of heartburn or regurgitation per week when not taking antisecretory medications; (2) confirmation of esophageal acid exposure, as evidenced by a sustained pH of less than 4 for greater than 4.2% of a 24-hour monitoring period; (3) dependency on antisecretory medications for symptom control; (4) history of gastric resection. Exclusion criteria included patients with (1) esophageal varices, (2) achalasia, (3) aperistalsis, (4) a history of gastric resection.

Baseline and follow-up examinations

GERD symptom evaluation (Table 1), upper endoscopy, 24-hour pH monitoring, and esophageal manometry were performed at baseline. Heartburn severity was assessed with a 32-point visual analog scale (VAS). “Severe” heartburn was defined as a VAS score of >24. Daily GERD medication intake was assessed through a patient diary. Medication diaries and GERD symptoms were evaluated at baseline, and at 12 and 24 months after the procedure. Data collection was conducted by each site and then entered into a central electronic database.
designed specifically for this study. Symptom score diaries were collected daily for a 7-day period immediately preceding the baseline, 12-month, and 24-month follow-up.

All patients were instructed to discontinue their medications within 2 weeks after the procedure and to resume taking medications only if they became symptomatic. Baseline and postprocedure symptom scores were obtained with patients off all antisecretory medications for at least 10 days.

The cost of GERD-related medication was calculated based on national U.S. average wholesale prices for each drug. Upper endoscopy was performed at baseline to document the grade and the severity of esophagitis (modified Savary-Miller scale), and/or hiatal hernia, if present. Esophageal manometry was performed at baseline and 3 months after the procedure, as previously described, to document esophageal motility and the location and function of the LES. Ambulatory, 24-hour pH monitoring was performed, as previously described, at baseline and at 3 months after the procedure to document changes in esophageal acid exposure.

**Study objectives**

The primary study objectives of this study were improvement in GERD symptom scores (heartburn frequency and severity, regurgitation symptoms) and the elimination or the reduction (50% or greater) of PPI use, both at 12 and 24 months after the procedure. Reduction in the cost of antisecretory medication was a surrogate indicator for symptom reduction. The secondary study objective was improvement in 24-hour esophageal pH at 3 months after the procedure.

**ELGP procedure**

ELGP was performed by using the EndoCinch device, as previously described. Patients were treated with one to 3 plications in either a linear or a circumferential configuration. These configurations have been described and evaluated in previous studies.

**Statistical analysis**

Analyses were performed with the Statistical Analysis System software package (SAS Institute Inc, Cary, NC) and StatXact, a Cytel statistical software (Cytel Software Corp, Cambridge, Mass). Outcomes from the Microsoft Office Access 2002 (Microsoft Corp, Redmond, Wash) for symptom scores, medication cost, pH, and motility were evaluated by computing the difference between 0- and 12- and 24-month values and by applying the Wilcoxon signed rank test.

Subgroup analyses were performed on symptom scores, PPI usage, and pH-metry to determine trend in symptoms resolution, PPI elimination, PPI dosage reduction, and pH normalization. Outcomes were dichotomized as follows: symptom scores (heartburn frequency score [HFS] ≤ 1, RSS > 1); PPI usage (On PPI, Off PPI; ≥ 50% dose reduction, < 50% dose reduction); and % time pH < 4.0 (≥ 4.2, < 4.2); these were analyzed with sign test and the confidence intervals (CI) for the estimated proportions based on the Blyth-Still-Casella test. Statistical significance was defined as a 2-tailed test, p < 0.05. There was no correction of p values for multiple statistical testing of outcome data arising from individual participants; however, it is noted that for the main results, a correction would not remove any findings of significance. The results relating to 24-hour pH monitoring and esophageal manometry are descriptive, with their p values listed only to indicate nominal differences without correction for multiple testing.

**RESULTS**

Baseline characteristics of the 85 patients are shown in Table 2. The number of patients enrolled at each site was as follows: site A (n = 31), site B (n = 28), site C (n = 17), site D (n = 6), site E (n = 3). A significant proportion of the patients had daily GERD symptoms; the majority had severe heartburn (Table 2). Many patients also had GERD-related unfavorable clinical parameters. Ten patients had esophagitis Grade > 3 (modified Savary-Miller scale ≥ 3), 9 had hiatal hernia (≥ 2 cm), and 4 had Barrett’s esophagus. Three patients had previous failed Nissen fundoplication (defined as patients requiring daily PPI or double-dose H2RA for symptom control after surgery). Ten patients had pulmonary symptoms.
including cough (7), wheezing (6), and hoarseness (1).
The number of patients with unfavorable clinical parameters was too small to allow for separate subgroup analysis.

As per the inclusion criteria for this study, all patients were dependent upon antisecretory medications. At baseline, all patients had adequate control of heartburn symptoms while on medications but may or may not have had any improvement in regurgitation symptoms. The majority (87.1%) were taking daily PPIs, with a minority (12.9%) taking double-dose H2RAs. (Double-dose H2RAs was defined as double the standard prescription dose approved by the FDA for GERD therapy.) Approximately a quarter of all subjects were taking standard-dose PPIs; nearly two thirds of all subjects (61.2%) were taking more than standard doses of PPIs. Many patients also used supplementary medications: 18.8% used prokinetics, 27.1% used antacids, and 14.1% used supplementary H2RAs.

In all, 59.3% of patients required only conscious sedation (moderate sedation) during the procedure. Approximately a fourth (26.7%) of the patients received monitored sedation (propofol intravenous drip). Only 14% required general anesthesia. The choice of sedation was at the discretion of the treating physician. The total number of plications ranged from one to 3 per patient; most had two plications (7.1%, 1 plication; 68.2%, 2 plications; 24.7%, 3 plications). Two plication patterns were used, according to investigator judgment. A circumferential configuration was performed in 64.9% of patients, and a linear configuration in 35.1%.

### Symptom scores

Two patients were lost to symptom score follow-up because of death unrelated to the study procedure. Two patients underwent Nissen fundoplication because of poor response to ELGP. The last recorded symptom scores for these patients, obtained immediately before Nissen fundoplication, were carried forward and were included in the 2-year follow-up. Changes in heartburn frequency, heartburn severity, and heartburn symptom score at 12 and at 24 months are shown in Figure 1. All 3 measures demonstrated improvements in heartburn after ELGP that were statistically significant and throughout the 24-month follow-up period. Regurgitation symptoms also
were significantly reduced. The median baseline regurgitation symptom score was 2 (IQR 3-1) and declined to a median of 0 (IQR 1-0) at 12 months ($p!0.0001$ vs. baseline). Regurgitation symptoms remained stable at 24 months, with a median score of 1 (IQR 1-0; $p!0.0001$ vs. baseline). The number of patients with complete symptom resolution (defined as a symptom score of 1, the lowest value, or zero) also was determined (Table 3). Approximately half of all patients had complete resolution of heartburn symptoms 12 and 24 months after ELGP ($p!0.0001$ vs. baseline). Three fourths of the patients had complete resolution of regurgitation symptoms at 12 months, and 69% had resolution 24 months after ELGP ($p!0.0001$ vs. baseline, 12 and 24 months).

Medication use

Daily GERD-related medication use was tracked by the use of patient medication diaries. Annualized medication costs were calculated at baseline and at 12 and 24 months after ELGP. At baseline, the median, annual per-patient cost for GERD medications was $1564 (IQR 2346-1123). Twelve months after the procedure, the annualized median cost was estimated to be $157 (IQR 1096-0; $p<0.0001$ vs. baseline) and remained approximately stable up to 24 months (median $183; IQR 1173-0; p<0.0001$ vs. baseline). The difference in median cost from baseline to 24 months was $1381 or a cost reduction of 88%. This analysis represents a surrogate measure of symptom reduction.

The use of PPIs also was significantly reduced after the ELGP procedure (Table 4). Among the 74 patients who reported PPI use at baseline, 32 (43.2%) reported no PPI use 12 months after ELGP, $p<0.0001$ (95% CI[31.9%, 55.1%]); a similar proportion (n = 30, 40.5%) reported no PPI use after 24 months, $p=0.0011$ (95% CI[29.3%, 52.3%]). Thus, 73% and 69% of all the patients who were on PPI achieved the primary study objective of elimination or reduction in PPI use at 12 months and 24 months after ELGP, respectively. Similarly, daily PPI use decreased from 87% of 85 study patients at baseline to 31% at 12 months ($p=0.002$) and 35% at 24 months ($p<0.001$).

**Twenty-four-hour pH monitoring**

Baseline pH monitoring was performed in all patients (n = 85). Because of patient preference, 17 patients did not undergo follow-up pH monitoring. At 3 months after ELGP, 51 patients had a postprocedure pH study. The percentage of time with esophageal pH less than 4.0 was significantly reduced from a median of 9.2 (IQR 6.9-14.4) to 6.3 (IQR 1.8-11.6), $p=0.0001$ at 3 months. At 6 months after ELGP, an additional 17 patients who did not have a pH study at 3 months underwent a postprocedure esophageal pH. The percentage of time with esophageal pH less than 4.0 was significantly reduced from a median of 14.0 (IQR 8.0-16.6) to 5.5 (IQR 3.4-8.6), $p=0.015$ at 6 months. Thus, a total of 68 patients (80.0%) had a postprocedure pH study, either at 3 months (n = 51) or at 6 months (n = 17). No study patient had repeated

| TABLE 3. Proportion of patients symptom free at 12 and 24 mo after ELGP |
|----------------|----------------|----------------|
| GERD symptom | Before ELGP N (%) | 12 mo N (%) | 24 mo N (%) |
| Heartburn none/minimal (HFS $\leq$ 1) | 7 (8) | 50 (59) | 43 (51) |
| Regurgitation none/minimal (RFS $\leq$ 1) | 23 (28) | 70 (83) | 66 (77) |
| **p Value** | $<0.0001$ | $<0.0001$ | $<0.0001$ |

ELGP, Endoluminal gastroplication; HFS, heartburn frequency score; RFS, regurgitation frequency score.

*For comparison with before ELGP value.

| TABLE 4. Improvement in PPI use at 12 and 24 mo after ELGP among 74 patients reporting daily PPI use before ELGP |
|----------------|----------------|----------------|
| 12 mo* | 24 mo |
| Improvement in PPI use | 54/74 | 73 (62, 82) | 51/74 | 69 (58, 79) |
| No PPI use | 32/74 | 43.2 (31.9, 55.1) | 30/74 | 40.5 (29.3, 52.3) |
| Dose reduced $\geq$ 50% | 22/74 | 29.7 (19.7, 40.8) | 21/74 | 28.4 (18.5, 39.4) |

PPI, Proton pump inhibitor; ELGP, endoluminal gastroplication; CI, confidence interval.

* $p$ Value $<0.0001$.

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ELGP, Endoluminal gastroplication; HFS, heartburn frequency score; RFS, regurgitation frequency score.

*For comparison with before ELGP value.
measures of post-procedure pH. The combined results of 24-hour pH monitoring are shown in Table 5. Overall, the percentage of time with esophageal pH less than 4.0 was significantly reduced compared with baseline at 3 to 6 months after ELGP. The total number of reflux episodes also was significantly reduced at 3 to 6 months after the procedure. Scores on the composite Johnson-DeMeester test also were significantly reduced, indicating a reduction in esophageal acid exposure.

Normalization of esophageal pH is considered to be an acid exposure of less than 4.2% of 24 hours at a pH less than 4.0. By using these criteria, all 68 evaluable patients had abnormal baseline esophageal acid exposure. At 3 months after ELGP, 20 of 51 evaluable patients (39.2%) had normalized esophageal pH ($p < 0.0001$ vs. baseline). At 6 months after ELGP, 7 of 17 evaluable patients (41.2%) had normalized esophageal pH ($p < 0.008$ vs. baseline). The proportion of patients who normalized their esophageal pH after ELGP was not significantly different between those patients who had their pH studies at 3 months and those who had their studies at 6 months. Thus, 27 of 68 patients (39.7%) had normalized esophageal pH studies at 3 to 6 months after ELGP.

Esophageal manometry

Baseline manometry was performed in all patients. Because of patient preference, follow-up manometry was obtained in less than half of the patients. There was a statistically significant improvement in the residual LES pressure compared with baseline ($n = 38$, $p = 0.017$). The post-ELGP manometry was obtained either at 3 months ($n = 28$) or at 6 months ($n = 10$) after ELGP. No patient had repeated measures of post-procedure manometry. There were no significant differences in any of the other manometric parameters measured. The combined results of esophageal manometry are shown in Table 6.

### TABLE 5. Esophageal acid exposure before ELGP and at 3 to 6 mo after ELGP, n = 68

<table>
<thead>
<tr>
<th></th>
<th>Before ELGP</th>
<th>After ELGP</th>
<th>$p$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total time pH $\leq$ 4</td>
<td>9.4 (7.1-14.8)</td>
<td>5.8 (2.0-10.8)</td>
<td>$&lt;0.0001$</td>
</tr>
<tr>
<td>Upright</td>
<td>11.0 (5.9-14.8)</td>
<td>5.2 (2.6-11.7)</td>
<td>$&lt;0.0001$</td>
</tr>
<tr>
<td>Supine</td>
<td>9.0 (4.0-14.5)</td>
<td>3.1 (0.7-10.8)</td>
<td>0.0003</td>
</tr>
<tr>
<td>JDS*</td>
<td>49.0 (34.3-68.9)</td>
<td>25.3 (11.6-50.2)</td>
<td>$&lt;0.0001$</td>
</tr>
<tr>
<td>Total episodes</td>
<td>137.0 (88.0-209.0)</td>
<td>79.0 (46.0-146.0)</td>
<td>$&lt;0.0001$</td>
</tr>
</tbody>
</table>

*ELGP, Endoluminal gastroplication; IQR, interquartile range; JDS, Johnson-DeMeester score. *Score of $<22$ is considered normal.

### TABLE 6. Esophageal manometric findings before ELGP and at 3 to 6 mo after ELGP, n = 38

<table>
<thead>
<tr>
<th></th>
<th>Before ELGP</th>
<th>After ELGP</th>
<th>$p$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>IA LES length</td>
<td>3.25 (2.0-4.0)</td>
<td>3.0 (2.5-4.4)</td>
<td>NS</td>
</tr>
<tr>
<td>LES length</td>
<td>4.5 (4.0-5.0)</td>
<td>4.0 (3.5-5.0)</td>
<td>NS</td>
</tr>
<tr>
<td>LES pressure</td>
<td>17.6 (10.0-22.7)</td>
<td>17.1 (9.4-25.0)</td>
<td>NS</td>
</tr>
<tr>
<td>Residual pressure</td>
<td>1.8 (0-3.6)</td>
<td>2.8 (0-4.7)</td>
<td>0.017</td>
</tr>
</tbody>
</table>

*ELGP, Endoluminal gastroplication; IQR, interquartile range; IA, intra-abdominal; LES, lower esophageal sphincter; NS, not significant.

Adverse events

Overall, the procedure was safe. Two patients had oozing at the suture site. These patients had stable hematocrit values and received epinephrine injections to control oozing during the ELGP procedure. One patient experienced melena and was kept under observation for 24 hours. This patient’s hematocrit also remained stable. One patient experienced bronchospasm and was intubated for the ELGP procedure. One patient experienced significant dysphagia; symptoms resolved after removal of the plication suture at day 10 after ELGP. No other patients required additional endoscopic intervention for adverse events after ELGP. There also were two sedation-related complications, both hypoxemia. These two patients were intubated during the procedure.

DISCUSSION

This trial is the only 24-month, prospective study of an endoscopic technology for the treatment of GERD published to date. This open-label, multicenter study evaluated the long-term safety and effectiveness of ELGP for patients with a range of GERD symptoms. The results demonstrate clinically and statistically significant reductions in the symptoms of heartburn and regurgitation after ELGP. These symptom reductions were durable, lasting throughout the 24-month follow-up period. Antisecretory medication use also was reduced, as were annualized medication costs; these reductions, too, were sustained through the 24-month study. Three- and 6-month, 24-hour pH monitoring data indicated that ELGP significantly reduced the duration and the number of episodes of esophageal acid exposure. Together, these results indicate that ELGP is an effective and lasting intervention for the treatment of GERD.

The ELGP procedure was safe. A total of 7 of 85 patients (8%) experienced some form of adverse event. Two patients were treated with epinephrine injections to control oozing at the suture site during ELGP. Only one
patient required removal of sutures to resolve dysphagia. One patient experienced melena but was stable, and the condition resolved without intervention. One patient required intubation for bronchospasm. Two events (hypoxemia) were related to the sedation; these patients were intubated and completed the procedure. No additional adverse events were noted during the long-term follow-up. While ELGP already appears to be safe, it is likely that the rate of adverse events will improve even further as physicians gain more experience with this new procedure and as the technology and technique are refined.

According to guidelines issued by the Practice Parameters Committee of the American College of Gastroenterology, the main goal of GERD treatment is the control of symptoms. Durable symptom control with ELGP is a main finding of this study. Heartburn frequency, severity, and symptom score, and regurgitation symptom score all were reduced by approximately 50% or more for the entirety of the 24-month trial. Over 50% of patients achieved resolution of heartburn symptoms (score of 1 or less). Approximately three fourths achieved resolution of regurgitation symptoms (score of 1 or less). Reduction in PPI use also was robust. Of the 74 patients taking PPIs at baseline, PPI use was eliminated in 43% at 12 months and in 41% at 24 months. An additional 30% and 18%, respectively, had a 50% or greater reduction in PPI use. It should be noted that the GERD symptom scoring system used in this study has not been validated. However, it has been used in previous studies of ELGP, allowing for comparison of results between this trial and earlier work (e.g., reference 9).

These findings compare favorably with results from studies of the RF and polymer-implant endoscopic technologies that also are approved for the treatment of GERD. A 12-month follow-up study of polymer implant use in patients with GERD (n = 81) reported that 80.3% of subjects reduced PPI use by at least 50%. These data demonstrate a slight drop off from the 6-month data from this same study (n = 85), in which 84% of patients had at least a 50% decrease in PPI use. In a 12-month follow-up of the RF procedure, daily PPI use dropped from 88.1% of patients at baseline to 30% at 12 months. These data are similar to the current ELGP study, in which daily PPI use dropped from 87% of patients at baseline to 31% at 12 months, and 35% at 24 months. In both the polymer implant and the RF studies, heartburn and regurgitation symptoms were improved significantly at 12 months, compared with baseline.

It should be noted, however, that patients with hiatal hernia >3 cm or with grade 3 or 4 esophagitis were excluded from the polymer implant study; patients with hiatal hernia >2 cm or esophagitis worse than grade 2 were excluded from the RF study. The patient population in this ELGP study included many patients with these potentially difficult-to-treat characteristics, as well as other unfavorable parameters. It is possible that inclusion of these patient types affected the response to ELGP treatment. Because such patients were included, however, this study may better represent the population of patients with GERD who will desire or require endoscopic intervention.

Esophageal acid exposure, as assessed by 24-hour pH monitoring, is considered by many to be a critical measure of GERD treatment outcomes. In the current study, the percentage of time at pH < 4.0, the total number of reflux episodes, and the Johnson-DeMeester scores were significantly reduced at both 3 and 6 months. Esophageal pH was considered normal (<4.2% of time pH < 4.0) in 39.2% of patients at 3 months and 41.2% at 6 months, compared with zero at baseline. While these findings are promising, most but not all of the study patients (80%) had a postprocedure pH evaluation. Because patients were not required to participate in pH monitoring at follow-up visits, some elected not to undergo the test. One way to address this shortcoming through statistical means is to consider all patients lost to follow-up to have abnormal esophageal pH. In this scenario, a total of 27 of 85 patients (31.8%) achieved normalized esophageal pH. Even this insensitive “intent-to-treat” approach suggests that a substantial number of patients can achieve sustained, normal esophageal pH. One possible explanation for the favorable difference in pH results compared with previous studies is that follow-up pH testing was obtained somewhat earlier in this study (at 3 or 6 months) than in some other studies (at 6 and 12 months). Also, there is a significant learning curve for performing this procedure, which may have influenced the outcomes of the initial trial.

Similarly, less than half of the study patients elected to undergo postprocedural manometry (n = 38). In contrast to the initial ELGP study, manometry results from the current study showed a statistically significant improvement in the residual LES pressure after ELGP. In this follow-up group, no patient had dysphagia, and this observed increase in residual pressure was well within the normal range of up to 8 mm. Animal studies also suggested that ELGP can improve LES pressures, possibly addressing the underlying pathophysiology of GERD. With regard to the rest of the manometric parameters, our findings are consistent with previous studies that showed no significant changes in esophageal manometry after ELGP and RF. In the absence of reproducible manometry results, the exact means by which ELGP reduces acid reflux remain unclear.

The total annualized cost of GERD-related medications was reduced by 88% after ELGP in this study, from $1564 at baseline to $183 at 24 months. While this study was not designed to perform a cost analysis, this finding provides additional evidence of the substantial and lasting reduction in GERD symptoms. Other investigators have conducted more thorough cost analyses, comparing endoscopic procedures with laparoscopic surgery, or
to PPI use.19 Total costs for Nissen fundoplication average about $7500 for the laparoscopic procedure, or $14,000 for the open procedure.18 By comparison, the endoscopic procedures have been estimated to cost approximately $3,000.18,19 Analysis of long-term costs associated with PPI use, the endoscopic RF procedure, and ELGP indicate that sustainable long-term outcomes are the key to the cost savings of one procedure over another or over medication use. Procedures that achieve durable long-term symptom improvement will likely reduce costs compared with medication. However, as is true of Nissen fundoplication,20-22 endoscopic procedures may be associated with degradation over time. Indeed, the 24-month results from the current study indicate a trend toward increased symptoms compared with the 12-month outcomes. Future, longer studies will help to determine the cost-effectiveness of ELGP.

Because multiple statistical comparisons were performed in this study, the actual statistical significance level might not be as high as the reported significance level. However, these are not a group of independent tests, instead, they are related variables that a priori were hypothesized to move in a certain direction after treatment and thus would be expected to covary. Also, it should be emphasized that no patient had repeated measures of postprocedure pH or manometry. Thus, it is extremely unlikely that this constellation of variables significantly varied in the predicted direction simply by chance.

The current study does not contain a nonplication sham group. However, a study currently is under way that includes a sham group as well as an ELGP group. Such studies are critical to differentiating the true effect of ELGP. Future studies also may take advantage of modifications to the procedure and greater experience of the operators. Indeed, recent data suggest that different configurations of the plications may markedly improve outcomes. A helical plication pattern, as opposed to linear or circumferential patterns used in the current study, has been associated with improved symptom relief in preliminary studies compared with either linear or circumferential configurations.23,24

In conclusion, the current study demonstrates that ELGP is safe and effective for the long-term control of GERD symptoms. The procedure also appears to reduce esophageal acid exposure substantially for at least 6 months. Use of antisecretory medications was significantly decreased after ELGP, resulting in a large reduction in annual drug costs. Patients with classic GERD symptoms responsive to antisecretory medications are good candidates for ELGP if an alternative to long-term medical therapy or if surgery is being considered. Whether the procedure should be routinely offered to patients who fail medical therapy or who have other unfavorable parameters, such as large hernias, will require additional studies.

DISCLOSURES

Drs Chen, Rajmman, Ben-Menachem, Starpolf, Liu, and Carr-Locke have received lecture honoraria and/or educational grants from C. R. Bard Inc. Drs Liu and Carr-Locke have received research grants from C. R. Bard Inc.

REFERENCES


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