Endoscopic fundoplication for the treatment of gastroesophageal reflux disease: Initial experience

Chaitan K. Narsule, MD,^a Miguel A. Burch, MD,^b Michael I. Ebricht, MD,^a Donald T. Hess, MD,^c Roberto Rivas, Jr, BS,^a Benedict D. T. Daly, MD,^a and Hiran C. Fernando, MD, FRCS^a

Objective: Transoral incisionless fundoplication (TIF) is a promising approach for gastroesophageal reflux disease (GERD) that may decrease morbidity compared with conventional antireflux procedures. We report our initial experience with this minimally invasive approach.

Methods: Over a 24-month period, 46 patients (mean age, 49 years; 50% female) underwent 48 TIF procedures. All procedures were performed under general anesthesia. Two surgeons participated in all cases; one served as the endoscopist, and the other performed the partial fundoplication. Heartburn severity was measured using the GERD health-related quality of life (GERD-HRQL) instrument (best score = 0, worst score = 45), which includes an additional question assessing overall satisfaction.

Results: Preoperatively, 33 (72%) of 46 patients had small (<3 cm) hiatal hernias, and none had undergone any previous antireflux procedures. Preoperative workup included manometry and barium esophagogram, with pH testing reserved for patients with atypical symptoms or typical symptoms and a lack of response to proton-pump inhibitors. The mean procedure time was 83 minutes (range, 36-180 minutes). The mean procedure time decreased after the first 5 cases from 122 to 78 minutes ($P = .001$). Mean length of stay was 1.3 days. One patient was readmitted with aspiration pneumonia. Three patients had minor complications (1 had minor bleeding from a suture site and 2 had urinary retention). There were no perioperative deaths. Mean follow-up was 140 days. The mean GERD-HRQL scores improved significantly (23 vs 7; $P < .001$). There were 22 patients with follow-up greater than 90 days (mean follow-up, 240 days). GERD-HRQL scores remained significantly improved for these patients (23 vs 8; $P = .001$). Four patients from the entire group (8.6%) had no improvement, in 3 instances due to breakdown of the wrap. Two patients were treated with repeat endoscopic fundoplication and 1 was treated with laparoscopic Nissen fundoplication, and all had a significant improvement in symptoms after reoperation.

Conclusions: TIF is effective at short-term follow-up and safe for patients with GERD. However, long-term follow-up and randomized trials are required to assess the efficacy and durability of this approach compared with conventional surgical repair. (*J Thorac Cardiovasc Surg* 2012;143:228-34)

Gastroesophageal reflux disease (GERD) is a common condition that is encountered in primary care practices throughout the United States.¹ Although proton pump inhibitors (PPIs) constitute the primary treatment for most patients with GERD,^{2,3} for those patients who have complications such as erosive esophagitis or Barrett's metaplasia, have intractable symptoms, or wish to discontinue medical

therapy, surgical intervention with a laparoscopic Nissen fundoplication is the conventional approach. Although it has been associated with great efficacy in treating reflux in patients with either typical or atypical symptoms,^{4,5} it may lead to postoperative symptoms such as dysphagia and bloating,⁶⁻⁸ and may have poorer outcomes when performed in low-volume centers.⁹

Endoscopic fundoplication, also known as transoral incisionless fundoplication (TIF), is an antireflux procedure that uses a proprietary device (EsophyX₂; EndoGastric Solutions, Redmond, Wash), which is approved by the Food and Drug Administration for the treatment of gastroesophageal reflux disease. This procedure creates a fold around the distal intra-abdominal esophagus, forming a valve that is similar physiologically to a partial fundoplication.¹⁰ It can be used in patients with small hiatal hernias. Although it has already been used in some European centers, few North American reports have been published.¹¹⁻¹⁴

The purpose of this study is to review our initial results with endoscopic fundoplication for the treatment of GERD.

From the Department of Cardiothoracic Surgery,^a Boston University School of Medicine, Boston, Mass; the Department of Surgery,^b Cedars-Sinai Medical Center, Los Angeles, Calif; and the Department of Surgery,^c Boston University School of Medicine, Boston, Mass.

Disclosures: Authors have nothing to disclose with regard to commercial support.

Read at the 91st Annual Meeting of The American Association for Thoracic Surgery, Philadelphia, Pennsylvania, May 7-11, 2011.

Received for publication May 9, 2011; revisions received Sept 15, 2011; accepted for publication Oct 3, 2011; available ahead of print Nov 10, 2011.

Address for reprints: Hiran C. Fernando, MD, FRCS, Department of Cardiothoracic Surgery, Boston University School of Medicine, 88 East Newton St, Robinson B-402, Boston, MA 02118 (E-mail: hiran.fernando@bmc.org).

0022-5223/\$36.00

Copyright © 2012 by The American Association for Thoracic Surgery

doi:10.1016/j.jtcvs.2011.10.008

Abbreviations and Acronyms

GERD	= gastroesophageal reflux disease
HRQL	= health-related quality of life
LES	= lower esophageal sphincter
PPI	= proton pump inhibitor
TIF	= transoral incisionless fundoplication

METHODS

Patient Selection

Patients with typical or atypical symptoms deemed to be related to gastroesophageal reflux disease were considered for endoscopic fundoplication. The presence of a hiatal hernia greater than 3 cm or a previous antireflux operation were considered exclusion criteria. Preoperative workup included a careful history and completion of the GERD health-related quality of life (GERD-HRQL) survey, a 9-item questionnaire that has previously been validated.¹⁵ Scores were expressed on a scale from 0 to 45, where 45 represented the worst possible score. An additional question assessed overall satisfaction.

All patients underwent upper endoscopy, esophageal manometry, and barium esophagogram. For patients with typical reflux symptoms without response to medications or with atypical reflux symptoms, esophageal pH or impedance testing was performed to confirm the presence of reflux before endoscopic fundoplication.

Description of Technique

All procedures were performed in the operating room with general endotracheal anesthesia. Patients were positioned in the left lateral decubitus position. A bite-block device was placed in the mouth. An initial esophagogastroduodenoscopy was performed, which served several purposes: (1) it allowed the surgeon to directly assess the esophagus for the presence of pathologic conditions (such as Barrett's esophagus or hiatal hernia); (2) it allowed for the assignment of a Hill score¹⁶ based on the shape of the gastroesophageal junction when viewed on retroflexion; and (3) it allowed the surgeon to determine whether the stomach was completely evacuated of food material. After the suitability of each patient was confirmed endoscopically, the EsophyX₂ device (Figure 1, A and B) was prepared for use on the back table.

The EsophyX₂ device has a tubular shape and slips over an endoscope. On the end that is inserted into the alimentary tract (Figure 1, B), it has a helical retractor that is advanced and anchored to the Z-line (Figure 2, A). Downward traction on the Z-line with the helical retractor helps to reconstitute the angle of His, which contributes to the antireflux mechanism. The gastric fundus is approximated to the distal intra-abdominal esophagus by closure of the tissue mold (Figure 2, B). In cases in which a small hiatal hernia is present, suction can be applied along the shaft of the device, bringing the esophagus into close apposition with the device. As traction is also maintained distally with the helical retractor at the gastroesophageal junction, when the whole device is advanced into the mouth and esophagus, small hiatal hernias can be reduced before fundoplication. Two stylets are used to deploy 2 polypropylene sutures, fashioned as H-shaped fasteners, that anchor the fundus to the esophagus (Figure 2, C). Sutures are placed along 2 semicircumferential rows opposite to the lesser curvature, 1 proximal to the other, until an omega-shaped wrap of 270° and 2-cm length is created (Figure 3). This procedure typically requires approximately 12 to 20 sutures and excludes the lesser curvature to avoid injury to the vagus nerves. Although a small hiatal hernia may be reduced during the creation of the wrap, herniorrhaphy is not achievable with this technique.

One surgeon acts as an endoscopist and the other operates the device during each procedure. Visibility is optimized by insufflating the stomach with carbon dioxide gas from a laparoscopic insufflation system that is set to a pressure between 12 and 15 mm Hg, and complete muscle relaxation is achieved with the administration of a paralytic medication. After the wrap is completed and the device is removed, endoscopy is repeated to evacuate air and accumulated secretions and to inspect the valve. Generally, we do not place a nasogastric tube.

All patients are observed overnight, undergo a barium esophagogram the following morning to evaluate for a leak (on account of the extent of manipulation about the gastroesophageal junction), and are discharged after starting liquids. Patients are followed up at 2 to 4 weeks, 6 to 8 weeks, 3 months, 6 months, and yearly. At all follow-up visits, we routinely use the GERD-HRQL survey to monitor their symptom severity and satisfaction.

Data Collection and Statistical Analysis

This study was approved by our institutional review board. Data were collected through a retrospective chart review using a data collection form that queried demographic and preoperative clinical information, studies performed as part of each patient's workup, and data from the perioperative and follow-up periods. Statistical analysis was conducted using the SPSS (version 11 for Windows) statistical software package (SPSS, Inc, Chicago, Ill). Descriptive statistics included mean and median values for numerical data. Paired sample *t*-tests were used to compare preoperative and most recent follow-up GERD-HRQL scores.

RESULTS

From February 2009 through January 2011, a total of 46 patients underwent 48 endoscopic fundoplication procedures. The mean and median ages were 49 and 48 years (range, 23-84 years), respectively, and 50% were women.

For all patients, the mean and median American Society of Anesthesiologists scores were both 2 (range, 1-3). Thirty-five (76.1%) patients had typical symptoms (ie, heartburn, regurgitation, or water brash) and the remaining 11 had atypical symptoms (ie, cough, rhinitis, asthma, or aspiration). All patients with atypical symptoms had objective confirmation of reflux with pH or impedance testing. Six patients had dysphagia preoperatively, and 42 had been using PPIs daily. The mean and median preoperative GERD-HRQL scores were 23.2 and 23, respectively. Twenty-two patients underwent pH probe evaluation. Thirty-three patients were found to have small hiatal hernias; the remaining patients had no hiatal hernias. The mean and median Hill scores were both 3 (range, 2-4).

The mean procedure time for endoscopic fundoplication was 83 minutes (range, 36-180 minutes). In comparing mean procedure times for the first 5 patients to the subsequent 41 patients, there was a significant difference (122 vs 78 minutes; *P* = .001).

The mean hospital length of stay was 1.3 days (range, 1-3 days). One patient had evidence of pneumoperitoneum on the immediate postoperative chest x-ray. There was no clinical evidence of peritonitis or perforation, which was confirmed by barium esophagogram. The patient was discharged on the second postoperative day without an incident.

There was one major complication in a patient who was readmitted postoperatively with an aspiration pneumonia,

FIGURE 1. The EsophyX₂ device. A, Handle. B, End. (Courtesy of EndoGastric Solutions, Inc, Redmond, Wash.)

which was due to perioperative nausea and vomiting after recovery from anesthesia for the procedure. She subsequently recovered and remains symptom-free. There were 3 minor complications. One patient had bleeding

from a suture site during the procedure. This was controlled with compression using the device for a few minutes and did not require a blood transfusion or an additional intervention. Also, 2 patients had postoperative

FIGURE 2. A, Helical retractor retracting the Z-line into the tissue mold. B, Tissue mold closed to approximate the fundus to the intra-abdominal esophagus. C, Placement of polypropylene H-fasteners to secure the fundoplication (Courtesy of EndoGastric Solutions, Inc, Redmond, Wash.).

urinary retention requiring catheterization. There were no postoperative deaths.

The mean and median follow-up times were 140 and 83 days, respectively (range, 15-602 days). At follow-up, there was a significant difference between the preoperative and postoperative mean GERD-HRQL scores (23 vs 6.7; $P < .001$) and the number of patients using PPIs (91.3% vs 47.8%; $P < .001$). Before therapy, 95.7% of patients were dissatisfied with their condition compared with 13% (6 patients) postoperatively ($P < .001$). Among the 6 patients who remained dissatisfied postoperatively, 4 had no symptomatic improvement and their treatments were considered confirmed failures. These failures occurred at a mean of 5.5 months after the procedure. Three of the 4 patients had wrap disruptions that were proven endoscopically; 2 were repaired by repeat endoluminal fundoplication and 1 by laparoscopic Nissen fundoplication. All 3 patients had a significant improvement in

symptoms after their subsequent procedures. The other dissatisfied patient whose treatment was considered to have failed had ongoing symptoms of reflux that was confirmed with a postoperative pH study. Further workup was arranged, but the patient has not followed up due to other unrelated medical issues. The 2 remaining patients had normal HRQL scores but also had symptoms of gas bloat leading to their dissatisfaction.

Thirty-five patients had typical symptoms of GERD, and 11 patients had atypical symptoms. Among patients with typical symptoms, a significant improvement was seen between the preoperative and postoperative mean GERD-HRQL scores (25.3 vs 4.7; $P < 0.001$) and satisfaction rates (0% vs 94.3%; $P < .001$). Among patients with atypical symptoms, there was no significant difference between the preoperative and postoperative mean GERD-HRQL scores (13.67 vs 9; $P = .61$). However, there was a significant improvement when comparing the preoperative and postoperative satisfaction rates (0% vs 63.6%; $P = .01$).

Among the 46 patients, 22 had more than 90 days of follow-up (mean, 240 days; range, 100-602 days). In this subset with longer follow-up, the differences between preoperative and postoperative mean GERD-HRQL scores (22.1 vs 8.3; $P < .005$), the number of patients using PPIs (90.9% vs 45.5%; $P < .001$), and the percentage of patients that were dissatisfied (90.9% vs 13.6%; $P < .001$) remained significant.

DISCUSSION

This study demonstrates that endoscopic fundoplication can be performed safely and is effective at short-term follow-up. The results of this study are similar to those of previous reports.

FIGURE 3. Omega-shaped valve created after endoluminal fundoplication, coronal view (Courtesy of EndoGastric Solutions, Inc, Redmond, Wash.).

For many years, the development of a totally endoscopic approach for the treatment of GERD has been the focus of intense efforts. To decrease the compliance of the lower esophageal sphincter (LES) to prevent reflux, strategies such as the injection of compounds into the submucosa of the LES,^{17,18} radiofrequency ablation of the submucosa of the LES,¹⁹ mucosal plication,²⁰ and full-thickness gastric plication²¹ have all been previously attempted. Unfortunately, none of these approaches has gained widespread acceptance owing to an increased rate of complications or recurrent symptoms.²² Perhaps what made most of these earlier approaches less successful was that they all ultimately led to a narrowing of the gastroesophageal junction, which in itself was not enough to mitigate acid reflux. In addition, none of these approaches truly emulated a surgical fundoplasty to restore the competency of the reflux valve. Endoluminal fundoplication using the EsophX₂ device represents the latest endoscopic approach associated with both short-term effectiveness in treating GERD and elimination of postoperative PPI use in several series.

One concern with endoscopic fundoplication is the durability of the procedure. With an open or laparoscopic operation, intra-abdominal adhesions form that help maintain the configuration of the fundoplication. It is unclear whether this occurs to the same extent with the endoscopic approach. Jobe and colleagues²³ reported their experience with endoluminal fundoplication in a canine model in 2008. Comparing 2 techniques—fundoplication of the stomach around the gastroesophageal junction (termed “TIF 1.0”) and around the distal, intra-abdominal esophagus (termed “TIF 2.0”)—the investigators demonstrated that the latter approach enabled “ink-welling” of the distal esophagus into the proximal stomach, generating a physiologic flap valve that could more effectively pinch shut with increasing intragastric pressure. They also demonstrated that the fundoplication along the distal esophagus and anchored by the polypropylene H-fasteners did indeed lead to the formation of serosal adhesions, which in theory should help preserve the reconstructed valve over time.

Subsequently, a group reported a clinical study involving 3 sites with a total of 19 patients. Interestingly, at 10.8 months of follow-up, more than half of all patients had an endoscopically confirmed wrap disruption necessitating subsequent laparoscopic fundoplication for persistent GERD.²⁴ It is unclear why the results of this study are inferior to those reported by other investigators. One issue may be that the wrap disruptions were related to learning curve issues, because the study enrolled the initial clinical cases from all 3 sites. Another factor may involve patient selection, which may affect eventual treatment outcomes. This has yet to be teased out from larger prospective studies.

Our experience with endoscopic fundoplication suggests that there is a learning curve associated with this technique, at least with respect to the duration of the procedure. As

mentioned previously, the mean procedure time dropped significantly when we compared our first 5 cases with the rest of our series. Also, our technique had evolved over time. For instance, early on in our series, distention of the stomach with insufflated air was obtained with the endoscope only. Later in the series (and for most patients), the use of insufflation with carbon dioxide gas from a laparoscopic insufflator system was adopted and improved endoscopic visualization dramatically. Additionally, we found that the exposure achieved by our standard left lateral decubitus positioning was improved by manipulating the position of the operating room table during the procedure. Specifically, rotating the table along the longitudinal axis or placing it in the reverse Trendelenberg orientation was frequently performed during the procedures. Also, we found that the application of cricoid pressure effectively prevented the escape of insufflated gas passing through the incompetent gastroesophageal junction, which helped to maintain the endoscopic view. Usually, after 1 or 2 sutures were placed and the valve reconstruction was begun, cricoid pressure was no longer necessary.

Another area of difficulty is manipulating the endoscope and device within a short and narrow stomach. Recently, a device with a smaller profile has become available that we hope will allow for easier maneuverability in such cases.

Although patients with typical symptoms had a significant improvement in their overall satisfaction and GERD-HRQL score, among those with atypical symptoms, a significant improvement was seen only in the number of satisfied patients. This is perhaps due to the insensitivity of the GERD-HRQL instrument in assessing atypical symptoms of reflux. Moreover, in this series, 3 patients experienced wrap disruption. Although the current set of data precludes a further investigation of causative factors, possible causes include (1) technical issues involving suboptimal placement of the polypropylene H-fasteners, (2) poor patient selection (such as those with large hiatal hernias or with a wide-open (ie, type 4 Hill) gastroesophageal valve in combination with a hernia), and (3) poor patient compliance in avoiding strenuous activity, which may affect the integrity of the repair.

Ultimately, the gold standard to which this technique will need to be compared is the laparoscopic Nissen fundoplication. In 2005, the first randomized controlled trial comparing laparoscopic Nissen fundoplication to PPIs demonstrated the superiority of operative intervention to medical therapy.²⁵ Among 109 patients treated with laparoscopic Nissen fundoplication, there were no operative deaths, but there were 4 major intraoperative complications (2 splenic injuries, 1 esophageal injury, and 1 liver injury) as well as 6 perioperative complications (including 3 wrap migrations, 2 respiratory tract infections, and the inclusion of a nasogastric tube by a wrap suture) that required 4 reoperations. Our series of 46 patients who underwent

endoscopic fundoplication compares favorably because there were no deaths and only 1 report of pneumonia, although there were 3 wrap disruptions in almost half as many total patients as treated with laparoscopy in the aforementioned randomized series. Laine and colleagues²⁶ had also previously reported a prospective randomized study comparing laparoscopic with open Nissen fundoplication for patients with GERD and demonstrated no operative mortality and a mean hospital stay of 3.2 days for the laparoscopic group and 6.4 days for the open group. Our series is comparable, with no mortality and a mean hospital stay of 1.3 days.

Our initial experience with endoscopic fundoplication is currently limited to 46 patients. In addition, our follow-up is of short duration. Moreover, although there was a significant reduction in the number of patients who were still taking PPIs postoperatively, almost half of the treatment population is still taking PPIs, either at a lower dose or at least occasionally.

It is unlikely that endoscopic fundoplication will ever completely replace laparoscopic fundoplication because endoscopic fundoplication can only be used for patients with small or no hiatal hernias. However, if results prove to be durable, endoscopic fundoplication may become the procedure of choice for those patients who are candidates for this less invasive procedure. There may be other advantages that may make this approach preferable for patients with impaired esophageal motility.

In conclusion, we have demonstrated that endoscopic fundoplication is feasible, can be performed with a low incidence of complications, and is effective in a majority of patients at short-term follow-up. Further study is needed to define long-term outcomes and predictors of treatment success to optimize patient selection for therapy.

References

1. American Gastroenterological Association. The burden of gastrointestinal diseases. Bethesda (MD): American Gastroenterological Association; 2001.
2. The American Gastroenterological Association Institute Medical Position Panel. American Gastroenterological Association medical position statement on the management of gastroesophageal reflux disease. *Gastroenterology*. 2008;135:1383-91.
3. Tytgat GN, McColl K, Tack J, Hotlmann G, Hunt RH, Malfertheiner P, et al. New algorithm for the treatment of gastro-oesophageal reflux disease. *Aliment Pharmacol Ther*. 2008;27:249-56.
4. Catania RA, Kavic SM, Roth JS, Lee TH, Meyer T, Fantry GT, et al. Laparoscopic Nissen fundoplication effectively relieves symptoms in patients with laryngopharyngeal reflux. *J Gastrointest Surg*. 2007;11:1579-88.
5. Westcott CJ, Hopkins MB, Bach K, Postma GN, Belafsky PC, Koufman JA. Fundoplication for laryngopharyngeal reflux disease. *J Am Coll Surg*. 2004;199:23-30.
6. Funch-Jensen P, Bendixen A, Iversen MG, Kehlet H. Complications and frequency of redo antireflux surgery in Denmark: a nationwide study, 1997-2005. *Surg Endosc*. 2008;22:627-30.
7. Hahnloser D, Schumacher M, Cavin R, Cosendy B, Petropoulos P. Risk factors for complications of laparoscopic Nissen fundoplication. *Surg Endosc*. 2002;16:43-7.
8. Hunter JG, Swanson L, Waring JP. Dysphagia after laparoscopic antireflux surgery. The impact of operative technique. *Ann Surg*. 1996;224:51-7.
9. Vakil N, Shaw M, Kirby R. Clinical effectiveness of laparoscopic fundoplication in a US community. *Am J Med*. 2003;114:1-5.
10. Cadie GB, Rajan A, Rqibate M, Germay O, Dapri G, Himpens J, et al. Endoluminal fundoplication (ELF): evolution of EsophyX, a new surgical device for transoral surgery. *Min Invasive Ther Allied Technol*. 2006;15:348-55.
11. Velanovich V. Endoscopic, endoluminal fundoplication for gastroesophageal reflux disease: initial experience and lessons learned. *Surgery*. 2010;148:646-53.
12. Barnes WE, Hoddinott KM, Mundy S, Williams M. Transoral incisionless fundoplication offers high patient satisfaction and relief of therapy-resistant typical and atypical symptoms of GERD in community practice. *Surg Innov*. 2011;18:119-29.
13. Ben-David K, Carreras J, Lopes J. Are incisionless fundoplication procedures a safer alternative to the laparoscopic Nissen for the treatment of chronic gastroesophageal disease? *J Gastrointest Surg*. 2001;15:885-90.
14. Demyttenaere SV, Bergman S, Pham T, Anderson J, Detorre R, Melvin WS, et al. Transoral incisionless fundoplication for gastroesophageal reflux disease in an unselected patient population. *Surg Endosc*. 2010;24:854-8.
15. Velanovich V. The development of the GERD-HRQL symptom severity instrument. *Dis Esoph*. 2007;20:130-4.
16. Hill LD, Kozarek RA, Kraemer SJ, Aye RW, Mercer DC, Low DE, et al. The gastroesophageal flap valve: in vitro and in vivo observations. *Gastrointest Endosc*. 1996;44:541-7.
17. Louis H, Deviere J. Endoscopic implantation of Enteryx for the treatment of gastroesophageal reflux disease: technique, preclinical and clinical experience. *Gastrointest Endosc Clin North Am*. 2003;13:191-200.
18. Cicala M, Gabbriellini A, Emerenziani S, Guarino MP, Ribolsi M, Caviglia R, et al. Effect of endoscopic augmentation of the lower oesophageal sphincter (gatekeeper reflux repair system) on intraoesophageal dynamic characteristics of acid reflux. *Gut*. 2005;54:183-6.
19. Torquati A, Richards WO. Endolumenal GERD treatments: critical appraisal of current literature with evidence-based medicine instruments. *Surg Endosc*. 2007;21:697-706.
20. Montgomery M, Hakanson B, Ljungqvist O, Ahlman B, Thorell A. Twelve months' follow-up after treatment with the EndoCinch endoscopic technique for gastro-oesophageal reflux disease: a randomized, placebo-controlled study. *Scand J Gastroenterol*. 2006;41:1382-9.
21. Pleskow D, Rothstein R, Kozarek R, Haber G, Gostout C, Al Lembo. Endoscopic full-thickness plication for the treatment of GERD: long-term multicenter results. *Surg Endosc*. 2007;21:439-44.
22. Fry LC, Monkemuller K, Malfertheiner P. Systematic review: endoluminal therapy for gastro-oesophageal reflux disease: evidence from clinical trials. *Eur J Gastroenterol Hepatol*. 2007;19:1125-39.
23. Jobe BA, O'Rourke RW, McMahon BP, Gravesen F, Lorenzo C, Hunter JG, et al. Transoral endoscopic fundoplication in the treatment of gastroesophageal reflux disease: the anatomic and physiologic basis for reconstruction of the esophago-gastric junction using a novel device. *Ann Surg*. 2008;248:69-76.
24. Hoppo T, Immanuel A, Schuchert M, Dubrava Z, Smith A, Nottle P, et al. Transoral incisionless fundoplication 2.0 procedure using EosphyX for gastroesophageal reflux disease. *J Gastrointest Surg*. 2010;14:1895-901.
25. Mahon D, Rhodes M, Decadt B, Hindmarsh A, Lowndes R, Beckingham I, et al. Randomized clinical trial of laparoscopic Nissen fundoplication compared with proton-pump inhibitors for treatment of chronic gastro-oesophageal reflux. *Br J Surg*. 2005;92:695-9.
26. Laine S, Rantala A, Gullichsen R, Ovaska J. Laparoscopic vs conventional Nissen fundoplication: a prospective randomized study. *Surg Endosc*. 1997;11:441-4.

Discussion

Dr W. Randolph Chitwood, Jr (Greenville, NC). I think the next step should be a randomized study between a laparoscopic Nissen operation and this procedure. Do these patients have the same postoperative characteristics as those having a laparoscopic Nissen as far as failure to eructate?

Dr Narsule. They have very similar characteristics. They sometimes have postoperative bloating that we have been able to control with simethicone effectively thereafter.

Dr Bryan Fitch Meyers (*St. Louis, Mo*). There are some end points that are often talked about around antireflux surgery, both before and after. One is a DeMeester score or 24-hour pH monitoring. I did not see any data there or for manometry. Did you observe any objective manometric change or objective reduction in the DeMeester score after the implementation of this device?

Dr Narsule. In this study, we did not, because we did not deliberately have all of our patients undergo further studies. Simply put, after they followed up with us, we assessed the efficacy of the endoscopic fundoplication on the basis of their symptomatology and their response to the HRQL survey instrument. If there were issues of dissatisfaction or persistent symptoms, we worked them up. But aside from that, we did not perform any additional studies.

Dr Meyers. Moving forward, I think that would be an important thing to truly demonstrate the clinical effectiveness of this therapy. Patients who undergo this treatment want to get better, and there is going to be a certain measurable placebo effect. The self-reported quality of life and the rate of change in the use of PPIs are pretty soft end points for something that could have a potentially big utilization and cost associated with it.

Dr G. Hossein Almassi (*Milwaukee, Wis*). Nice work. I have 2 questions. How easy is it to do a redo after a failed endoscopy? Have you had any failures and did you do a redo endoscopic Nissen again?

Dr Narsule. The redo is very similar to the initial operation. We were fortunate to have information as to where the wrap had disrupted and, endoscopically, we were able to see the points of laxity that occurred after the first procedure. We were able to target where exactly to place the polypropylene H-fasteners. It was far easier than we had anticipated preoperatively.

Dr Almassi. I know gastroenterologists are not cardiologists, but what do you think will happen in the future? Are gastroenterologists going to be doing this procedure?

Dr Narsule. I do not think that the future of this procedure would be in the hands of the gastroenterologists alone, because I think that there is an increased complexity to performing a fundoplasty. There have been other endoscopic approaches to the treatment of GERD, and they have not persisted. Although they tried to decrease the compliance of the LES, perhaps because a fundoplasty had not fully been considered with those interventions, they were not durable. Adding a fundoplasty as part of the endoscopic approach requires the special perspective that the surgeon has in performing this procedure. Although it is an endoscopic procedure, it is a procedure that is performed along the same principles. I think that the results will be better and more durable in the hands of surgeons.

Dr Toni Lerut (*Leuven, Belgium*). I have a follow-up question on that. In Europe, the future is already in the hands of the gastroenterologists, because they are doing most of these procedures. It is so in our institution, but they do it together with us, and we do have a similar experience. What it shows on 24-hour pH monitoring is that this procedure decreases the volume of reflux, but it does not abolish it as efficiently as after a laparoscopic Nissen procedure. Would you advocate this type of procedure, for instance, in patients with Barrett's metaplasia?

Dr Narsule. For patients who do have Barrett's metaplasia, depending on whether it is dysplastic or not, I think that this procedure would still be very applicable. In fact, 5 of our patients had Barrett's esophagus, had an intervention for the metaplasia, and then subsequently underwent this procedure.