Outcomes of endoluminal gastric plication for the treatment of gastroesophageal reflux disease

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Gastroesophageal reflux disease (GERD) is very common in the USA. Although proton-pump inhibitors are effective in alleviating GERD symptoms, many patients do not find relief with medication alone or become dependent on these medications for life. The lifelong cost of such medications can be burdensome.

For these reasons, many patients with GERD have undergone invasive procedures including Nissen fundoplication and more recent endoscopic techniques to alter their anatomy enough to prevent the reflux of acid into the esophagus. Newer procedures including endoluminal gastric plication (ELGP) look promising, but long-term follow-up is needed to more thoroughly assess outcomes. We have studied the outcomes of 43 patients who underwent ELGP and analyzed the efficacy of this particular technique in alleviating symptoms and eliminating the need for proton-pump inhibitors.

METHODS

Patients

The study examined patients who underwent ELGP between October 2000 and April 2001. Some who underwent the procedure were referred by their physicians, and others self-referred after hearing about the procedure through the media. To be a candidate for the procedure, the patient had to have reflux symptoms that were relieved or partially relieved by H_2 blockers or proton-pump inhibitors. Classic symptoms of GERD were defined as regurgitation of sour material in the mouth or heartburn. The patients also underwent initial diagnostic tests including manometry, 24-hour pH testing, and endoscopy. Patients with Barrett's esophagus, motility disorders, or large hiatal hernias, as determined by endoscopy, were excluded as candidates. Patients who had documented reflux by pH probe testing with no contraindications to the procedure were candidates. During this time period, 43 patients met the criteria and underwent ELGP.

Procedure

After consents were obtained, patients were placed in the left lateral decubitus position, and a trained anesthesiologist administered general anesthesia or deep conscious sedation using propofol. An overtube was placed in the patient's esophagus. The endoscope was then passed through the overtube to the level of the squamocolumnar junction. The suturing device located at the tip of the endoscope was then placed in apposition to the luminal wall, and suction was applied to draw and hold tissue in the suture chamber. Once an adequate amount of tissue was in the chamber, a suture was placed. A second suture was then placed adjacent to the first, and the 2 were tied together to create a plication. This technique was repeated, and all patients received 1 to 3 plications depending on their anatomy and the endoscopic appearance after placement of each suture.

Endpoints

The goal of this study was to determine the long-term effectiveness of ELGP for the treatment of GERD. To achieve this with a retrospective review of medical records alone, we confined our endpoints to 1 objective outcome: whether patients were taking proton-pump inhibitors or H_2 blockers 1 year after the procedure.

Follow-up

The patients in the study were monitored up to 2 years after their procedure. Initially, each patient had a 3-day and a 3-month follow-up visit with a trained gastroenterologist. The physician's office also contacted patients by telephone 1 year after the procedure. At that time, the patients were asked 2 questions to determine the effectiveness of the procedure. The first question was whether they were on or off their medicines for the treatment of reflux symptoms. If they were still taking medicines, they were asked if the amount of medicine was the same as before the procedure or less. Their answers were recorded, and the information in the charts was reviewed retrospectively.

RESULTS

All 43 patients were successfully contacted by telephone, and the results were recorded in the charts. When the patients were asked if they were still on medicines, 19 patients (44%) responded yes. Of these patients, 11 responded that they were on less medicine, and 8 replied that they were on the same doses. Twenty-four patients (56%) reported no reflux and no medicines for GERD 1 year after ELGP. There were no major complications in any of the procedures. Minor complications included sore throat and chest pain immediately after the procedure. These symptoms generally resolved within 72 hours.

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DISCUSSION

In our study, 56% of the patients who underwent ELGP were able to discontinue their reflux medicines up to 1 year after the procedure. Another 19% were able to reduce the frequency of their medicines. These success rates are lower than those found with the Nissen procedure, which resolved GERD in 80% to 90% of cases (5, 6). The hope is that future advances in endoscopic techniques will allow for less-invasive alternatives for the treatment of persistent and refractory GERD.

The limitations to the study lie in the subjective nature of the follow-up questions. The amount of benefit achieved by the procedure was based solely on the patients' answers to the questions that were asked. By asking the patients to quantify the medicine they were on after the procedure, we hoped to limit the subjectivity of this approach.

Performing a 24-hour pH probe and comparing the results before and after the procedure could provide a more objective analysis of the impact of ELGP on reflux. One patient underwent a follow-up 24-hour pH study, but the results remain insufficient for publication. Currently, the technical aspects of ELGP, including risks of the procedure, are still being examined. Once the preliminary data from such studies as this one show a presumed benefit with the procedure, larger-scale studies should be performed.

Also, there was no control group in this study to evaluate placebo effect. We feel that the placebo effect is minimized by the long-term outcomes. It is probable that patients may feel initial relief secondary to placebo effect; however, true reflux should return with time unless the procedure is successful. Regardless, a placebo-controlled study would be of great benefit in assessing the effectiveness of ELGP. Currently, a controlled multicenter study is under way.

ELGP is not the only innovation for the treatment of GERD. Many institutions are exploring other endoluminal techniques to treat reflux. These endoscopic methods can be categorized into plicating, injection of bulking agents, and radiofrequency techniques. Injecting bulking agents into the mucosa of the squamocolumnar junction has shown some promise (1–3). The bulking agents studied include collagen, polytetrafluoroethylene paste, polymethylmethacrylate, and ethylene vinyl alcohol with tantalum. Preliminary testing by Enteryx showed that its bulking agent allowed 70% of patients to stop taking antireflux medication and another 10% of patients to reduce their medications by half (7).

The Stretta procedure uses radiofrequency energy to "scar down" the lower esophageal sphincter and has been shown to reduce the number of relaxations and decrease the size of the lumen space (4). Initial studies on the efficacy of the Stretta procedure have shown improvement in GERD symptoms; however, complications including aspiration and esophageal perforation were notable in preliminary testing. The Food and Drug Administration has approved the Stretta procedure for use. These endoluminal approaches have not been formally compared, primarily due to the lack of initial long-term data for each technique.

Endoluminal techniques will certainly play a role in the treatment of GERD for years to come. Technical advances are being made every day that are helping to increase the success rate and decrease the complication rate for such procedures. Aside from these advances, practicing gastroenterologists will need to learn how to advise their patients on the various treatment options. These options include not only the endoluminal techniques discussed, but surgical and medical therapies as well. Larger studies will need to be done to aid the physician in evidence-based decision making for treatment of GERD.

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