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Endoscopic Treatment (522)

Endoscopic Antireflux Therapy:
Stretta and EndoCinch

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Though medical and surgical therapies for GERD are extremely successful and well-studied, and both effective alternatives for patients with need for long-term therapy, many patients who require long-term pharmacologic (drug) therapy would prefer a non-surgical, non-pharmacologic option for treatment of their symptoms. This has led to extensive research and development of endoscopic procedures designed to treat gastroesophageal reflux disease. Recently, two of these procedures were approved by the FDA for treatment of GERD; radiofrequency energy delivery to the gastroesophageal junction (Stretta) and transoral flexible endoscopic suturing (EndoCinch). Both attempt to reduce reflux by mechanically altering the lower esophageal sphincter. The exact mechanism for their efficacy is unknown. Several other procedures are currently in clinical trials.

Several key generalizations can be made. To date, a relatively small number of patients have been studied, follow up is relatively short (less than or equal to two years), and side effects have been reported. The patient should be reminded that the studies have been performed in patients with heartburn and regurgitation as their primary symptoms so other manifestations of gastroesophageal reflux disease have not been systematically studied. Patients with mild erosive esophagitis (grade 2 or less) and small hiatal hernias have been evaluated. All patients have had at least a partial response to proton pump inhibitors (drugs that limit acid secretion in the stomach – also called PPIs). Therefore, patients with severe erosive esophagitis, Barrett's esophagus (a condition that involves a cellular change in the tissue of the esophagus), and other manifestations of GERD have not been studied. Patients in these categories should likely not be treated outside of a clinical trial. Though side effects are few, several deaths have been reported and other rare major complications such as excess fluid in the lining of the lungs (pleural effusion), esophageal perforation, and aspiration have also been reported.

Stretta: Radiofrequency Energy Procedure

For the Stretta procedure, the patient is given a mild sedative (conscious sedation) to minimize discomfort. Following an endoscopy to measure the distance, the gastroenterologist inserts a balloon-tipped catheter into the patient's mouth, and advances it down the esophagus until it reaches the lower esophageal sphincter (LES). [The LES is a band of muscle at the junction of the stomach and esophagus that acts as a barrier to prevent back-flow (reflux) of stomach contents into the esophagus.] The balloon-tipped catheter has electrodes on its surface. The electrodes are placed into the tissue and radiofrequency energy is delivered to create thermal lesions in the vicinity of the LES—the energy causes tiny burns that heal and form scar tissue. Over the next several weeks, the scar tissue tightens the area around the LES, thereby increasing lower esophageal sphincter pressure.

The Bard EndoCinch™ Suturing Procedure

In the Bard EndoCinch System, a doctor places a series of stitches (sutures) in the lower esophagus near the lower esophageal sphincter. Using an endoscope, the doctor lowers the suturing system to the site where the esophagus and the stomach meet. The sutures are tied together to alter the gateway between the stomach and esophagus and potentially prevent acid from refluxing into the esophagus.

The procedure is performed in the doctor's office or outpatient center. There is no hospitalization required. Typically, only mild sedation is required (no general anesthesia), so normal activities can be resumed the next day.

Stretta

Six months after therapy, patients in a recently reported study in the U.S. that were treated with radiofrequency energy showed an improvement in heartburn score, regurgitation, quality of life and patient satisfaction compared to initial measurements (baseline) without any changes in esophageal motility. This improvement in symptom relief was also associated with statistical improvement in esophageal acid exposure compared to baseline.[1]

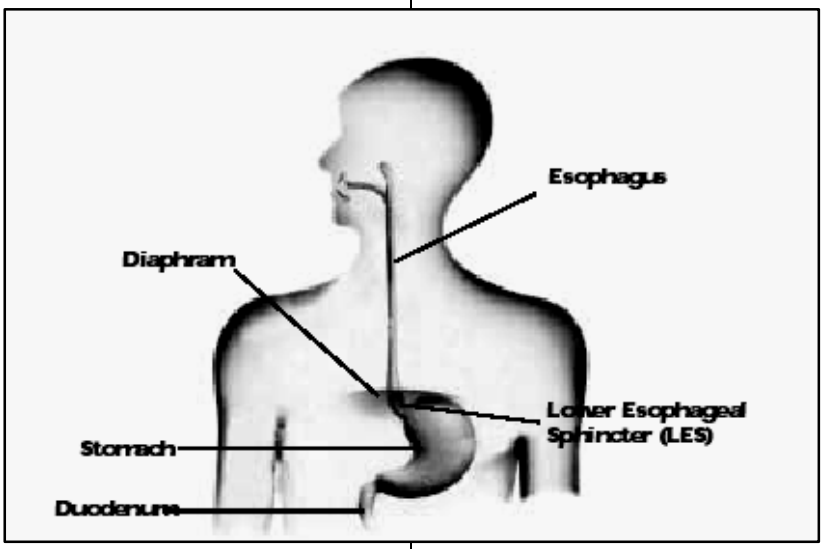
The initial study reported no major complications. At six months, 70% were not on any antisecretory therapy (i.e., drugs that reduce acid secretion such as H2 Blockers or PPIs), and 87% were able to discontinue PPIs. At one year follow up, over 60% continued to be off antisecretory therapy and had sustained improvement in heartburn. Unfortunately, serious side effects have been reported to the FDA, including aspiration, pleural effusion, abnormal heartbeat (atrial fibrillation), and deaths in the first thousand cases performed. A controlled trial comparing radiofrequency energy delivery to placebo treatment [i.e., balloon distention without needles or radiofrequency application] has been completed and will be reported shortly.

EndoCinch

The second approved procedure, transoral flexible endoscopic suturing (EndoCinch), was initially reported in a multicenter trial of 64 patients with heartburn more often than three times a week, dependence on antisecretory medication, mild erosive esophagitis, and abnormal 24-hour pH monitoring. They were treated with EndoCinch, an endoscopic suturing system designed to create an "internal plication" of the stomach.[2]

In this uncontrolled trial, improvement in the number of reflux episodes was seen. No change in upright, recumbent, or total esophageal acid exposure was seen at three and six months. Sixty-two percent of patients were able to decrease drugs to less than four doses of antisecretory medications per month. Improvement was seen in patient satisfaction, heartburn severity, and heartburn score compared to the initial measurements. With the exception of a "stitch" perforation requiring short-term hospitalization, no major complications were reported. To date, no control trials (comparing this treatment to no active treatment) have been reported using this method.

Most recently, a two-year follow up study in 33 patients originally treated with this endoscopic device was reported.[3] After a mean follow up of 25 months, heartburn severity and score, and frequency of regurgitation showed continued improvement compared to baseline measurements. However, only eight patients (25%) initially on antisecretory therapy (specifically, proton pump inhibitors) were completely off of antisecretory medications, with 9% taking half of their initial dose or less. Forty percent required full dose medications and 6% had undergone a laparoscopic Nissen fundoplication because of therapeutic failure. These two-year follow up data are disappointing and suggest that long-term efficacy of this originally designed procedure will not be forthcoming.



Other Procedures

Other endoscopic procedures currently being evaluated in which preliminary information has been reported include injection of a biopolymer ethylene vinyl alcohol (EVA) into the muscular layer of the lower esophageal sphincter. The biopolymer is injected through a sclerotherapy needle under fluoroscopy and data was recently reported in abstract form. A European and North American multicenter open label trial of PPI-dependant GERD patients shows promising results. Abnormal 24 hour pH monitoring studies showed improvement in symptom scores by an average of 64, 83, and 82 percent at 1, 3, and 6 months respectively after initial injection. Thirty-two of thirty-five discontinued all antisecretory therapy at one month, 18 of 21 at three months, and 7 of 9 at six months. No clinically important complications were reported in this initial uncontrolled trial. FDA approval is pending.[4]

Other modifications of the EndoCinch device are in current development as are other modifications to existing treatments. At present, the reader should be aware of short follow-up, with clear decrease in efficacy over time. A narrow spectrum of patients has been treated.

Summary

The concept of endoscopic therapy is excellent, the hope exciting. Nonetheless, it is not here as definitive therapy until we have more data and results are compared to the safe and highly effective medical therapies. Patients should have these procedures only after careful consideration of the alternatives with clear understanding of the absence of long-term data and the small risk of major complications.

References:

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