ADVANCES IN GERD

Current Developments in the Management of Acid-Related GI Disorders

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The Use of Endoscopy and Radiofrequency Ablation for the Treatment of GERD

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G&H When is endoscopic therapy, rather than surgical therapy, considered for the treatment of gastroesophageal reflux disease?

JP This is a difficult question to answer because the indications for either therapy are very similar in terms of treating and correcting the anatomic issue, as opposed to merely treating the causticity of the gastric reflux. A reasonable use for endoscopic therapy is in a patient with proven pathologic reflux (eg, history of esophagitis, Barrett esophagus, or abnormal acid exposure on reflux testing) who presents with heartburn or regurgitation despite previous proton pump inhibitor (PPI) therapy, and in whom an endoscopy reveals no herniation. Any time a patient has regurgitation, does not have a large hernia, and is truly refractory to PPI therapy, an endoscopic approach could be considered for the treatment of gastroesophageal reflux disease (GERD).

G&H What endoscopic therapies are available for the treatment of GERD, and how effective are they?

JP The 2 therapies that are currently being utilized involve the Stretta (Mederi Therapeutics) and the EsophyX (EndoGastric Solutions) devices. These devices have been in use for 10 to 15 years and have undergone refinements to improve their outcomes and ease of use.

It is difficult to determine how effective these devices are because there has been a lack of sham-controlled trials or head-to-head trials against PPIs; the high-level evidence backing PPIs or Nissen fundoplication is not available for these endoscopic therapies. However, uncontrolled trials, as well as controlled trials, have reported that specific patient populations do experience a reduction in acid exposure and an improvement in symptom control. The reasoning is not clear from the data that have been presented thus far; one of the areas that still needs more research is what pathophysiologic changes occur in reflux that would be mitigated by these endoscopic techniques.

G&H What are the challenges associated with treating GERD via an endoscopic approach?

JP The challenge across the spectrum of GERD is trying to tailor the therapy for the patient. Beyond looking at the pathophysiology of the patient and determining the disease burden in terms of acid reflux, the clinician needs to consider the expectations of the patient and how he or she wants to be treated. That is an important issue that is sometimes forgotten. Some patients are quite comfortable with being on a PPI for the rest of their lives, whereas others view taking medicine for the rest of their lives as a reduction in quality of life. There are some patients who do not want to undergo surgery. When patients are at that point—when an alternative option is necessary—an endoscopic therapy may be a nice middle-of-the-road approach.

G&H How is the Stretta procedure performed?

JP First, the patient undergoes an endoscopy, and the endoscopist notes the landmarks. Once the endoscope is removed, the Stretta delivery system is then placed in the esophagogastric junction, and a balloon-like bag is expanded through insufflation. There are small metal

hooks at the end of the bag that are oriented at 90 degrees, and they hook into the deep layers of the esophagus. This helps deliver the radiofrequency ablation (RFA) energy. By twisting the delivery system, the endoscopist can change the angle of approach and provide a more circumferential, uniform RFA energy delivery to the entire distal high-pressure zone or esophagogastric junction.

G&H Who is the optimal candidate for this procedure?

JP The ideal candidate is any patient with proven GERD who is breaking through PPI therapy, or who is continuing to experience significant symptoms of heartburn or regurgitation, but does not want to undergo surgery. Some people are inherently nervous about undergoing surgery for a condition that is not life-threatening; their symptoms are more lifestyle and quality-of-life issues. Likewise, there are many people who take a PPI and are not satisfied, and they want to try a noninvasive approach. Any patient with a relatively normal anatomy may be considered as a potential candidate for this particular therapy.

G&H In whom should this procedure be avoided?

JP With any GERD treatment, the most important patient to be avoided is one who does not have acid reflux. Many people are told that they have GERD but actually have either a functional bowel problem or a functional overlap syndrome. Thus, the patient with functional heartburn or functional reflux sensitivity should avoid RFA treatment. Patients who have significant alterations in their anatomy should also be avoided because these particular treatments will not dramatically improve reflux in the context of a large hiatus hernia.

G&H Are there any limitations or adverse events associated with this procedure?

JP One of the adverse events, which is more of a temporary side effect, is chest pain. This adverse event is not uncommon or unusual; the endoscopist is delivering energy to and injuring the distal esophagus. There are also very rare case reports of gastroparesis and potential heart block or injury to the heart; however, these have not been conclusively proven to be related to the procedure. Because of the proximity of the esophagus to the heart, injury of that type is plausible. Any time a procedure is being performed or energy is being delivered in the distal esophagus or the esophagus overall, the endoscopist should be cognizant of the fact that nerves, the heart, the lungs, and so forth all share space in the mediastinum and chest. Overall, though, the safety of the device is very good.

G&H Have there been any long-term studies to examine the durability of this procedure?

JP There have not been any high-level, long-term, well-controlled studies with a systematic outcome. However, there have been several large, observational studies that have evaluated patients for 8 to 10 years. These studies suggest that the Stretta device does have a durable benefit in a specific patient population. There are patients who certainly do fail therapy and require further treatment along the way; unfortunately, the nature of these studies does not lend them to a discussion about the patients who were lost to follow-up.

G&H What training is required to use this procedure?

JP Typically, the required training is 1 to 2 days with a training team that is usually sent from the manufacturer. The device is not very difficult to use; if an endoscopist can place a Bravo capsule or any type of transoral catheter, the delivery system should be very easy to intubate.

G&H How does RFA affect the use of PPI therapy in PPI-dependent patients?

JP RFA appears to reduce overall PPI utilization, which makes sense because uncontrolled data have shown that there are many patients who experience symptom resolution. The decrease in PPI use seems to be less robust in randomized, controlled trials, however.

G&H Is RFA a viable alternative to traditional surgical therapy?

JP No, because the 2 therapies are not interchangeable; they should be used for different types of patients. If a patient is a surgical candidate, it is because he or she has a hernia or very severe acid reflux. It is unlikely that the Stretta device would ever work in that situation, just as it is unlikely that a PPI would work. However, there are specific populations that could potentially benefit from the device: a patient with normal anatomy, perhaps with a hypotensive lower esophageal sphincter or slightly effaced flap valve, who continues to have significant symptoms and abnormal reflux burden despite PPI therapy.

G&H What are the priorities for research and development in this field?

JP It is necessary to better understand what RFA energy is doing to the physiology of the esophagogastric junction. The esophagogastric junction is very complex; it

is comprised of the lower esophageal sphincter and the crural diaphragm. It is also a very dynamic zone that has to move up and down, and into and out of the abdomen in order for certain physiologic functions to occur, such as a transient lower esophageal sphincter relaxation. The Stretta device could certainly augment the lower esophageal sphincter by causing a collagen-induced constriction, although there is some evidence from animal studies to suggest that RFA energy may injure the lower esophageal sphincter and the distal esophagus, which will lead to remodeling and hypertrophy of the muscle. Therefore, understanding that pathophysiology is very important.

Studying patients using more high-level manometry techniques and different techniques such as an endolumenal functional lumen imaging probe (EndoFLIP, Crospon), which measures the compliance of the esophagogastric junction, would also be beneficial.

Overall, the more well-done, sham-controlled or PPI-comparator trials there are, the more clinicians will be able to better define where these particular devices can be best utilized. Unfortunately, these studies are difficult to perform because it is difficult to recruit patients, as well as to apply the technique in a systematic way that can be generalizable.

Dr Pandolfino has received speaking fees from AstraZeneca, Takeda, Medtronic, and Sandhill. He serves as a consultant for Medtronic, Sandhill, Ironwood, and Crospon, and has stock options in Crospon as well.

Suggested Reading

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