

ADVANCES IN GERD

Current Developments in the Management of Acid-Related GI Disorders

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Recent Research on Pneumatic Dilatation Versus Laparoscopic Heller Myotomy for Achalasia Treatment



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G&H What are the most common treatment options for achalasia?

JER Achalasia cannot be cured because the nerves of the esophagus are damaged, peristalsis in the esophageal body is lost, and the lower esophageal sphincter is hypercontracting and not relaxing. Therefore, the goal of achalasia treatment is to disrupt the lower esophageal sphincter as much as possible, while understanding that it still must be able to open (to allow food to go through) and close (to avoid acid reflux). If achalasia is detected before too much damage occurs, 90% of patients can resume fairly normal eating habits.

The 2 most common treatment options for achalasia are pneumatic dilatation and laparoscopic Heller myotomy. Pneumatic dilatation, which involves the use of balloons that can range in size from 30 mm to 40 mm, is a simple outpatient procedure in which a gastroenterologist inflates balloons to stretch and tear the lower esophageal sphincter. If the procedure is successful, the patient can go home and begin to eat normally the next day. Because every patient is different, 1 balloon might not be enough to dilate the esophagus; a second or even third balloon might be needed. These subsequent dilatations are usually performed at separate sessions, days to weeks apart. Balloons are more effective in certain individuals, for example, women and individuals older than 40 years of age (probably because it is easier to tear the esophagus of these patients due to their lower muscle mass). Ten years after the procedure, approximately 66% of patients will need 1 or 2 more dilatations, and the remaining 33% of patients will not need any more dilatations. In my

personal experience, some patients have gone more than 15 years before needing another dilatation.

With laparoscopic Heller myotomy, patients remain in the hospital for 2–3 days and return to work in approximately 2 weeks. Because surgery cuts the muscle better than the stretching of a balloon, patients tend to do better with laparoscopic Heller myotomy in the long term; however, many of these patients are plagued by the side effect of acid reflux. Ten years after laparoscopic Heller myotomy, approximately two thirds of patients are doing well, and approximately one third of patients experience recurrence of their swallowing problem. These patients may need another operation or may respond to pneumatic dilatation. Therefore, we never permanently “cure” a patient with achalasia.

Laparoscopic Heller myotomy is the more popular of the 2 procedures in the United States because US gastroenterologists are not as familiar with pneumatic dilatation (and, thus, do not know how to handle its complications); in addition, more money can be made with laparoscopic Heller myotomy. In contrast, pneumatic dilatation is the more popular treatment modality in Europe, where doctors are more cost-conscious and those in centers of excellence are experienced at performing the procedure.

G&H Could you discuss the design of the recent European study that compared pneumatic dilatation with laparoscopic Heller myotomy for treatment of achalasia?

JER This head-to-head study, which was published in *The New England Journal of Medicine*, was the first study to evaluate these 2 treatment modalities with adequate patient

populations and state-of-the-art technology. Approximately 200 patients diagnosed with achalasia (based upon symptoms, radiographs, and manometry findings) were randomized to 1 of these 2 modalities (with no placebo arm); these patients were followed for 2–3 years at approximately 20 centers in Europe by gastroenterologists or surgeons who were experts at their respective treatments.

G&H What were the study's main findings and conclusions, and why were they significant?

JER The researchers found that symptoms improved by 90%, and this improvement was maintained over a period of 2–3 years in both groups. When the procedures were performed by experienced gastroenterologists or surgeons, the outcomes of each group were the same over this time period; there was no superiority of surgery over pneumatic dilatation, as some researchers had expected. The researchers were allowed to perform 1 or 2 additional dilatations, but that was reminiscent of usual achalasia management. In addition, symptom improvement correlated with physiologic improvement (ie, there was a marked decrease in lower esophageal sphincter pressures and improvement in esophageal emptying). These findings were very encouraging.

This study was powerful because each arm had approximately 100 patients. It was the first study of its caliber to be conducted and the first study to follow more than just symptoms in achalasia patients; it also examined esophageal emptying, lower esophageal sphincter pressures, and quality of life.

G&H What were the limitations of this study?

JER The only limitation was that the researchers did not follow the patients long enough. In the life of an achalasia patient, 2–3 years is not very long. The average achalasia patient is 40–50 years of age, which gives the patient 30–50 more years of life. The real question is not what happens during a window of 2–3 years but what happens during a window of 5–10 years.

G&H Are there plans to follow these patients further and/or perform any subanalyses of the study data?

JER Yes, the researchers are planning to follow these patients over a longer time period. Over time, I think the researchers are also planning to perform a cost-analysis of their data. Modeling studies have shown that botulinum toxin A (Botox, Allergan)—a medical treatment option for achalasia—is not cost-effective unless the patient's life expectancy is less than 2 years, and surgery has been shown not to be cost-effective unless it cures the patient's symptoms and prevents the need for any other treatment for 10–12 years. Otherwise, pneumatic dilatation

appears to be more cost-effective for treating achalasia. However, the total cost of pneumatic dilatation depends on the number of treatments needed to keep the esophagus open. A long-term study would be helpful because it would consist of patients being treated and followed at centers of excellence by surgeons or gastroenterologists who have experience in these procedures. The researchers would see firsthand how many pneumatic dilatations are actually needed in achalasia patients.

G&H How do the European study's findings compare to the findings of earlier studies?

JER As most earlier studies were small (eg, only 20–40 patients) and were conducted by doctors who did not have great expertise in achalasia treatment (particularly pneumatic dilatation), their findings were not very valuable. Therefore, doctors often looked at other studies, such as The Cleveland Clinic study that examined approximately 200 patients; 1 surgeon performed all of the surgeries, while I was the gastroenterologist who performed all of the pneumatic dilatations. We saw comparable findings between the modalities for 4 years and then slight superiority of surgery 5–8 years later, but by then, the number of patients was small. Doctors have also looked at literature reviews of surgical and medical experiences, which often suggested that surgery was better than pneumatic dilatation, but, again, these retrospective or anecdotal studies pale in comparison to randomized studies, such as the previously mentioned European study.

G&H Based on the findings of the European study, should pneumatic dilatation be used more commonly?

JER Yes. A common misconception is that pneumatic dilatation is dangerous, difficult to perform, and not very successful in the treatment of achalasia. The gastroenterology community has essentially abdicated achalasia treatment to their surgical colleagues, partly because many gastroenterologists were never trained to perform pneumatic dilatation (although the procedure is simple and adds only approximately 5 minutes of work). In addition, gastroenterologists are often overly concerned about the risk of perforation, which is not very high. In contrast, young surgeons have enthusiastically embraced treatment for this disease. I have written several editorials supporting the use of pneumatic dilatation over laparoscopic Heller myotomy and asking gastroenterologists to stop turning achalasia treatment over to surgeons. Surgeons should primarily operate on young, otherwise healthy individuals with achalasia, particularly young men, in whom balloons are not as effective for opening the esophagus. However, older patients and women who are otherwise healthy

can achieve symptom-free relief for 10–20 years with pneumatic dilatation without having to undergo a major operation. Unlike in Europe, where gastroenterologists have always treated the majority of achalasia patients with pneumatic dilatation, many US gastroenterologists fear the procedure, which is a shame.

G&H Should the risk of perforation limit the use of pneumatic dilatation?

JER The risk of perforation in pneumatic dilatation is 2–4%, with the European study reporting a risk of 4%. This risk is unfortunate and may discourage some doctors from performing pneumatic dilatation, but it means that 96–98% of procedures occur without perforations. Perforation should be viewed merely as a potential side effect of the procedure. If a perforation does develop, it can be managed, either conservatively or with surgery.

Interestingly, pneumatic dilatation actually has a lower perforation rate than laparoscopic Heller myotomy. This major operation has a perforation rate of 5–10%, compared to pneumatic dilatation's perforation rate of 2–4%; in addition, there is a mortality rate of approximately 0.1% with laparoscopic Heller myotomy. However, surgeons can usually identify and repair perforations quickly; when gastroenterologists detect perforations, they may have to ask their surgical colleagues to repair them.

Another interesting point is that the gastroenterology community has no concerns about performing endoscopic retrograde cholangiopancreatography, which has a complication rate of 10–15% and may cause pancreatitis and/or death, but gastroenterologists are hesitant to perform pneumatic dilatation, which has a lower complication rate. This reaction is probably due to the low volume of achalasia patients seen by the average gastroenterologist; gastroenterologists who see a higher volume of achalasia patients are very comfortable performing pneumatic dilatation.

G&H Are there any contraindications to the use of pneumatic dilatation?

JER There are not many contraindications to this procedure, as long as the patient is healthy. The current contraindications include large epiphrenic diverticulum and, some suggest, large hiatal hernias. A prior failed myotomy is not a contraindication. Age is relative—pneumatic dilatation can be performed in young patients, but their relapse rates and need for further dilatations are higher than in older patients. In addition, this procedure should not be performed in individuals with significant comorbid illnesses, such as heart disease or lung disease, due to their increased morbidity and mortality, should a perforation occur.

G&H Are gastroenterologists starting to more frequently choose pneumatic dilatation over laparoscopic Heller myotomy due to recent study findings?

JER Not really, although more researchers are certainly writing about pneumatic dilatation now. The European study was powerful and put a small dent into the surgeons' bravado that they were the best at treating achalasia. However, treatment choice is affected by the doctor's comfort level. The European study confirmed what doctors who have been performing pneumatic dilatation already know: There are 2 equally good therapies. Will more doctors start performing pneumatic dilatation in the United States? Right now, doctors can make more money by performing laparoscopic Heller myotomy. Until health care is dispersed based upon patient outcomes rather than opportunities to make money, I think there will be a bit of a disincentive for doctors to choose pneumatic dilatation.

G&H What are the next steps in research?

JER Achalasia treatment is beginning to focus on peroral endoscopic myotomy (POEM), an emerging therapy developed by Inoue in Japan that is currently being experimentally used by gastroenterologists and gastrointestinal surgeons. POEM enables doctors to perform myotomy endoscopically, which is an exciting concept because it avoids the disadvantages of surgery, especially the risk of gastroesophageal reflux disease. The key will be to examine the long-term success of patients after they undergo POEM. It is easy to evaluate symptom relief in patients 3–6 months after the procedure, but it will be important to determine whether there is a parallel improvement in patients' physiology as well. The better the improvement of their physiology, the less their lower esophageal sphincter pressure will be, and the better the esophagus will empty in an upright position. These factors are predictors of long-term success in achalasia patients.

Suggested Reading

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