

ADVANCES IN GERD

Current Developments in the Management of Acid-Related GI Disorders

Section Editor: Joel E. Richter, MD

Weighing the Option of Surgical Therapy in the Treatment of Gastroesophageal Reflux

Carlos A. Pellegrini, MD
Department of Surgery
University of Washington School of Medicine

G&H Can you describe the overall place of surgical therapies in the armamentarium of therapeutic options for gastroesophageal reflux?

CP I think of surgery as an alternative to medical therapy and as one of several possible treatments for patients with reflux. Surgery is not, and I do not think it will ever be, a replacement for medical therapy, and the two options should not be viewed as competing. However, surgery can now be performed in a minimally invasive way with a short hospital stay, more predictable results, and few complications. Therefore, whereas surgical therapy was once considered the therapy of last resort, today it is an option for many patients who are not quite obtaining the hoped-for relief from medical therapy and/or for those whose conditions are known to respond to surgery better than to medicine.

G&H What are the main surgical options for the treatment of gastroesophageal reflux?

CP Currently, the most common and best-tested surgical option is a Nissen fundoplication. Other options, such as posterior or anterior partial funduplications or valvuloplasty of the sphincter, are used less, but they have some application for certain patients. If a patient were to come back after surgery with a recurrent problem or an ongoing problem despite the initial treatment, these other options might be considered.

G&H Who are the reflux patients best suited to treatment with surgical therapy?

CP The primary indication for surgical therapy stems from the fact that surgical therapy restores the compe-

tency of the gastroesophageal sphincter, whereas medical therapy primarily addresses acid secretion, leaving the sphincter incompetent and allowing regurgitation of food and other gastric substances. With that in mind, patients who have reflux associated with airway complications, laryngeal problems, pulmonary problems, asthma, or other diseases of the lung are known to have these complications because of the regurgitation of gastric content into the esophagus and subsequently into the airway. That regurgitation includes acid as well as bile and other gastric content. In these individuals, it is important to restore the competency of the cardia in a mechanical way. Although some of these patients may obtain benefit by reducing acid secretion, because acid is a very prominent component in the stomach, there are others in whom the decrease of acid secretion is not enough to control their disease.

Another potential indication for surgical therapy is that of ongoing gastroesophageal reflux disease (GERD) lasting longer than 5 years, despite patient adherence to lifestyle modification options of losing weight, changing dietary habits, stopping smoking, and changing the quality and quantity of their diet. These patients are known in terms of the natural history as having lifelong symptoms. They are also known to require increasing doses of antireflux medication over time. These individuals should be seriously considered for surgery.

The third group of patients who might benefit most from surgery is very young patients who have developed reflux at an early age and have a total incompetence of the esophageal sphincter. These patients have very dysfunctional manometrics, dysfunctional physiology of the gastroesophageal junction, and they will not recover if left untreated. They are usually physically fit and are good surgical candidates who can be operated on with a high degree of accuracy.

There is also currently a question as to whether patients who have Barrett esophagus (BE) benefit from fundoplication or other forms of surgical therapy. Patients with BE are at increased risk of developing cancer, and the

process of developing BE and cancer has been associated with the regurgitation of bilious material and nonacid components. Therefore, in these patients, stopping all regurgitation from the stomach may lead to a decrease in the chance of developing cancer or a decrease in the extent and severity of their BE. By extension, restoring the competency of the gastric cardia in patients who have severe reflux has been shown in some studies to decrease the chance of developing new-onset BE in the future. If patients are treated with medical GERD therapy chronically, some studies have shown that 10–12% of them will develop BE over the next 5 years. If the reflux is controlled after surgery, the development of BE is an extremely rare occurrence, in less than 0.5% of cases over the same period of time.

G&H Who are the GERD patients in whom surgical therapy is specifically not indicated?

CP Patients who are not candidates for treatment of this sort include those who are morbidly obese, because the operation is much more difficult, the pressures on the sphincter are much greater, and the chances of redevelopment of hernia are greater. These patients are most likely better suited to treatment with a gastric bypass operation, which significantly reduces the amount of acid available for reflux and at the same time can achieve significant weight loss.

G&H Are patients of older age considered to be at higher risk for surgical GERD therapy?

CP Our group published research that considered the risk of the operation in different age groups, gathering data on surgical patients from across the United States and following them for 5 years. At the time, these procedures were performed as open surgery, but I believe that the findings carry over into the laparoscopic era because they measured relative risk of young versus older patients, although it should be stressed that in the laparoscopic era, mortality of surgical GERD therapy has decreased for all age groups. However, we found that patients who were over 80 years old had a 10-fold increase in mortality when compared to patients younger than 60 years of age. Other studies have found that elderly surgical patients face the same mortality as those who are younger. However, looking at these studies, the data are skewed because they compare all patients younger than 65 with all patients older than 65. Patients who are 65–67 years old constitute the vast majority of “older” patients receiving this therapy. To include them in statistical analysis with all older patients cancels out the elevated mortality in the far smaller group of patients over 80. Happily, as we age, our acid secretion

decreases naturally and the need for patients in their 80s to undergo reflux surgery is rare.

G&H What data are available regarding the long-term efficacy of antireflux surgical procedures and the requirement for repeat procedures among reflux surgery patients?

CP Many studies have addressed the need for repeat procedures. When our group looked at a population of over 1,500 patients who had undergone surgery in the last 15 years, approximately 3% of that group came back for re-operation. Others have examined populations in a similar manner and found 5–8% re-operation rates. These rates are dependent not only on the technique of the surgeon but also the patient’s desire for another operation. The most common finding in follow-up is that patients return to the clinic complaining that some of their pre-surgery symptoms have returned but not all of them. These patients are also more likely to be able to control their remaining symptoms with medical therapy, whereas, before surgery, this was not a possibility.

Another way to examine the need for repeat procedures is to administer postoperative pH monitoring to measure the competence of the gastroesophageal junction. Studies performed in this manner have found that approximately 20% of patients, 5–10 years after the operation, do not have complete control of reflux. Yet, among these patients with measurably raised esophageal acid exposure, a full half of them have no symptoms. Often these patients, before their first operation, have an extremely abnormal pH score, and though the operation does not bring them to a normal score, it does bring the score down significantly enough to alleviate symptoms. Most surgeons would determine that patients with alleviated symptoms, regardless of pH status, do not require repeat surgery. The other half of these patients with abnormal pH have symptoms. However, only about half of the patients who have symptoms elect to undergo another surgery because they are able to control their symptoms medically.

Still other studies consider the number of patients who have undergone surgery for GERD and subsequently require medical therapy to control symptoms. In our own recent study, we looked at patients 7–10 years after undergoing surgery, in order to see how many were taking proton-pump inhibitors (PPIs). We found that 25–30% had taken some form of PPI by 5–7 years after the operation. However, in looking at these patients, it is important to look at their pH levels and establish whether or not they are genuinely experiencing GERD. When these patients are tested with 24-hour pH monitoring, it is found that only half or sometimes even less of those

taking PPIs have objectively demonstrable acid reflux. Many of these patients will see their gastroenterologist for reasons ranging from a common cold to transient diarrhea or bloating. Regardless of their symptoms, their history of reflux surgery will lead the gastroenterologist to believe that they have recurrent GERD and should go back on PPI therapy. Furthermore, among those patients taking PPIs 7–10 years after surgery, evidence suggests that they uniformly require a smaller PPI dose than they did before surgery, in order to control their symptoms. In one study, a full 60% of patients required double-dose PPI therapy before surgery but none required this level of therapy even 7 years after the operation.

G&H What cost/benefit analysis has been performed regarding the use of surgical versus medical therapy for GERD?

CP Cost/benefit analyses have been conducted in several studies. Looking simply at the cost of the operation plus follow-up versus the cost of continuous PPI therapy, studies show that the two methods equal out between 4 and 7 years, after which medical therapy becomes more expensive. However, this formula does not consider the structure of different national healthcare systems or examine the overall cost to society versus cost to individual patients.

In studies from the United Kingdom and Sweden, both of which have socialized national health systems, the two methods even out at 7 years. This measure reflects the total expenditure of the system in the treatment of these patients. However, when considering the patient's perspective in the United States, prescription drug payments vary depending on the insurance plan. This is particularly relevant to patients who are over 65 and are covered solely by Medicare. They may have an out-of-pocket expense ranging anywhere from \$100 to \$250 per month in order to receive continuous PPI therapy. However, these same

patients, if they undergo surgery, are most likely fully covered under Medicare Part B and will have no out-of-pocket expense. In my personal treatment experience in this country, I find it is much cheaper for many older patients to undergo the surgery than to buy 1 month of reflux medication. As many of my patients reach 65, they elect to undergo surgery for precisely this reason.

Further, in systems like that of the United States, where there is a fee-for-service model, the cost to visit a doctor and receive a prescription renewal must be factored, as must periodic endoscopic examination. The cost of a single endoscopy is generally approximately 20–30% of that for a surgical procedure. Thus, yearly endoscopy would equal the cost of surgery in 5 years, without even factoring the cost of PPIs. On the other hand, there is follow-up associated with surgery as well, particularly in those patients with symptoms afterward.

Overall, in order to make an informed decision, cost analysis must be considered in terms of cost to society, cost to individual, and cost per the individual's insurance when deciding on a medical versus a surgical course of treatment.

Suggested Reading

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