



An overview of the success and failure of surgical therapy: standards against which the outcome of endoscopic therapy is measured

Nimish Vakil, MD*, Christino Canga III, MD

*University of Wisconsin Medical School, Aurora Sinai Medical Center, 945 North 12th Street,
Room 4040, Milwaukee, WI 53233, USA*

Gastroesophageal reflux disease (GERD) is a chronic recurrent condition in most patients and maintenance medical therapy is often required to control symptoms and prevent relapse. Surgical and endoscopic techniques have been pursued with the hope that they might offer a definitive treatment for chronic reflux disease. These procedures have been adopted with enthusiasm by some practitioners but a careful appraisal of the techniques is necessary before they become routine in clinical practice. Recent innovations in the management of GERD include: (1) laparoscopic fundoplication, (2) endoscopic suturing, (3) Stretta[®] procedure, and (4) endoscopic injection therapies. In this article we will provide an overview of the studies that have been with each of the treatment modalities and focus on the standards against which these new treatments should be measured.

Surgery

Laparoscopic fundoplication has replaced open surgery for the treatment of reflux disease because it is less invasive and recovery from the surgical procedure is faster than with the open procedure [1]. Early results from expert centers have suggested that symptom control is excellent after this procedure and it has been suggested that this operative procedure may be effective as a maintenance therapy for reflux disease [2,3]. Four major arguments have been proposed for surgery as a treatment modality for reflux disease: (1) It eliminates the need for long term maintenance therapy, (2) it prevents esophageal cancer, (3) it is cost-effective

* Corresponding author.

E-mail address: nvakil@facstaff.wisc.edu (N. Vakil).

compared with chronic medical therapy, and (4) it is safe and has few side-effects. Despite the large numbers of descriptive studies on laparoscopic fundoplication, several questions remain unanswered and are considered later.

Need for long-term maintenance therapy

Early results suggested that many patients are able to discontinue medical therapy soon after surgery whereas long-term data have been sobering. Ten years after open fundoplication, 60% of patients required regular medical therapy for heartburn. Data from an expert group of laparoscopic surgeons suggest that 40% of patients undergoing laparoscopic fundoplication have symptoms of heartburn after 5 years of follow-up. These data suggest that the long-term outcome of surgical therapy may not be the same as in the early period after surgery. A well-conducted study of surgery showed that the outcome of laparoscopic fundoplication was similar to that of medical therapy (if dose-adjustment to control symptoms were permitted). [4]

Prevention of cancer

The suggestion that surgery might prevent cancer of the esophagus has been based on conjecture and uncontrolled data. A large well-designed, population-based study recently examined the risk for esophageal cancer in a large cohort of subjects and concluded that there was no significant difference in the rates of cancer in medically and surgically treated patients. [5]

It is a cost-effective alternative to medical therapy

Computer models of costs have suggested that surgery is cost-effective when compared with medical therapy. These models have generally used assumptions that cannot be justified in the light of available data. Most of the models have assumed no costs for surgical complications, premature death, dilation procedures or repeat operations [6–8]. These cost models therefore underestimate the cost of surgical therapy. Complications and repeat operations can be expensive and repeat surgery is required in a substantial number of patients even in expert hands. Lafullarde et al [9] recently reported 900 patients followed for 5 years or longer after laparoscopic fundoplication. Re-operation was required in 3.9% of patients for dysphagia and 7.3% of patients for para-esophageal hernias.

Safety and side-effects

In a randomized, prospective trial of laparoscopic and open fundoplication, Luostarinen et al [10] reported dysphagia in 30% of patients one year after surgery in the open and laparoscopic fundoplication groups. Another long-term study from a single expert center found dysphagia in 27.5% of patients and a need for dilation in 7% [11]. In another study of 39 patients from a single community-based hospital center in Finland, Rantanen et al [12] found that

dysphagia occurred in 31% of patients after surgery, flatulence was seen in 67% and bloating was reported by 46%. Other studies have reported minimal side-effects such as dysphagia. A small but persistent mortality rate with laparoscopic fundoplication ranging from 0.1% to 0.2% should also be considered in comparisons with medical therapy.

Limitations of surgical studies

Although laparoscopic fundoplication has been practiced for a decade, there are no randomized controlled trials comparing it to medical therapy. Although the procedure is widely practiced in the community, more data are needed on the outcome of surgery in routine practice. Although a large number of surgical groups have published uncontrolled reports of the procedure, the data are limited for several reasons (incomplete follow-up, unvalidated instruments, etc). In some studies, patient satisfaction and symptom relief was elicited by the surgeon performing the procedure [13].

Standards against which surgery should be measured

Medical therapy is the standard against which laparoscopic surgery should be measured. A randomized controlled trial comparing medical therapy to laparoscopic fundoplication is needed. Symptoms should be measured using validated instruments and side-effects and costs should be determined over a prolonged follow-up.

Laparoscopic fundoplication is performed by many surgeons in the community and surgical experience has been shown to affect the outcome of the therapy [14]. The outcome of surgery in routine clinical practice is unknown in the United States. Data from expert groups with extensive experience cannot be extended to community practice where patient selection and surgical experience may vary. Cost-effectiveness determinations need to be performed using data from clinical trials that include the costs of adverse outcomes, repeat procedures and interventions for the management of complications.

Finally the safety of surgery needs to be compared with medical therapy. Long-term studies of medical therapy have demonstrated its safety and efficacy over long periods. [15]. Similar data are lacking for laparoscopic fundoplication.

Endoscopic therapy for GERD

Three types of endoscopic procedures are available for the treatment of GERD and are discussed in detail in other articles in this publication. Approved procedures include the Stretta[®] procedure and the Bard endoscopic suturing system. Several different suturing devices have been described and are under investigation. Injection of non-absorbable material (methyl-methacrylate micro-

spheres or polyvinyl alcohol) into the muscle of the lower esophageal sphincter is under investigation but is not yet approved by the Food and Drug administration.

There are several questions that should be addressed with each of the endoscopic therapies: (1) What is the mechanism of action of the intervention? (2) What are the selection criteria for patients in the studies? (3) What is the effect of the procedure on the lower esophageal sphincter and esophageal pH measurements? (3) What are the effects on symptoms and erosive esophagitis? (4) What are the side-effects of the procedure?

Needed studies on endoscopic procedures

There are major gaps in our knowledge of the endoscopic procedures. Randomized controlled trials comparing endoscopic therapy to medical therapy are necessary to determine the efficacy of these procedures compared with less invasive treatment strategies. Sham controlled trials are available with each of the procedures to determine if symptom improvement after the procedure is a “placebo” effect. Perforation and death are complications that are not acceptable for the therapy of a disease with a benign course, for which adequate therapy exists. The frequency of these complications deserves careful study.

Follow-up has been limited with the procedures that are currently approved by the FDA (Stretta[®] procedure and endoscopic suturing). Long-term studies are required to determine if the results seen in short-term studies are sustained. The cost of the procedures can only be justified if a substantial proportion of patients remain symptom free and off medical therapy. Economic analyses are therefore necessary to determine if the endoscopic procedures are cost-effective compared with medical therapy.

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