

## AGA Institute Medical Position Statement on the Use of Endoscopic Therapy for Gastroesophageal Reflux Disease

*This document presents the official recommendations of the AGA Institute on "Endoscopic Therapy for Gastroesophageal Reflux Disease." It was approved by the Clinical Practice and Economics Committee on June 20, 2006, and by the AGA Institute Governing Board on July 24, 2006.*

A variety of endoscopic techniques for the treatment of gastroesophageal reflux disease (GERD) have been developed as alternatives to antisecretory therapy or antireflux surgery. These techniques include the delivery of radiofrequency energy to the gastroesophageal junction, injection of bulking agents, or implantation of a bioprosthesis into the lower esophageal sphincter (LES) zone, and suture plication of the proximal fundic folds. Current techniques are less invasive than antireflux surgery and are performed in the outpatient setting.

Each of these endoscopic antireflux techniques is designed to alter the anatomy or physiology of the gastroesophageal junction to decrease gastroesophageal reflux. However, only limited data are available on the mechanism of action of the various endoscopic techniques.<sup>1</sup> It is hypothesized that radiofrequency ablation results in augmentation of the barrier between the stomach and the esophagus by either collagen deposition or disruption of vagally mediated transient LES relaxation. The decrease in transient LES relaxation is presumably caused by either altering the mechanics of the cardia or interrupting afferent nerve transmission to the brainstem control mechanisms. A variety of injectable agents have been studied for bulking the gastroesophageal junction, including Plexiglas microspheres, ethylene vinyl alcohol (Enteryx), and a hydrogel prosthesis (Gatekeeper). It is hypothesized that Enteryx leads to an increased barrier to reflux, whereas the hydrogel prosthesis may exert its effect by decreasing the aperture through which refluxate may flow, thus resulting in less proximal migration of the refluxate. Endoscopic plication is hypothesized to impede reflux by approximating tissue at or below the gastroesophageal junction. The effect of all techniques to date on LES pressure and 24-hour acid exposure measures is modest, at best. While some studies demonstrate improvement in 24-hour intraesophageal acid exposure, normalization of acid exposure is the exception rather than the rule for all of these techniques.

Studies to date of endoscopic therapy have primarily enrolled proton pump inhibitor (PPI)-dependent patients without severe esophagitis or large hiatus hernias. However, few patients with high-grade esophagitis, larger hiatus hernias, atypical manifestations of GERD, failure of PPI therapy, and complications such as stricture, Barrett's esophagus, or failed antireflux therapy have been studied. Each of these techniques results in lessening of GERD symptoms, improvement of quality of life, and decrease in esophageal acid exposure, while concomitantly decreasing the need for antisecretory medications in observational studies. Results of a sham-controlled trial of radiofrequency ablation in 64 patients demonstrated decreased heartburn symptoms and improved quality of life in the active therapy group compared with the sham group at 6 months.<sup>2</sup> However, there was no difference in acid exposure, need for medications, or healing of esophagitis in the 2 groups at 6

months. A sham-controlled trial of Enteryx in 64 patients demonstrated decreased PPI use, improvement in GERD symptoms, and improved quality-of-life scores in the Enteryx group compared with the sham group at 3 months.<sup>3</sup> However, there was no difference in esophageal acid exposure between the 2 groups. Only preliminary results of sham-controlled trials of gastroplication have been reported.<sup>1</sup> All of these clinical trials demonstrate a striking sham response rate and highlight the need for randomized controlled trials of sufficient size to understand the true effectiveness of all of the endoscopic therapies for GERD.

Most studies of endoscopic therapy have only limited follow-up information of a relatively small number of patients. Thus, the durability of these technologies beyond 1-2 years remains unclear. Short-term and long-term safety issues are unresolved, but serious adverse events led to the voluntary withdrawal of Enteryx by the manufacturer in September 2005 and suspension of the Gatekeeper clinical program in late 2005. The economics of all techniques for the patient, practitioner, and society are unknown. While newer devices and improvements in endoscopic antireflux techniques may yield better and more durable treatment outcomes, current data suggest that there are no definite indications for endoscopic therapy for GERD at this time. Both practitioners and patients need to be aware of the limitations in the evidence that exist with these devices at present.

GARY W. FALK  
M. BRIAN FENNERTY  
RICHARD I. ROTHSTEIN

### References

1. Falk GW, Fennerty MB, Rothstein RI. AGA Institute technical review on the use of endoscopic therapy for gastroesophageal reflux disease. *Gastroenterology* 2006;131:1315-1336.
2. Corley DA, Katz P, Wo J, Stefan A, Patti M, Rothstein R, Edmundowicz S, Kline M, Mason R, Wolfe MM. Improvement of gastroesophageal reflux symptoms after radiofrequency energy: a randomized, sham-controlled trial. *Gastroenterology* 2003;125:668-676.
3. Deviere J, Costamanga G, Neuhaus H, Holzer W, Louis H, Tringali A, Marchese M, Fiedler T, Darb-Esfahani P, Schumaker B. Non-resorbable copolymer implantation for gastroesophageal reflux disease: a randomized sham-controlled multicenter trial. *Gastroenterology* 2005;128:532-540.

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Discuss this and other medical position statements online at the AGA Member Fora. Dr. Falk will be online answering questions regarding Endoscopic Therapy of Gastroesophageal Reflux Disease through October. Register for the online Member Fora by going to [www.gastro.org](http://www.gastro.org) and clicking on the "Discuss" button.

Address requests for reprints to: Chair, Clinical Practice and Economics Committee, AGA Institute National Office, c/o Membership Department, 4930 Del Ray Avenue, Bethesda, Maryland 20814. Fax: (301) 654-5920.

*The Medical Position Statements (MPS) developed under the aegis of the AGA Institute and its Clinical Practice and Economics Committee (CPEC) were approved by the AGA Institute Governing Board. The data used to formulate these recommendations are derived from the data available at the time of their creation and may be supplemented*

*and updated as new information is assimilated. These recommendations are intended for adult patients, with the intent of suggesting preferred approaches to specific medical issues or problems. They are based upon the interpretation and assimilation of scientifically valid research, derived from a comprehensive review of published literature. Ideally, the intent is to provide evidence based upon prospective, randomized placebo-controlled trials; however, when this is not possible the use of experts' consensus may occur. The recommendations are intended to apply to health care providers of all specialties. It is important to stress that these recommendations should not be construed as a standard of care. The AGA Institute stresses that the final decision regarding the care of the patient should be made by the physician with a focus on all aspects of the patient's current medical situation.*