Editorial

Surg Endosc (2007) 21: 695–696
DOI: 10.1007/s00464-007-9343-4

SURGICAL ENDOSCOPY and Other Interventional Techniques

Endoluminal GERD therapy: inside, outside, upside, downside

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Received: 8 February 2007/Accepted: 13 February 2007/Online publication: 28 March 2007

In this issue of Surgical Endoscopy, Torquati and Richards provide an excellent, evidence-based review of the status of endoluminal therapy for gastroesophageal reflux disease (GERD) [1]. Their review highlights some of the challenges faced by evolving techniques and technologies in minimally invasive surgery and surgical gastroenterology. The issues raised are worthy of reflection for what they can teach us about evolving areas of gastrointestinal surgical practice.

The obvious draw of endoluminal therapies for GERD was their collective potential to allow an *inside* or minimally invasive approach to a highly prevalent medical problem. The potential for such treatments to be done in outpatient settings, under sedation rather than anesthesia, without violation of the peritoneal space, all made great intuitive sense from a patient care and cost perspective. Based on understanding of the anatomic and physiologic functions of the gastroesophageal junction that was derived from open and laparoscopic experience with antireflux surgery, a number of techniques that attempted to augment the lower esophageal sphincter area via an endoluminal approach were developed. Bulking agents, suturing techniques, and even novel thermal deployment strategies were developed and brought to trial. Credible investigators worked with industry on the development of these tools and their initial trialing in both animal and human settings. The future seemed hopeful, the opportunity significant, the approach scientific.

From the start however, there was, at least from the standpoint of surgical experience, something of interest, if not concern with these techniques. Their application was targeted on patients who fell *outside* the range of disease the surgical practitioner would have normally deemed appropriate for invasive intervention. Moderately sized hiatal hernias (> 2 cm), intestinal metaplasia, patients with atypical symptomatology, and advanced esophagitis patients were excluded. As at least one experienced medical esophagologist commented, as the techniques were deployed and initial data on their efficacy began to accumulate, they seemed to work best on the patients who needed them least. The main benefit, it seemed, would be a perhaps transient reduction in medication usage, an arguable expectation of cost savings if that could be achieved, and this would of course all be excusable because the techniques were noninvasive, and could even be applied repetitively if necessary.

As Torquati and Richards so nicely summarize, the evidence to date does now allow some conclusions and observations regarding these techniques. On the *upside* the techniques were evaluated with some well-executed, randomized, sham controlled trials. In addition, outcome measures were assessed with validated tools in a number of the studies. Collectively, the techniques appear to have merit in relieving symptoms of pyrosis and reducing medication usage, although a significant placebo effect in these regards is also documented in some of the sham trials. Certainly some of the pioneers who led in the design and conduct of a number of the early trials deserve recognition for contributing good science and methodology to the early human evaluation of these techniques. In addition, these techniques did not seem to produce some of the side effects not uncommonly seen in the early follow up after Nissen fundoplication, including gas bloat and dysphagia.

On the *downside* however, most of the techniques showed either no or at best inconsistent capacity to reduce esophageal acid exposure. Furthermore, the one technique that did seem to accomplish this goal with some consistency did so with little associated correlation with symptom outcome. The recently published multicenter NDO plication randomized, sham controlled trial in fact documented that symptomatic responders and nonresponders had similar degrees of acid exposure control in the treatment arm, and lack thereof in the sham arm [2]. Thus the techniques collectively appeared to have offered more supratentorially than they did at the level of the distal esophagus, and when the goal of pH control was achieved, this did not correlate well with symptom outcome. In addition, while improvement in pyrosis control was clearly documented in many of the studies, control of regurgitative symptoms was less impressively impacted in at least some of the trials [3].

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Perhaps the most important *downside* to the techniques is the fact that three of them are already off the market because of concerns over efficacy, safety, or fiscal solvency on the part of the manufacturing company. Indeed, taken collectively, the failure of even those techniques that demonstrated promise in well-designed trials to gain more widespread support in clinical volume raises several important questions about the forces that govern application of new methodologies. On the one hand, one could argue that the Enteryx technique was brought to application too quickly or with inadequate preparation of and/or judgement by some of the practitioner workforce, given its precipitous withdrawal from the market after several serious complications and deaths were reported related to deep injection into the aorta. Conversely, some of the other techniques, such as Stretta, a generally safe and at least modestly efficacious procedure, languished over issues of reimbursement, at least in some locales (enough for the company not to remain solvent). Relatively early designation of a procedure-specific CPT code for the Stretta procedure may have been a kiss of death in this regard, in that it led to standardized (and diminished) reimbursements for a procedure that some practitioners quickly found time intensive and fiscally inefficient. Reflecting on these two failures in particular, one is confronted with the challenging menagerie that influences medical innovation. Federal regulators, venture capitalists, start-up entrepreneurs, third-party payers, hospitals, physicians, and patients all have major stakes in this enterprise, but not always with the balance of influence that facilitates the best outcome, clinically or economically.

In summary, if we are to learn from the experience with endoluminal GERD therapy to date, as Torquati and Richards are helping us to do, we might suggest the following maxims:

1) It is possible to develop new techniques with well-designed initial human trials that provide meaningful data within 3 to 5 years to guide further application. Surgeons can and should be part of these efforts, as individuals applying other technical interventions for the disease process being treated.
2) The marketing pressure (on both physician and manufacturer) to cash in on a product's potential value remains a real patient safety concern to be reckoned with, and dictates that expert-derived data be available before the product is detailed, promoted, or embraced by practitioners on a widespread basis.
3) Education of individuals applying the new methodology remains critical in its transition from the development to marketing phase of application.
4) Reliance on third-party payer recognition and reimbursement for service is a pitfall in medically appropriate product penetration into the health care marketplace, although it is an important fiscal check and balance in a cost-escalating health care system.
5) Early special CPT code designation for a new procedure is a double-edged sword, and may fiscally impair a developing promising technology, in that it commonly leads to standardization of reimbursement at a lower (and potentially unsustainable) level.
6) Aiming low (e.g., symptom vs. acid control, excluding patients normally deemed most appropriate for invasive therapy) does not ensure the success of a new technique, and may in fact highlight its shortcomings. Sometimes the straw man wins.
7) While the laparoscopic revolution may have taught many surgeons of the current generation the power of market force and innovation in directing the course of clinical practice, it should not become an excuse for the entire development, delivery, and reimbursement system to excuse itself for mistakes on the premise that it was justifiable in the hopes of being a step ahead. We are accountable to our patients first and foremost.
8) Transitional treatments that attempt to bridge the gap between purely medical and more-aggressive surgical therapies, like their life form counterparts in evolutionary theory, are easier to imagine than to find.

References

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