



SAGES Position Statement on Endolumenal Therapies for Gastrointestinal Diseases

Surgery involves the manipulation, repair or resection of tissue. Two decades ago, we saw progression in surgical technique from traditional 'open' surgery to laparoscopic surgery. With improvements in technology and the development of new techniques, endolumenal and translumenal therapies have the potential to treat many common gastrointestinal conditions as effectively as more traditional invasive procedures. This significant paradigm shift will result in benefits to our patients and their employers, and improve access to surgical care I. ***SAGES fully endorses the evolution of new treatments for gastrointestinal conditions that provide patients a faster recovery from their procedures while at the same time providing high quality outcomes.*** This document addresses the rationale for endolumenal therapies, considers the provider qualifications needed to perform these procedures, and discusses the issues of reimbursement and future directions.

Background:

Gastroenterologists and Surgeons have been performing therapeutic endoscopy for decades. Recent developments have enabled providers to perform larger and more complex resections and more importantly, reconstruct deformed or damaged tissue. New technology has fostered the development of minimally invasive techniques can now treat diseases once only amenable to major open surgery. As endolumenal techniques are an extension of existing surgical techniques, they must be developed with adherence to sound surgical principles.

Current gastrointestinal applications for endolumenal surgery include endoscopic drainage of pancreatic pseudocysts, excision of large colonic polyps, excision of large gastric and esophageal mucosal lesions, transanal endoscopic microsurgery (TEMS) as well as endolumenal therapies for gastroesophageal reflux disease (GERD), and obesity. Endolumenal treatments for GERD and obesity are likely to impact a large group of patients, minimizing wound, anesthetic, and anastomotic complications. Natural orifice approaches to other diseases, and even natural orifice translumenal endoscopic surgery (NOTES), may offer further benefits; therefore these techniques warrant development.

Endolumenal Therapies for GERD:

Ideally, the therapy for GERD should progress from the least invasive to most invasive to maximize benefit and minimize risk to patients with reflux. Traditionally, only medical acid suppressive therapy or trans-abdominal surgical therapy was available. With the advent of endolumenal therapy utilizing flexible endoscopy, there is now a less invasive approach that has been shown to be effective for the treatment of GERD.[1-3] The lower cost and morbidity of these procedures can relieve symptoms in a majority of appropriately selected patients. A variety of devices for endolumenal antireflux surgery have been developed and some of these therapies are clearly no longer experimental.[4] Patients who fail to benefit from endolumenal therapies can almost always proceed to surgical treatment as the next step in their management without any increase in complexity of a subsequent surgical procedure. Likewise, some endolumenal therapies may be a useful remedial option for those patients who have had a partially failed surgical procedure. Endolumenal techniques, either existing or still in development, may well represent the procedure of choice for selected patients with GERD in the future.

Therapies for Obesity

Nearly one in four Americans is overweight with a BMI > 30 and morbid obesity is now a major health problem. [5] The need for weight loss surgery is increasing as the obese population expands. Obese patients are at higher risk for complications following surgery of almost any type than normal weight individuals.[6, 7] For the morbidly obese (BMI>40), surgery is the only effective durable treatment .[8] Surgical approaches to weight loss can be restrictive, malabsorptive, a combination of these techniques. Technology currently being developed in the endolumenal bariatric field includes procedures that address any of the possible weight loss mechanisms: restriction, malabsorption, neurological or combined approaches. This field holds great promise since endolumenal therapy avoids the morbidity associated with abdominal incisions and gastrointestinal anastomoses. Outcomes data on these techniques are limited at this time, but many trials are underway.

Rationale for Endolumenal Therapy

Despite some limitations with currently available therapies, SAGES fully endorses the appropriate use of procedures with proven efficacy in properly selected patients. SAGES supports research to identify those patients who would derive the greatest benefit from endolumenal treatment of GERD and obesity, and to identify the procedures producing the best results. Effective endolumenal or transluminal therapies for morbid obesity and GERD could positively impact the treatment of more than one million patients a year in the USA. SAGES is supportive of properly conducted trials of new devices as well as procedure development that minimizes pain and recovery time while correcting the anatomic and physiologic causes of disease states. SAGES is willing to participate in evaluation and training for new treatment modalities. Several of the reasons for this position include the following: 1) Paradigm shifts do not happen overnight, but take time to evolve, and 2) There are significant numbers of patients who would need surgical correction of gastrointestinal conditions yet are not good candidates for laparoscopic or traditional 'open' surgery. Endolumenal therapy could nicely fill this void as an alternative to transabdominal surgery.

To facilitate progress in endolumenal therapy, several key issues still need to be addressed beyond the needed technology development. These include defining criteria for patient selection, defining the requisite skill set needed by the treating physician, defining the setting for these procedures to be performed in, and addressing reimbursement/coding issues.

Patient Selection for Endolumenal Therapy

There is data to support the position that endolumenal therapies are efficacious [1-4, 9-12]. Among the unanswered questions is which patients derive the most benefit from endolumenal treatment? Research efforts should be directed towards identifying the pre-procedure characteristics and intra-operative findings that predict which patients benefit from these techniques. As these techniques develop it is critical to offer these patients the same rigorous evaluation and comprehensive support as patients undergoing surgical procedures by more traditional routes SAGES believes that there is a place for endolumenal surgery as part of a comprehensive treatment algorithm for relevant conditions. As experience and data are accumulated, these algorithms should be evidenced based.

The Endolumenal Practitioner

Caring for patients with surgical diseases requires knowledge of the full disease spectrum, and not simply the technique itself. Surgeons are broadly trained for management of all aspects of surgical diseases and their complications and are appropriate practitioners to care for surgical patients. Gastroenterologists can also cross train to become facile with the surgical aspects of these procedures, including the management of the potential complications that may occur. The ideal care setting for these patients will be a practice that is disease or organ system based without regard for the traditional barriers found between departments. Ideally, well trained and supported gastrointestinal proceduralists, from either surgical or medical roots, will be performing endolumenal therapies.

Where Should These Procedures be Performed?

Endolumenal surgical procedures should be performed at centers, either free-standing or hospital based that can offer the full spectrum of patient care, including management of complications.

Reimbursement/Coding

It is nearly impossible to adequately evaluate new procedures in the setting of financial disincentives. Reimbursement has traditionally been based on the work involved relative to comparable procedures. Since many endolumenal procedures are not experimental, withholding or denying reimbursement to providers for their efforts is ultimately unfair primarily to patients that would benefit from endolumenal approaches. Consideration needs to be given to the benefits of diminished hospital costs as well as shortened recovery times by employers that purchase insurance for their workers. SAGES feels that pre-existing endoscopy codes do not accurately reflect the work and complexity required to deliver complex endolumenal therapies. Rather, these procedures are often more equivalent to their surgical counterparts, thus the reimbursement and coding algorithms should mirror those of existing surgical procedures. The current economic climate needs to be re-examined to foster ongoing refinement of approved concepts and devices that ultimately will benefit millions of patients.

Future Directions

SAGES supports the further development of endolumenal and transluminal surgery. The progress of this field is dependent on the development of new technology from clinician innovators as well as the medical device industry. We hope to enhance collaboration between surgeons, gastroenterologists, and engineers in the development of the future of surgery. As the spectrum of available technology grows SAGES supports responsible introduction of new technology into clinical practice based on accurate data and clinical outcomes. The socioeconomic environment must be flexible enough to support the development of new procedures that show promise to benefit patients and society.

Appendix:

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