TECHNOLOGY STATUS EVALUATION REPORT

Endoscopic anti-reflux procedures

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INTRODUCTION

In order to promote the appropriate use of new or emerging technologies, the ASGE Technology Committee has developed a series of status evaluation papers. This process may present relevant information about these technologies to practicing physicians for the education and care of their patients. In many cases, data from randomized controlled trials are lacking and only preliminary clinical studies are available. Because this is a rapidly evolving area, practitioners should continue to monitor the medical literature for subsequent data about the efficacy, safety, and social economic aspects of the technologies.

BACKGROUND

Gastroesophageal reflux disease (GERD) results when there is increased exposure of the esophageal mucosa to reflux of gastroduodenal contents. GERD occurs in susceptible patients in whom there is increased frequency, duration, and/or potency of refluxate. Pharmacotherapy is used to reduce the frequency, duration, and/or potency of refluxate. Surgical approaches are used to create barriers to impede reflux. Endoscopic or endoluminal approaches are being developed to similarly impede reflux and may be categorized into injection bulking, plicating, and radiofrequency techniques.

TECHNOLOGY UNDER REVIEW

Injection bulking

Bulking agents are substances injected under endoscopic guidance into the esophageal wall at the level of the esophagogastric junction. Intended to impede reflux, the bulking effect results from a combination of the retained material and consequent tissue response. A number of injectable bulking agents have been considered including collagen, polytetrafluoroethylene paste, polymethylmethacrylate (PMMA), and ethylene vinyl alcohol with tantalum (Enteryx Polymer, Enteric Medical Technologies, Inc., Palo Alto, Calif. and Boston Scientific International, Cedex, France).[1-4] These materials are injected in a low-viscosity state through standard or large-bore injection needles. Fluoroscopic guidance may be used to monitor delivery and retention of radio-opaque components. These methods are not approved by the Food and Drug Administration (FDA) for treatment of GERD and remain investigational at the time of this writing.

Endoluminal plication

Endoluminal plication uses mechanical techniques to impede reflux by approximation of tissue at or below the gastroesophageal junction.

The EndoCinch (Bard, Billerica, Mass.) system is used through an oroesophageal overtube to create an endoluminal gastroplication (ELGP) and is FDA-approved for treatment of GERD. The EndoCinch device is sold in a procedure kit, which contains the following single-use components: a suturing capsule, 17-gauge needle, pusher wire, guidewire, suture tags, suture loader, suture anchor delivery device, suture anchor loading tool, and suture threading tool. An EndoCinch handle and overtube are also required, and are reusable up to 25 and 50 times, respectively.

An oroesophageal overtube (19.7-mm outside diameter, 30-cm length) is placed to facilitate passage of the suturing device. The suture capsule is attached to the tip of a 9-mm outside diameter endoscope and loaded with a tilt-tagged suture. After positioning the suture capsule over the selected site, suction through the external vacuum line is applied. Tissue is suctioned into the capsule cavity, and the suture placed by the needle driver. Suction is released and the tis-

sue is withdrawn from the capsule. The procedure is repeated on an adjacent site. Drawing two adjacent sutured sites together creates a plication. Sutures are cinched together with a ceramic plug and ring assembly. Additional sutures are deployed in either a linear or circumferential configuration.

The ESD (Wilson-Cook Medical, Winston-Salem, N.C.) is an endoscopically assisted endoluminal suturing device that is FDA-approved for soft-tissue apposition. The ESD system is single-use and includes a Sew-rite device, 2 quick-load sutures, a loading wire, 4 vacuum caps, 1 Tie-rite Knot device, 2 knot-loaders, 1 external accessory channel, 1 seal cap, 1 scissors, and 1 vacuum cap remover. The endoscope is inserted with the External Accessory Channel (EAC) attached, and the operative site is determined. The Sew-Right Device is inserted into the EAC and advanced until viewed endoscopically. Tissue is aspirated into the vacuum cap, and while maintaining suction, a lever is activated to deploy the needle to which the suture is attached. When the lever is released, the needle will retract placing the suture. Suction is then discontinued, releasing the tissue. These steps are repeated for a second suture placement, followed by the knot tying process and the cutting of excess suture material.

The Full-Thickness Plicator (Ndo Surgical, Inc, Mansfield, Mass.), is an endoluminal plication device that deploys pre-tied implants to secure full-thickness tissue apposition. The resultant single plication is intended to enhance the valvular mechanism of the gastroesophageal junction.[5] A single transluminal plication is placed near the gastroesophageal junction under direct endoscopic visualization. The resulting serosa-to-serosa tissue union is intended to restore the valvular mechanism of the gastroesophageal junction. This device is not FDA-approved at the time of this writing.

Radiofrequency

Stretta (Curon Medical Inc., Sunny Vale, Calif.) is an endoscopically mediated endoluminal device that is FDA-approved for the treatment of GERD. The Stretta catheter comprises a wire-guided bougie-tip, a balloon-basket assembly, and 4 electrode delivery sheaths positioned radially around the balloon. The catheter is passed transorally and positioned at the Z-line. The balloon is inflated and 4 nickel-titanium needle electrodes (22 g, 5.5-mm length) are deployed into the luminal wall. Radiofrequency energy is delivered while cooling the mucosa with iced saline solution irrigation through a temperature-controlling generator. Additional lesion sets are created in the region from 2 cm proximal to 1 cm distal to the Z-line by rotating the catheter 45 degrees and varying its linear position. Fifteen to 25 lesion sets are typically created.

The mechanism of action of radiofrequency is reported to be a reduction in the frequency of lower esophageal sphincter relaxations, as well as a physical alteration in tissue compliance and wall thickness of the gastroesophageal junction.[6]

Other attempts to augment gastroesophageal junction form and function by injection of sclerosants and thermal injury with Nd:YAG laser have been described and abandoned.[7]

EFFICACY AND EASE OF USE

Injection bulking agents

PMMA was injected submucosally in 10 patients with GERD who had abnormal esophageal acid exposure while on proton pump inhibitor therapy.[2] Patients with hiatal hernia greater than 3-cm, Barrett's esophagus, and/or peptic stricture were excluded. All patients underwent pretreatment assessment to rule out hypersensitivity to the injectate. At 5 to 11 months' follow-up (mean = 7.2 months), a statistically significant decrease in symptom severity score and mean total time with esophageal pH less than 4 was noted.

Ethylene-vinyl alcohol injection for treatment of GERD is reported in 15 patients with heartburn, abnormal 24-hour pH, symptoms responsive to proton-pump inhibitor (PPI) therapy and return of symptoms after PPI discontinuation.[4] Patients with prior antireflux surgery, esophageal motility disorders, esophagitis greater than grade II, and obesity were excluded. All procedures were performed under fluoroscopic guidance with forward and side-viewing scopes. A 23 g, 4-mm injection needle was used to inject 1 to 2 mL of the biopolymer in 4 quadrants close to the squamocolumnar junction to observe a ring fluoroscopically. Lower esophageal sphincter pressure was increased in 12 of 15 patients measured 3 to 12 months after the procedure. Clinical heartburn score was improved at 1 and 6 months ($p < 0.001$). Four patients resumed PPI use within 4 to 12 months.

Endoluminal plication

A multicenter trial evaluated 79 Endocinch procedures for the treatment of GERD in 64 patients.[8] Patients had 3 or more episodes of heartburn per week off medications, dependency on antisecretory medication, and abnormal 24-hour pH. Patients with dysphagia, esophagitis greater than grade II, obesity, and/or hiatal hernia greater than 2 cm were excluded. Eleven patients required repeat procedure for suboptimal results and 10 patients withdrew. In 47 patients with complete follow-up, gastroesopha-

Table 1. New technology APC

APC	HCPCS	APC title	Payment rate
0979	C9703	New technology-level X, $1500-$1750	$1625

Table 2. Hospital billing: new technology procedure/service APCs

HCPS	SI	APC	Descriptor
C9701	T	980	Stretta procedure

geal reflux symptoms improved ($p < 0.001$). Twenty-four–hour pH monitoring at 3 and 6 months improved in 24 patients studied. Esophageal manometry and the mean grade of esophagitis were unchanged.

There are no peer-reviewed data on the Ndo Full-Thickness Plicator or the Wilson-Cook ESD for treatment of GERD at the time of this writing.

Radiofrequency

The Stretta procedure was evaluated in a prospective study of 118 patients with chronic heartburn and/or regurgitation that required antisecretory medicine and had abnormal 24-hour pH study.[6] GERD symptoms scores, quality of life (SF-36), and PPI use were assessed at 0, 1, 4, 6, and 12 months. Esophageal acid exposure, motility, and endoscopy were assessed at 2 and 6 months. Patients with Barrett's esophagus, esophagitis greater than grade II, and hiatal hernia greater than 2 cm were excluded. The procedure was successfully performed in all patients. At 12 months, 94 patients were available for follow-up. GERD symptom scores, patient satisfaction score, SF-36, and esophageal acid exposure by 24-hour pH improved significantly ($p \leq 0.0001$). PPI use decreased. The incidence and grade of esophagitis were unchanged.

SAFETY

Reported adverse events associated with injection bulking agents include chest pain, dysphagia, fever, bleeding, and bloating.[2-4,9] Reported adverse events associated with the EndoCinch include pharyngitis, vomiting, abdominal/chest pain, mucosal tear, hypoxia, and clinically significant bleeding. One of 64 patients had fever, abdominal pain, and pneumomediastinum, recovering with a 3-day hospitalization and antibiotics.[8] There are insufficient safety data on the Full-Thickness Plicator or Wilson-Cook ESD. Reported adverse events associated with the Stretta procedure occurred in 8.6% of patients and included chest pain, fever, mucosal tear, and dysphagia.[6] A review of the FDA Manufacturer And User Facility Device Experience database (MAUDE) identified 2 deaths occurring 3 and 7 days after the Stretta procedure, attributed to vomiting and aspiration, and 4 esophageal perforations requiring surgery.[10]

FINANCIAL CONSIDERATIONS

Injection bulking

There are, as yet, no costs or charge data for the injection bulking materials or techniques.

Endoluminal plication

EndoCinch: The EndoCinch single use procedure kit lists for $1295. The handle lists for $1500 and the overtube for $150. (Per case instrumentation costs: When the handle is used 50 times and the overtube is used 25 times, the per case costs are $30 and $6 per use, respectively). Including the kit cost of $1295, this equates to a procedure instrumentation cost of $1331.

CPT 43499: Unlisted endoscopic procedure, esophagus in conjunction with CPT 0008T: Upper gastrointestinal endoscopy with suturing of the esophagogastric junction.

Facility coding and reimbursement: In the final ruling related to the Hospital Outpatient Prospective Payment System for calendar year 2002, the Centers for Medicare & Medicaid Services (CMS) designated the Bard Endoscopic Suturing System to New Technology APC (Table 1).

ESD: ESD-5, including the Sew Right Device and Tie Knot Device, 2 Suture QuickLoad Units, 2 Tie Knot QuickLoad Units, and the External Accessory Channel, lists for $2000. The SRF-5QL, a box of 6 Suture QuickLoad Units lists for $600. The TKF-5QL, a box of 6 Tie Knot QuickLoad Units lists for $600.

The start-up cost is $5200, and subsequent orders are $2000 with the cost of any additional sutures as needed.

Regarding reimbursement, the ESD has not yet received a New Technology APC code.

Radiofrequency

Stretta: Start-up cost: The Stretta Control Module, which administers the radiofrequency, costs $24,200. There is one disposable catheter used per procedure, which lists for $940, or for a box of 3, $2820. The disposable guidewire lists for $45 and a box of 3 costs $135.

CPT Procedure codes used for Stretta: The Stretta procedure should be coded with a combination of the following codes: 43235- *"Upper gastrointestinal endoscopy including the esophagus, stomach… as appropriate;* "43499-51-*"Unlisted procedure, esophagus."* In addition, CPT 43499 is used in reporting the

delivery of the radiofrequency energy to the lower esophageal sphincter and the gastric cardia.

Hospital billing is shown in Table 2. Additional cost may include physician and GI Assistant training.

COMPARISONS TO EXISTING TECHNOLOGY

There are no published sham-controlled trials among the endoscopic antireflux therapies. There are no published comparative trials evaluating the endoscopic antireflux therapies versus medical or surgical treatments.

EASE OF USE

There are no established training, credentialing, or privileging guidelines regarding the adoption of endoscopic reflux therapies. The use of the EndoCinch incorporates an organized hands-on training program at the time of this writing.

These procedures vary in their technical complexity and dexterity demands. It is anticipated that further device modifications and user experience will contribute to ease of use. Injection bulking techniques borrow from existing standard endoscopic skill sets. Familiarity with fluoroscopic guidance may be required. Plication and radiofrequency ablation techniques requires proficiency in advanced therapeutic endoscopy.

Procedure times for EndoCinch and Stretta are approximately one hour. Treatment time for injection bulking is shorter. Prolonged procedure times and procedure related discomfort might require sedation beyond that used for routine upper endoscopy.

CONCLUSIONS

A variety of endoscopic or endoluminal approaches are FDA approved and available or under development to treat GERD. Initial uncontrolled results are favorable. Comparative and longer-term efficacy and safety data are needed.

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