Communication from the ASGE Technology Committee

TECHNOLOGY STATUS EVALUATION REPORT

Radiofrequency ablation devices

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This document was reviewed and approved by the governing board of the American Society for Gastrointestinal Endoscopy (ASGE).

The American Society for Gastrointestinal Endoscopy (ASGE) Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have an impact on the practice of GI endoscopy. Evidence-based methods are used, with a MEDLINE literature search to identify pertinent clinical studies on the topic and a MAUDE (Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported adverse events of a given technology. Both are supplemented by accessing the "related articles" feature of PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but in many cases data from randomized controlled trials are lacking. In such cases, large case series, preliminary clinical studies, and expert opinions are used. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors.

Technology Status Evaluation Reports are drafted by 1 or 2 members of the ASGE Technology Committee, reviewed and edited by the committee as a whole, and approved by the Governing Board of the ASGE. When financial guidance is indicated, the most recent coding data and list prices at the time of publication are provided. For this review the MEDLINE database was searched through January 2016 for articles related to radiofrequency ablation and electrocoagulation, Barrett's esophagus, radiation proctitis, biliary radiofrequency ablation, cholangiocarcinoma, endoscopic retrograde cholangiopancreatography, endoscopic ultrasound, neuroendocrine tumors, and Habib catheter. Technology Status Evaluation Reports are scientific reviews provided solely for educational and informational purposes. Technology Status Evaluation Reports are not rules and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment or payment for such treatment.

BACKGROUND

Radiofrequency ablation (RFA) uses thermal energy to accomplish targeted tissue destruction. Within the GI tract, RFA was initially studied for the treatment of dysplastic Barrett's esophagus (BE), and this continues to be a common application. Indications for RFA within the GI tract continue to evolve. It has been used in the treatment of esophageal squamous cell dysplasia, gastric antral vascular ectasia (GAVE), radiation proctopathy, cholangiocarcinoma, and pancreatic neoplasia, among other conditions.[1-9] This report focuses on devices and techniques used to perform RFA in the GI tract.

TECHNOLOGY UNDER REVIEW

RFA devices use an electrosurgical generator connected to bipolar electrode arrays to deliver thermal energy to tissue. Electricity travels through tissue between alternating positive and negative poles along the electrode arrays of the RFA device in the radiofrequency range of 450 to 500 kHz. This current generates thermal energy within tissue in direct contact with the radiofrequency (RF) electrode, resulting in coagulation necrosis of the targeted tissue. The spacing and geometry of the electrodes on the RFA device and the preset parameters (energy, power) within the RFA generator allow achievement of a consistent depth of ablation. For instance, in the treatment of mucosal pathologic conditions, the dosimetry is designed to yield an ablation depth to the muscularis mucosae (700-800 μm deep).[10,11]

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RFA DEVICES

Barrx Flex energy generator and RFA catheters

Description of device. *Barrx Flex energy generator.* The Barrx Flex energy generator (Medtronic Inc, Sunnyvale, Calif) is a bipolar RF energy generator designed to ablate mucosal tissue in the GI tract. This generator has ports for connection of the Barrx Flex foot switch and the Barrx Flex output cable. The foot switch has 2 pedals that permit hands-free activation of a pneumatic balloon inflation system and the delivery of a dose of RF energy. The output cable connects various single-use RFA catheters to the energy generator. The Barrx Flex Energy Generator received U.S. Food and Drug Administration (FDA) clearance in 2014, updating a previous iteration, the HALOFLEX energy generator. However, a software upgrade to existing HALOFLEX energy generators allows compatibility of this older generator with newer ablation catheters. The generator measures tissue impedance during RF energy delivery and automatically adjusts energy outflow to obtain a uniform depth of tissue ablation throughout the field.

Circumferential ablation catheters. The Barrx 360 Express RFA balloon catheter (Medtronic Inc) comprises a cylindrical, self-adjusting balloon surrounded circumferentially by a 4-cm-long flexible copper sheet of bipolar RF electrodes that is mounted at the distal end of a 85-cm catheter with a 7-mm outer diameter, a central wire-guide channel, and external markings to denote distance from the incisors. The self-adjusting balloon is 8 cm long, including a soft rubber wire-guide at its distal end, with a variable diameter ranging from 18 to 31 mm, and allows a maximum balloon pressure of 4 psi. After pedal activation, the balloon automatically inflates to 3 psi, a pressure intended to correspond to an appropriate diameter based on the patient's esophageal anatomy. Use of this device eliminates the presizing process, which shortens procedure time compared with earlier-generation devices.[1] Radiofrequency energy is delivered through the electrodes at a recommended preset energy density of 10 J/cm^2, which results in circumferential mucosal ablation over a distance of 4 cm.

A previous version of this device, the Barrx 360 RFA balloon catheter (Medtronic Inc), remains commercially available for now. This earlier-generation RF balloon catheter features a shorter 3-cm-long electrode positioned circumferentially around a 4-cm-long cylindrical balloon. This balloon does not have autosizing capabilities, so a separate soft sizing balloon must initially be used to measure the esophageal diameter in the segment to be treated. This allows preselection of the treatment balloon diameter, which is fixed, and is available in 5 sizes ranging from 18 mm to 31 mm.

Focal ablation catheters (over-the-scope). Three related devices (Barrx 90 RFA focal catheter, Barrx Ultra Long RFA focal catheter, and Barrx 60 RFA focal catheter, Medtronic Inc) are used for focal mucosal ablation. These catheters all feature a hinged rectangular electrode attached to a rubber sleeve that mounts onto the tip of a standard endoscope; an attached 4-mm-diameter, 160-cm-long catheter runs alongside the endoscope rather than through the instrument channel. The electrode dimension for Barrx 90 is 20 mm (l) × 13 mm (w) (ablation area 2.6 cm^2); for Barrx Ultra Long is 40 mm (l) × 13 mm (w) (ablation area 5.2 cm^2); and for Barrx 60 is 15 mm (l) × 10 mm (w) (ablation area 1.6 cm^2).

Focal ablation catheter (through-the-scope). The Barrx Channel RFA endoscopic catheter is a 135-cm-long through-the-scope device compatible with endoscopes with a 2.8-mm or larger working channel. A small funnel assists in folding the flexible 7.5 mm × 15.7 mm distal electrode (ablation area 1.2 cm^2) into a cylindrical shape as it enters the endoscope instrument channel, permitting advancement through the scope.

Description of technique. *RFA technique in the esophagus.* ***Circumferential ablation.*** Upper endoscopy is performed to define the extent of the abnormal mucosa to be treated with RFA. Mucosal irrigation with 1% N-acetylcysteine may be performed to assist in mucus clearance. A 0.035- to 0.038-inch guidewire is advanced into the antrum of the stomach, and the endoscope is removed over the wire. The Barrx 360 Express RFA balloon catheter is then advanced over the guidewire, approximating the external distance mark on the catheter with the measured proximal aspect of the mucosal pathologic area. The endoscope is advanced alongside the catheter into the esophagus to visualize the proximal end of the balloon. The ablation balloon is positioned in such a manner that the proximal aspect of the electrode overlaps the proximal extent of the targeted mucosa. Depression of the autoinflation pedal results in balloon inflation, and once an audible tone conveys good mucosal contact, the RF power foot pedal is depressed, resulting in RF energy discharge from the electrode over an interval of approximately 1 second. After the ablation, the balloon automatically deflates, and the circumferential burn is typically visible. The balloon is advanced distally, keeping its most proximal portion in the region that has already been ablated, creating a minimal zone of overlap. These steps are repeated until the gastroesophageal junction is reached. The catheter is removed, and the electrodes are cleared of debris. In the manufacturer's suggested protocol, the treated area is then mechanically debrided with a transparent cap on the tip of the endoscope, the catheter is repositioned over the wire, and a second application of RF energy is subsequently delivered to improve the extent of the ablation. The manufacturer-recommended settings for ablation are 40 W/cm^2, for total energy delivery of 10 J/cm^2. Video 1 (available online at www.VideoGIE.org) demonstrates circumferential RFA of dysplastic Barrett's