



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

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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}

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/cm², 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 cm²); for Barrx Ultra Long is 40 mm (l) × 13 mm (w) (ablation area 5.2 cm²); and for Barrx 60 is 15 mm (l) × 10 mm (w) (ablation area 1.6 cm²).

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 cm²) 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/cm², for total energy delivery of 10 J/cm². [Video 1](#) (available online at www.VideoGIE.org) demonstrates circumferential RFA of dysplastic Barrett's

epithelium using the Barrx 360 Express RFA balloon catheter.

When use of the first-generation Barrx 360 RFA balloon catheter is planned, a 4-cm sizing balloon is advanced into the esophagus over a guidewire and positioned 1 to 3 cm above the proximal aspect of the mucosa to be ablated. The balloon is then inflated to a pressure of 3 psi, allowing esophageal diameter calculation by the generator by use of pressure and volume data. Serial measurements are taken at 1-cm intervals through the segment of interest, starting proximally and proceeding distally. The smallest diameter treatment balloon indicated during the sizing process is suggested as the appropriate ablation catheter. The suggested settings for ablation are 12 J/cm² for dysplastic BE and 10 J/cm² for nondysplastic BE.

Focal ablation. Focal RFA is performed in the treatment of more limited areas of abnormal mucosa, either as an initial treatment or during follow-up after initial circumferential RFA. Focal RFA is frequently used in treating mucosa at the gastroesophageal junction because circumferential balloon contact may be suboptimal in this topographically complex area.¹ The Barrx 90, 60, and Ultra Long RFA focal catheters all mount on the distal tip of the endoscope in such a manner that the electrode is oriented to the 12 o'clock position on the video image. After esophageal intubation, the endoscope is positioned to place the targeted mucosa at the 12 o'clock position of the endoscopic image. The tip of the endoscope is then deflected upward to bring the electrode into contact with the target tissue. Radiofrequency energy (15 J/cm²) is automatically delivered by the generator using the foot pedal as described above. Treatment of dysplastic Barrett's epithelium using the Barrx 90 RFA focal catheter is shown in [Video 2](#) (available online at www.VideoGIE.org). For focal ablation, the manufacturer-recommended protocol is 2 applications of energy to the targeted area, followed by removal of the coagulum from the mucosa and the electrode surface, followed by 2 additional applications of RF energy. An exception to this protocol is noted with the use of Ultra Long RFA catheters, where the recommended dosimetry is 1 application of energy followed by removal of the coagulum, then 1 additional application to the targeted area. The Barrx Channel RFA endoscopic catheter is introduced through the instrument channel of the endoscope, and the same treatment dosimetry as with the Barrx 60 and 90 scope-mounted focal RFA catheters is followed.

RFA technique in the stomach. For GAVE, RFA may be performed with any focal RFA device.² Two consecutive applications of energy are delivered to the same mucosal area with a preset energy density of 12 to 15 J/cm². Unlike RFA delivery for BE, the gastric mucosal coagulum is not scraped between RFA applications to minimize the risk of mucosal bleeding.³ The process is repeated at different sites

until all GAVE lesions have been ablated. During this process, the electrode is repeatedly cleaned, and if an over-the-scope catheter is used, the endoscope can be rotated or the endoscope may need to be removed to rotate the cap in order to facilitate circumferential treatment as needed.

RFA technique in the rectum. For radiation proctopathy, RFA is performed with the use of similar devices, techniques, and energy settings as for GAVE. As with RFA for GAVE, the coagulum is not scraped to minimize the risk of bleeding.⁴

Habib Endo HPB catheter

Description of device. The Habib Endo HPB (EMcision Ltd, London, UK) is a single-use, bipolar device designed for RFA of malignant biliary strictures during ERCP. It has also been used to ablate tissue ingrowth after metallic biliary stent placement.^{5,6} The device comprises an 8F catheter with a 180-cm working length, which can be deployed through endoscope instrument channels at least 3.2 mm in diameter.^{5,7} The distal end of the RFA catheter has a 5-mm leading tip, proximal to which there are 2 circumferential, 8-mm-long stainless-steel electrodes separated by a distance of 8 mm; this configuration provides a cylindrical ablation over an approximate 25-mm length.^{5,7} The proximal end of the catheter permits connection to any electrosurgical generator.

Description of RFA technique in the bile duct. After cholangiography to define stricture length and diameter, the RFA catheter is introduced into the biliary tree over a 450 cm or longer 0.035-inch guidewire, and the electrodes are positioned within the stricture. Ablation is performed with the electrosurgical generator set at 7 to 10 W of coagulation current for a time period of up to 2 minutes.⁸ Use of the SOFT COAG mode, effect 8 with ERBE electrosurgical generators and 400 kHz with RITA Medical Systems electrosurgical generators, has been reported.^{7,8} A 1-minute resting period after energy delivery is recommended before moving the catheter to avoid tissue adhesion to the heated electrodes, which might cause further tissue or vascular injury on withdrawal.⁸ For longer strictures, RFA can be delivered at additional sites along the length of the stenosis. Biliary stent placement is recommended after RFA to ensure adequate biliary drainage and to facilitate hemostasis after thermal injury induced by RFA.⁸

Habib endoscopic ultrasound radiofrequency ablation catheter

Description of device. The Habib EUS-RFA catheter is 190 cm long and 1F (0.33 mm) diameter, and has a 20-mm electrode at its distal tip. The single-use catheter is flexible and can be inserted through a 19- or 22-gauge FNA needle.⁹ This is a monopolar device and thus requires placement of a grounding/diathermy pad on the

patient. An adaptor cable is used to connect the EUS-RFA catheter to an electrosurgical generator.

Description of RFA technique. EUS-RFA has been described in the management of various neoplastic conditions, including solid pancreatic malignancies, cystic pancreatic neoplasia, and malignant lymph nodes. Under EUS guidance, a 19- or 22-gauge FNA needle is introduced into the target lesion, and the stylet is then removed. For EUS-RFA of pancreatic cystic lesions, complete aspiration of the cyst is recommended before the application of RFA.⁹ The tip of the FNA needle is positioned deep in the target lesion. The EUS-RFA catheter is gently advanced within the needle until resistance is encountered. While the position of the RFA probe is carefully maintained, the FNA needle is gradually withdrawn 3 cm to expose the active electrode at the tip of the RFA catheter and to disengage contact between the electrode and the metal FNA needle. Although the tip of the RFA probe may be visible on EUS, fluoroscopy may be helpful in visualization of the RFA probe protruding beyond the tip of the needle. RF energy is applied for 90 to 120 seconds with the electrosurgical generator set at 10 W. The use of SOFT COAG mode, effect 4 has been reported with ERBE electrosurgical generators.⁹ [Video 3](#) demonstrates RFA of a pancreatic neuroendocrine tumor using the Habib EUS-RFA catheter (available online at www.VideoGIE.org). For larger lesions, the EUS-RFA probe and needle are pulled back as a unit and repositioned to sequentially ablate the portion of the lesion that is closer to the echoendoscope tip. Additionally, repeated puncture with the FNA needle may be performed in a different axis to facilitate ablation of additional tissue.⁹

OUTCOMES AND COMPARATIVE EFFECTIVENESS DATA

Barrett's esophagus

Ablation therapy destroys dysplastic epithelium without acquiring tissue. Although this is a potential disadvantage of RFA compared with EMR and endoscopic submucosal dissection (ESD), ablative techniques permit expeditious treatment of large areas of abnormal epithelium. In many patients, RFA is used in combination with EMR or (less commonly) ESD. In these cases, RFA is used to ablate flat BE that remains after an initial resection of a raised or nodular focal lesion.

A systematic review and meta-analysis identified 3802 patients across 18 studies that evaluated the efficacy of RFA for BE.¹² Complete eradication of intestinal metaplasia (CE-IM) was achieved in 78% of patients (95% confidence interval [CI], 70%-86%). Complete eradication of dysplasia (CE-D), including low-grade dysplasia (LGD), high-grade dysplasia (HGD), and intramucosal carcinoma (IMC) was achieved in 91% of patients (95% CI, 87%-95%). The individual studies reported 1 to 3.4 RFA sessions

on average, with 2 to 3 sessions in most studies. CE-IM was achieved in 68% of patients with HGD and in 72.4% of patients with LGD.¹² Progression to cancer occurred in 0.2% of patients during treatment and during follow-up in 0.7% of the patients in whom CE-IM was initially attained, over a median follow-up time of 1.5 years.¹² A meta-analysis of 37 studies including 521 patients with LGD evaluated the efficacy of RFA in this patient subset.¹³ Over 1282 patient-years of follow-up, CE-IM and CE-D were achieved in 87.2% (range, 76.2%-93.5%) and 90.6% of patients (range, 81.0%-95.6%), respectively, with RFA. In a meta-analysis of 6 trials comprising 540 patients with LGD, HGD, or IMC, the recurrence rate for intestinal metaplasia (IM) in patients who initially attained CE-IM was 13% (95% CI, 9%-18%) over a median follow-up time of 1.5 years.¹² At the time of recurrence, the prevalence of dysplasia and mucosal carcinoma were 0.9% and 0.7%, respectively.¹² In a prospective cohort study of 54 patients with dysplastic BE treated with RFA, 49 (90%) were free of intestinal metaplasia at 5 years after treatment.¹⁴ In data from a large U.S. registry, among 1634 patients followed up after BE ablation with RFA, recurrence of IM occurred in 334 patients (20%) over a mean follow-up time of 2.4 ± 1.3 years.¹⁵ The mean length of BE at recurrence was 0.6 cm. In a multivariate analysis, nonwhite race, length of BE, and age were independent predictors of IM recurrence.¹⁵ The likelihood of recurrence was not influenced by sex, pretreatment dysplasia, treatment with EMR, number of RFA sessions, or treatment at an academic versus a community-based practice.

With regard to dosimetry, a recent multicenter randomized trial of 41 patients with limited Barrett's epithelium reported that a simplified focal RFA regimen (3 applications at 15 J/cm² without debridement of the coagulum) was not inferior to the standard regimen (2 applications at 15 J/cm², debridement, then 2 additional applications at 15 J/cm²) for the eradication of residual Barrett's islands.¹⁶ This modification may shorten the overall procedure time and limit the number of endoscopic intubations per session.

A retrospective case series evaluated 86 consecutive patients with dysplastic BE undergoing either photodynamic therapy (PDT) or RFA treatment at a single center over a 9-year period.¹⁷ Thirty-three patients with HGD underwent PDT with porfimer sodium photosensitizer and a 630-nm laser (130 J/cm), with a maximum of 3 treatment sessions. Fifty-three patients with BE with dysplasia (47 LGD, 6 HGD) underwent stepwise circumferential and focal ablation with RFA. Patients undergoing PDT received an average of 1.4 treatment sessions, whereas patients undergoing RFA received an average of 2.6 treatment sessions. CE-D was achieved in 18 of 33 (54.5%) patients receiving PDT and 47 of 53 (88.7%) patients receiving RFA. Posttreatment strictures were observed in 9 of 33 (28%) patients in the PDT group and 2 of 53 (4%) patients in the RFA group. The reported facility cost for an RFA session was \$1888, and a PDT session was \$9449.¹⁷

Esophageal squamous cell dysplasia

The use of RFA for the treatment of esophageal squamous cell dysplasia is off label. A prospective series evaluated RFA for the treatment of squamous cell dysplasia in 96 patients (45 with moderate-grade intraepithelial neoplasia, 42 with high-grade intraepithelial neoplasia, and 9 with early squamous cell carcinoma).¹⁸ A complete response was observed in 70 of 96 patients (73%) at 3 months and in 81 of 96 patients (84%) at 12 months. Two patients (2%) had histologic progression (1 moderate grade to high grade and 1 high grade to T1M2 carcinoma) during follow-up; both were treated endoscopically and achieved a complete response. Similar efficacy of RFA for squamous dysplasia was also noted in several other small studies.¹⁸⁻²²

Treatment of GAVE

A prospective cohort study evaluated the role of RFA in 21 patients with GAVE who remained transfusion-dependent despite prior treatment(s) with argon plasma coagulation (APC).²³ A median of 2 (range, 1-3) RFA sessions were required for each patient and were 4 weeks apart on average. At 6 months after completion of RFA, 18 of 21 patients (86%) were transfusion-independent. Mean hemoglobin increased from 7.8 g/dL to 10.2 g/dL in the 18 responders.²³ A retrospective case series evaluated RFA in 24 patients with GAVE (17 of whom were refractory to prior endoscopic treatments).²⁴ Fifteen patients (65%) had no transfusion requirement after RFA (mean, 1.8 RFA sessions), and a significant increase in mean hemoglobin levels was reported (6.8-9.8 g/dL). Other small case series have also reported similar outcomes for treatment of refractory GAVE with RFA.^{25,26}

Treatment of radiation proctopathy

In a prospective multicenter study, 39 patients with hemorrhagic radiation proctopathy (RP) were treated with RFA (72% undergoing a single session).²⁷ Fourteen patients (39%) had received a previous endoscopic treatment for RP (mostly APC). During a mean follow-up time of 28 months, bleeding stopped in all 39 patients (100%), and an endoscopic RP severity score improved in 38 patients (96%). Discontinuation of transfusion was achieved in 11 of 12 patients (92%) who were transfusion dependent before RFA. Iron therapy could be discontinued in 14 of 17 patients (82%). In a subsequent retrospective multicenter study, the efficacy of RFA was reported in 17 patients with RP, of whom 7 patients had undergone a previous treatment (APC in most cases).²⁷ After a mean of 1.8 RFA sessions, bleeding symptom scores significantly decreased in 16 patients (94%). In the 13 patients who were transfusion-dependent before RFA, discontinuation of transfusion was achieved in 9 patients (69.2%). Similar outcomes have also been observed in smaller case series.²⁸⁻³²

Treatment of malignant biliary strictures

In an initial, single-center, prospective pilot study, the feasibility of RFA was evaluated in 21 patients with unresectable malignant biliary strictures.³³ All patients had placement of a metallic biliary stent after RFA. There was a posttreatment increase in median bile duct diameter from 0 to 4 mm as measured at a 3-month follow-up ERCP. No significant adverse events attributable to RFA were noted. A retrospective, single-center, case series described 66 patients with malignant biliary strictures (36 with cholangiocarcinoma) who underwent either stent placement alone or RFA followed by stent placement.⁷ The rates of stent patency were similar between the 2 groups, but on multivariate analysis, RFA was found to be an independent predictor of survival (hazard ratio = 0.29; 95% CI, 0.11-0.76; $P = .012$).⁷ A retrospective single-center series described 12 patients (9 with cholangiocarcinoma [CCA]) with malignant distal or perihilar biliary strictures who underwent 19 RFA applications during ERCP followed by placement of plastic stents.³⁴ Severe bleeding was noted in 3 patients at 4 to 6 weeks after treatment, resulting in 2 patient deaths.³⁵ The use of RFA to treat tumor ingrowth within uncovered biliary self-expanding metal stents and to treat intraductal extension of ampullary neoplasms and intraductal papillary neoplasm of the bile duct has been described in case reports.^{8,36-38}

Two retrospective cohort studies have compared ERCP-directed RFA versus PDT for the treatment of malignant biliary strictures.^{39,40} In 1 study, patients undergoing RFA ($n = 16$) were shown to have an overall survival rate similar to that in patients who underwent PDT ($n = 32$), with a median survival of 9.6 versus 7.5 months, respectively ($P =$ not significant).³⁹ In a different study of 34 patients with hilar cholangiocarcinoma, 14 patients who received 31 biliary RFA treatments were compared with 20 historical control patients who had received 36 PDT treatments.⁴⁰ Within the RFA group, a significant decrease of the bilirubin level at 14 days was noted, whereas no significant decrease was noted in the PDT group. Unplanned early stent exchanges were observed more frequently in the PDT group than in the RFA group (65% vs 29%, $P < .01$).⁴⁰

EUS-RFA

EUS-guided RFA with the Habib catheter was initially evaluated in animal studies, in which mediastinal lymph nodes⁴¹ and normal pancreatic head tissue⁴² were ablated in live pigs. Moderate pancreatitis developed in 1 of 5 pigs, and at necropsy 3 additional pigs had mild inflammatory changes evident in the head of the pancreas. Human experience is limited to a small case series of 8 patients with pancreatic neoplasia (6 cystic neoplasms and 2 neuroendocrine tumors [NET]). EUS-RFA was technically successful in all patients, and no

TABLE 1. Radiofrequency ablation devices

System or catheter	Catheter / cord diameter	Length	Electrode dimensions	Price
Barrx Flex generator (includes Flex RFA foot switch: FlexFS-010A and Flex RFA output cable: FlexCC-020A)	-	-	-	\$135,000
Barrx 360 Express RFA balloon catheter	7 mm	85 cm	Electrode length 4 cm, variable diameter ranging from 18 to 31 mm	\$2000
Barrx 360 RFA balloon catheter	7 mm	80 cm	Electrode length 3 cm, variable diameter ranging from 18 to 31 mm	Ablation balloon \$1800; sizing balloon \$350 (both single use)
Barrx 90 RFA focal catheter	4 mm	160 cm	20 mm length × 13 mm width	\$1200
Barrx 90 Ultra Long RFA focal catheter	4 mm	160 cm	40 mm length × 13 mm width	\$1200
Barrx 60 RFA focal catheter	4 mm	160 cm	15 mm length × 10 mm width	\$1200
Barrx Channel RFA catheter	2.8 mm	135 cm	7.5 mm length × 15.7 mm width	\$1200
Habib EUS-RFA	1F	220 cm	20 mm length × 1F diameter	\$1795
Habib Endo HPB	8F	200 cm	8 mm length × 8F diameter (2 electrodes)	\$1495

RFA, Radiofrequency ablation.

adverse events were noted.¹¹ Among the 6 patients with a cystic neoplasm, complete resolution of the cyst was noted in 2 patients, and a reduction in cyst size was noted in 3 patients. EUS-RFA induced a decrease in vascularity and central necrosis in the 2 NET patients, but no decrease in tumor diameter was observed. Although a different EUS-RFA probe has been evaluated in the treatment of pancreatic insulinoma and pancreatic adenocarcinoma, it is not FDA approved.^{43,44}

EASE OF USE

RFA devices are widely available, are portable, and are compatible with all modern electrosurgical generators. RFA is of similar technical complexity as other ablative techniques such as APC. RFA can be safely performed with a variety of sedation approaches, including moderate sedation, deep sedation, or general anesthesia. The sedation approach should be individually tailored for each patient based on comorbidities, body habitus, and anticipated procedure duration.

RFA for BE or squamous dysplasia frequently requires multiple sessions and does not obviate the need for surveillance endoscopies. Circumferential ablations may be difficult to perform when luminal stenosis is present, and focal ablation techniques may be preferred in such patients. The autosizing capability of the Barrx 360 Express RFA catheter appears to simplify and shorten circumferential RFA procedures. The through-the-scope nature of the Barrx Channel RFA catheter also appears to simplify procedures in which limited focal RFA is needed and may reduce patient discomfort compared with over-the-scope catheters, which require multiple introductions of the endoscope.

SAFETY

Patients frequently experience chest pain and odynophagia after esophageal RFA and may be provided with prescriptions for liquid pain medication, viscous xylocaine, or both, before discharge. These symptoms usually last for 1 week or less after treatment and resolve spontaneously.^{45,46} A systematic review and meta-analysis of 3802 patients across 18 studies evaluated the safety of RFA for BE.¹² Strictures were the most commonly reported adverse event (pooled estimate 5%; 95% CI, 3%-7%), followed by pain (3%; 95% CI, 1%-6%), and bleeding (1%; 95% CI, 1%-2%).¹² Longer length of Barrett's epithelium ablated and prior EMR were risk factors for post-RFA stricture development. Post-RFA strictures typically respond favorably to endoscopic dilation.¹² No deaths have been reported after RFA with the Barrx system.⁴⁷ In a different systematic review and meta-analysis of 9200 patients across 37 studies, perforation was reported in 0.06% of patients (95% CI, 0.04%-0.09%). In this meta-analysis, perforations were reported in 4 studies totaling 5 patients. Of those 5 cases, 2 perforations were attributed to EMR rather than RFA. In addition, 1 perforation occurred in a patient with a prior history of PDT.⁴⁸

Stricture rates after RFA for squamous dysplasia appear higher (14%-29%) than in patients treated for BE; a contributing factor may be the smaller diameter of the upper esophagus compared with the lower esophagus.^{49,50} In a report of 96 patients who underwent RFA for squamous dysplasia, a posttreatment stricture was observed in 20 patients (21%), all of which occurred after circumferential RFA.¹⁸ All strictures resolved with dilation (median, 4 sessions; interquartile range, 2-6).

Reported adverse events after biliary RFA have included hemobilia (in some cases fatal), cholangitis, cholecystitis, hepatic encephalopathy, liver infarction, and pancreatitis.⁵¹

Potential adverse events of pancreatic EUS-RFA include pancreatitis, injury to the gastric wall, and peritonitis.^{52,53}

FINANCIAL CONSIDERATIONS

The costs of devices are shown in [Table 1](#). Relevant current procedural technology (CPT) codes for RFA include 43270 (EGD with ablation of tumor, polyp, or other lesion(s) (includes predilation and postdilation and guidewire passage, when performed) and 43229 (esophagoscopy with ablation). Note that facility reimbursement has been higher for the esophagoscopy code, better reflecting the resource costs of RFA. The 2017 facility reimbursement decisions are being finalized by the Centers for Medicare and Medicaid Services. The CPT code for sigmoidoscopy with ablation is 45346. The CPT code for ERCP with RFA is 43270. There is not a dedicated CPT code for EUS-RFA. Potentially applicable codes might include 43242 (EUS with FNA), 43253 (EUS with ultrasound-guided injection), and 43999 (unlisted procedure, stomach; 48999 for pancreas, 44799 for small intestine).

AREAS FOR FUTURE RESEARCH

Studies comparing RFA with other technologies such as cryoablation for the treatment of BE would be useful to evaluate relative efficacy and cost-effectiveness. More robust data evaluating endoluminal RFA for indications other than BE are needed, including long-term effectiveness data. Existing data for both biliary and EUS-RFA devices remain limited and of low quality. Additional prospective data to better establish safety and clinical benefit, including meaningful outcomes such as survival, are required. Optimal dosimetry and treatment protocols for biliary RFA and EUS-RFA are unknown at this time. The comparative effectiveness of these devices with competing technologies (eg, biliary PDT or ethanol injection at EUS) should be evaluated.

SUMMARY

The use of RFA as a treatment modality in gastrointestinal endoscopy is expanding. RFA is frequently used in combination with focal EMR for the treatment of dysplastic BE and as standalone therapy for flat BE. Its efficacy in the treatment of esophageal squamous dysplasia appears promising. RFA appears to be successful and safe in the management of refractory GAVE and RP, and it may also be beneficial in treatment-naïve patients. Biliary RFA and EUS-RFA are emerging technologies.

DISCLOSURE

Dr Sullivan is a consultant and performs contracted research for USGI Medical, Obalon Therapeutics, GI

Dynamics; is a consultant for Elira Therapeutics and Enteromedics; is on the advisory board of Takeda Pharmaceuticals; and performs contracted research for Aspire Bariatrics, Baronova, and Paion. All other authors disclosed no financial relationships relevant to this publication.

Abbreviations: ASGE, American Society for Gastrointestinal Endoscopy; APC, argon plasma coagulation; BE, Barrett's esophagus; CCA, cholangiocarcinoma; CE-D, complete eradication of dysplasia; CE-IM, complete eradication of intestinal metaplasia; CI, confidence interval; CPT, current procedural technology; ESD, endoscopic submucosal dissection; GAVE, gastric antral vascular ectasia; HGD, high-grade dysplasia; IMC, intramucosal carcinoma; LGD, low-grade dysplasia; NET, neuroendocrine tumors; PDT, photodynamic therapy; RF, radiofrequency; RFA, radiofrequency ablation; RP, radiation proctopathy.

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