Radiofrequency ablation of Barrett’s esophagus: outcomes of 429 patients from a multicenter community practice registry

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Background and study aims: The use of radiofrequency ablation (RFA) for complete eradication of Barrett’s esophagus has shown promise in trials conducted at predominantly tertiary academic centers; however less is known regarding outcomes in the community. We evaluated the safety and efficacy of RFA for Barrett’s esophagus delivered in a community practice setting.

Patients and methods: This was a multicenter registry conducted in community-based gastroenterology practices. Patients had confirmed intestinal metaplasia with or without dysplasia on biopsy of a Barrett’s esophagus. Intervention was step-wise RFA with follow-up esophageal biopsies. Endpoints were histology-based; complete response was defined as all biopsies at most recent endoscopy negative for intestinal metaplasia (CR-IM) or dysplasia (CR-D). Three cohorts were reported: 1) safety cohort, all patients; 2) efficacy cohort A, patients with at least one biopsy session after initial treatment; 3) efficacy cohort B, patients with at least one biopsy session ≥ 1 year after initial treatment.

Results: The safety cohort included 429 patients (71% men, median age 59 years, median Barrett’s segment 3.0 cm). There were no serious adverse events (bleeding, perforation, death), and a stricture occurred after 1.1% of cases (2.1% of patients). In efficacy cohort A (n = 338), CR-IM and CR-D were achieved in 72% and 89% of patients, respectively (median follow-up 9 months). In efficacy cohort B (n = 137), CR-IM and CR-D were achieved in 77% and 100% of patients, respectively (median follow-up 20 months).

Conclusions: In this multicenter registry conducted at four community-based practices, the observed safety and efficacy outcomes associated with RFA for Barrett’s esophagus are comparable to those previously reported in multicenter trials from predominantly tertiary academic centers.

Introduction
Barrett’s esophagus is defined as a columnar-lined esophagus with intestinalized epithelium on biopsy (intestinal metaplasia). Barrett’s esophagus is thought to develop as a result of chronic injury from gastroesophageal reflux disease [1–4]. The reported prevalence of Barrett’s esophagus varies based on the patient population studied. For example, studies have demonstrated the presence of Barrett’s esophagus in 6%–25% of patients in gastroenterology practice and in 1%–2% of general adult populations [5–10].

Biopsies from a Barrett’s esophagus are categorized histologically as non-dysplastic intestinal metaplasia (ND-IM), indefinite for dysplasia (IND), low-grade dysplasia (LGD), high-grade dysplasia (HGD), or adenocarcinoma (EAC). The worst histological grade observed in a set of biopsies defines the patient’s overall diagnosis and dictates subsequent management. Medical society guidelines recommend life-long surveillance endoscopy for patients with ND-IM, IND, and LGD to detect progression to HGD or EAC, which would prompt intervention with endoscopic or surgical therapy.

Clinicians have studied a number of endoscopic interventions that either irreversibly injure or resect the Barrett’s epithelium. These include argon plasma coagulation (APC), photodynamic therapy (PDT), bipolar electrocoagulation (MPEC), laser therapy, cryotherapy, radiofrequency ablation (RFA), endoscopic resection, and endoscopic submucosal dissection. While technological aspects and physician technique differ considerably between these modalities, as do the reported safety and efficacy outcomes, each is capable of removing the Barrett’s epithelium with varying degrees of complete restoration of a neosquamous epithelium.
In the past 5 years, a large number of new clinical trials, including a randomized sham-controlled trial, have assessed the safety and effectiveness of endoscopic RFA for the treatment of patients with each of the Barrett’s esophagus histological grades. RFA appears to result in a high complete eradication rate for Barrett’s, while having a low rate of adverse events including few buried glands. These trials, however, have been conducted at predominantly academic tertiary care centers. In our study, we sought to evaluate the safety and efficacy of RFA for eradicating Barrett’s esophagus when delivered in a community practice setting.

Patients and methods

Study design
This was a multicenter registry conducted at four community-based gastroenterology practices with experience in managing all grades of Barrett’s esophagus. The clinical protocol was reviewed and approved by a centralized institutional review board (IRB), which permitted the collection of data for patients who had undergone RFA during the previous 4 years. The IRB approved a waiver for patient informed consent for the data collection process. Each patient had signed a separate institution-specific patient informed consent form prior to undergoing any endoscopic procedure.

Patients
We included all consecutive patients in our practices with histological confirmation of intestinal metaplasia with or without IND, LGD, or HGD who underwent RFA. Patients with baseline HGD underwent evaluation to rule out cancer, including computed tomography of the chest, endoscopic ultrasound and/or endoscopic resection.

Endoscopic resection
Endoscopic resection was utilized for the staging of any mucosal irregularity prior to RFA, using the cap and snare technique. Patients with invasive cancer on endoscopic resection were referred for surgery and not included in this study. Those with intramucosal cancer (IMC) and negative margins were offered the choice of surgery or endoscopic therapy with RFA. If eligible for RFA after any endoscopic resection, persistent intestinal metaplasia was confirmed by biopsy prior to initiating RFA, and the post-endoscopic resection diagnosis was used as the entry diagnosis for the patient. RFA was performed > 8 weeks after endoscopic resection to allow for adequate healing.

Study devices
Circumferential RFA was applied using a balloon-based system (HALO®). BARRX Medical, Sunnyvale, California, USA). Focal RFA was applied using an endoscope-mounted system (HALO®). A radiofrequency generator delivers a short burst of radiofrequency energy via a bipolar array placed in contact with the tissue. Treatment parameters include high-power density (40W/cm²) and standardization of energy density (10 or 12J/cm²). The depth of ablative injury, as reported in prior studies [11–13], was the muscularis mucosa or superficial submucosa.

Primary radiofrequency ablation
Prior to ablation, esophageal mapping was carried out by measuring the total Barrett’s esophagus segment length from the most proximal margin of columnar tissue to the top of the gastric folds. Primary RFA was preferentially performed with the circumferential balloon-based device. A sizing balloon was used to measure the esophagus inner diameter. Based on the measured values, an ablation catheter (22, 25, 28, 31 or 34 mm outer diameter) was introduced over a guide wire, followed by the endoscope. Using endoscopic guidance, the most proximal 3 cm of the Barrett’s segment was ablated. The catheter was moved distally in 3-cm increments, minimizing overlap, and ablation was repeated to encompass the entire Barrett’s segment plus proximal cardia. The endoscope and catheter were removed and the electrode was cleaned of debris. The ablation zone was cleaned using endoscopic irrigation and suction, as well as an endoscopic resection cap or magnification cap in some cases. After it had been cleaned, the ablation zone was treated once again.

Follow-up radiofrequency ablation and biopsy sessions
After primary RFA, patients underwent follow-up endoscopy every 2–4 months to assess the degree of eradication of visible Barrett’s esophagus. Three centers alternated secondary ablation visits with endoscopy and biopsy visits every 2–4 months until patients were endoscopically and histologically clear. One center performed ablation every 2–4 months until all Barrett’s esophagus was visually eradicated, followed by biopsy to confirm histological eradication. Secondary ablation was preferentially performed with the focal ablation device mounted on the distal end of the endoscope. Each site was ablated twice at 12J/cm², followed by removal of the coagulum with the tip of the device. The endoscope was removed to clean the electrode, and then reintroduced to treat all areas twice more. When indicated, biopsies of the columnar and/or neosquamous epithelium were obtained with maximum capacity or jumbo forceps from four quadrants every 1–2 cm, and encompassed the entire original extent of the Barrett’s esophagus. Endoscopic images demonstrating RFA treatment course of a registry patient are shown in Fig. 1.

Pathology
All baseline and follow-up esophageal biopsy specimens were processed and reviewed at the participating center. Hematoxylin and eosin staining was used. Accepted standards for defining intestinal metaplasia (presence of goblet cells in biopsies obtained from the Barrett’s segment within esophageal body) and degree of dysplasia were followed. A diagnosis of dysplasia was confirmed by two independent pathologists from the same institution. Determination of the presence of buried glandular mucosa was based on a finding of “glandular epithelium beneath an intact layer of squamous epithelium without communication to the surface” [14].

Data collection and data analysis
Data were collected by the investigators at the four participating institutions for all consecutive patients who had undergone RFA for Barrett’s esophagus between December 2004 and November 2008. Parameters recorded in the database included: age at first RFA session, sex, baseline Barrett’s length, history of endoscopic resection and results, worst baseline histological grade (ND-IM, IND, LGD, HGD) after endoscopic resection where applicable, number and type of RFA sessions, date and worst histological grade of intestinal metaplasia at last biopsy session, presence of buried glandular mucosa on any interval or final biopsy, and complications related to RFA. Three cohorts for analysis were identified: 1) safety cohort, all consecutive patients treated; 2) efficacy cohort A, all patients
with at least one biopsy session after primary RFA; 3) efficacy cohort B, all patients with at least one biopsy session ≥ 1 year after primary RFA.

Effectiveness outcomes were based on histology from the last available biopsy session. A complete response for intestinal metaplasia (CR-IM) was defined based upon work by others as “all biopsies negative for intestinal metaplasia” at the last biopsy session. A complete response for dysplasia (CR-D) was similarly defined as “all biopsies negative for IND, LGD, HGD, cancer” at the last biopsy session [15–27]. For entry and last biopsy session histology, IND was considered as dysplasia.

To evaluate the effect of baseline Barrett’s segment length on longer-term efficacy outcome variables and number of RFA treatments, we performed two post-hoc subgroup analyses for efficacy cohort B. We separately compared the percentage of patients with CR-IM and CR-D according to baseline Barrett’s segment length (short segment ≤ 3 cm) vs. long segment > 3 cm) to determine whether there was a relationship between likelihood of response to therapy and length of diseased esophagus. We also separately assessed the number of RFA sessions required to achieve CR-IM in subgroups according to 1-cm intervals of baseline Barrett’s segment length.

Results

The safety cohort included 429 patients (71% men; median age 59 years; interquartile range [IQR] 51–69 years). Median baseline endoscopic Barrett’s length was 3.0 cm (IQR 2.0–5.0), and 24% (n = 103) had dysplasia at entry (Table 1). A total of 788 RFA procedures were performed (429 primary and 359 secondary). Primary RFA was preferentially performed with the circumferential device (77% of cases), whereas secondary RFA was preferentially performed with the focal device (76% of cases). Baseline endoscopic resection was performed in seven patients for visible lesions: IMC with negative margins (n = 6), HGD (n = 1).

Nine strictures occurred in 788 procedures (1.1% of cases), affecting nine patients (2.1% of patients). The likelihood of stricture formation was non-differential between circumferential (77% of cases), whereas secondary RFA was preferentially performed with the focal device (76% of cases). Baseline endoscopic resection was performed in seven patients for visible lesions: IMC with negative margins (n = 6), HGD (n = 1). Nine strictures occurred in 788 procedures (1.1% of cases), affecting nine patients (2.1% of patients). The likelihood of stricture formation was non-differential between circumferential (77% of cases) and focal RFA (11% of cases) procedures. All strictures resolved with dilation (median dilations 3, range 1–8). Other complications included: transient bradycardia during endoscopy (n = 3), mild, self-limited bleeding during endoscopy (n = 4), and superficial mucosal injury noted during endoscopy (n = 1), none of which required intervention. One patient developed a mild fever (37.8°C maximum) on postprocedure day 1, which was managed with acetaminophen and empiric oral antibiotics and resolved in less than 48 hours. One patient vomited blood-tinged mucus in the recovery room. This patient was observed for 1 additional hour and then discharged without complication. There were no esophageal
perforations, bleeding that required intervention, infection, death or other serious adverse events.
Efficacy cohort A (all patients with at least one biopsy session after primary RFA) comprised 338 patients (71% men; median age 59 years [IQR 50–68 years]). Median baseline endoscopic Barrett’s length was 3.0 cm (IQR 2.0–4.0 cm), and 25% (n = 83) had dysplasia. Patients had a mean (± SE) of 1.8 ± 0.1 RFA procedures. At a median follow-up of 9 months (IQR 4–18 months), a CR-IM was achieved in 72% (244/338) of patients. For those with ND-IM as baseline diagnosis (n = 255), a CR-IM was achieved slightly more often than in the group as a whole (75% vs. 72%). Of patients with baseline dysplasia (n = 83), 63% achieved CR-IM (n = 52), and 89% achieved CR-D (n = 74) (Table 2). Subgroup analysis according to baseline grade demonstrated CR-IM and CR-D, respectively, of 55% and 83% in HGD patients, 71% and 95% in LGD patients, and 60% and 100% in IND patients. There was a median of 1 (IQR 1–2) follow-up biopsy sessions performed after the last RFA treatment in this analysis. No buried glands were detected on follow-up biopsy.

Three patients (0.9%) demonstrated evidence of cancer within 2–4 months of primary RFA; for efficacy analysis, treatment was considered to have failed in these patients. One patient had baseline LGD and then IMC at 2 months, which was treated with Ivor-Lewis esophagectomy (presently no evidence of disease at 19 months). One patient had baseline HGD, then IMC at 2 months, and is now awaiting additional therapy. The third patient had HGD and then T1sm1 cancer at 4 months, which was treated with chemotherapy and external beam radiation therapy due to poor surgical candidacy.
Efficacy cohort B (all patients with at least one biopsy session ≥1 year after primary RFA) comprised 137 patients (66% men; median age 60 years [IQR 52–68 years]). Median endoscopic Barrett’s length was 3.0 cm (IQR 2.0–4.0 cm), and 20% (n = 27) had dysplasia. Patients had a mean (± SE) of 2.1 ± 0.1 RFA procedures. At a median follow-up of 20 months (IQR 17–26 months), a CR-IM was achieved in 77% (105/137) of patients. CR-IM did not vary significantly between non-dysplastic and dysplastic baseline cohorts (76% vs. 78%). Of patients with baseline dysplasia (n = 27), 78% achieved CR-IM (n = 21) and 100% achieved CR-D (n = 27) (Table 2). Subgroup analysis according to baseline grade showed a CR-IM and CR-D, respectively, of 80% and 100% in HGD patients, 85% and 100% in LGD patients, and 50% and 100% in IND patients. A median of 2 (IQR 1–2) follow-up biopsy sessions were performed after the last RFA treatment. No buried glands were detected on follow-up biopsy.

The likelihood of CR-IM in efficacy cohort B inversely correlated with baseline segment length. CR-IM was achieved in 89% of patients (78/88) with a baseline length of 3 cm or less, compared with 55% of patients (27/49) with length greater than 3 cm. The likelihood of CR-D, however, did not correlate with baseline length of disease. CR-D was achieved in 100% (14/14) of patients having a baseline length of 3 cm or less, compared with 100% (13/13) of patients with greater than 3 cm. For the subgroup of efficacy cohort B that achieved CR-IM (n = 105), the number of RFA sessions performed increased as baseline segment length increased (Fig. 2).

In efficacy cohort B, one patient (0.7%) had 7 cm of ND-IM at baseline, did not achieve CR-IM by 1 year, and then showed LGD (failure in analysis). No patients have demonstrated cancer at 1 year or more after the first ablation.

Discussion

This registry represents the first community-based, multicenter series inclusive of patients who have undergone circumferential and focal RFA for Barrett’s esophagus, and may also represent the largest reported series of any type to date. Under an IRB-approved protocol, we identified 429 consecutive patients, all of whom had undergone RFA between December 2004 and November 2008 at one of four US centers.
In the safety cohort, which included all 429 patients, there was a 2.1% stricture rate per patient (1.1% stricture rate per procedure), which comports with the 0%–6% reported in the existing RFA literature. Also in keeping with previous series, there were no serious adverse events related to the procedure (such as perforation, bleeding requiring intervention, infection, or death) [15–27]. We believe these results compare favorably to the safety data reported for PDT, endoscopic resection, and other ablative modalities. Specifically, the PHOBAR trial described 36% stricture and 69% photosensitivity rates in patients undergoing PDT [28]. Extensive endoscopic resection therapy has been associated with stricture rates ranging from 0% to 70% and perforation rates from 0% to 5% [29]. Finally, in patients undergoing APC, stricture and perforation have been reported in up to 15% and 3.6% of patients, respectively [30,31].

In two separately reported efficacy cohorts A and B, we observed CR-IM rates of 72% and 77%, respectively, and CR-D rates of 89% and 100%, respectively. These efficacy results are comparable to published reports from trials conducted predominantly at academic tertiary care centers [15–27]. Specifically, in a randomized controlled trial by Shaheen et al., which evaluated RFA in 127 patients with dysplastic Barrett’s esophagus, CR-IM was achieved in 77.4%, and CR-D in 81.0%–90.5% of patients [21]. Sharma et al. reported a CR-IM of 70% in 69 patients with ND-IM after treatment with circumferential ablation only. In this group of patients, application of focal ablation resulted in a CR-IM of 98.4% at 30 months’ follow-up [15,16]. In a smaller series of 10 patients with ND-IM, LGD, and HGD, a CR-IM of 70% and CR-D of 100% was achieved [27]. A recent multicenter trial including 24 dysplastic patients reported CR-IM of 88% and CR-D of 95%. After rescue endoscopic resection was performed in two patients, these rates increased to 96% and 100%, respectively [26].

The efficacy outcomes of RFA reported herein for intestinal metaplasia (CR-IM) compare favorably to those reported for other thermal modalities, such as APC and MPEC, although many of these other studies have used different methodologies for determining complete response (e.g., endoscopic regression vs. histological eradication). A recently published meta-analysis of ablative therapy reports a wide range of efficacy rates for APC of 36%–100% and MPEC of 65%–100% in treating ND-IM [32]. In a multicenter trial of 60 patients undergoing ablation with APC, Manner et al. reported a CR-IM of 77% with mean follow-up of 14 months [33]. Two randomized trials comparing APC and MPEC reported CR-IM rates of 63% and 65% for APC, and 65% and 81% for MPEC, respectively [14,34]. For the endpoint of CR-D, a randomized controlled trial of PDT plus surveillance compared with surveillance alone resulted in 77% (PDT) vs. 39% (surveillance alone) of patients demonstrating eradication of HGD at some point during follow-up [28]. Overall, outcomes for RFA compare favorably with outcomes reported for APC, MPEC, and PDT for eradication of both intestinal metaplasia and dysplasia. However, the clinical utility of the latter modalities has been limited due to inconsistency in outcomes, lack of uniformity of ablative, adverse events, and disease recurrence.

Prior to ablation, it is important to emphasize the role of endoscopic resection for removing endoscopically visible abnormalities suggestive of advanced neoplasia (ulcer, nodule, irregularity, suspicious glandular or vascular pattern on advanced imaging). In our trial, seven patients had such visible abnormalities at baseline and underwent endoscopic resection prior to RFA (six with HGD and one with IMC). The significance of endoscopic resection in the management of Barrett’s esophagus patients is underscored by reports of a change in histological diagnosis between initial biopsy and ensuing endoscopic resection in up to 49% of lesions, as well as the presence of cancer with submucosal invasion in 4% of endoscopically flat 0-IIb lesions that had suggestive glandular and vascular patterns [35,36]. By having more robust histological staging, patients with submucosal invasion are appropriately referred to surgery, while IMC and less can be treated with endoscopic therapy (resection and ablation). In our series, three patients demonstrated a more advanced lesion (IMC or T1sm1) than that of their baseline grade within 4 months of enrollment. One went from LGD to IMC, one from HGD to IMC, and one from HGD to T1sm1 EAC. These cases may represent disease progression in the setting of ablation. However, given the very short time interval between ablation and detection of the advanced lesion, it is most likely that these cancers were prevalent at the time of enrollment and missed due to failure to biopsy the specific lesion during initial work-up, obtaining a biopsy sample that was too small to make the diagnosis, and/or intra- or inter-observer discordance in pathologic interpretation. These cases reiterate the importance of a thorough baseline diagnostic endoscopic exam, use of endoscopic resection for mucosal abnormalities, and follow-up during and after ablative therapy. We recognize that society guidelines recommend surveillance endoscopy with biopsy as the preferred management strategy for patients with ND-IM and LGD; however this has become a topic of debate with the emergence of safety, efficacy, and cost-effectiveness data related to RFA [37–42]. Historically, clinicians...
have exclusively utilized a surveillance strategy designed to detect disease progression at the earliest possible stage. More recently, many clinicians are considering whether it makes more sense to intervene at the beginning of the metaplasia–neoplasia continuum, rather than the end, by treating ND-IM and LGD prophylactically. It has been suggested that such an approach should only be undertaken in the research setting, so as to accurately track adverse events, efficacy, and durability [37, 38]. While an evidence-based assessment of the utility of RFA for ND-IM may call for a randomized controlled trial with comparison of neoplastic progression rates between groups as the only avenue by which to determine whether or not RFA can be considered for these patients, such a trial is not presently underway and, if it materializes at all, may not provide data for more than 10 years. In the interim, we can consider large-scale registry data, cost-utility data, and longer-term trial data related to RFA to begin to answer this question. We presently enroll all patients at our centers undergoing RFA in the prospective multicenter registry described herein. Acknowledging that a finding of ND-IM is the first step in the metaplasia–neoplasia–invasive carcinoma process and that we currently lack a biomarker capable of stratifying risk for these patients, we offer RFA plus surveillance along with surveillance-alone to our non-dysplastic Barrett’s patients after a thorough discussion of the risks and benefits. Our risk–benefit discussion is tailored to each patient’s needs, with perhaps a higher emphasis on enrolling higher-risk patients with long-segment disease, a family history of esophageal adenocarcinoma, and significant anxiety associated with the diagnosis.

We include two efficacy cohorts to fully disclose the outcomes related to this intervention, as our retrospective design prevented us from defining a standardized follow-up interval to perform endoscopy with biopsy, such as imposing an annual biopsy requirement. We defined efficacy cohort A as “any patient with any follow-up biopsy,” fully recognizing that this would include some patients who had not yet completed therapy and might demonstrate suboptimal efficacy relative to other reports. Additionally, we defined a smaller, later-stage efficacy cohort B as “any patient with follow-up biopsy ≥ 1 year after primary RFA” with the assumption that a larger proportion of this cohort would have had ample time to complete therapy. Indeed, patients in efficacy cohort B had more ablation sessions (mean 2.1 vs. 1.8) and longer follow-up (median 20 months vs. 9 months) than patients in efficacy cohort A. These factors may have contributed to the higher CR-IM and CR-D seen in this group.

One strength of this study is that the primary endpoints are histology based, ignoring less relevant and perhaps more easily met endpoints such as endoscopically apparent surface area regression. Other strengths include the large number of total patients (n = 429) and the relatively long follow-up in efficacy cohort B (median 20 months, IQR 17–26 months) compared with other published reports.

There are several limitations to this study. The timings of treatment and follow-up biopsy sessions were not standardized, with three sites alternating biopsy and ablation visits every 2–4 months and one site ablating every 2–4 months until endoscopic clearance (followed by biopsy to confirm histological clearance). Furthermore, scheduled patient follow-up was conducted under the US healthcare system standards of care, with frequency of patient visits significantly influenced by the local reimbursement. As such, treatment and follow-up biopsy intervals may have been lengthier than if they had been performed under the auspices of a prospective trial. In the attrition between the safety cohort (n = 429), shorter-term follow-up cohort A (n = 338), and longer-term follow-up cohort B (n = 137), it is unclear what percentage of patients was truly lost to follow-up and what percentage simply had incomplete follow-up due to timing. Biased attrition rates between efficacy cohorts A and B, with preferential attrition of failures prior to inclusion in the longer-term cohort, could have resulted in over-estimates of complete response rates for efficacy cohort B and partly contribute to the improved efficacy seen in this group.

The biopsy acquisition methodology was not standardized (biopsy procurement, handling, and processing), nor did we perform centralized expert histopathological interpretation as others have done. The latter omission could have introduced bias in our results, given the reported discordance between pathologists for determining the histological grade of dysplastic Barrett’s esophagus [43–45]. Finally, we did not compare the studied intervention (RFA) with other management strategies, such as surveillance, surgery, endoscopic resection, or other ablative techniques.

Despite these stated limitations, we submit that these results reflect what is garnered in a real-world patient care environment. Our goal in managing this disease state is to perform a rigorous baseline work-up as described in this report, perform staging endoscopic resection as indicated, achieve complete eradication of Barrett’s esophagus with serial RFA, biopsy to confirm histological CR-IM, then perform surveillance to assure durability of eradication. Patients provide informed consent after a detailed discussion of available options, including published complication and efficacy rates related to RFA. We continue to collect data prospectively on this study cohort as well as on all new patients, via an IRB-approved multicenter national web-based registry along with over 100 other participating US centers. Our safety and efficacy results reported herein are relevant to the Barrett’s literature in that they comport with those reported from more structured prospective studies conducted predominantly at academic centers.

**Competing interests:** Dr Pruitt has given lectures and conducted teaching sessions for the purpose of clinical education on behalf of BARRX Medical.

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