

## ORIGINAL ARTICLE

# Radiofrequency ablation for intraductal extension of ampullary neoplasms

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**Background and Aims:** Extension of ampullary adenomas into the common bile duct (CBD) or pancreatic duct (PD) may be difficult to treat endoscopically. We evaluated the feasibility, safety, and efficacy of endoscopic radiofrequency ablation (RFA) in the management of ampullary neoplasms with intraductal extension.

**Methods:** This was a multicenter, retrospective analysis of all patients with intraductal extension of ampullary neoplasms treated with endoscopic RFA between February 2012 and June 2015. Treatment success was defined as the absence of detectable intraductal polyps by ductography, visual inspection, and biopsy sampling.

**Results:** Fourteen patients with adenoma extension into the CBD ( $13 \pm 7$  mm,  $n = 14$ ) and PD ( $7 \pm 2$  mm,  $n = 3$ ) underwent a median of 1 RFA sessions (range, 1-5). Additional modalities (thermal probes, argon plasma coagulation, and/or photodynamic therapy) were also used in 7 patients, and prophylactic stents were routinely placed. Thirteen assessable patients underwent a median of 2 surveillance ERCPs after completion of treatment over a median follow-up of 16 months (range, 5-46), with intraductal biopsy specimens showing no neoplasm in 12 patients at the conclusion of endoscopic treatment. Treatment success was achieved in 92%, including 100% of those treated with RFA alone. Adverse events occurred in 43% and included ductal strictures (5 patients) and retroduodenal abscess (1 patient), all of which were successfully treated endoscopically.

**Conclusions:** Endoscopic RFA, alone or in combination with other modalities, may effectively treat intraductal extension of ampullary neoplasms. Ductal strictures were common after RFA but responded to endoscopic stent therapy. RFA may be appropriate in selected patients, particularly when the main treatment alternative is pancreaticoduodenectomy. (Gastrointest Endosc 2016; ■:1-7.)

*Abbreviations:* APC, argon plasma coagulation ablation; CBD, common bile duct; PD, pancreatic duct; RFA, radiofrequency ablation.

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Ampullary adenomas are the most common ampullary tumors and are increasingly detected because of the widespread use of upper GI endoscopy and CT.<sup>1,2</sup> Complete resection of ampullary adenomas is advised because they are premalignant lesions that may undergo malignant transformation through the adenoma–carcinoma sequence.<sup>3</sup> Currently, endoscopic papillectomy is a preferred approach for management of ampullary adenomas not known to contain invasive cancer. Intraductal extension of ampullary adenomas into the common bile duct (CBD) or pancreatic duct (PD) is challenging to treat endoscopically and may be considered a contraindication to endoscopic therapy.<sup>4-7</sup> Intraductal biliary radiofrequency ablation (RFA) is an ablative therapy that has been used to treat malignant biliary strictures and tumor ingrowth into biliary self-expandable metal stents.<sup>8-12</sup> The aim of this study was to evaluate the feasibility, safety, and efficacy of endoscopic RFA in the management of ampullary neoplasms with intraductal extension.

## METHODS

This is a multicenter, retrospective analysis of all patients with ampullary neoplasms with intraductal extension treated with an endoscopic biliary RFA catheter at 3 referral centers between February 2012 and June 2015. The study was approved by the respective institutional review boards. Data were collected regarding (1) patient demographics, (2) initial indication for ERCP, (3) ampullary adenoma characteristics, (4) details of adenoma therapy and extent of eradication, (5) number of procedures necessary for complete adenoma eradication, (6) adverse events, and (7) follow-up after eradication.

ERCP was performed with standard duodenoscopes (Olympus, Center Valley, Pa) either under moderate sedation or with anesthesia support. A cholangiogram and pancreatogram were performed to determine the presence and the extent of intraductal involvement. The length of intraductal involvement was determined from magnetic resonance, EUS, or ERCP images, depending on which modality most clearly showed the extent of the intraductal polyp.

The duodenal portion of the polyp was snare-resected en bloc or in piecemeal fashion by using standard electro-surgical generators (ERBE ICC200EA, ERBE USA, Marietta, GA; or Beamer, ConMed, Utica, NY, USA). After ampullectomy, biliary and/or pancreatic sphincterotomies were performed as appropriate. In some cases of suspected intraductal polyp extension, endoscopic balloon dilation of the bile duct and/or PD orifices was performed to a diameter of 4 to 10 mm (Hurricane Rx balloon dilators; Boston Scientific, Natick, Ma or Quantum TTC biliary balloon dilators, Cook Endoscopy, Winston-Salem, NC) to directly visualize the polyp in the affected ducts. Biopsy specimens of polypoid tissue within the distal CBD or PD were obtained, with endoscopic treatment at the same time and/or during subsequent ERCP procedures.

Single-use, disposable, bipolar RFA catheters (HabibTM EndoHPB, EMcision Ltd, London, U.K. [12 patients] or STARmed Co. Ltd, Korea [2 patients]) suitable for endoluminal delivery of RFA were passed into the biliary tree over a .035-inch guidewire and centered in the bile duct. The entire linear extension of the intraductal neoplasm was treated, with overlapping applications if necessary. When less than 2 cm of duct required treatment, the probe was positioned with its proximal electrode visible endoscopically at the ductal orifice or several millimeters into the duodenal lumen, and the duodenal lumen was deflated by constant suction during RFA. The catheter was connected to an electrosurgical generator (RITA 1500X [Angiodynamics, Latham, NY], Erbe [Surgical Technology Group, Hampshire, England, U.K.], or Beamer [ConMed]). To ensure effective delivery of RF energy, we instilled saline solution into the bile duct before treatment to remove air from the duct, limited insufflation before RFA, and suctioned air from the duodenum before and during each application.

After RFA, repeat cholangiography or pancreatography was performed to assess response to treatment. Biliary (plastic or metal) stents were placed based on endoscopist preference. Prophylactic 5F or 7F PD stents (length 3 or 5 cm, Geenen PD stent; Cook Endoscopy) were placed routinely. A follow-up ERCP with intraductal biopsy sampling was performed as clinically indicated to evaluate for and treat residual polyp tissue until no remaining adenoma was identified.

A variety of other non-RFA thermal therapies, alone or in combination, including snare resection, 10F heater probe (HPU/HPU20; Olympus) ablation, 7F and 10F bipolar electrocoagulation probes (Gold probe; Boston Scientific), argon plasma coagulation (APC) ablation (Erbe APC 300 with an end-fire probe at .7- to 1.0-L flow and 30-60 W), and photodynamic therapy (1-cm cylindrical diffusing fiber at a power output of 400 mW/cm<sup>2</sup> in 1 application for a total dose of 80 J/cm<sup>2</sup>, Pinnacle Biologics, Chicago, Ill) were used as adjunctive therapies for intraductal extension based on the response to RFA, availability of modalities, and endoscopist preference. Typically, APC and thermal probes were used to treat either the polyp around the ductal orifices during the same session in which RFA was performed or the noncircumferential intraductal polyp that was within ready endoscopic view during follow-up examinations.

Successful endoscopic treatment was defined as the absence of adenomatous tissue or detectable recurrence by visual inspection, ductography, and follow-up biopsy sampling, regardless of the number of treatment sessions required. Annual surveillance ERCP was advised after all adenoma had apparently been eradicated.

## RESULTS

Fourteen patients (mean age, 68 ± 7.3 years; 64% women) who underwent endoscopic RFA treatment for intraductal extension of ampullary adenoma between February 2012 and June 2015 were identified, 1 of whom was mentioned in a previous publication.<sup>2</sup> The clinical presentation included jaundice in 6 patients and abdominal pain in 7, and 3 patients were asymptomatic with incidentally detected lesions. Evaluation before endoscopic treatment included CT in 8, magnetic resonance imaging in 7, EUS in 13, and ERCP in 14 patients. Balloon dilation of the distal bile duct or PD to facilitate assessment of the intraductal polyp was performed in 7 patients. Polyp features, histology, intraductal extension characteristics, treatment modalities, and follow-up are shown in Table 1, and representative magnetic resonance and ERCP images are shown in Figures 1 and 2, respectively.

The mean size of the ampullary lesions was 2.4 ± 1 cm. A sessile extension into the CBD was present in all 14 patients for a mean of 13 ± 7 mm, and extension to PD was present in 3 patients for a mean of 7 ± 2 mm. Nine of 14 patients

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