

ENDOSCOPIC RFA

VER #03

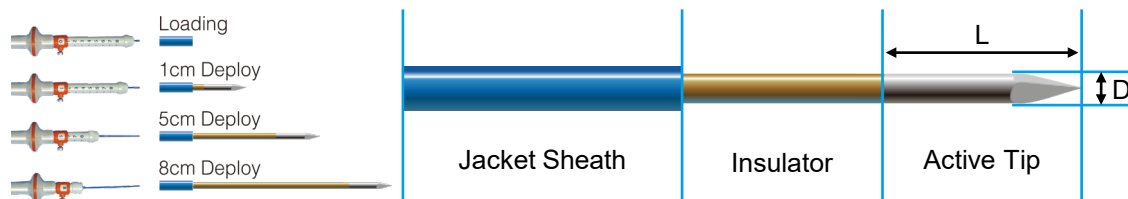
VER #03



EUSRA INTRODUCTION

Catheters (blue and white)
for Water Cooling

Power
Line

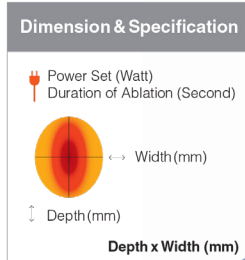
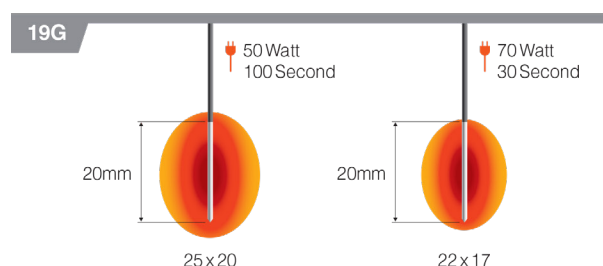
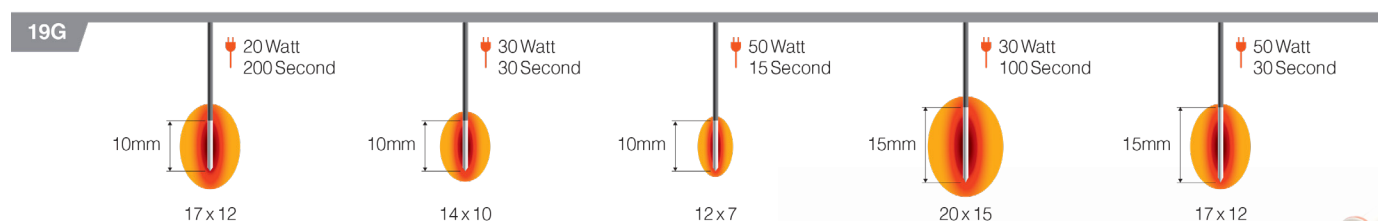
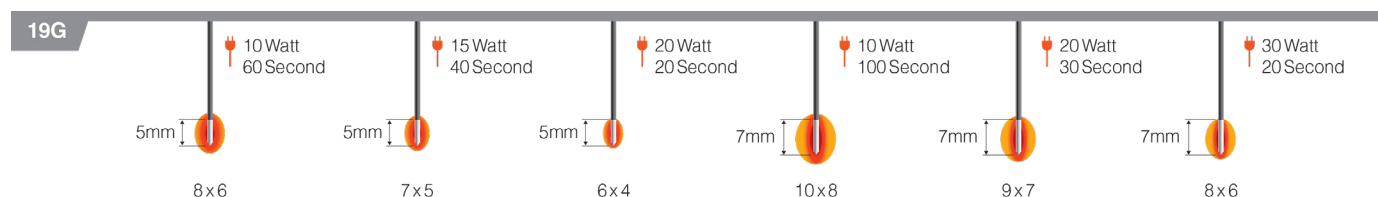


Art Number	Needle		Catheter
	Active Part Length (L, mm)	Diameter (D)	
19-05E	5	19G	Length : 140cm Profile (P) : 7Fr
19-07E	7		
19-10E	10		
19-15E	15		
19-20E	20		
19-25E	25		
19-30E	30		

Needle
Length
Adjuster

Sheath
Length
Adjuster

Power Setting / Continuance Mode		
RF electrode (mm)	Power (Watt)	Duration (When to stop)
5	10	Until echogenic bubble is visible along the whole body of the needle or Until impedance rises enough (above 4-500 ohm.)
7	20	
10	30-50	
15, 20	50	

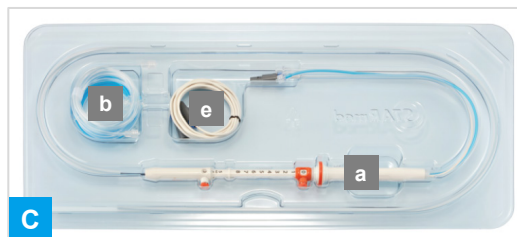


EUSRA SETTING

PRODUCT KITS

A. VIVA Combo™ RF Generator / **B.** Pump / **C.** EUSRA™ Electrode

- a. EUSRA™ Electrode X 1
- b. Blue&White tube connector X 1
- c. Blue&White tubing set X 1
- d. Ground pad X 2
- e. Electrode Cable X 1



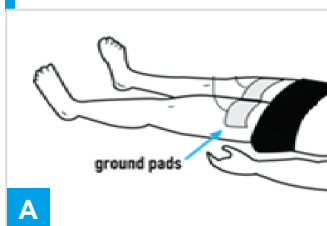
01

Press the **power button** to turn the VIVA combo™ Generator on or off. When the system is turned on, a green light and a sound will emit.



02

- A.** Place the ground pads on the patient's both thighs.
- B.** Connect the pad cables to the VIVA combo™ Generator.



03

Turn the Pump's tube compression lever to the left to open. Ensure the inflow tubing (blue) is properly positioned, matching the arrows in the picture.



04



Raise the tube automatic clamp and place the inflow tubing (blue) in the roller.



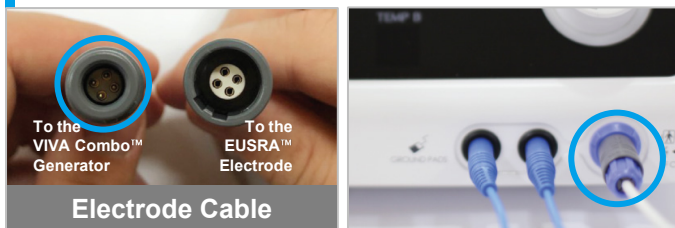
Make sure the inflow tubing (blue) is centered in the roller.
[Caution: Pull the inflow tubing (blue) down firmly to secure it in the proper position.]



Turn the Pump's tube compression lever to the right to tighten the inflow tubing (blue).
[Caution: Ensure the inflow tubing (blue) is secure before releasing the lever.]

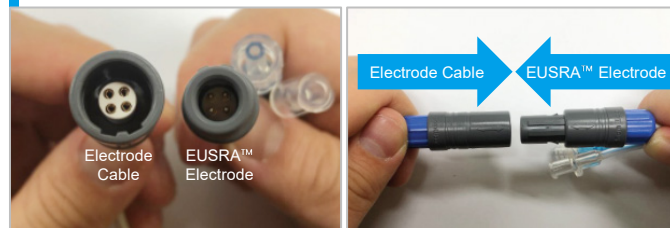
05

Connect the Electrode Cable to the **VIVA Combo™** Generator.



06

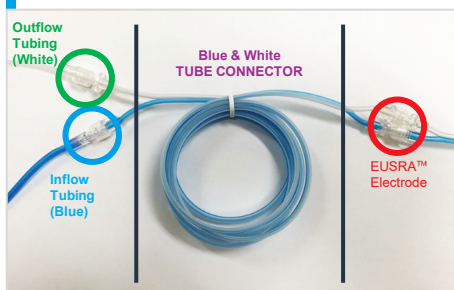
Connect the Electrode Cable to the **EUSRA™** Electrode.



07

Connect the blue & white tubing set to the **EUSRA™** Electrode using the blue & white tube connector.

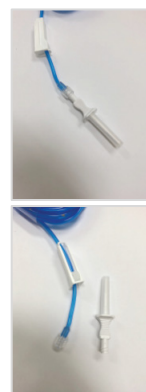
[Caution: Make sure all the tubing connections are secure and colors match.]



Outflow tube (White): To discharge saline used to cool the **EUSRA™** Electrode. Place the tip in the waste bin.



Inflow tube (Blue) : To supply saline that will be used to cool the **EUSRA™** Electrode. After placing through the pump, connect the tip to the saline bag.



*The blue tubing set saline inserter is removable.

08

Select **Continuance Mode** by pressing the Mode Button until the display window shows "**Continuance mode**". Turn the RF Power Control Knob clockwise and select the desired power level(watts).

CONTINUANCE MODE



09

Turn on the Pump and wait for air bubbles in the inflow tube (blue) disappear. Now you are ready to start the procedure. Press "**Start/Stop**" button to activate the output power.

[Caution: Always turn on the Pump before activating the **VIVA Combo™** Generator.]



EUSRA PROCEDURE

01

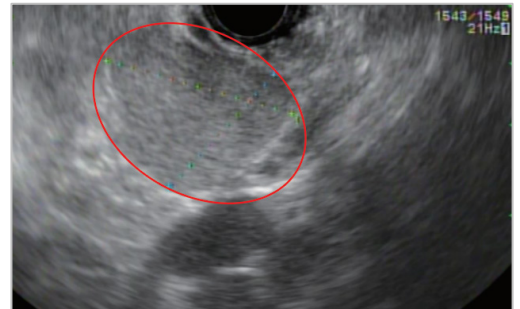
Find a target lesion under EUS-guidance.



[Oblique-viewing
Echoendoscope]



[Forward-viewing
Echoendoscope]



02

Pass EUSRA™ into the target lesion. Real-time doppler helps visualize major vessels, potentially reducing risk of inadvertent puncture and ensuring accurate ablation.

03

Position the echogenic needle tip of EUSRA™ at far end within the lesion.

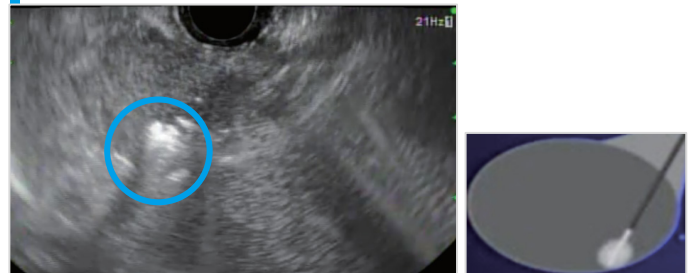


04

Activate RFA by either "Foot Pedal" or "Start Button" of VIVA Combo™. Both 'Foot Pedal' and 'Start Button' can activate power.

05

Stop RFA in about 10 seconds when white bubbles appear on EUS monitor.

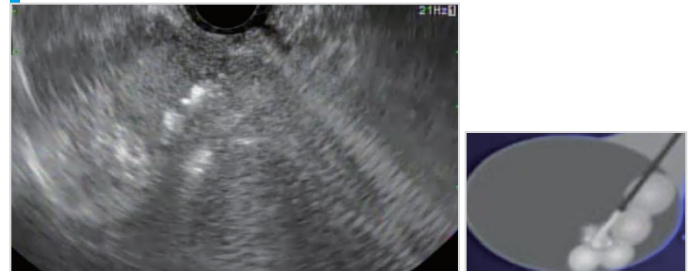


06

Withdraw EUSRA™ while its tip is still inside the lesion to ablate another unburnt area in the same trajectory.

07

Additional passage can be made to ablate other area in the same lesion. "Fanning Technique"



EUSRA STUDIES BY INDICATION

Pancreatic Neuroendocrine Tumor (PNET) & Pancreatic Cystic Neoplasm (PCN)

- #1 Long-term outcome after EUS-guided radiofrequency ablation: Prospective results in pancreatic neuroendocrine tumors and pancreatic cystic neoplasms by Marc Barthet et al. [Endosc Int Open. 2021 Aug;9(8):E1178-E1185.]
- #2 Risk factors for endoscopic ultrasound-guided radiofrequency ablation adverse events in patients with pancreatic neoplasms a large national French study (RAFPAN study) by Bertrand Napoléon et al. [Gastrointest Endosc 2023;98:392-9.]

Pancreatic Cystic Neoplasm (PCN)

- #3 Endoscopic ultrasound-guided radiofrequency ablation of pancreatic microcystic serous cystic neoplasms: a retrospective study by Dongwook Oh et al. [Endoscopy. 2021 Jul;53(7):739-743.]

Pancreatic Neuroendocrine Tumor (PNET) : Insulinoma

- #4 EUS-guided radiofrequency ablation for management of pancreatic insulinoma by using a novel needle electrode (with videos) by Sundeep Lakhtakia et al. [Gastrointest Endosc. 2016 Jan;83(1):234-9.]
- #5 Immediate and durable therapeutic response after EUS-guided radiofrequency ablation of a pancreatic insulinoma by Nicholas G Brown et al. [VideoGIE. 2020 Aug 29;5(12):676-678.]

Pancreatic Cancer

- #6 Initial experience of EUS-guided radiofrequency ablation of unresectable pancreatic cancer by Tae Jun Song et al. [Gastrointest Endosc. 2016 Feb;83(2):440-3.]
- #7 EUS-guided Radiofrequency Ablation (EUS-RFA) of Solid Pancreatic Neoplasm Using an 18-gauge Needle Electrode: Feasibility, Safety, and Technical Success by Stefano Francesco Crinò et al. [J Gastrointest Liver Dis. 2018 Mar;27(1):67-72.]
- #8 Clinical outcomes of EUS guided radiofrequency ablation for unresectable pancreatic cancer: A prospective observational study by Dongwook Oh et al. [Endosc Ultrasound. 2022 Jan-Feb;11(1):68-74.]

Pancreatic Metastases from Renal Cancer

- #9 Endoscopic Ultrasound-Guided Radiofrequency Ablation as an Future Alternative to Pancreatectomy for Pancreatic Metastases from Renal Cell Carcinoma: A Prospective Study by Brice Chanez et al. [Cancers (Basel). 2021 Oct 20;13(21):5267.]

Hepatocellular Carcinoma (HCC)

- #10 EUS-guided radiofrequency ablation of a hepatocellular carcinoma of the liver by Fabia Attili et al. [VideoGIE. 2018 Mar 28;3(5):149-150.]
- #11 Endoscopic ultrasound-guided radiofrequency ablation for hepatocellular carcinoma in cirrhosis: a case report test for efficacy and future perspectives by Germana de Nucci et al. [Endosc Int Open. 2020 Nov;8(11):E1713-E1716.]

Adrenal Gland Tumor

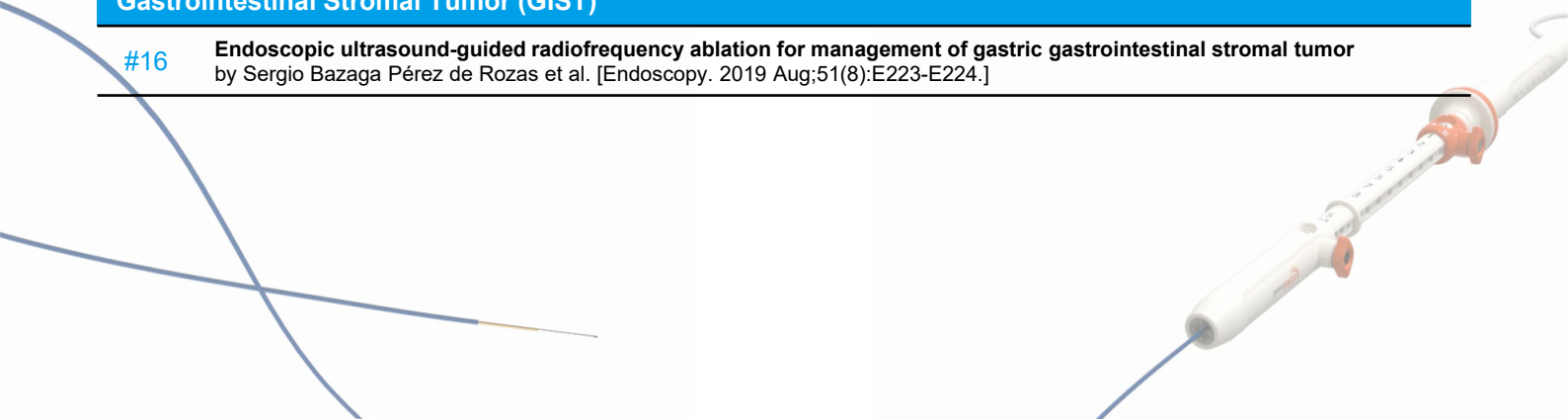
- #12 Cushing's syndrome managed by endoscopic ultrasound-guided radiofrequency ablation of adrenal gland adenoma by Sun-Ho Lee et al. [Endoscopy. 2017 Feb;49(S 01):E1-E2.]
- #13 EUS-guided radiofrequency ablation for a left adrenal oligometastasis of an esophageal adenocarcinoma by Akin Inderson et al. [VideoGIE. 2018 Apr 12;3(5):159-161.]
- #14 Expanded indication for EUS-guided RFA : management of adrenal tumors by Sung Hyung Cho et al. [Gastrointest Endosc 2023;98:790-6]

Celiac Ganglion

- #15 EUS-guided celiac plexus radiofrequency ablation using a novel device by Zaher S Houmani et al. [VideoGIE. 2020 Jun 16;5(9):395-396.]

Gastrointestinal Stromal Tumor (GIST)

- #16 Endoscopic ultrasound-guided radiofrequency ablation for management of gastric gastrointestinal stromal tumor by Sergio Bazaga Pérez de Rozas et al. [Endoscopy. 2019 Aug;51(8):E223-E224.]



Long-term outcome after EUS-guided radiofrequency ablation: Prospective results in pancreatic neuroendocrine tumors and pancreatic cystic neoplasms

Marc Barthet, Marc Giovannini, Mohamed Gasmi, Nathalie Lesavre, Christian Boustière, Bertrand Napoleon, Arthur LaQuiere, Stephane Koch, Geoffroy Vanbiervliet, Jean-Michel Gonzalez

BACKGROUND AND STUDY AIMS

Endoscopic ultrasoundguided radiofrequency ablation (EUS-RFA) for pancreatic neuroendocrine tumors (NETs) and intraductal pancreatic mucinous neoplasia (IPMN) with worrisome features or high-risk stigmata (WF/HRS) has been evaluated in few series with short-term outcomes. This study's primary endpoint was to assess the long-term efficacy of EUS-RFA in patients with NETs or pancreatic cystic neoplasms (PCNs) over at least 3 years.

PATIENTS AND METHODS

Twelve patients had 14 NETs with a mean 13.4-mm size (10–20) and 17 patients had a cystic tumor (16 IPMN, 1 MCA) with a 29.1-mm mean size (9–60) were included. They were treated with EUS-guided RFA, evaluated prospectively at 1 year, and followed annually for at least 3 years.

RESULTS

The mean duration of follow-up was 42.9 months (36–53). Four patients died during follow-up (17–42 months) from unrelated diseases. At 1-year follow-up, and 85.7 % complete disappearance was seen in 12 patients with 14 NETs. At the end of follow up (45.6 months), complete disappearance of tumors was seen in 85.7 % of cases. One case of late liver metastasis occurred in a patient with initial failure of EUS-RFA. At 1-year follow-up, a significant response was seen in 70.5 % of 15 patients with PCNs. At the end of the follow-up, there was a significant response in 66.6 % with no mural nodules. Two cases of distant pancreatic adenocarcinoma unrelated to IPMN occurred.

CONCLUSIONS

EUS-RFA results for pancreatic NETs or PCNs appear to be stable during 42 months of follow-up.

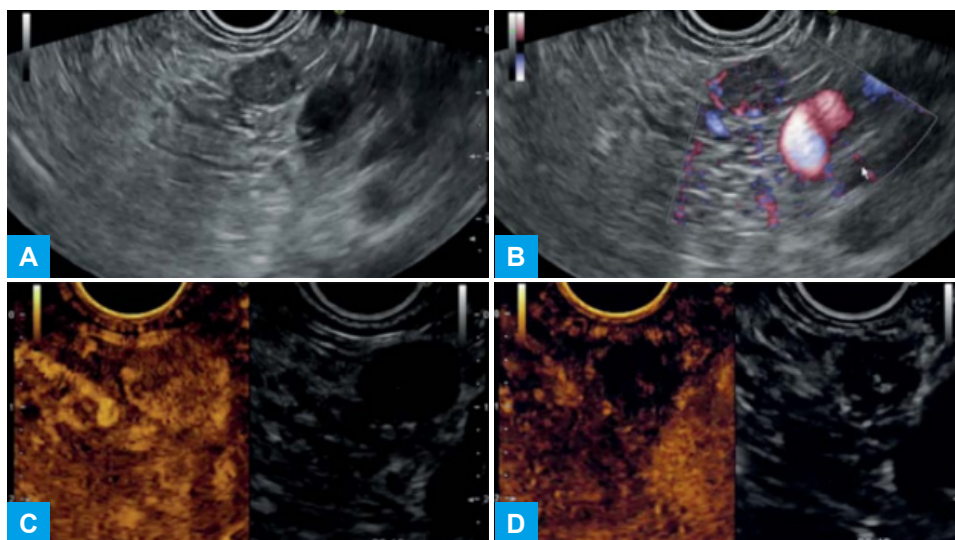


Fig. 2 EUS-guided RFA with CEH control for NET located to the body of the pancreas.

- A. EUS view of NET located to the body of the pancreas, 11mm size, homogenous.
- B. EUS view of NET with fine Doppler showing peripheral arterial vascularization.
- C. CEH EUS view of NET showing early hyperenhancement.
- D. immediate CEH EUS view of NET after EUS-RFA showing no more enhancement of the treated NET.

Table 2. NET follow-up

Inclusion	1-year follow-up	>3-year follow-up	Final results
14 NETS 12 patients	12 disappearance	11 successes 1 late recurrence	Success 85.7%
	2 failures	1 late success 1 metastatic evolution	Failure 14.3%

Risk factors for EUS-guided radiofrequency ablation adverse events in patients with pancreatic neoplasms: a large national French study (RAFPAN study)

Bertrand Napoléon, Andrea Lisotti, Fabrice Caillol, Mohamed Gasmi, Philippe Ah-Soune, Arthur Belle, Antoine Charachon, Franck Cholet, Pierre-Yves Eyraud, Philippe Grandval, Jean-Michel Gonzalez, Francois Habersetzer, Stéphane Koch, Marc Le Rhun, Luigi Mangialavori, Nicolas Musquer, Maxime Palazzo, Laurent Poincloux, Jocelyn Privat, Adrien Sportes, Morgane Stouvenot, Clement Subtil, Lucie Thomassin, Geoffroy Vanbiervliet, Guillaume Vidal, Lucine Vuitton, Marc Giovannini, Marc Barthet

BACKGROUND AND AIMS

EUS-guided radiofrequency ablation (EUS-RFA) has been described as a potentially curative option for solid and cystic pancreatic neoplasms. We aimed to assess the safety and efficacy of pancreatic EUS-RFA in a large study population

METHODS

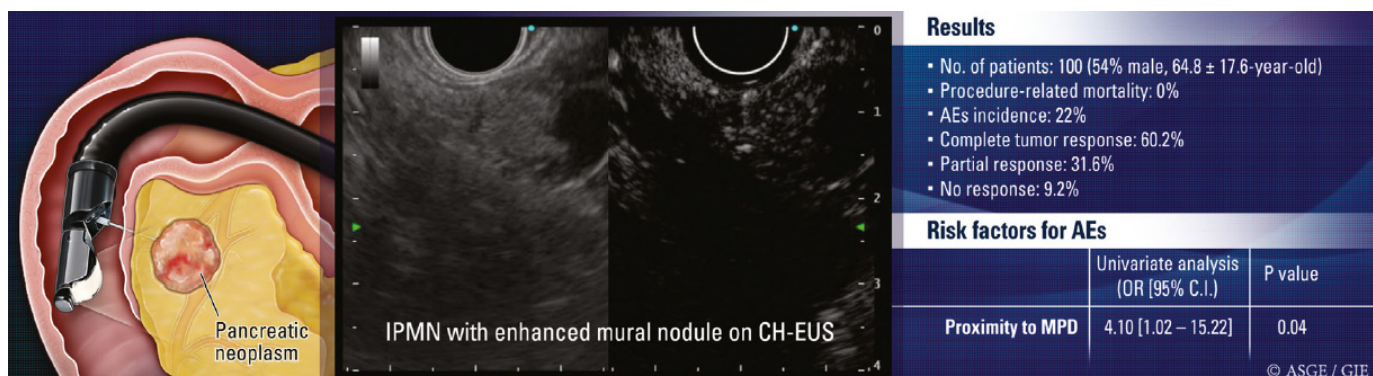
A retrospective study retrieving all consecutive patients who underwent pancreatic EUS-RFA during 2019 and 2020 in France was conducted. Indication, procedural characteristics, early and late adverse events (AEs), and clinical outcomes were recorded. Risk factors for AEs and factors related to complete tumor ablation were assessed on univariate and multivariate analyses.

CONCLUSIONS

The results of this large study confirm an overall acceptable safety profile for pancreatic EUS-RFA. Close proximity (≤ 1 mm) to the main pancreatic duct represents an independent risk factor for AEs. Good clinical outcomes in terms of tumor ablation were observed, especially for small NENs.

RESULTS

One hundred patients (54% men, 64.8 ± 17.6 years old) affected by 104 neoplasms were included. Sixtyfour neoplasms were neuroendocrine neoplasms (NENs), 23 were metastases, and 10 were intraductal papillary mucinous neoplasms with mural nodules. No procedure-related mortality was observed, and 22 AEs were reported. Proximity of pancreatic neoplasms (≤ 1 mm) to the main pancreatic duct was the only independent risk factor for AEs (odds ratio [OR], 4.10; 95% confidence interval [CI], 1.02-15.22; $P = .04$). Fifty-nine patients (60.2%) achieved a complete tumor response, 31 (31.6%) a partial response, and 9 (9.2%) achieved no response. On multivariate analysis, NENs (OR, 7.95; 95% CI, 1.66-51.79; $P < .001$) and neoplasm size ($< .001$) were independently related to complete tumor ablation.



Endoscopic ultrasound-guided radiofrequency ablation of pancreatic microcystic serous cystic neoplasms: a retrospective study

Dongwook Oh, Sung Woo Ko, Dong-Wan Seo, Seung-Mo Hong, Jin Hee Kim, Tae Jun Song, Do Hyun Park, Sung Koo Lee, Myung-Hwan Kim

BACKGROUND

Endoscopic ultrasound-guided radiofrequency ablation (EUS-RFA) has been increasingly used for the management of various solid pancreatic tumors. This study aimed to evaluate the feasibility and safety of EUS-RFA for serous cystic neoplasms (SCNs).

METHODS

13 patients with microcystic SCNs with honeycomb appearance underwent EUS-RFA using a 19-gauge RFA needle. Before ablation, cystic fluid was aspirated until a thin layer of fluid remained.

RESULTS

EUS-RFA was successful in all patients. Seven patients underwent a single session and the remaining six patients underwent a second session of EUS-RFA. One patient (7.7%) experienced self-limited abdominal pain after EUS-RFA. During a median follow-up period of 9.21 months (interquartile range [IQR] 5.93 – 15.38), the median volume of the SCNs decreased from 37.82mL (IQR 15.03 – 59.53) at baseline to 10.95mL (IQR 4.79 – 32.39) at the end of follow-up. A radiologic partial response was achieved in eight patients (61.5%).

CONCLUSIONS

EUS-RFA is technically feasible and showed an acceptable rate of adverse events for patients with SCNs. A long-term follow-up study is required to evaluate the efficacy of EUS-RFA.

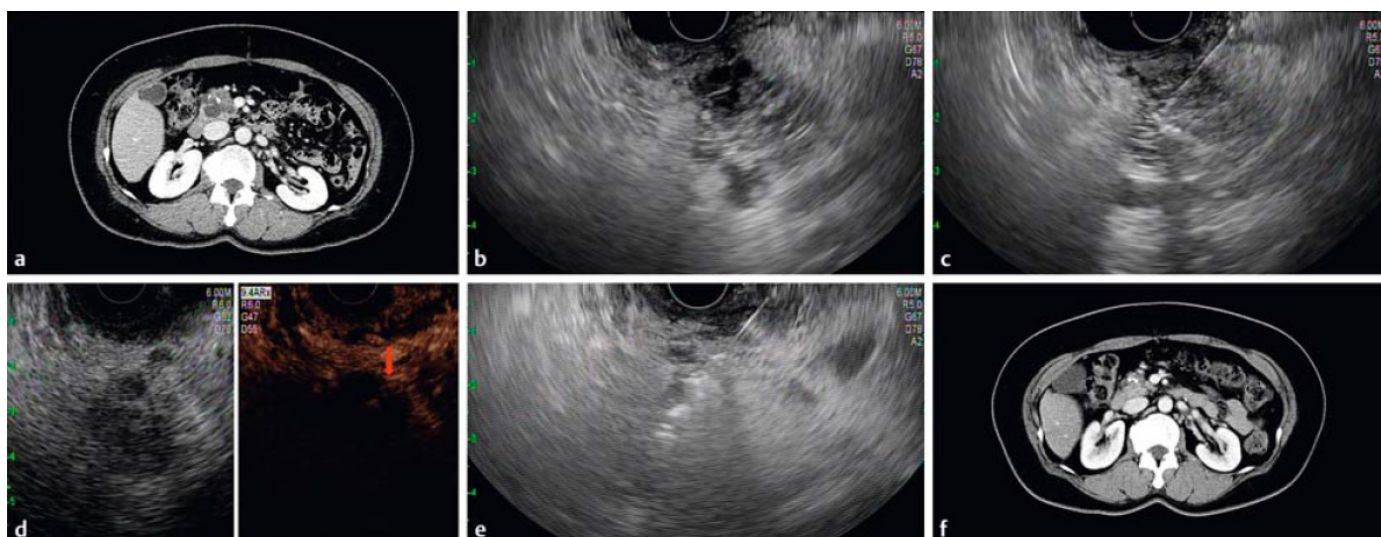


Fig. 2 Radiologic images of a 3-cm microcystic serous cystic neoplasm (SCN) in the head of the pancreas (**a**, **f** on computed tomography [CT] scanning; **b** – **e** on endoscopic ultrasound [EUS]) showing: **a**, **b** the appearance before treatment; **c** EUS-guided radiofrequency ablation (EUS-RFA) being performed; **d** a viable portion of the SCN (arrow) on follow-up with contrast-enhancement; **e** a second session of EUS-RFA being performed to ablate the viable SCN; **f** the SCN, now decreased to 1.4 cm, at the 12-month follow-up.

EUS-guided radiofrequency ablation for management of pancreatic insulinoma by using a novel needle electrode (with videos)

Sundeep Lakhtakia, Mohan Ramchandani, Domenico Galasso, Rajesh Gupta, Sushma Venugopal, Rakesh Kalpala, DNB, Nageshwar Reddy

BACKGROUND AND AIMS

Insulinomas are one of the most common functional pancreatic neuroendocrine tumors. Surgical removal is the standard of care. Patients unfit for or refusing surgery need an alternative nonsurgical method to alleviate symptoms. EUS has been used to localize, aspirate, and tattoo insulinomas and to inject alcohol for local ablation. This study is aimed at assessing the feasibility of EUS-guided radiofrequency ablation (EUS-RFA) for managing patients with a symptomatic insulinoma by using a novel EUS-RFA needle electrode.

METHODS

The EUS-RFA system used consists of a prototype 19-gauge needle electrode, generator, and internal cooling system. EUS-guided RFA is performed under real-time visualization at 50 W to ablate pancreatic insulinomas.

RESULTS

In this observational human case series from a tertiary care center, 3 patients with a symptomatic pancreatic insulinoma, not eligible for surgery, underwent EUS-RFA by using an internally cooled prototype needle electrode. All had rapid symptom relief with biochemical improvement and remained symptom free at 11 to 12 months of follow-up. There were no procedure-related adverse events.

CONCLUSIONS

EUS-RFA with the novel device can be considered in select patients with a symptomatic pancreatic insulinoma based on preliminary findings of a beneficial effect without adverse events. Assessment of the safety profile requires larger prospective trials.



Figure 5. Abdominal contrast-enhanced CT in the arterial phase shows a large enhancing lesion in the head and genu of the pancreas (arrow).

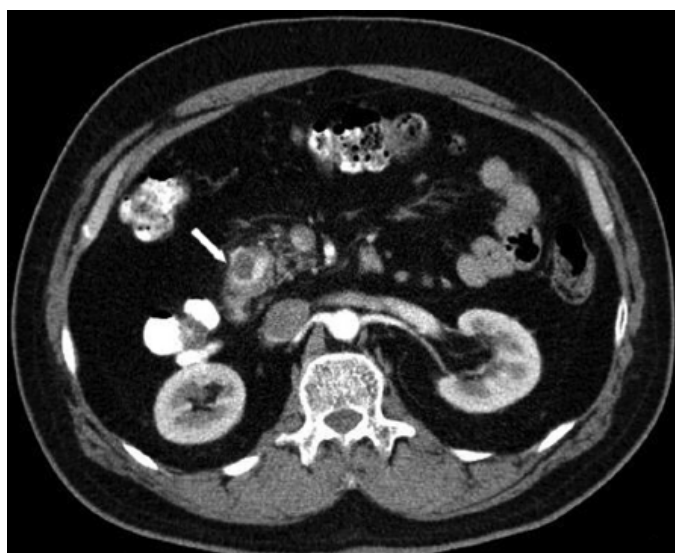


Figure 6. Post-EUS-guided radiofrequency ablation at 3 months. Abdominal contrast-enhanced CT shows a pancreatic head lesion with rim enhancement and a central nonenhancing hypodense area (arrow).

Immediate and durable therapeutic response after EUS-guided radiofrequency ablation of a pancreatic insulinoma

Nicholas G. Brown, Anish A. Patel, Tamas A. Gonda

EUS-guided radiofrequency ablation (RFA) is an endoscopic procedure and emerging therapeutic option for the treatment of pancreatic tumors. It has been described in recent years for local therapy of pancreatic adenocarcinoma and neuroendocrine tumors in patients for whom operative management is deemed unsuitable. Hyperthermic ablation using radiofrequency waves at 500 kHz is used to induce irreversible cellular injury and necrosis of the target lesion. Precise delivery of thermal energy is critical to spare the normal surrounding pancreatic tissue from injury. There is a modest but growing body of literature regarding the use of this technique in pancreatic neuroendocrine tumors, and our case demonstrates the feasibility of achieving immediate and durable response.

A 66-year-old woman with morbid obesity and type 2 diabetes was referred for management of a pancreatic insulinoma after multiple episodes of hypoglycemia. Biochemical markers were diagnostic of an insulinoma, with a fasting C-peptide level of 4 (reference: 0.8-3.5) and serum insulin of 27 mIU/L (reference: <25 mIU/L) in the setting of a fasting glucose level of 44 mg/dL (reference: 65-95 mg/dL). CT imaging revealed an early arterial phase-enhancing lesion measuring 1.8 × 0.9 × 1.3 cm in the pancreatic head. After a multidisciplinary discussion, the patient was deemed a high-risk surgical candidate because of her comorbidities, and it was therefore decided to offer EUS-guided RFA of the tumor.

The patient was admitted to the hospital for glucose monitoring before the procedure. Outpatient diazoxide, which was used to maintain her blood glucose, was discontinued before the procedure (T½ 24-36 hours). Informed consent was obtained, and the following day the patient underwent diagnostic and therapeutic EUS. From the duodenal bulb, a well-defined, hypoechoic, bilobed tumor was noted in the head of the pancreas. Fine-needle biopsy using a 22-gauge fine-needle biopsy needle was performed, and a visible core tissue was submitted for pathology review.

The needle was exchanged for the EUS-RFA electrode system (STARmed; Koyang, South Korea). We used a 19-gauge RFA needle with a 7-mm radiopaque exposed electrode tip attached to a radiofrequency generator with an internal cooling system. The RFA system has a 7F diameter; it requires a working channel of at least 2.4 mm and is compatible with a therapeutic linear echoendoscope. Under ultrasound guidance, the tumor was again punctured. Energy was applied at 20 W for 15 seconds. Special care was taken to ensure the hyperechoic treatment effect did not extend beyond the tumor margin. RFA applications were repeated until the entire tumor area showed hyperechoic bubbles suggestive of thermal injury.

After the procedure, the patient was pain free and was observed for 72 hours. Within 12 hours of the ablation, there was a dramatic increase in random and fasting glucose values, which required initiation of insulin therapy. Eight months after the procedure the patient remains well and without further symptoms; as a result coordinating follow-up imaging has been a challenge. Pathology review confirmed a low-grade neuroendocrine tumor with a Ki-67 of less than 1%.

This case supports that EUS-guided RFA can be a safe and effective local therapy for functional pancreatic insulinoma. Video 1 (available online at www.VideoGIE.org) provides additional guidance for physicians who are pursuing this alternative treatment for patients for whom surgical management is not feasible. This also demonstrates the necessity of postprocedural blood glucose monitoring and anticipation of profound changes in blood glucose. Although very long-term efficacy studies of pancreatic neuroendocrine tumors are lacking, this is a promising endoscopic therapy.

Initial experience of EUS-guided radiofrequency ablation of unresectable pancreatic cancer

Tae Jun Song, Dong Wan Seo, Sundeep Lakhtakia, Nageshwar Reddy, Dong Wook Oh, Do Hyun Park, Sang Soo Lee, Sung Koo Lee, Myung-Hwan Kim

BACKGROUND AND AIMS

Radiofrequency ablation (RFA) has been used as a valuable treatment modality for various unresectable malignancies. EUS-guided radiofrequency ablation (EUS-RFA) of the porcine pancreas was reported to be feasible and safe in our previous study, suggesting that EUS-RFA may be applicable as an adjunct and effective alternative treatment method for unresectable pancreatic cancer. This study aimed to assess the technical feasibility and safety of EUS-RFA for unresectable pancreatic cancer.

METHODS

An 18-gauge endoscopic RFA electrode and a radiofrequency generator were used for the procedure. The length of the exposed tip of the RFA electrode was 10 mm. After insertion of the RFA electrode into the mass, the radiofrequency generator was activated to deliver 20 to 50 W ablation power for 10 seconds. Depending on tumor size, the procedure was repeated to sufficiently cover the tumor.

RESULTS

EUS-RFA was performed successfully in all 6 patients (median age 62 years, range 43-73 years). Pancreatic cancer was located in the head (n Z 4) or body (n Z 2) of the pancreas. The median diameter of masses was 3.8 cm (range 3cm-9cm). Four patients had stage 3 disease, and 2 patients had stage 4 disease. After the procedure, 2 patients experienced mild abdominal pain, but there were no other adverse events such as pancreatitis or bleeding.

CONCLUSIONS

EUS-RFA could be a technically feasible and safe option for patients with unresectable pancreatic cancer.

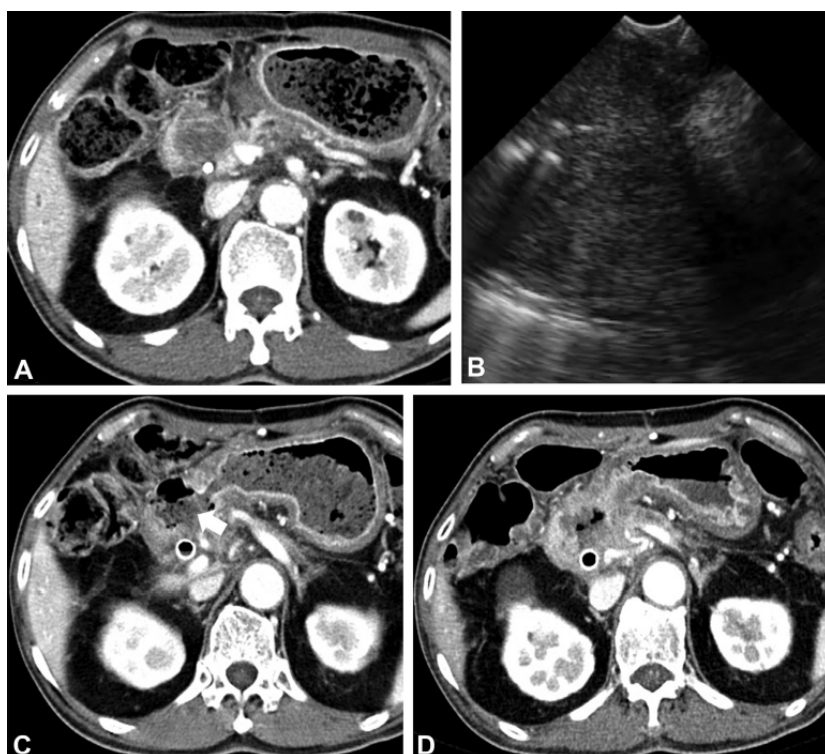


Figure 3. Imaging findings of patients with cancer of the pancreatic head.

- A. CT shows a low-density mass at the pancreas head, which did not respond to second-line chemotherapy.
- B. EUS-guided radiofrequency ablation (RFA) was performed by using forward-viewing EUS with 50 W of ablation power for 10 seconds and was repeated 8 times.
- C. One month after RFA, follow-up CT showed necrosis and air bubbles in the mass (arrow).
- D. Two months after RFA, CT showed a decrease of the low density mass.

EUS-guided Radiofrequency Ablation (EUS-RFA) of Solid Pancreatic Neoplasm Using an 18-gauge Needle Electrode: Feasibility, Safety, and Technical Success

Stefano Francesco Crinò, Mirko D'Onofrio, Laura Bernardoni, Luca Frulloni, Michele Iannelli, Giuseppe Malleo, Salvatore Paiella, Alberto Larghi, Armando Gabbrielli

BACKGROUND & AIMS

Endoscopic ultrasound-guided radiofrequency ablation (EUS-RFA) is a promising technique for the treatment of pancreatic neoplasm. We evaluated the feasibility, safety, and technical success of pancreatic EUS-RFA performed in a single center.

METHODS

9 consecutive patients (8 with pancreatic adenocarcinoma and 1 with renal cancer metastasis) were referred for EUS-RFA between November 2016 and July 2017. EUS-RFA was performed using 18-gauge internally cooled electrode with a 5 or 10 mm exposed tip. Feasibility, technical success or early and late adverse events were assessed.

RESULTS

One patient was excluded because of a large necrotic portion. EUS-RFA was feasible in all the other 8 (100%) cases. An ablated area inside the tumor was achieved in all treated patients. No early or late major adverse event was observed after a mean follow-up of 6 months. Three patients experienced mild postprocedural abdominal pain.

CONCLUSIONS

EUS-RFA seems a feasible, safe, and effective procedure for pancreatic neoplasms. Its role in the treatment and management of pancreatic masses must be further investigated.

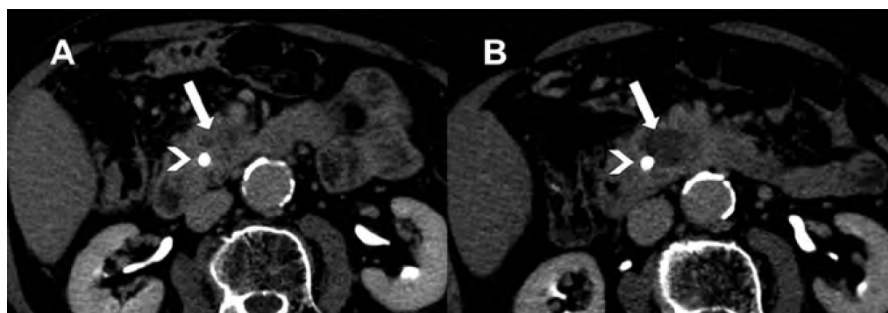


Fig. 4. Contrast-enhanced computed tomography (late phase) scans before (A) and after (B) endoscopic ultrasound-guided radiofrequency ablation (EUS-RFA), in a patient with pancreatic head cancer (arrows). A plastic stent is visible in the bile duct (arrowheads).

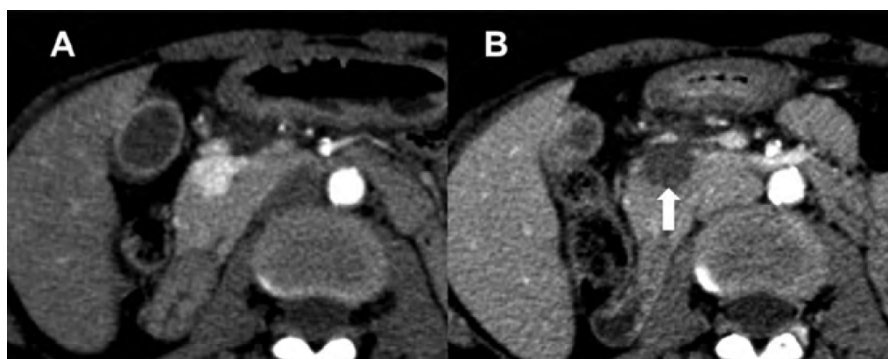


Fig. 5. (A) A case of pancreatic head hypervascular metastasis from renal cell carcinoma. (B) After endoscopic ultrasound-guided radiofrequency ablation, a markedly hypodense area is detectable instead of the tumor (arrow).

Clinical outcomes of EUS guided radiofrequency ablation for unresectable pancreatic cancer: A prospective observational study

Dongwook Oh, Dong Wan Seo, Tae Jun Song, Do Hyun Park, Sung Koo Lee, Myung Hwan Kim

BACKGROUND AND OBJECTIVES

EUS guided radiofrequency ablation (EUS RFA) has been increasingly used for the treatment of pancreatic neoplasms. The role of EUS RFA in the management of pancreatic cancer has not yet been elucidated. This study aimed to evaluate the survival impact of EUS RFA in unresectable pancreatic cancer.

METHODS

Twenty two patients (n = 14, locally advanced unresectable; n = 8, metastatic) with unresectable pancreatic cancer underwent EUS RFA combined with subsequent chemotherapy between May 2016 and June 2019. Survival outcomes including overall survival (OS) and progression free survival (PFS) were evaluated.

RESULTS

EUS RFA was successful in all patients. The median number of RFA sessions was 5 (interquartile range, [IQR], 3.25–5.75). After successful EUS RFA, subsequent gemcitabine based chemotherapy was performed. Early procedure related adverse events occurred in 4 out of 107 sessions (3.74%), including peritonitis (n = 1) and abdominal pain (n = 3). During follow up over a median of 21.23 months (IQR, 10.73–27.1), the median OS and PFS were 24.03 months (95% confidence interval [CI], 16–35.8) and 16.37 months (95% CI, 8.87–19), respectively.

CONCLUSIONS

EUS RFA is technically feasible and safe for the management of unresectable pancreatic cancer. EUS RFA combined with systemic chemotherapy may be associated with favorable survival outcomes. Further larger scale prospective comparative study is required to confirm these findings.

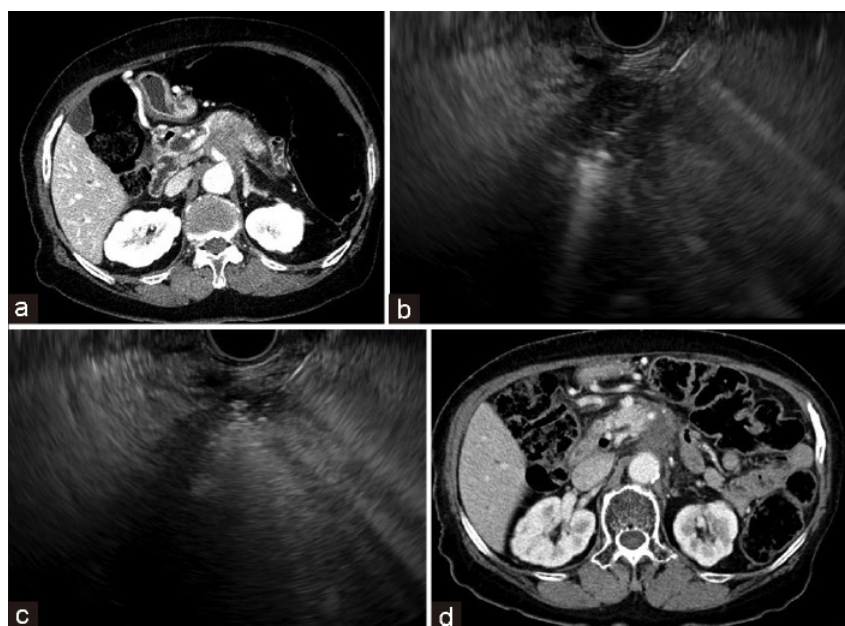


Figure 2. (a) Computed tomography showing a pancreatic body cancer before treatment. (b) EUS-guided radiofrequency ablation is performed. (c) Electrode was repositioned to ablate different areas. (d) At 14-months of follow-up, computed tomography showing necrosis of tumor without increase in size

Endoscopic Ultrasound-Guided Radiofrequency Ablation as an Future Alternative to Pancreatectomy for Pancreatic Metastases from Renal Cell Carcinoma: A Prospective Study

Brice Chanez, Fabrice Caillol, Jean-Philippe Ratone, Christian Pesenti, Philippe Rochigneux, Géraldine Pignot, Jeanne Thomassin, Serge Brunelle, Jochen Walz, Naji Salem, Marc Giovannini, Gwenaelle Gravis

BACKGROUND

Pancreatic metastases (PM) from renal cell carcinoma (RCC) are rare, are associated with favorable outcomes and are usually handled by surgery or VEGFR inhibitors, which both have side effects. Endoscopic Ultrasound (EUS)-guided radiofrequency ablation (RFA) is an innovative approach to treat focally deep metastases and could be a relevant technique to control PM from RCC.

METHODS

This monocentric, prospective study aimed to evaluate the safety and efficacy of EUS-RFA to treat PM. We included patients with confirmed and progressive PM from RCC. PM was ablated under general anesthesia with a linear EUS scope and a EUS-RFA 19-gauge needle electrode placed into the tumor.

CONCLUSIONS

In this series, which is the largest ever reported, we showed that EUS-RFA is feasible and yields an excellent local control rate for PM from mRCC. With manageable complications, it could be a valuable alternative to pancreatic surgery in well-selected patients.

RESULTS

Twelve patients from Paoli-Calmettes Institute were recruited between May 2017 and December 2019. Median age was 70.5 years (range 61–75), 50% were female, 100% were ECOG 0–1. At inclusion, mean PM size was 17 mm (range 3–35 mm); and all were progressive before EUS-RFA. Seven patients had EUS-RFA as the only treatment for RCC. We performed 26 EUS-RFA procedures and 21 PM was ablated. Median follow up was 27.7 months (range 6.4–57.1). For evaluable PM, the 6- and 12-month focal control rates were 84% and 73% respectively. One patient treated with TKI developed a paraduodenal abscess 2 months after EUS-RFA and another patient with biliary stent developed hepatic abscesses few days after EUS-RFA. No other severe side effects were experienced.

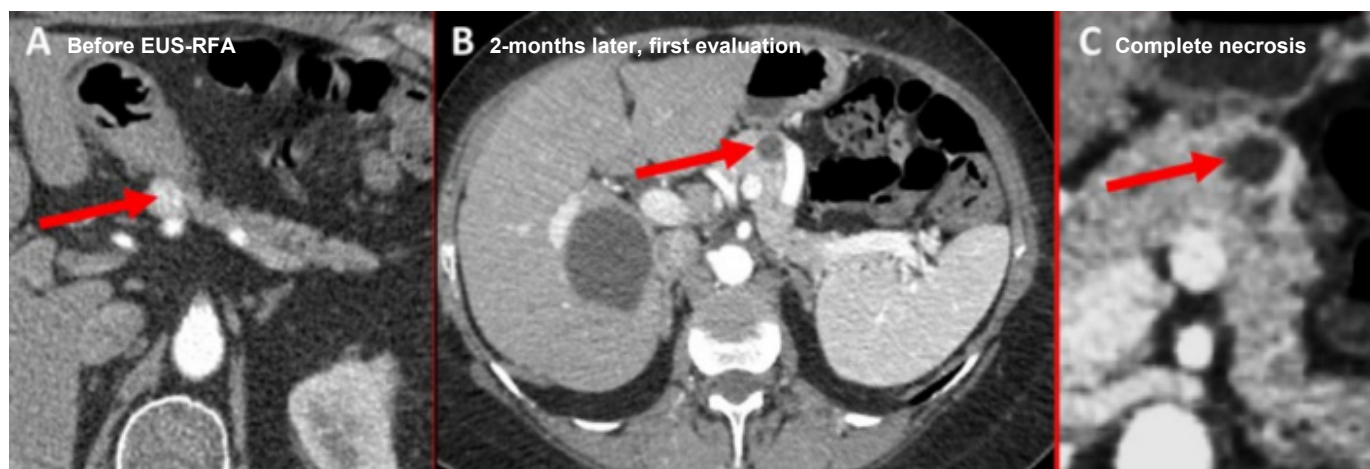


Figure 1. Following contrast enhancing PM with CT-scan before and after EUS-RFA. Abdomen CTScan with contrast injection at artery phase, before (A) and after endoscopic radiofrequency ablation of PM in the body of the pancreas, displaying complete response without contrast enhancement in RFA scar ((B) and at magnification (C)). PM: pancreatic metastases, CT: computed tomography, EUS-RFA: Endoscopic Ultra-Sound guided RadioFrequency Ablation.

EUS-guided radiofrequency ablation of a hepatocellular carcinoma of the liver

Fabia Attili, Ivo Boskoski, Vincenzo Bove, Pietro Familiari, Guido Costamagna

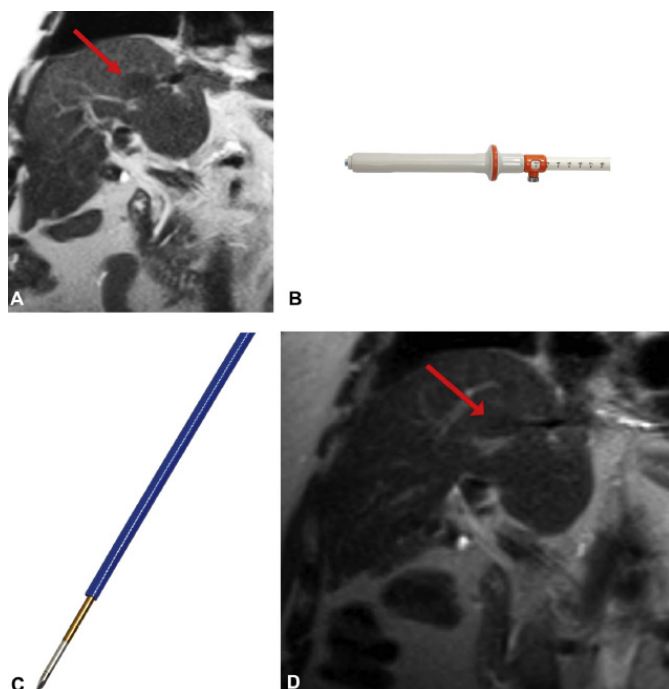


Figure 1. A, MRI showing 25- × 20-mm hypovascular lesion of the III liver segment (arrow). B, C, The EUS 19-gauge 10-mm-long needle for EUS-guided radiofrequency ablation. D, Abdominal MRI 1 month after the procedure showing complete disappearance of lesion in the III liver segment.

Percutaneous and intraoperative radiofrequency ablations (RFA) of hepatocellular carcinoma (HCC) are widely used treatment methods. EUS-guided RFA has recently been used for pancreatic tumors, whereas, to our knowledge, there are no reports of EUS-guided RFA for HCC. We present the case of a 75-year-old man with hepatitis C virus–related cirrhosis who, in May 2015, underwent percutaneous RFA for an HCV-related HCC in the VIII liver segment. The patient was in good clinical condition until June 2017, when a follow-up abdominal MRI showed a 25- × 20-mm hypovascular lesion of the III liver segment (Fig. 1A).

At evaluation by a multidisciplinary board, percutaneous RFA was not taken into account because of the difficult approach to the III liver segment with that technique. Therefore, EUS-guided RFA of the lesion was planned (Video 1, available online at www.VideoGIE.org). The EUS-RFA procedure was done with an Olympus GF-UCT180 (Olympus, Tokyo, Japan) EUS endoscope and an EUS-guided RFA 19-gauge 10-mm-long needle (Starmed-Taewoong Medical, Seoul, South Korea) (Figs. 1B and C) for EUS-guided RFA. After the lesion was punctured with the RFA needle, a 30-W per 3 to 8 seconds monopolar electric current was delivered under direct EUS control directly into the principal lesion and into the satellite lesions. This was done multiple times until all areas of the lesions had acquired echogenic changes.

No immediate adverse events were registered, and the patient was discharged the following day. Abdominal MRI 1 month after the procedure showed evidence of complete disappearance of the lesion in the III liver segment (Fig. 1D). At the follow-up visit, the patient was in good clinical condition.

To our knowledge, this is the first report of EUS-guided RFA of HCC. The treatment was technically and clinically successful. This treatment could be a good therapeutic option for patients who are not candidates for percutaneous RFA because of a difficult approach. The safety and efficacy of this treatment should be evaluated in a larger series because major adverse events such as liver abscess, bile leaks, and bleeding might occur.

Endoscopic ultrasound-guided radiofrequency ablation for hepatocellular carcinoma in cirrhosis: a case report test for efficacy and future perspectives

Germana de Nucci, Cristina della Corte, Raffaella Reati, Nicola Imperatore, Ilaria Arena, Alberto Larghi, Gianpiero Manes

BACKGROUND

The percutaneous approach allows for effective and safe treatment of liver lesions. But in case of subcapsular or left segments location, this approach seems to be less effective or unsafe. Endoscopic ultrasound-guided radiofrequency ablation (EUS-RFA) is a new technique used to treat pancreatic and neuroendocrine tumors in patients unfit for surgery.

METHODS

Hereby, we describe the case of a 70-year-old patient with cirrhosis with a large subcapsular hepatocellular carcinoma (HCC) in II-III-IVb segments, in which surgery or percutaneous therapies were not feasible, treated with EUS-RFA. The HCC was treated using an EUS-RFA (EUSRA) system, which consists of a 19G water-cooled monopolar RFA needle and a dedicated generator system.

RESULTS

After a multidisciplinary discussion, the lesion was ablated in two different sessions, which resulted in destruction of about 70% of neoplastic tissue. A second step surgery was required but initially refused by the patient.

CONCLUSIONS

EUS-RFA could be an effective way to treat left hepatic lesions not manageable with conventional percutaneous methods. This case report does not highlight concerns about safety of this approach and this observation needs to be validated in a larger cohort of patients with cirrhosis.

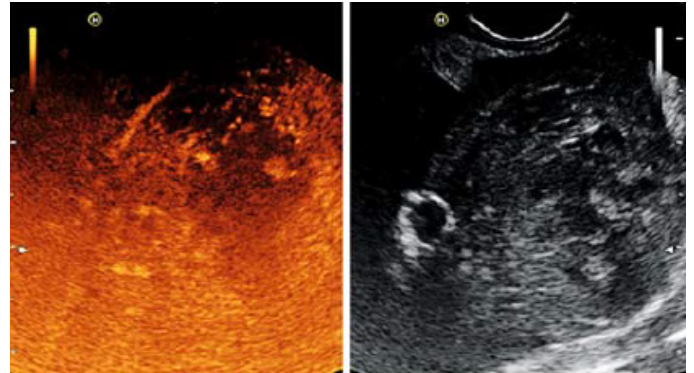


Fig. 3 CH-EUS control after first RFA showing effective central necrosis area as a result of the ablation.

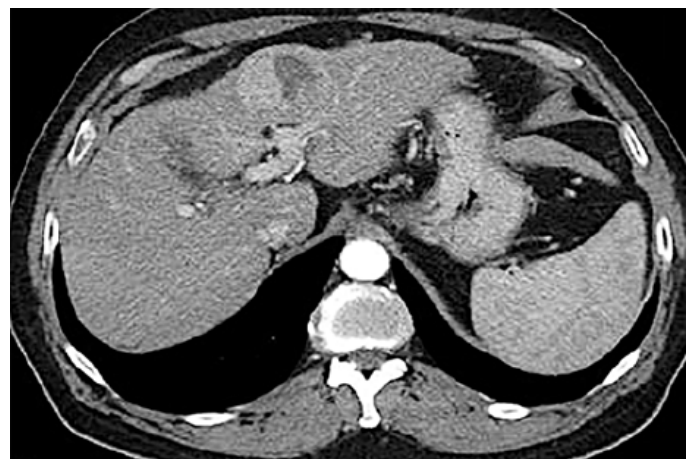


Fig. 4 CT control after second EUS-RFA treatment showing a 20-mm peripheral vital remnant at the IVb segment.

Cushing's syndrome managed by endoscopic ultrasound-guided radiofrequency ablation of adrenal gland adenoma

Sun-Ho Lee, Dong Wan Seo, Dongwook Oh, Tae Jun Song, Do Hyun Park, Sang Soo Lee, Myung-Hwan Kim

A 38-year-old woman presented with “moon face,” “buffalo hump,” and weight gain of 9 kg in 12 months. Overnight, 1mg dexamethasone failed to suppress the morning level of cortisol, and the 24-hour urine cortisol level was elevated to 101 µg/day (normal range 0 – 50). Initial contrast-enhanced abdominal computed tomography (CT) showed a 2.8-cm left adrenal mass enhanced in arterial phase, and the patient was diagnosed with Cushing's syndrome due to left adrenal adenoma. She refused surgical treatment but agreed to undergo endoscopic ultrasound-guided radiofrequency ablation (EUS-RFA; STARmed, Koyang, Korea).

Prior to RFA, contrast-enhanced EUS with SonoVue (Bracco, Inc., Milan, Italy) was performed. Findings of early enhancement and delayed washout were compatible with adrenal adenoma (► Fig. 2 a).

A 19-gauge needle electrode was positioned inside the adenoma. Using realtime EUS imaging, RFA (50W) was performed at five different sites (► Fig. 2 b).

Four days later contrast-enhanced EUS revealed viable tissue remaining at the marginal edge of the previously ablated portion of the adenoma (► Fig. 3 a).

EUS-RFA was repeated at five more sites in the remaining viable tissue (► Fig. 3 b).

Follow-up CT at 1 week showed the adrenal mass almost completely replaced with necrotic tissue, without complications. Serum and urine cortisol levels returned to normal the following day and remained normal for the next 2 months, with no adverse events related to RFA. However after the third month, the cortisol levels were re-elevated and this time the patient agreed to surgery.

Until recently, there were only a few case reports of RFA for the treatment of Cushing's syndrome; all of them were treated via the CT-guided percutaneous method [1, 2]. The present case is the first in which EUS-RFA was used to manage Cushing's syndrome caused by adrenal adenoma. This case report supports EUS-RFA as a safe and feasible alternative method that should be considered in patients who refuse surgical treatment. Further evidence and experiences are required.

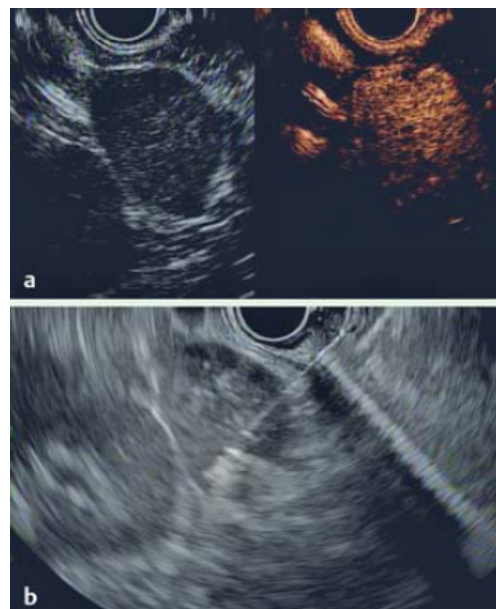


Fig. 2 Endoscopic ultrasound-guided radiofrequency ablation (EUS-RFA) of the left adrenal adenoma. **a** Contrast-enhanced EUS with early enhancement. **b** The EUS-RFA needle positioned inside the adenoma.

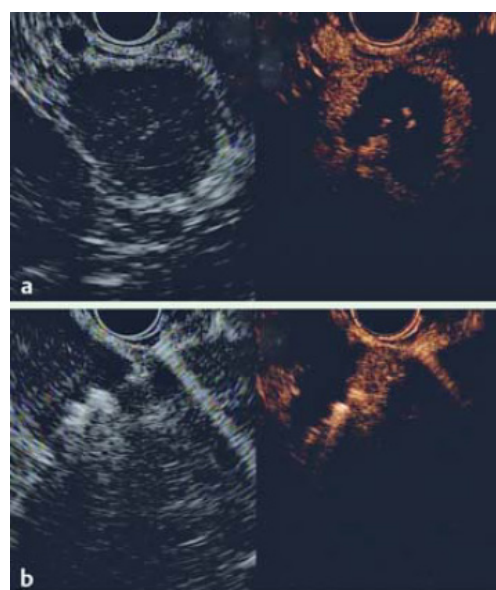


Fig. 3 Contrast-enhanced endoscopic ultrasound (EUS) 4 days after the first EUS-guided radiofrequency ablation (RFA) treatment. **a** Central hypo-echogenicity with enhancement remained at the marginal edge of the adenoma. **b** Repeat EUS-RFA was performed.

EUS-guided radiofrequency ablation for a left adrenal oligometastasis of an esophageal adenocarcinoma

Akin Inderson, Marije Slingerland, Arantza Farina Sarasqueta, Wobbe O. de Steur, Jurjen J. Boonstra

A 65-year-old man was referred for treatment of a poorly differentiated Her2-negative adenocarcinoma of the distal esophagus. Staging, according to the guidelines of the European Society of Digestive Oncology (ESMO) for esophageal cancer,¹ showed locoregional lymph nodes and was suspicious for a solitary metastasis in the left adrenal gland (T3N1M1) (Fig. 1).

Additional percutaneous cytologic puncture confirmed the diagnosis of an oligometastasis. After 3 cycles of induction chemotherapy (oxaliplatin and capecitabine), restaging showed partial response of the primary tumor and the left adrenal gland metastasis. No additional metastases were detected.

In the multidisciplinary meeting, it was decided to treat the patient with neoadjuvant chemoradiotherapy (paclitaxel and carboplatin) and concurrent radiotherapy with 41.4 Gy to downstage the primary tumor and to facilitate radical surgical resection. It is believed that the chemotherapy regimen has a radiosensitizing effect rather than a systemic effect. Adding the left adrenal gland to the radiation field would cause significant injury to the kidneys and was therefore not considered an option.

To prevent growth of the left adrenal metastasis during chemoradiotherapy, 3 options were discussed: laparoscopic extirpation, percutaneous radiofrequency ablation (RFA), and EUS-guided RFA. The first option, being an invasive approach, was considered least attractive. Because of the location of the left adrenal gland and adjacent vessels, the percutaneous route was considered too dangerous. Therefore, after the patient gave informed consent, we decided to perform EUS-guided RFA of the metastasis of the left adrenal gland (Video 1, available online at www.VideoGIE.org).

CONCLUSIONS

We conclude that EUS-guided RFA is safe and feasible for local disease control of left adrenal gland metastasis. Settings should be optimized, and more ablation and resection studies are necessary to determine the optimal RFA settings in correlation with histopathologic findings and patient outcome. A prospective study is conducted to determine the feasibility and safety of EUS-guided RFA in the treatment of patients with oligometastasis in the left adrenal gland or upper abdominal lymph nodes.

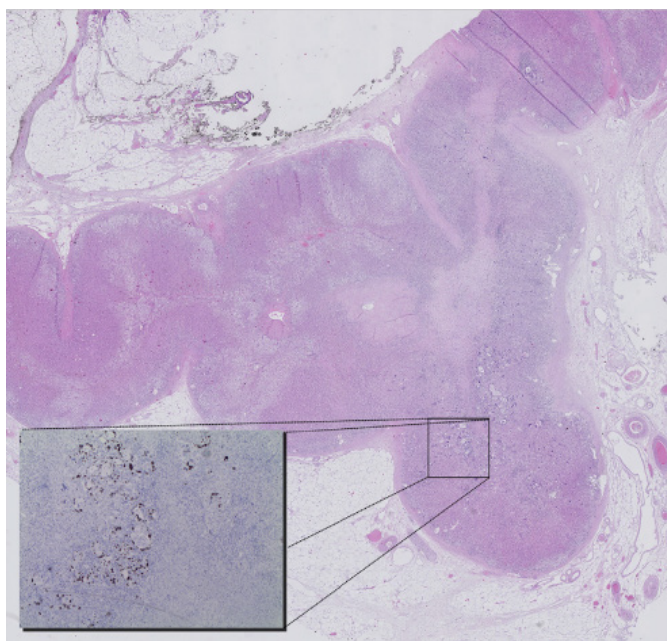


Figure 4. Hematoxylin and eosin–stained specimen showing extensive fibrosis but still vital tumor cells at edge of adrenal gland. At lower left, P53 staining that confirmed the presence of tumor cells at the margin.

Expanded indication for EUS-guided radiofrequency ablation: management of adrenal tumors

Sung Hyun Cho, Dae Hyeon Kim, Dong-Wan Seo, Seul Ki Yoo, Dongwook Oh, Tae Jun Song, Sung Koo Lee

BACKGROUND AND AIMS

EUS-guided radiofrequency ablation (EUS-RFA) has been performed as an alternative to surgery for the treatment of pancreatic tumors. The promising results obtained using this procedure suggest that the indication for EUS-RFA could be expanded to the management of extrapancreatic tumors. Here, we evaluate the feasibility, efficacy, and safety of EUS-RFA in the treatment of left adrenal tumors.

METHODS

This single-center, prospective study was conducted at Asan Medical Center between January 2016 and November 2021. A total of 11 patients with left adrenal tumors were enrolled in the study. The technical success rate, treatment response, and adverse events were evaluated.

RESULTS

EUS-RFA was performed successfully in all patients (technical success rate, 100%). The indications for the procedure were an increase in tumor size ($n = 8$), and adrenal tumor with adrenal hormone excess ($n = 3$).

After a median of 2 EUS-RFA sessions (range, 1-2), 73% of patients had a complete response, and 27% had a partial response. During follow-up, 5 patients experienced self-limiting mild abdominal pain; no moderate or severe adverse events were reported.

CONCLUSIONS

EUS-RFA showed high technical feasibility, clinical success, and an acceptable safety profile in the treatment of left adrenal tumors. In patients at high surgical risk, EUS-RFA can be considered as an alternative therapeutic modality to surgery for the treatment of left adrenal tumors. (Gastrointest Endosc 2023;98:790-6.)

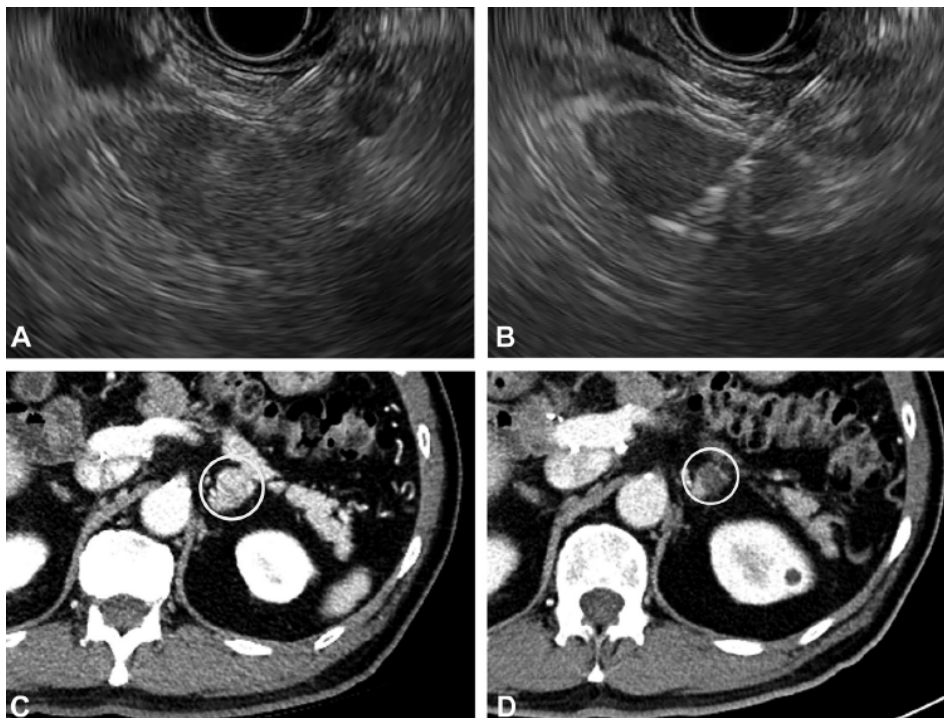
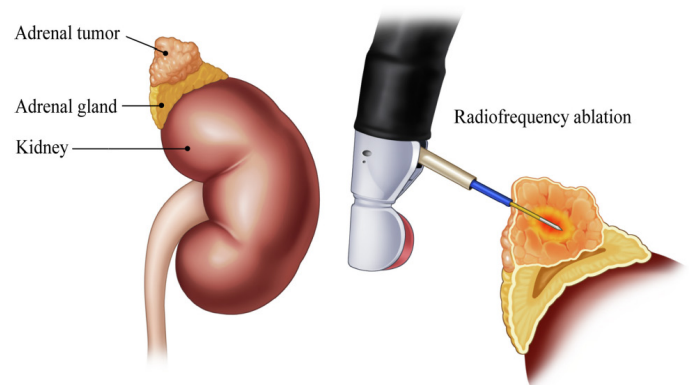


Figure 1. EUS-guided radiofrequency ablation.

- A 19-gauge radiofrequency ablation needle puncturing the left adrenal tumor.
- After the generator was activated, the hyperechoic zone (white bubble sign) was visualized around the radiofrequency ablation electrode on real-time EUS images.
- Before the procedure, the initial CT scan showed a left adrenal tumor (white circle).
- Six months after the procedure, a follow-up CT scan showed that the left adrenal tumor had become a hypodense lesion (white circle).

EUS-guided celiac plexus radiofrequency ablation using a novel device

Zaher S. Houmani, Malak S. Nouredine

The incidence of pancreatic cancer in the U.S. population was estimated to be 53,670 in 2017. Abdominal pain is common in patients with pancreatic cancer and can be intense, debilitating, and refractory to medical treatment. EUS celiac plexus neurolysis (CPN) is considered efficacious in the management of pancreatic cancer pain and can be used early at the time of diagnosis of inoperable disease.

However, EUS-CPN has significant variation in analgesic effectiveness in these patients (24%-80%). Recently, EUS-guided celiac plexus radiofrequency ablation (RFA) has been administered using dedicated probes in a new technique for pain management in patients with pancreatic cancer. Despite limited data on efficacy, preliminary evidence reveals acceptable tolerability and a good safety profile with likely more focused targeting of the celiac plexus.

The currently available dedicated device for EUS-RFA is the Habib monopolar EUS-RFA catheter (EMcision Ltd, London, UK), which is a 1F wire with a working length of 190 cm. This probe is gently inserted inside the hollow of a 19-gauge FNA needle after removal of the stylet until the needle tip is reached. The needle then is withdrawn 1 cm as the RFA catheter is advanced.

Here, we introduce a new device for EUS-guided celiac plexus RFA using the novel RFA EUS needle (Starmed; Taewoong Medical, Seoul, Korea) used in 2 patients with inoperable pancreatic cancer (Video 1, available online at www.VideoGIE.org).

The first case was a 45-year-old woman with newly diagnosed pancreatic neuroendocrine tumor who had a visual analog scale (VAS) score of 8 and received intravenous morphine (10 mg standing dose) twice daily. The second case was an elderly male with metastatic pancreatic head adenocarcinoma who had a VAS score of 8 and received 40 mg oral opioid analgesics every 4 hours. Both underwent EUS-guided celiac plexus RFA for pain control.

First, the EUS device was positioned in the stomach to locate the aorta, celiac artery, and diaphragm (Fig. 1). The tip of the 19-gauge Endoscopic ultrasound guided radiofrequency ablation (EUSRA) needle (Starmed; Taewoong Medical, Seoul, Korea) was introduced into the celiac plexus space (Fig. 2). We used Doppler to confirm that the needle tip was not intravascular. The ablation parameters were set as follows: radiofrequency power 30 W, continuance mode. Once the ablation began, within 12 seconds, the echogenic bubbles around the celiac plexus were visible on the EUS monitor and the impedance reached 400 Ω (Fig. 3). After 4 days, both patients' VAS score decreased to 3, without the need for opioid analgesics. Three weeks after the procedure, VAS score stabilized at 2 for the first patient and 4 for the second, thereby eliminating the need for opioid analgesics.

Common adverse events are similar to those of EUSCPN and include transient diarrhea, orthostatic hypotension, fever, nausea/vomiting, and transient increase in abdominal pain, which are all considered minor.

In our cases, no adverse events were noted; both patients were monitored for 24 hours, and they were stable during and after the procedure. The present treatment of pancreatic cancer pain with narcotics and EUS-CPN is inadequate. EUS-RFA may just be the beginning of improved regimens. Use of the Taewoong device appears to be a precise, feasible, safe, and effective technique. More studies are needed to better assess the long-term efficacy and safety of this novel technique.

Endoscopic ultrasound-guided radiofrequency ablation for management of gastric gastrointestinal stromal tumor

Sergio Bazaga Pérez de Rozas, Mario Alberto Gallardo Ramírez, Francisco Javier García-Alonso, Ana Yaiza Carbajo, Manuel Pérez-Miranda Castillo, Carlos de la Serna Higuera

A 56-year-old man presented with abdominal pain and dyspepsia. On upper digestive endoscopy, a submucosal lesion was found in the distal gastric lesser curvature, but no conclusive diagnosis could be achieved with conventional biopsies. Endoscopic ultrasound (EUS) showed a 12 × 7mm well-defined, homogeneous, hypoechoic nodule without signs of infiltration into the muscularis propria, suggestive of benign gastrointestinal stromal tumor (GIST) (► Fig. 1). Fine-needle aspiration with a 22-gauge needle (Expect; Boston Scientific, Marlborough, Massachusetts, USA) was performed, confirming a low risk GIST. Histopathological examination revealed a GIST presenting less than 5 mitoses per high-power field.

The patient rejected surgical treatment, so we proposed EUS-guided radiofrequency ablation (RFA) (► Video 1). We punctured the lesion with an 18-gauge EUS-RFA electrode needle connected to a radiofrequency generator (VIVA-RF generator; STARme, Seoul, South Korea), and applied ablative radiofrequency four times (50W for 10 seconds).

EUS follow-up was performed after 4 weeks, and showed a slight mural thickening of the muscularis propria and submucosal layers; the lesion itself could not be identified (► Fig. 2). A fine-needle biopsy with 22-gauge histological needle (Acquire; Boston Scientific) was performed and confirmed the absence of GIST-type mesenchymal structures. A second EUS 6 months later confirmed eradication of the lesion, and showed a well-preserved layer pattern (► Fig. 3).

Guidelines recommend radical surgical resection with a clear margin (R0) as the gold standard for localized primary GIST [1]. Although endoscopic resection of GISTs has been reported [2], it is not supported by current guidelines because of the low rate of successful R0 resections achieved [1]. RFA uses high frequency alternating current applied via an electrode to generate localized areas of coagulative necrosis and tissue desiccation [3, 4]. Although it is usually applied percutaneously or laparoscopically, successful outcomes of EUS-guided RFA using an 18-gauge needle for benign and malignant pancreatic lesions have been reported recently [5]. To our knowledge, this is the first report of a successful ablative radiofrequency therapy of a gastric GIST.

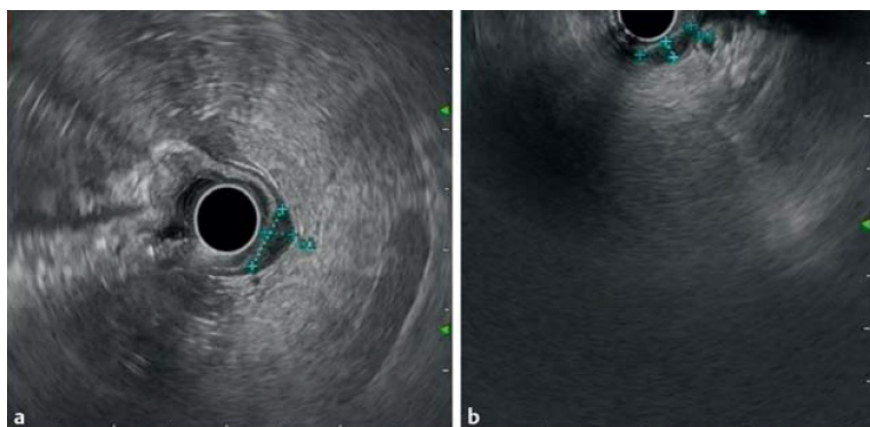
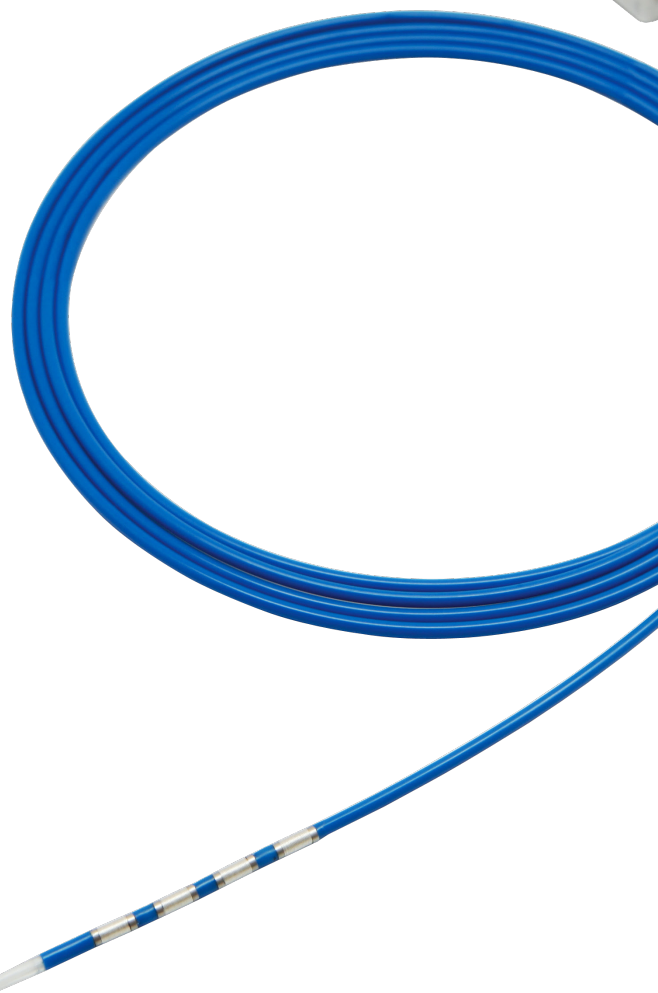


Fig. 2 Endoscopic ultrasound image of gastrointestinal stromal tumor after treatment with ablative radiofrequency. **a** Radial view. **b** Linear view.



Fig. 3 Endoscopic ultrasound 6 months later confirmed eradication of the lesion, and showed a preserved layer pattern.

ELRA INTRODUCTION



Endoscopic Approach			
Code	Total Length (cm)	Electrode Length (mm)	Diameter
7-4B18L	175	18	7 Fr (2.31mm)
7-4B33L		33	
7-2B11L		11	
7-2B22L		22	

Percutaneous Approach			
Code	Total Length (cm)	Electrode Length (mm)	Diameter
7-4B18S	40	18	7 Fr (2.31mm)
7-4B33S		33	
7-2B11S		11	
7-2B22S		22	

	Setting	7 watt / 2 min
	Indication	Hilar, distal lesion
	Setting	10 watt / 2min
	Indication	Distal lesion
	Setting	7 watt / 2min
	Indication	Hilar, distal, ingrowth inside stent
	Setting	10 watt / 2min
	Indication	Distal lesion

Mode	- Temperature mode
Temperature	- 80°C - 75 ~ 85°C is still OK
Watt	- 10W for 22mm and 33mm. - 7W for 11mm and 18mm. - Bigger power than standard power (10W or & 7W) makes the ablation fast, difficult to control the temperature precisely - Smaller power than standard makes the ablation too slow
Time	- 2 minutes - Less time than 2 minutes make the ablations smaller - More time than 2 minutes makes no difference in volume

ELRA SETTING

PRODUCT KITS

A. VIVA Combo™ RF Generator

B. ELRA™ Electrode



A



B



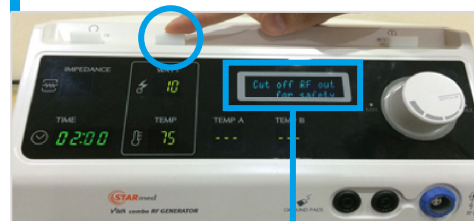
01

Press the **power button** to turn the VIVA combo Generator on or off. When the system is turned on, a green light and a sound will emit.



02

Pressing "Mode" button sets the operation mode. Select **"Temperature Mode"**.



**TEMPERATURE MODE
*READY**

03

Press the RF power control knob to activate **"Set temp"** and turn clockwise to set the target temperature.



04

Press the RF power control knob to activate **"Set watt"** and turn clockwise to set the RF output power.



05

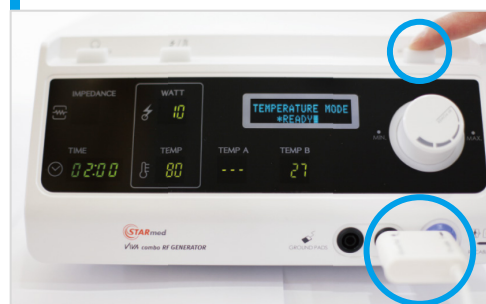
Press the RF power control knob to activate **"Set time"** and turn clockwise to set the time.



06

Connect ELRA™ to the bipolar instrument port in the front panel and press "Start/Stop" button to activate the output power.

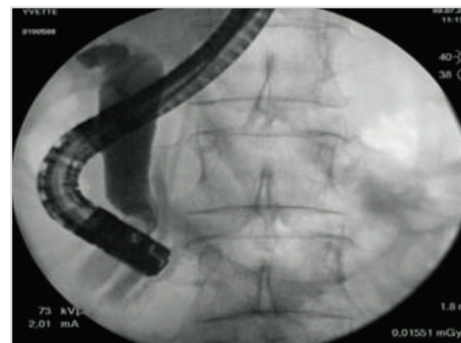
*Contrast medium or saline water around the electrode can cause low impedance and generator to stop. When the generator stops unexpectedly, flushing with distilled water can help.



ELRA PROCEDURE

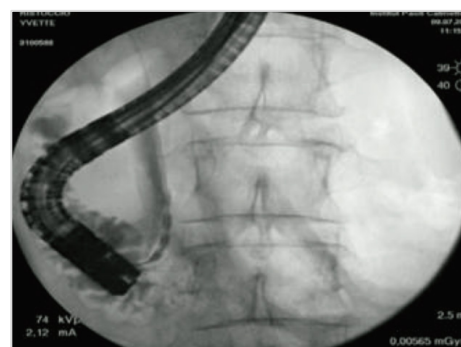
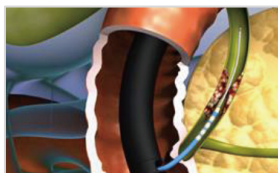
01

Pass the guidewire fully across the stricture under fluoroscopic view.



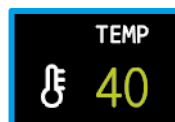
02

Insert a guidewire into the olive tip of ELRA™ and advance ELRA™. Place the 4 electrode fully across the stricture. If the length of the electrode is shorter than the stricture, multiple ablations can be done by withdrawing the electrode. (*Overlapping the ablated area can be done.)



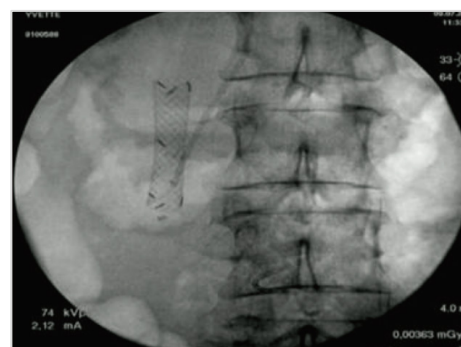
03

Before repositioning or removing the electrode, please wait for the probe to cool down enough (at least below 40 C).
You may see the temperature drop down in the display of the VIVA Combo™ Generator.



04

Post stent procedure is recommended.



CAUTION MESSAGES UNDER TEMPERATURE MODE FOR ELRA™



Operating with "Temperature mode"

This "Cut off RF out for safety" message may appear, and the generator will automatically stop in following cases:

- if the temperature strays +5/-5 from initially selected temp for more than 6 seconds.
- if the impedance exceeds 150Ω from the initial number.
(eg. start with 30Ω, but it increased to 180Ω)
- if the shortage of temperature and watt occurs significantly compared to initial setting number.
(eg. the setting number is 80°C&7watt, but during the ablation the monitor shows only 72°C&5watt)

ELRA STUDIES BY INDICATION

Malignant Biliary Obstruction : Hilar Lesion

- #1 **Intraductal temperature-controlled radiofrequency ablation in malignant hilar obstruction: a preliminary study in animals and initial human experience** by Eui Joo Kim et al. [Endosc Int Open. 2019 Oct;7(10):E1293-E1300.]

Malignant Biliary Obstruction

- #2 **The safety of newly developed automatic temperature controlled endobiliary radiofrequency ablation system for malignant biliary strictures: A prospective multicenter study** by Yun Nah Lee et al. [J Gastroenterol Hepatol. 2019 Aug;34(8):1454-1459.]
- #3 **A new intraductal radiofrequency ablation device for inoperable biliopancreatic tumors complicated by obstructive jaundice: the IGNITE-1 study**
by obstructive jaundice: the IGNITE-1 study by Wim Laleman et al. [Endoscopy. 2017 Oct;49(10):977-982.]
- #4 **Efficacy and safety of palliative endobiliary radiofrequency ablation using a novel temperature controlled catheter for malignant biliary stricture: a single center prospective randomized phase II TRIAL**
by Huapyeong Kang et al. [Surg Endosc. 2021 Jan;35(1):63-73.]

Malignant Biliary Obstruction : Percutaneous Approach

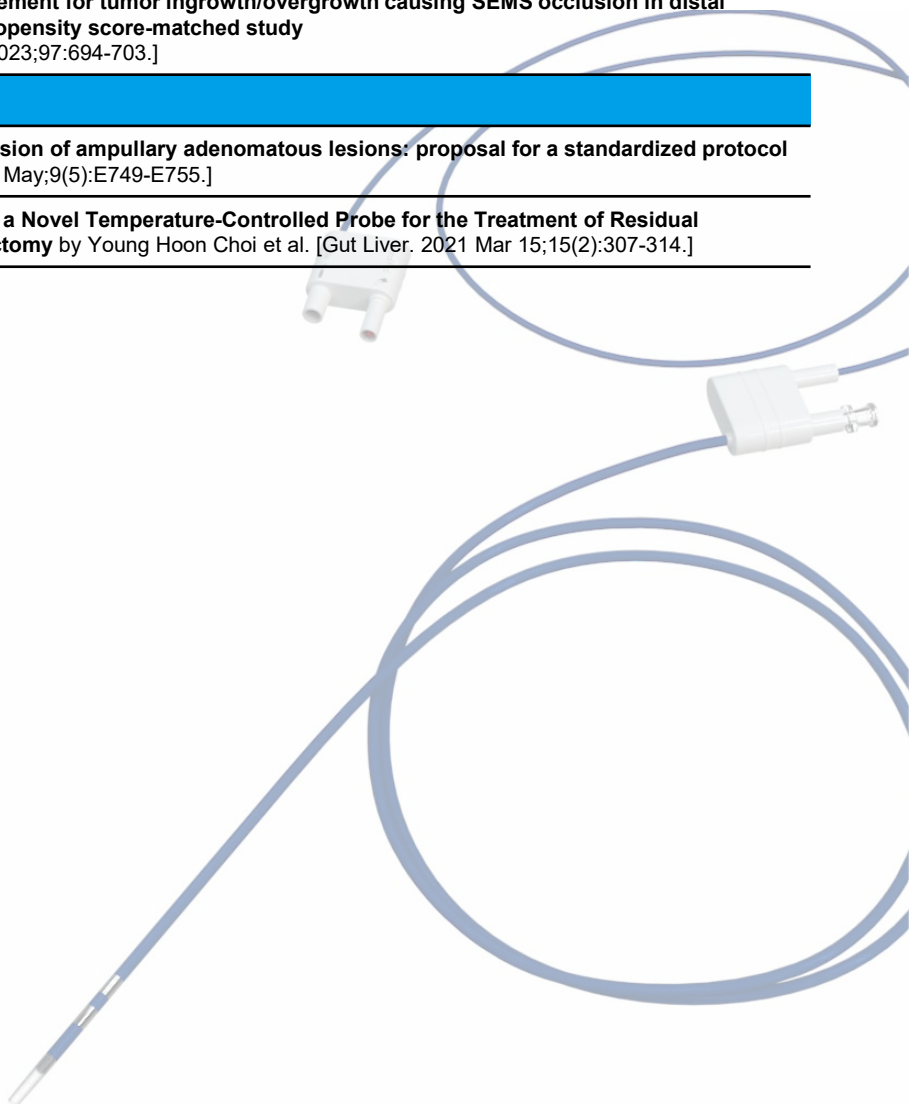
- #5 **Percutaneous endobiliary ablation of malignant biliary strictures with a novel temperature-controlled radiofrequency ablation device** by Sadik Ahmet Uyanik et al. [Diagn Interv Radiol. 2021 Jan;27(1):102-108.]

Ingrowth Inside of Metal Stent

- #6 **Novel temperature-controlled RFA probe for treatment of blocked metal biliary stents in patients with pancreaticobiliary cancers: initial experience** by Manu K Nayar et al. [Endosc Int Open. 2018 May;6(5):E513-E517.]
- #7 **Feasibility and Safety of Endoluminal Radiofrequency Ablation as a Rescue Treatment for Bilateral Metal Stent Obstruction Due to Tumor Ingrowth in the Hilum: A Pilot Study** by Hoonsub So et al. [J Clin Med. 2021 Mar 1;10(5):952.]
- #8 **In-stent RFA with uncovered metal stent placement for tumor ingrowth/overgrowth causing SEMS occlusion in distal malignant biliary obstruction : multicenter propensity score-matched study**
by Namyong Park et al. [Gastrointest Endosc 2023;97:694-703.]

Ampullary Residual Tissue

- #9 **Radiofrequency ablation for intraductal extension of ampullary adenomatous lesions: proposal for a standardized protocol** by Andrea Tringali et al. [Endosc Int Open. 2021 May;9(5):E749-E755.]
- #10 **The Safety of Radiofrequency Ablation Using a Novel Temperature-Controlled Probe for the Treatment of Residual Intraductal Lesions after Endoscopic Papillectomy** by Young Hoon Choi et al. [Gut Liver. 2021 Mar 15;15(2):307-314.]



Intraductal temperature-controlled radiofrequency ablation in malignant hilar obstruction: a preliminary study in animals and initial human experience

Eui Joo Kim, Jae Hee Cho, Yoon Jae Kim, Tae Hoon Lee, JoonMee Kim, Seok Jeong, Yeon Suk Kim

BACKGROUND AND STUDY AIMS

Intraductal radiofrequency ablation (ID-RFA) is a recently developed method widely used for treatment of malignant extrahepatic biliary tract obstructions. However, its safety in hilar application has yet to be clearly demonstrated. The aim of this study was to evaluate the safety of ID-RFA in the treatment of malignant hilar obstruction.

PATIENTS AND METHODS

Endoscopic retrograde cholangiography followed by temperature-controlled ID-RFA at the hilar area using different probe lengths (11, 18, and 22mm) and settings (7 or 10W for 60 – 120 s) was performed in six mini-pigs. In addition, patients with malignant hilar obstruction who underwent palliative ID-RFA were retrospectively evaluated.

RESULTS

In the animal study using different ID-RFA settings, post-ID-RFA fluoroscopic radiocontrast leakage and microscopic bile duct perforation with hepatic abscess were observed in four of the six mini-pigs. Only two of the them, in which an 11-mm ID-RFA probe at a target temperature of 80 °C, power of 7W, and duration of 60 s was used, underwent successful ID-RFA without any immediate adverse events (AEs). Clinically, ID-RFA was performed using the 11-mm probe with the setting of 80 °C, 7W, and 60 – 120 s for malignant hilar obstruction, and total of 11 patients underwent successful ID-RFA without AEs.

CONCLUSIONS

Our study suggests that ID-RFA performed using a short-length probe with settings of 80 °C, 7W and 60 – 120 s is a safe and feasible palliative treatment for malignant hilar obstruction.

Table 3 Baseline characteristics of included patients.

Variables	Patients (n = 11)
Age, mean (SD)	73.7 (7.7)
Sex, male, n (%)	5 (45.5)
Etiology of hilar obstruction, n (%)	
• Gallbladder cancer	2 (18.2)
• Metastatic tumor	1 (9.1)
• Klatskin tumor	8 (72.7)
ID-RFA probe length, n (%)	
• 11mm	11 (100)
Ablation power, n (%)	
• 7W	11 (100)
Ablation duration, n (%)	
• 60 seconds	7 (63.6)
• 120 seconds	4 (36.4)
Bilateral stenting, n (%)	8 (72.7)
Number of overlapping ablation attempts, median (range)	4 (2– 8)

ID-RFA, intraductal radiofrequency ablation

Table 4 Clinical outcome of included patients.

Variables	Patients (n = 11)
Technical success, n (%)	11 (100)
Total bilirubin, median (range), mg/dL	
• At admission	5.8 (2.8 – 32.1)
• 1 day after ID-RFA	2.4 (0.6– 8.0)
• 4 weeks after ID-RFA	1.1 (0.5– 4.7)
ID-RFA related early adverse events, n (%)	
• Perforation	0
• Hemobilia	0
• Cholangitis	0
• Pancreatitis and fever	1 (9.1)
• Fever only	5 (45.5)
Total follow-up duration, median (range), d	
• 30-day stent patency, n (%)	11 (100)
• Stent occlusion, n (%)	3 (27.3)
• Mortality during follow-up period, n (%) ¹	2 (18.2)

ID-RFA, intraductal radiofrequency ablation

¹ Overall survival was 151 days and 191 days for each case.

The safety of newly developed automatic temperaturecontrolled endobiliary radiofrequency ablation system for malignant biliary strictures: A prospective multicenter study

Yun Nah Lee, Seok Jeong, Hyun Jong Choi, Jae Hee Cho, Young Koog Cheon, Se Woo Park, Yeon Suk Kim, Don Haeng Lee, Jong Ho Moon

BACKGROUND AND AIMS

Catheter-based endobiliary radiofrequency ablation (RFA) is an endoscopic local treatment for patients with malignant biliary stricture (MBS). However, excessive heating of the bile duct by the current RFA system can induce serious complications. Recently, a new RFA system with automatic temperature control was developed. In the present study, we examined the safety of the new RFA system in patients undergoing endobiliary RFA for extrahepatic MBS.

METHODS

This prospective, multicenter study enrolled patients with unresectable or inoperable extrahepatic (> 2 cm from the hilum) MBS. Endobiliary RFA was performed using a newly developed RFA catheter (ELRA™, STARmed, Goyang, Korea) at a setting of 7 or 10 W for 120 s and with a target temperature of 80°C. A self-expandable metallic stent was inserted after endobiliary RFA. The rate of procedure-related adverse events was assessed.

RESULTS

The 30 patients were enrolled in this study. Cholangiocarcinoma was diagnosed in 19 patients, pancreatic cancer was found in 9, and gallbladder cancers were recorded in 2. The mean stricture length was 22.1 ± 6.6 mm. Post-procedural adverse events occurred in three patients (10.0%; 2 mild pancreatitis and 1 cholangitis) without hemobilia and bile duct perforation. The pancreatitis and cholangitis resolved with conservative treatment. The cumulative duration of stent patency and survival were 236 and 383 days, respectively.

CONCLUSIONS

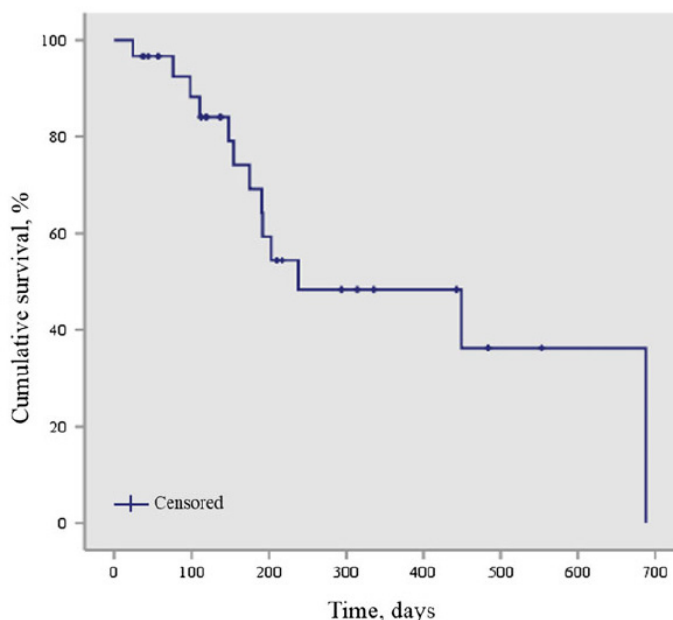
Automatic temperature-controlled endobiliary RFA using a newly developed catheter was safely applied in patents with extrahepatic MBS. Further prospective studies are needed to confirm the efficacy of endobiliary RFA for MBS.

Table 3 Long-term outcomes of temperature-controlled endobiliary RFA

Characteristics	n = 30
Follow-up duration, mean $\pm$ SD, days	208.4 $\pm$ 169.4
Stent dysfunction, n (%)	10 (33.3)
Stent patency, mean (95% CI), days [†]	236 (171–301)
Survival, mean (95% CI), days [†]	383 (264–502)

CI, confidence interval; RFA, radiofrequency ablation; SD, standard deviation.

[†]Kaplan–Meier.



A new intraductal radiofrequency ablation device for inoperable biliopancreatic tumors complicated by obstructive jaundice: the IGNITE-1 study

Wim Laleman, Schalk van der Merwe, Len Verbeke, Dirk Vanbeckevoort, Raymond Aerts, Hans Prenen, Eric Van Cutsem, Chris Verslype

BACKGROUND AND STUDY AIMS

Biliary stenting of unresectable malignant bile duct obstruction is generally accepted as the standard of care but it can be hampered by tumor ingrowth and stent dysfunction. We aimed to test the feasibility, safety, and biliary patency rate of a new endoscopically applied intraductal radiofrequency ablation (RFA) device.

PATIENTS AND METHODS

Eighteen patients with inoperable malignant biliary obstruction underwent endoscopic retrograde cholangiopancreatography (ERCP)-directed RFA and stenting.

CONCLUSIONS

Intraductal RFA using a new device in patients with inoperable biliopancreatic cancer complicated by jaundice appeared feasible and safe with acceptable biliary patency. Randomized trials with prolonged follow-up are warranted.

RESULTS

Between December 2014 and November 2015, 18 patients underwent RFA to the intended region, with no complications within 3 months of the procedure. Bilirubin levels post-RFA and stenting decreased significantly ($7.8 \pm 1\text{mg/dL}$ to $1.7 \pm 0.4\text{mg/dL}$; $P < 0.001$). At 90 and 180 days post-intervention, biliary patency was maintained in 80% and 69% of patients still alive at that time, respectively. The median overall stent patency was 110 days (range 16 – 374), with a median patient survival of 227 days (range 16 – 374).

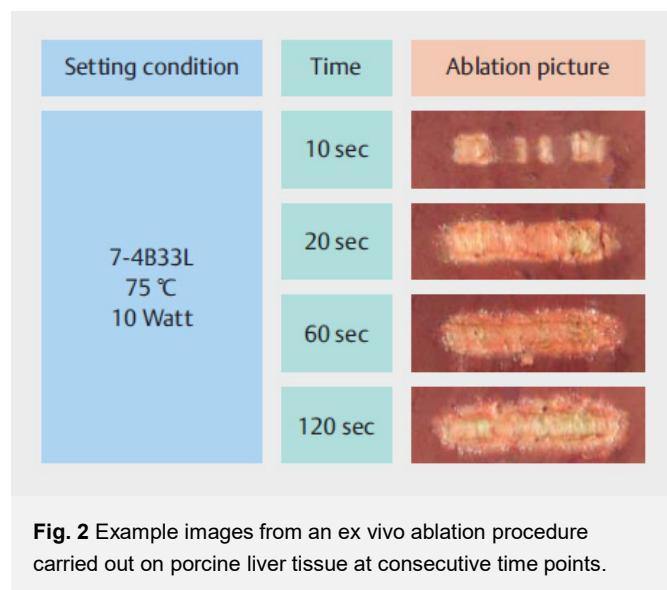


Table 3 Data on the 18 radiofrequency ablation (RFA) procedures performed.

Procedure was feasible, n (%)	18 (100%)
Patient alive with biliary patency, n (%)	
• at 90 days	12/15 (80%)
• at 180 days	9/13 (69 %)
SurMedian stent patency (range), days	
• Overall	110 (16 – 374)
• Distal stenting	187 (16 – 374)
• Hilar stenting	139 (50 – 340)

Efficacy and safety of palliative endobiliary radiofrequency ablation using a novel temperature controlled catheter for malignant biliary stricture: a single center prospective randomized phase II TRIAL

Huapyeong Kang, Moon Jae Chung, In Rae Cho, Jung Hyun, Hee Seung Lee, Jeong Youp Park, Seung Woo Park
Si Young Song, Seungmin Bang

BACKGROUND

Endobiliary radiofrequency ablation (EB-RFA) has emerged as a palliative treatment for malignant biliary strictures (MBSs); however, concerns about complications related to thermal injury remain. In this study, we evaluated the efficacy and safety of EB-RFA with a novel catheter for MBS.

METHODS

Patients with inoperable cancer causing MBS were randomly assigned to either the radiofrequency ablation (RFA) group or the non-RFA group. The RFA group underwent EB-RFA at the stricture site with a temperature-controlled catheter (ELRA™; STARmed Co., Goyang, Korea) followed by deployment of a self-expanding metal stent (SEMS). For the non-RFA group, only SEMS placement was performed. The duration of stent patency, overall survival (OS), and 30-day complication rate were evaluated. This trial was registered at ClinicalTrials.gov (number NCT02646514).

RESULTS

A total of 48 patients were enrolled (24 in each group). During a median follow-up period of 135.0 days (RFA group) and 119.5 days (non-RFA group), the 90-day stent patency rate, median duration of stent patency, and median OS were not different between the groups (58.3% vs. 45.8% [$P=0.386$], 132.0 days vs. 116.0 days [$P=0.440$], and 244.0 days vs. 180.0 days [$P=0.281$], respectively). In the RFA group, procedure-related complications including thermal injury-related complications, such as bile duct perforation or hemobilia, were not reported. The early complication (< 7 days) rates were not different between the groups (4.2% vs. 12.5%, $P=0.609$), and there were no late complications (7–30 days) in both groups.

CONCLUSIONS

EB-RFA with a temperature-controlled catheter followed by SEMS placement for patients with inoperable MBS can be safe and feasible with acceptable biliary patency.

Table 3. Comparison of outcomes

Variables	RFA group (n = 24)	Non-RFA group (n = 24)	P
Technical success	24 (100)	24 (100)	1.000
Clinical success	21 (87.5)	20 (83.3)	1.000
Stent diameter (mm)	10 (10–10)	10 (10–10)	0.301
Stent length (cm)	7 (6–8)	7 (6–7)	0.806
Via percutaneous transhepatic route	4 (16.7)	4 (16.7)	1.000
Follow-up period (days)	135.0 (80.3–190.8)	119.5 (85.5–255.0)	0.621
90-day stent patency	14 (58.3)	11 (45.8)	0.386
Duration of stent patency, median (95% CI) (days)	132.0 (99.6–164.4)	116.0 (52.4–179.6)	0.440
OS, median (95% CI) (days)	244.0 (117.8–370.0)	180.0 (27.8–332.2)	0.281

All categorical variables are presented as n (%). All continuous variables are presented as median (interquartile range)
RFA radiofrequency ablation, OS overall survival, CI confidence interval

Percutaneous endobiliary ablation of malignant biliary strictures with a novel temperature-controlled radiofrequency ablation device

Sadık Ahmet Uyanık, Umut Ögüslü, Halime Çevik, Eray Atlı, Birnur Yılmaz, Burçak Gümüş

PURPOSE

We aimed to determine the safety and effectiveness of percutaneous endobiliary radiofrequency ablation of malignant biliary obstructions with a temperature-controlled radiofrequency ablation device.

METHODS

In this single center retrospective study, a total of 62 consecutive patients with malignant biliary obstruction were evaluated. Thirty patients who underwent endobiliary radiofrequency ablation with metallic stent placement were in the study group and 32 patients who underwent only metallic stenting were in the control group. Outcomes of this study were technical success, complications related to the procedure, stent patency, and overall survival.

CONCLUSIONS

Percutaneous endobiliary radiofrequency ablation is safe and feasible with this novel radiofrequency ablation device in patients with malignant biliary obstruction. Percutaneous endobiliary radiofrequency ablation has a potential to improve both stent patency and survival.

RESULTS

All procedures were technically successful in both groups. There was no procedure-related mortality in either group. Procedural complication rates were similar between the groups. Although statistically not significant, the only two major complications (hemobilia requiring endovascular treatment) were in the control group. Median primary stent patency was significantly longer in the study group than in the control group (223 days vs. 158 days; $P = 0.016$). Median survival rates were also longer in the study group (246 days vs. 198 days; $P = 0.004$).

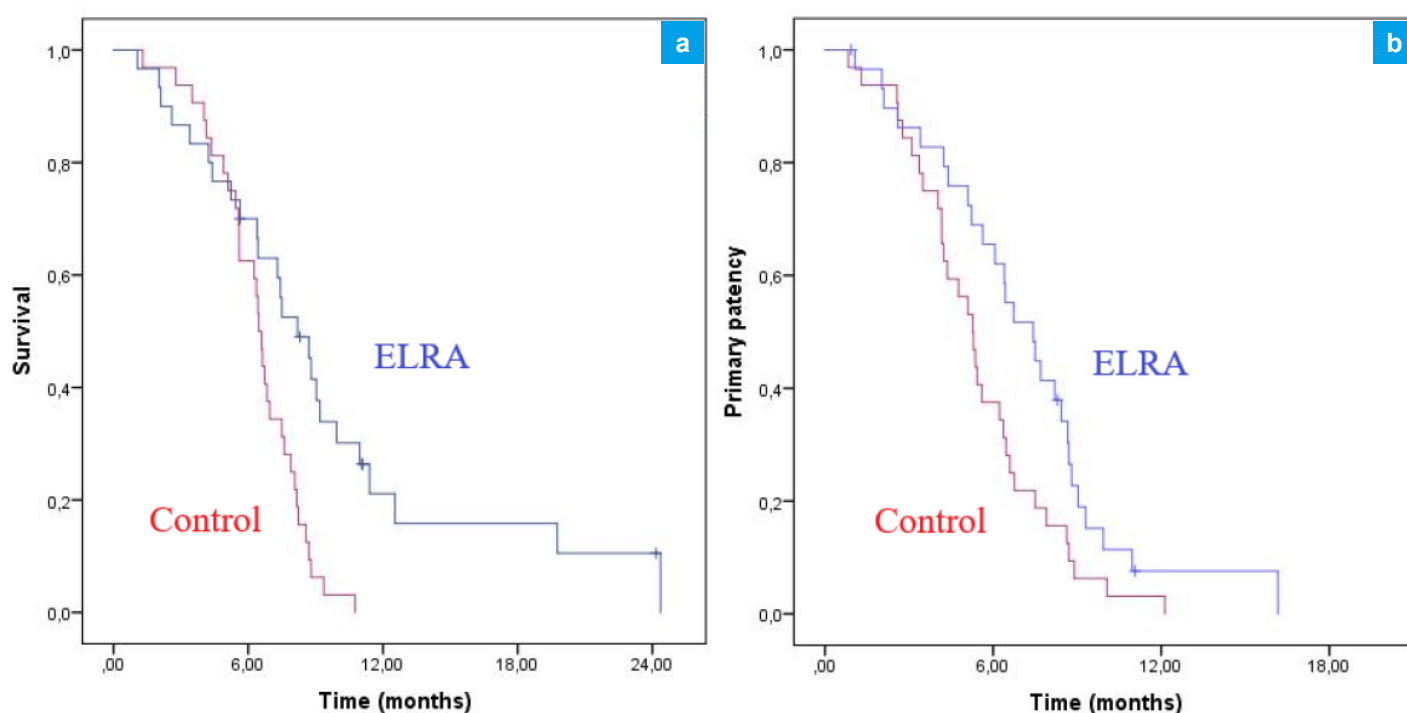


Figure 2. a, b. Kaplan-Meier analysis of survival (a) and stent patency (b) curves of the patients. ELRA, study group with radiofrequency ablation and metallic stenting; Control, metallic stenting only.

Novel temperature-controlled RFA probe for treatment of blocked metal biliary stents in patients with pancreaticobiliary cancers: initial experience

Manu K. Nayar, Kofi W. Oppong, Noor L.H. Bekkali, John S. Leeds

BACKGROUND AND STUDY AIMS

Radiofrequency ablation (RFA) is used to treat blocked biliary stents in patients with pancreaticobiliary (PB) tumors with varying results. We report our experience with a novel temperature-controlled probe for treatment of blocked metal stents.

PATIENTS AND METHODS

Patients with histologically proven PB cancers and a blocked biliary stents were treated using ELRA™ electrode (Taewoong Medical) under fluoroscopic guidance. Demographics, clinical outcome, stricture diameter improvements, complications and mortality at 30 days were prospectively recorded.

RESULTS

Nine procedures were performed on seven patients (4 male, 3 female); mean age 65.33 (range 56 – 82 years). Mean stricture diameter prior to RFA was 1.13mm (SD ± 0.54) and 4.42mm (SD ± 1.54) following RFA ($P < 0.0001$). Five of seven patients (71%) required additional stents to ensure optimal drainage. There were no procedure-related complications. Mean follow-up was 193.55 days (range 31 – 540) and three of nine patients (33%) died due to terminal cancer.

CONCLUSIONS

These are the first reported data on use of a temperature-controlled RFA catheter in humans to treat blocked metal biliary stents. The device is safe but further randomized trials are required to establish the efficacy and survival benefits of this probe.

Table 1 Demographics and clinical details.

Age	Sex	Type of tumor	Stricture length	Stricture diameter pre-RFA (mm)	Stricture diameter post-RFA (mm)	Bilirubin pre-procedure	Bilirubin post-procedure	Out-come
74	F	Gallbladder cancer	15 mm	1.55	3.79	129	43	Alive
69	F	Pancreatic cancer	25 mm	1.2	4.48	4	6	Alive
63	M	Hilar cholangiocarcinoma	20 mm	1.29	6.26	231	265	Died
62	M	Distal cholangiocarcinoma	20 mm	1.33	3.57	66	18	Died
70	F	Pancreatic cancer	20 mm	2.04	6.15	114	81	Alive
82	M	Hilar cholangiocarcinoma	15 mm	0.30	2.34	90	86	Alive
56	M	Colorectal cancer metastasis	15 mm	1.28	5.21	208	173	Died

F, female; M, male.

Feasibility and Safety of Endoluminal Radiofrequency Ablation as a Rescue Treatment for Bilateral Metal Stent Obstruction Due to Tumor Ingrowth in the Hilum: A Pilot Study

Hoonsub So, Chi Hyuk Oh, Tae Jun Song, Hyun Woo Lee, Jun Seong Hwang, Sung Woo Ko, Dongwook Oh, Do Hyun Park, Sang Soo Lee, Dong-Wan Seo, Sung Koo Lee, Myung-Hwan Kim

BACKGROUND

Radiofrequency ablation (RFA) is a palliative method known for its application in the endoscopic treatment of malignant bile duct obstruction. It may be a useful rescue method for metal stent malfunction caused by tumor ingrowth. This study aimed to examine the feasibility and safety of endoluminal RFA for occluded bilateral hilar metal stents due to tumor ingrowth in patients with malignant hilar bile duct obstruction.

METHODS

From March 2016 to June 2018, 11 patients with unresectable malignant hilar bile duct stricture with occluded bilateral hilar metal stents due to tumor ingrowth were enrolled. Endoluminal RFA was performed through a novel temperature-controlled catheter at a setting of 7W power for 120 s with a target temperature of 80 °C via endoscopic retrograde cholangiopancreatography (ERCP). The patients' demographics, clinical outcomes, and adverse events were investigated.

KEYWORDS

cholangiocarcinoma; endoscopic retrograde cholangiopancreatography; radiofrequency ablation

RESULTS

The median age was 64 (interquartile range, 54–72) years. All RFA procedures were successful. Clinical success was achieved in eight patients (72.7%). During the follow-up, eight patients (72.7%) showed stent dysfunction, and the median patency after RFA was 50 days (95% confidence interval (CI): 34–not available (NA)). All stent dysfunctions were successfully managed with ERCP. Ten patients died, and the median overall survival was 289 days (95% CI, 107–NA) from RFA to death. There was one case of mild abdominal pain after the procedure without serious adverse events.

CONCLUSIONS

As a rescue therapy for occluded bilateral hilar metal stents due to tumor ingrowth, endoluminal RFA seemed to be safe and useful in selected patients.

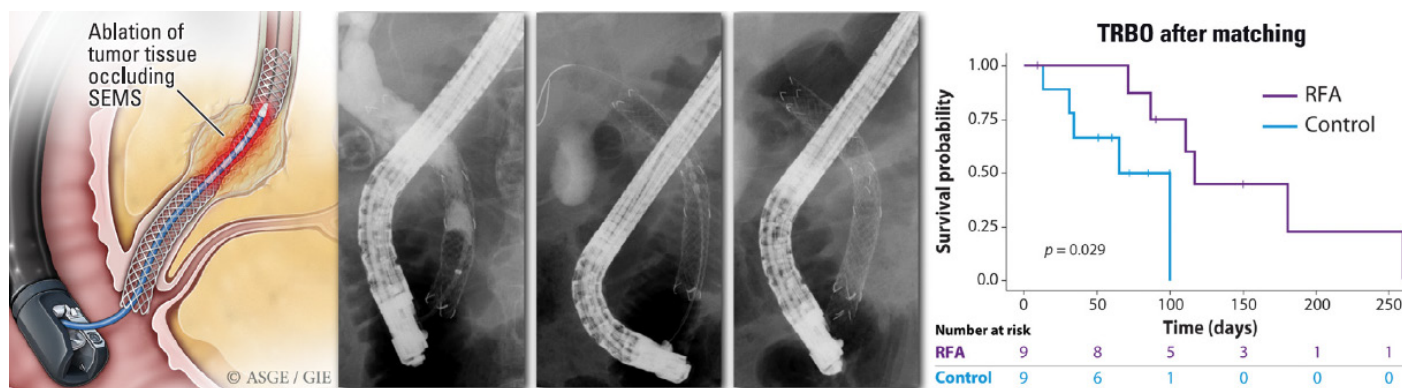
Table 2. Outcomes and adverse events of endobiliary radiofrequency ablation for hilar cholangiocarcinoma.

Outcomes	n = 11
Technical success, n (%)	11(100)
Clinical success, n (%)	8 (72.7)
Stent dysfunction, n (%)	8 (72.7)
Stent patency, days	50 (95% CI, 34–NA)
Death, n (%)	10 (90.9)
Overall survival, days	289 (95% CI, 107–NA)
Adverse events	
Intra-procedure	None
Post-procedure, n	
Abdominal pain	1

CI: confidence interval; NA: not available.

In-stent radiofrequency ablation with uncovered metal stent placement for tumor ingrowth/overgrowth causing selfexpandable metal stent occlusion in distal malignant biliary obstruction: multicenter propensity score-matched study

Namyoung Park, Min Kyu Jung, Eui Joo Kim, Woo Hyun Paik, Jae Hee Cho



BACKGROUND AND AIMS

In patients with unresectable malignant biliary obstruction (MBO), endoscopic drainage with a self-expandable metal stent (SEMS) is a well-established treatment, but stent patency is limited. This study aimed to evaluate the efficacy of in-stent radiofrequency ablation (IS-RFA) followed by uncovered SEMS placement for the management of occluded SEMSs.

METHODS

From 2016 to 2020, 48 patients with recurrent biliary obstruction due to tumor ingrowth or overgrowth after SEMS placement for pancreaticobiliary cancer in 3 tertiary hospitals were analyzed. For distal MBO, patients in the RFA group were treated with IS-RFA and uncovered SEMS placement, and those in the control group were treated with uncovered SEMS placement alone. Patients in both groups were matched on the basis of propensity scores in a 1:1 ratio.

RESULTS

The median time to recurrent biliary obstruction (TRBO) was 117 days in the RFA group and 82.5 days in the control group ($P = .029$). No significant differences in median overall survival were detected between the 2 groups (170 days vs 72 days; $P = .902$). No significant adverse events were reported after the second SEMS placement in either group, but 2 cases of mild cholangitis were reported in the control group. Ablation was interrupted in 5 patients (35.7%) of the RFA group owing to in-stent contact, but sufficient ablative energy was delivered in the majority of the patients (92.9%) after IS-RFA was repeated in the same session.

CONCLUSIONS

IS-RFA followed by an uncovered SEMS is safe and feasible and may improve TRBO as a stent revision for occluded SEMSs in pancreaticobiliary cancer.

Radiofrequency ablation for intraductal extension of ampullary adenomatous lesions: proposal for a standardized protocol

Andrea Tringali, Maria Valeria Matteo, Beatrice Orlandini, Federico Barbaro, Vincenzo Perri, Qianqian Zhang, Riccardo Ricci, Guido Costamagna

BACKGROUND AND STUDY AIMS

Intraductal extension of ampullary adenoma represents a challenging endoscopic issue. Intraductal radiofrequency ablation (RFA) has been recently suggested, but evidence and standardization of this technique are still lacking. This study aimed to provide a long-term evaluation of clinical efficacy and safety of intraductal RFA ablation with a standardized algorithm of treatment.

PATIENTS AND METHODS

Data were prospectively collected from consecutive patients with intraductal extension of adenomatous ampullary lesions from January 2016 to November 2018. Endpoints of the study were clinical success evaluated on histology results at the last follow-up, technical success, and adverse events assessment.

RESULTS

Nine patients with intraductal (biliary $\pm$ pancreatic) extension of ampullary adenomas were treated with RFA during the study period.

Histology on the papillectomy specimen confirmed intraductal involvement with lowgrade dysplasia (LGD) in five cases (56 %), high-grade dysplasia (HGD) in three (33 %), and HGD with intramucosal adenocarcinoma in one patient (11 %). Additional argon plasma coagulation to ablate the adenoma on the duodenal mucosa was applied in five patients (56 %). Technical success was 100 %. One patient (11 %) with failed pancreatic stenting, developing acute pancreatitis after RFA, recovered with medical therapy. After a median follow-up of 21 months (IQR 20–31), six patients (67 %) achieved clinical success being free of recurrence, whereas one was diagnosed with persistence of adenocarcinoma, one with recurrent HGD, and one with recurrent LGD.

CONCLUSIONS

In our experience, intraductal RFA achieved acceptable results after a 2-year follow-up. Further studies are required to confirm our results and to select those patients most likely to respond.

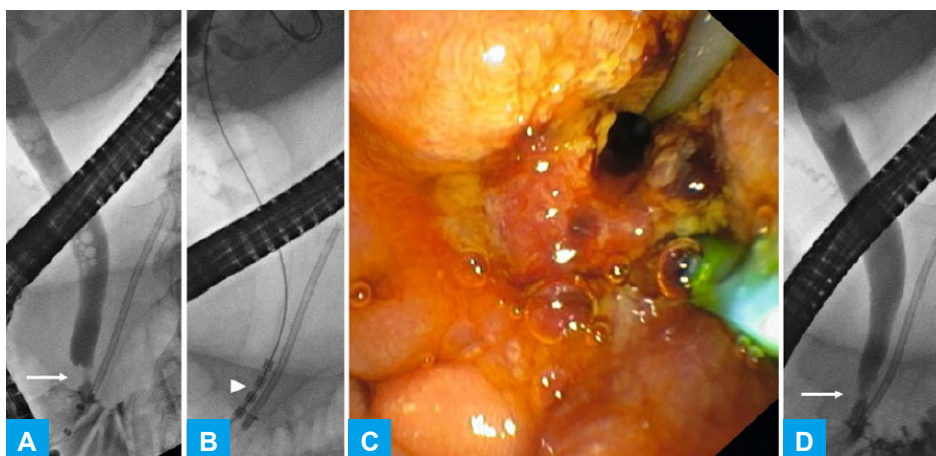


Fig. 2 Intraductal radio frequency ablation (RFA).

- A. Cholangiogram with intrabiliary ingrowth (arrow) after papillectomy and pancreatic stenting. RFA application showing
- B. the intraductal probe (arrowhead), and
- C. endoscopic results.
- D. Resolution of the intrabiliary defect after RFA (arrow).

The Safety of Radiofrequency Ablation Using a Novel Temperature-Controlled Probe for the Treatment of Residual Intraductal Lesions after Endoscopic Papillectomy

Young Hoon Choi, Seung Bae Yoon, Jae Hyuck Chang, and In Seok Lee

BACKGROUND/AIMS

Treatment of residual intraductal lesions after endoscopic papillectomy for ampullary adenomas is relatively difficult. Few studies have been conducted using intraductal radiofrequency ablation (RFA) in the treatment of such lesions, and no study has aimed to reduce the side effects of excessive heat caused by RFA. Recently, a temperature-controlled RFA probe was developed to avoid excessive heat. This study aimed to investigate the safety of this new RFA probe in the treatment of intraductal lesions of ampullary adenoma.

METHODS

Patients who received RFA for residual intraductal lesions after endoscopic papillectomy between November 2017 and June 2019 were retrospectively reviewed. A novel temperature-controlled probe (ELRA) was used for intraductal RFA, and clinical data including adverse events were collected.

RESULTS

Ten patients were included in this study. Intraductal adenomas showed low-grade dysplasia in eight patients and high-grade dysplasia in two patients. The median diameter of intraductal adenomas was 9 mm (range, 5 to 10 mm) in the common bile duct and 5 mm (range, 4 to 11 mm) in the pancreatic duct. Adverse events occurred in three patients (30.0%), of which two were mild pancreatitis and one was asymptomatic biliary stricture. Over a median follow-up period of 253 days, only one patient underwent additional surgery, as the remainder showed no adenomatous lesions on follow-up biopsies.

CONCLUSIONS

The new temperature-controlled RFA probe can be used with acceptable safety for the treatment of residual intraductal lesions after endoscopic papillectomy. Further evaluation through future prospective studies is needed. (Gut Liver 2021;15:307-314)

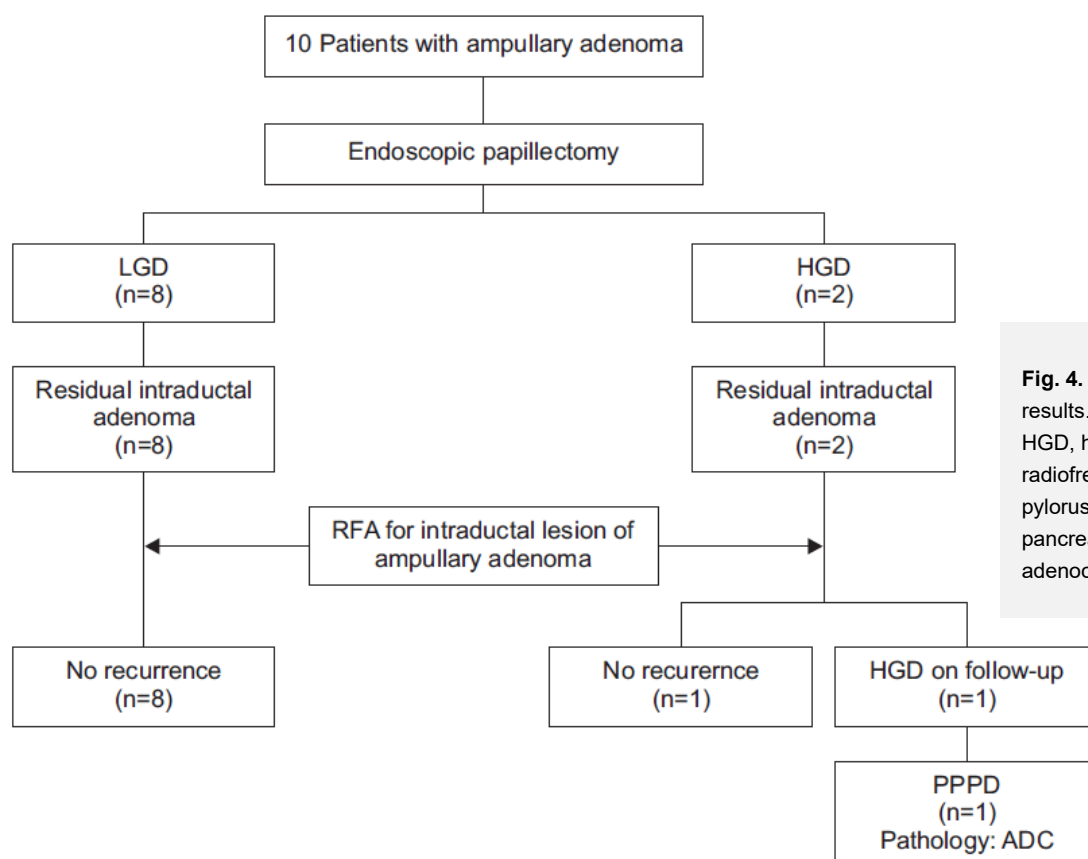


Fig. 4. Flowchart summarizing overall results. LGD, low grade dysplasia; HGD, high grade dysplasia; RFA, radiofrequency ablation; PPPD, pylorus preserving pancreaticoduodenectomy; ADC, adenocarcinoma.

