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Safety of intrabiliary radiofrequency ablation in cases of residual and recurrent neoplasia after endoscopic papillectomy

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ABSTRACT

Background and study aims Intrabiliary radiofrequency ablation (IB-RFA) is a therapeutic option for cases of positive margin or recurrence after endoscopic papillectomy (EP) for superficial neoplasia. We report our experience concerning safety and efficiency of IB-RFA.

Patients and methods This was a single tertiary center retrospective study. All patients who underwent IB-RFA indicated for residual or recurrent neoplasia after EP were included. We assessed morbidity (<30 days) and late complications (>30 days). Secondary outcomes were clinical success and late recurrence (absence of recurrence at the papillectomy site 12 months after IB-RFA and recurrence beyond 12 months, respectively).

Results Twenty-five patients were included and underwent IB-RFA for deep positive margins (20/25, 80%) or relapse (5/25, 20%) and 40 sessions were delivered. The morbidity rate was 8% (2/24) (1 pancreatitis, 1 bleeding). Acute pancreatitis was significantly more common in the absence of pancreatic stenting (0% vs. 22%, $P=0.046$). One patient for whom pancreatic stenting failed died from acute severe pancreatitis in the first month (mortality rate=4%). Late complications occurred in 12 of 24 patients (50%) concerning only biliary stricture, all of which were managed endoscopically without sequelae. The clinical success rate was 92% (22/24), and late recurrence occurred in two of 24 patients (8%).

Conclusions IB-RFA is relatively safe and efficient in cases of residual or recurrent neoplasia after EP and is an alternative to surgery in well-selected cases. Biliary stricture occurred frequently (50%) but could be managed endoscopically without sequelae in all cases. In cases of pancreatic stenting failure and because of the risk of severe and potentially lethal acute pancreatitis, IB-RFA should be postponed.

Introduction

The first snare endoscopic papillectomy (EP) was described in 1983 [1], this procedure is the gold standard for managing benign tumors of the papilla of Vater and is acceptable for adenocarcinomas strictly limited to the mucosa [2, 3].

This technical endoscopic procedure has a high resection rate of up to 90% considering the need for subsequent endoscopic sessions; in fact, positive margins and relapse are common, occurring in up to 30% of patients [4, 5, 6, 7]. Most of the time, positive lateral margins can be monitored and managed endoscopically with standard tools such as snare resection (SR)

or argon plasma coagulation (APC), whereas deep positive margins are more challenging to manage. In fact, their treatment depends on histology and the length of intraductal extension.

In the case of adenocarcinoma in deep positive margins and because of node risk, surgery is indicated, with morbidity and mortality rates of up to 49% and 9%, respectively [8, 9, 10].

For many years, biliary and pancreatic intraductal benign tissue involvement was considered a failure criterion for EP, and because endoscopic tools do not permit complete intraductal ablation, a length >1 cm was considered a surgical indication [11, 12].

Recently, procedure improvements that involve radiofrequency probes have consisted of applying these probes to the lower part of the biliary and pancreatic ducts to induce coagulative necrosis of the surrounding tissu. Several case reports and more recent series of intraductal ablation techniques using cystostomes [13] or radiofrequency probes [14, 15, 16, 17] have been published, and showed promising results, with a clinical success rate of approximately 70%. Adverse events (AEs) occurred in 11% to 50% of cases and mostly consisted of mild acute pancreatitis or duct stenosis [13, 14, 15, 16, 17]. However, these outcomes have mainly been observed over short-term follow-up periods.

We aimed to share our long-term experience with use of intrabiliary radiofrequency ablation (IB-RFA) indicated in cases of residual tissue or relapse after EP to assess the AE rate and clinical success.

Patients and methods

Study design and data collection

Data were retrospectively reviewed from our endoscopy database, and information was collected from consecutive patients who benefited from IB-RFA as indicated for treatment of ampullary lesions from October 2015, the time when we performed the procedure for the first time, until October 2022.

Patients who benefited from IB-RFA in cases of positive margins or relapse after EP with a minimum endoscopic monitoring time of 12 months were included.

Patients whose follow-up was shorter than 12 months and whose ampulla specimens showed adenoma without dysplasia (adenomyoma) were excluded.

Biliary and pancreatic intraductal involvement were assessed before EP via cross-sectional imaging (computed tomography [CT]) and/or magnetic resonance imaging [MRI]), endoscopic ultrasonography (EUS), endoscopic retrograde cholangiopancreatography (ERCP), and visual inspection.

Data concerning demographic characteristics, imaging prior to EP (CT, MRI and/or EUS), ERCP, repeat ablative techniques prior to IB-RFA (APC or SR), IB-RFA, procedure-related AEs, histology, and the endoscopic follow-up course were collected.

EUS and MRI were not routinely performed during follow-up except in cases of suspected metastasis.

The last follow-up was defined as the last endoscopic course or the date of death.

Our institutional ethical review board and human research committee (2021–053; 27/07/2021) approved the study.

Definitions and outcomes

The primary outcome was the rate of AEs with morbidity and late complications.

The secondary outcomes were clinical success and late recurrence.

Morbidity was the rate of AEs occurring during the 30 days after IB-RFA and was assessed with the AGREE classification [18]. Late complications were defined as AEs occurring beyond 30 days.

AEs included pancreatitis, bleeding, and biliary stricture that was asymptomatic or associated with cholangitis and/or abnormal liver blood tests. Pancreatitis was defined as a threefold increase in serum lipase in the presence of abdominal pain.

Clinical success was defined by absence of residual tissue 12 months after IB-RFA which was identified macroscopically and/or with tissue sampling.

A positive margin was defined as presence of neoplastic tissue on the deep margin of the ampullary specimen. In the case of highly suspicious intrabiliary ingrowth visible by EUS and/or MRI in patients whose histological specimens showed free margin, margins were considered positive when two operators agreed.

Lateral margins included tissue on the duodenal side and deep margins included tissue on the biliary and pancreatic duct sides.

Recurrence was defined by presence of neoplastic tissue, which was histologically proven, at the papillectomy site after at least one normal endoscopic course. Presence of macroscopically highly suspicious tissue ingrowth was considered recurrence when two operators agreed even without histological proof.

Clinical failure was defined as persistence of neoplasia after two sessions of IB-RFA. Late recurrence was defined as recurrence of neoplastic tissue at the papillectomy site or metastasis, beyond the time that defined clinical success (> 12months), which was determined macroscopically and/or with tissue sampling.

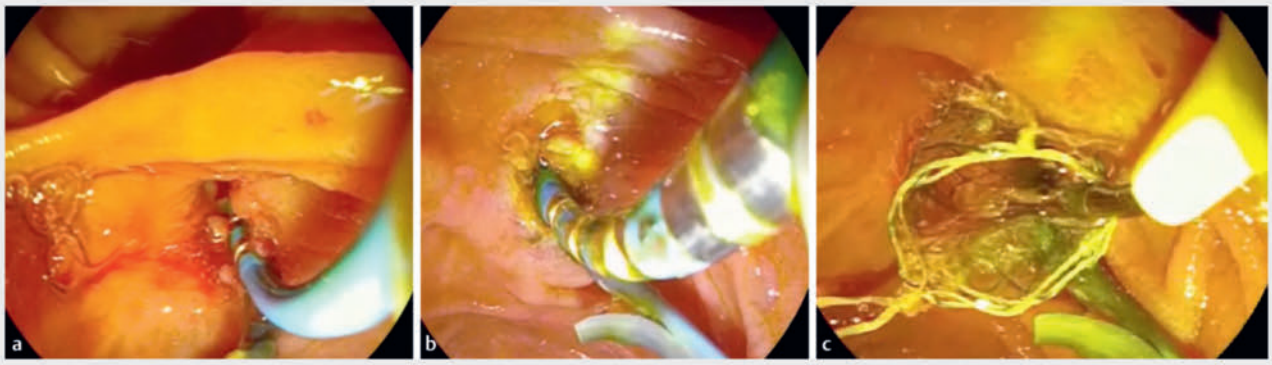
Technical success was defined as successful placement of the radiofrequency probe in the lower part of the common bile duct and complete ablation of neoplastic tissue was identified based on whitening of tissue at the ductal orifice.

Follow-up started on the day of papillary resection and ended on the date of death or final follow-up until October 2022, which was the end of the study.

Endoscopic procedure, equipment and follow-up

IB-RFA was performed under general anesthesia using a 4.2-mm channel duodenoscope (Pentax Medical, EG38J10 Tokyo, Japan) (▶ **Fig. 1**). Rectal indomethacin was administered prior to ERCP. Depending on operator convenience, additional endoscopic resection (SR and/or APC) was performed at the same time as the IB-RFA procedure.

Prior to applying IB-RFA and depending on technical feasibility, a 5F 5-cm pancreatic prophylactic plastic stent was introduced into the main pancreatic duct in the same session. A dedicated 7F, 18-mm probe (ELRA catheter, Taewong, Seoul,



▶ **Fig. 1** IB-RFA procedure. **a** Insertion of the blue radiofrequency catheter in the lower part of the common bile duct. **b** Delivery of radiofrequency from the golden active mark with the creation of bubbles and whitening of mucosae. The pancreatic plastic stent is in place. **c** Fully covered metallic stent placed in the main biliary duct to prevent biliary stricture.

South Korea), 0.035-inch guidewire-guided, was then introduced into the lower part of the common bile duct under fluoroscopic guidance, delivering a power of 10 W at 75°C, for 120 seconds using a VIVA Combo generator (STARmed, Seoul, South Korea).

A biliary stent was systematically introduced into the main biliary duct after IB-RFA to prevent stricture. The type of stent depended on operator convenience (fully-covered self-expendable metallic stent [FCSEMS] or plastic stent).

Patients were followed up clinically and endoscopically with standard duodenoscopy 3, 6, and 12 months after IB-RFA and then annually or sooner in cases of AEs.

The decision to perform forceps biopsy during follow-up was based on the operator choice.

In cases of histologically proven relapse or if the endoscopic aspect was highly suspicious (presence of macroscopically suspicious tissue ingrowth with agreement of two operators), a new session of IB-RFA was applied.

Statistical analysis

Continuous variables are presented as medians and ranges. Categorical variables are presented as numbers and percentages. Risk of acute pancreatitis was calculated with Fisher's exact test. The significance threshold used was P <0.05. Statistical analysis was performed with EasyMedStat (version 3.24).

Results

Population characteristics

From October 2015 to October 2022, 42 patients underwent IB-RFA for ampullary neoplasia (▶ **Table 1**). We excluded 17 patients: Eight had a follow-up shorter than 12 months, four had IB-RFA without EP, two had ampullary samples showing adenomyoma, two had IB-RFA validated by an oncology committee for patients with unresectable ampullary adenocarcinoma responding to therapy, and one was lost to follow-up (▶ **Fig. 2**).
We ultimately included 25 patients (14 males, 56%) with a median age of 66 years (range 30–87), all of whom benefited from EP. Median size of histological specimens was 18.8 mm (range 10–40). Six patients (24%) had a history of familial adenomatous polyposis.

▶ **Table 1** Population characteristics.

Number of patients, n (%)	25 (100)
Male, n (%)	14 (56)
Mean age, years (range)	66 (30–87)
FAP history, n (%)	6 (24)
Ampullary specimen size, mm (range)	18.8 (10–40)
Intraductal ingrowth, n (%)	11 (44)
▪ Length, mm (range)	7.7 (2–15)
▪ Visualizing with EUS, n (%)	11 (44)
▪ Visualizing with MRI, n (%)	3 (12)
Complementary endoscopic resection prior to RFA, n (%)	4 (16)

EUS, endoscopic ultrasound; FAP, familial adenomatous polyposis; MRI, magnetic resonance imaging; RFA, radiofrequency ablation.

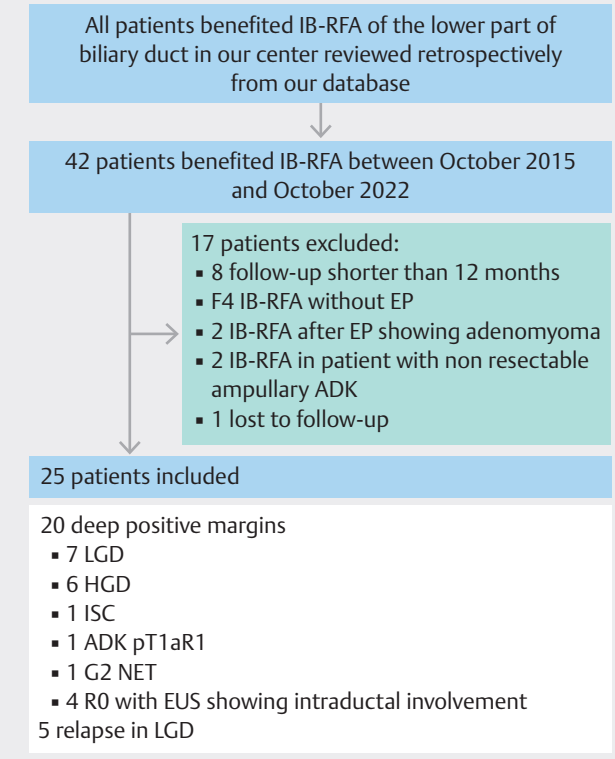
Before EP, intrabiliary duct involvement was present in 11 of 25 patients (44%), which was visible via EUS in all patients (11/11) and visible via MRI in three of 11 patients.

Length of ductal extension was available for eight of 11 patients with a median intrabiliary duct involvement of 7.7 mm (range 2–15). None of our patients had pancreatic intraductal involvement.

After EP, a tissue remnant was endoscopically visible in the lower part of the biliary duct in 11 of 25 patients (44%).

Histological results

Among the 25 patients included, five (20%) had free margins after EP and experienced histologically proven relapse with low-grade dysplasia (LGD). Relapses occurred at a median time of 60 months (3–159) after EP (▶ **Table 2**).



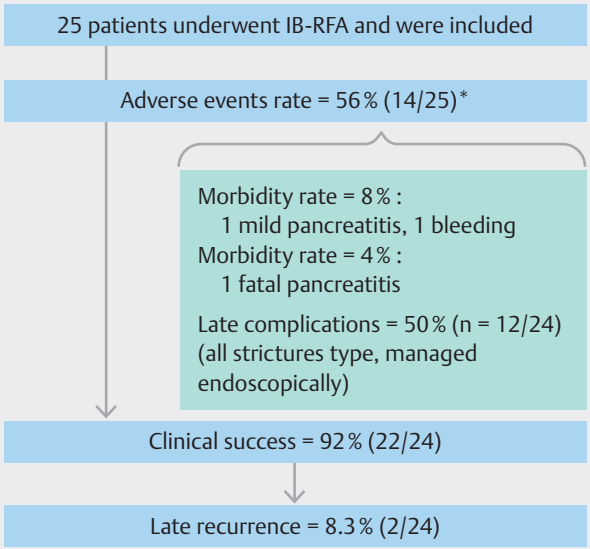
▶ **Fig. 2** Flow chart of included patients. EP: Endoscopic papillectomy, LGD: Low grade dysplasia, HGD: High grade dysplasia, ISC: In situ carcinoma, ADK: Adenocarcinoma, NET: Neuroendocrine tumor.

▶ **Table 2** Histological results.

Patient, n (%)	25 (100)
Positive margin	20 (80)
LGD	7 (28)
HGD	6 (24)
In situ Carcinoma	1 (4)
Adenocarcinoma pT1aR1	1 (4)
G2 NET	1 (4)
R0 with EUS intraductal involvement	4 (16)
Relapse	5 (20)
LGD	5 (20)

LGD: Low grade dysplasia, HGD: High grade dysplasie, NET: Neuroendocrine tumor.

Twenty patients (80%) had positive margins after EP. We considered deep margins to be positive because of histological analysis in 16 patients and because of invasion of the bile duct on imaging independent of histological analysis in four patients. In these four patients, invasion of the bile duct was diagnosed via preoperative EUS, and the bile duct was dilated.



▶ **Fig. 3** Intrabiliary radiofrequency ablation outcomes, adverse events, and late recurrences.

Histological analysis of deep positive margins (16/20 patients) revealed LGD (n = 7), high-grade dysplasia (HGD) (n = 6), in situ carcinoma (ISC) (n = 1), G2 neuroendocrine tumor (n = 1), and adenocarcinoma pT1aR1 in patients who refused surgery.

Four patients (4/25, 16%), two of whom had positive margins, underwent complementary endoscopic resection between the time of EP and IB-RFA with SR (n = 3) or SR with APC (n = 1). Histological results revealed LGD in three patients and HGD in one patient.

Eight patients (8/25, 32%), four of whom had positive margins, underwent concomitant endoscopic resection at the same time as the first IB-RFA because of neoplastic tissue surrounding the papillectomy area (SR, n = 6; APC, n = 1; and SR with APC, n = 1). Histological results revealed LGD in six patients and HGD in one patient.

IB-RFA

During the study period, our 25 patients underwent 40 IB-RFA sessions with a technical success rate of 100%. Median follow-up was 37 months (range 12–81) (▶ **Fig. 3**). All the data concerning the results are available in ▶ **Table 3**.

Because one patient died during the first 30 days (see below), clinical success was calculated based on 24 patients. Pancreatic stenting failed in 22.5% of the sessions (9/40).

Biliary stenting was performed in 100% of the sessions, with FCSEMS in 60% of the sessions (24/40) and the plastic stent in 40% of the sessions (16/40).

Adverse events

Fifty-six percent of our patients (14/25) experienced at least one AE (▶ **Table 3**).

▶ **Table 3** Adverse events.

Patients, n (%)	25 (100)
Adverse events, n (%)	14 (56%)
Morbidity, n (%)	2 (8)
▪ Acute pancreatitis	1 (4)
▪ Bleeding	1 (4)
Mortality, n (%)	1 (4%)
AGREE classification, n (%)	3 (12)
▪ A2	1 (4)
▪ A3a	1 (4)
▪ A5	1 (4)
Late complication, n (%)	12 (50)*
▪ Stricture	12 (50)
▪ Managed endoscopically	12 (50)

*Calculation done on 24 patients (the dead patient was excluded).

The morbidity rate was 8% (2/25), with one case of mild pancreatitis and one case of bleeding; these cases were managed endoscopically and the patients were discharged from the hospital after 13 and 3 days, respectively.

The mortality rate was 4% (1/25), with one case of fatal acute pancreatitis. The patient died 13 days after a second IB-RFA session. In the two cases of acute pancreatitis, we failed to introduce a pancreatic stent. Risks of acute pancreatitis per patient and per session were 8% (2/25) and 5% (2/40), respectively.

Risk of acute pancreatitis in patient with pancreatic stenting failure was 22% (2/9). Accounting for all 40 sessions, acute pancreatitis risk was significantly greater in patients with pancreatic stenting failure (22% vs. 0%, P = 0.046)

Using the AGREE classification, the AEs were classified as A2 (n = 1), A3a (n = 1), and A5 (n = 1).

The late complication rate was 50% (12/24), and these complications consisted of only biliary stricture type, which occurred at a median time of 17 months (range 2–74).

At the first endoscopic control, 58% of FCSEMSs (13/24) and 12.5% of plastic stents (2/16) had migrated. In the case of FCSEMS migration, strictures were found during the first endoscopic course in four patients or occurred during follow-up in four patients.

Stricture was asymptomatic in 58% of patients (7/12) or was diagnosed because of cholangitis (n = 3), abdominal pain (n = 1), or an elevated liver function test (n = 1).

One patient experienced both one early complication (bleeding) and one late complication (stricture), both of which were managed endoscopically.

All strictures were successfully managed endoscopically using a FCSEMS, plastic stent, balloon dilation, or a new sphincterotomy in eight of 12 patients (67%), two of 12 patients (17%), one of 12 patients (8%), and one of 12 patients (8%), respectively. Ongoing stenting was not needed after calibration.

Accounting for patients in whom strictures were managed with stents (FCSEMS n = 8, plastic stent n = 2), median calibration time was 10 months (range 5–20).

Median follow-up after stricture treatment was 17.6 months (range 0–56).

▶ **Table 4** Outcomes of intrabiliary radiofrequency ablation.

Patients, n (%)	25 (100)
Clinical success, n (%)	22 (92)*
RFA session needed, median (range)	1.1 (1–2)
Follow-up, months (range)	37 (12–81)
Concomitant treatment, n (%)	8 (32)
Clinical failure, n (%)	2 (8)
Late recurrence, n (%)	2 (9)†

*Calculation done on 24 patients (the dead patient was excluded).
†Calculation done on 22 patients (only patients who reached clinical success).

Clinical success, clinical failure, and late recurrence

The clinical success rate was 92% with 22 patients free from disease 12 months after IB-RFA (histologically proven in 11/22 patients and macroscopically validated in 11/22 patients) (▶ **Table 4**). Median number of IB-RFA sessions needed was 1.1 (range 1–2).

In cases of IB-RFA indicated for positive margins, the clinical success rate was 90% (17/19), with a median follow-up of 41 months (range 12–81). Patients with positive margins that were histologically proven or unproven had clinical success rates of 80% (12/15) and 100% (4/4), respectively.

In the case of IB-RFA indicated for relapse, clinical success was observed in all patients (5/5) (100%), with a median follow-up of 24 months (range 12–35).

Our patient with pT1aR1 adenocarcinoma who refused surgery was free from disease after 44 months of follow-up.

Two patients (2/24, 8%) experienced clinical failure. One patient who was unfit for surgery had persistent LGD on biopsy even after 12 IB-RFA sessions. One patient underwent pancreaticoduodenectomy 12 months after the first session of IB-RFA because of a lesion that continued to grow into the common bile duct. The surgical specimen was an LGD with 25-mm invasion of the common bile duct.

Two patients (2/24, 8%) experienced late recurrence at a median time of 42.5 months (range 33–52). One patient with ISC on the margin after EP experienced lymph node relapse 33 months after IB-RFA and was still treated with chemotherapy at 55 months.

One patient had a villous aspect of the biliary orifice 52 months after the IB-RFA session, with a negative biopsy. A second IB-RFA session was applied, and the patient was free from disease at 77 months.

Discussion

We report our experience concerning the safety of IB-RFA in cases of deep positive margins or relapse after EP. This procedure led to non-negligible risk of potentially lethal acute pancreatitis, which could be avoided with pancreatic stenting. Moreover, we report a higher risk of biliary stenosis than expected. We also confirmed that this procedure is efficient, with a clinical success rate of 92%.

Use of an intrabiliary radiofrequency probe is a recently developed tool for treatment of intraductal involvement in ampullary neoplasia, but the AE rate is not well established.

Incidence of AEs rates reported in series using IB-RFA varies from 11% to 43% [14, 15, 16, 17]. In our study, the total AE rate, including morbidity and delayed complications, was 56% (n = 14/25), and these AEs involved mainly biliary strictures (n = 12).

We report two cases of acute pancreatitis, one of which was lethal. The mortality rate was 4% (n = 1), and this complication is the only death reported in studies concerning IB-RFA after EP. Excluding case series, a total of 97 cases have been published, which represents a mortality rate of 1.03% and suggests that the procedure is safe [14, 15, 16, 17].

Our patient who died consulted clinicians 11 days after onset of abdominal pain (12 days after IB-RFA). He was diagnosed with acute severe pancreatitis, which was likely due to a pancreatic duct stricture, and he underwent surgery because of high intraabdominal pressure. He died the next day.

Acute pancreatitis occurred only in patients for whom pancreatic stenting failed.

When pancreatic stenting was successful, the rate of acute pancreatitis was 0% in our series. Therefore, IB-RFA is not advised in cases of pancreatic stenting failure because is not an emergency procedure. In our practice, IB-RFA is postponed in this situation because of these findings.

Biliary strictures were present in 48% of our patients (12/25) and were prevented using plastic or FCSEMS stenting, selected based on operator convenience. There was no statistically difference in stricture occurrence depending on type of stent, presumably due to the limited number of patients. In fact, we noticed that most cases of stricture occurred due to FCSEMS migration (n = 8/12). To avoid this migration, plastic stents or FCSEMSs anchored with external plastic stents should be placed [19].

The safety of IB-RFA must be compared with that of surgery, which yields morbidity and mortality rates of up to 49% and 9%, respectively [8, 9, 10]. Studies evaluating IB-RFA have used different brands of probes, which differ in length and generator settings. These differences could be responsible for the heterogeneous AE rates. Nevertheless, we cannot yet reach a conclusion in favor of safer settings or materials due to the small sample size and heterogeneity of populations (role of stenting, complementary treatment prior to IB-RFA, and setting of generators).

In our series, we observed a high efficiency (92%) compared with that reported in the literature, with approximately 70% clinical success [14, 15, 16, 17]. Concomitant therapy (APC and/or SR) could increase clinical success even if it is performed in the case of lateral neoplastic tissue and is a therapeutic tool that can be used in routine practice. Absence of systematic forceps biopsy during follow-up is also a limit, but the long follow-up time decreases risk of a missed relapse (median time 37 months).

The margins of four patients which were initially classified as free on the papillectomy specimen were later reclassified as positive because EUS revealed intrabiliary involvement associated with bile duct dilation. Conversely, the five patients who underwent IB-RFA for relapse, all of whom were histologically proven to have LGD, had free margins on the EP specimen. Two patients experienced relapse in the first 6 months following EP and may have been misdiagnosed with positive margins. This finding underscores that histological analysis of margins in EP is difficult and that treatment of patients with free margins but positive EUS results needs to be discussed, especially because the burning effect on the edge of the papillectomy site can lead to misdiagnosis [7]. In our practice, we consider all available examinations (endoscopy, cholangiogram, EUS, CT, and MRI) in association with histological results to discuss indications for IB-RFA procedures, with consideration of their limitations.

Our patient with ISC on the margin after EP was considered to have achieved clinical success after a single session of IB-RFA but experienced metastatic relapse because of metachronous node metastasis 33 months later. Such patients likely warrant increased attention, and surgical options should be considered in cases of positive margins or relapse with ISC for patients suitable for surgery.

Based on the above findings and given the difficulty of precisely assessing the length of intraductal involvement and the risk of surgery, we suggest that IB-RFA could be used in cases of benign intrabiliary involvement (positive margin or relapse), up to 20 mm, after eliminating infiltrative tissue with MRI and EUS. Furthermore, this approach requires rigorous follow-up. IB-RFA should not be performed in cases of ISC on the ampullary specimen margin or pancreatic stenting failure prior to IB-RFA.

Surgery should be considered in cases involving a length >2 cm, intraductal involvement that increases after the first session of IB-RFA, or failure of a second session of IB-RFA.

Two key points of our study are the need to avoid IB-RFA in cases of pancreatic stenting failure and the high risk of biliary stricture, the prevention of which by FCSEMS was associated with a high migration rate.

Moreover, our long period of follow-up revealed the efficiency of IB-RFA throughout the period: Relapse was uncommon among our patients and few data were missing.

The major limitation of our study was the retrospective design, which led to possible misdiagnosis of AEs; however, in cases of major symptoms and external consultation, our patients are usually referred quickly to us because of the specific care needed. The four patients treated without histological results could have falsely improved the clinical success rate, but EUS and biliary duct dilation strongly suggested intraductal involvement. Measurement of intraductal ingrowth was not standardized and histological proof of absence of recurrence

was not systematically obtained; however, because of the long monitoring time, relapse was likely not missed.

Intraductal involvement and IB-RFA must be evaluated and discussed by an experienced team because of the difficulty of assessment mentioned above. Confirmation of the efficiency of this technique in well-selected patients avoids surgery and the related morbidity and mortality for these patients.

Further large-scale studies with standardized generator settings, probes, intraductal assessments, and efficient prophylactic stenting are needed to decrease the morbidity of this very promising technique.

Conclusions

IB-RFA in cases of benign positive margins or relapse after EP leads to a non-negligible AE rate but is efficient over time. Pancreatic stenting is mandatory before the session because of risk of acute pancreatitis. Stricture is the main complication, but it was always successfully managed endoscopically in our population. IB-RFA can avoid unnecessary surgery but still needs to be discussed by medical and surgical staff in expert centers.

Conflict of Interest

Marc Giovannini is a consultant for Taewong company. The remaining authors have no conflicts of interest to declare.

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