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INTERVENTIONAL RADIOLOGY

ORIGINAL ARTICLE

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

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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.

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; $p = 0.004$).

CONCLUSION
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.

Malignant biliary obstruction (MBO) continues to be a challenging issue in interventional radiology. Since most patients are diagnosed at inoperable stage, palliation with biliary drainage and stent placement is the most widely accepted treatment (1). Self-expandable metallic stents (SEMS) have the best patency rates among other options, but stent occlusion is the main drawback, and stent occlusion rates within 6 months are high (2, 3). Reported stent patency rates of SEMS varies widely, ranging from 3 months to 1 year (4–9). Tumor ingrowth is usually the main problem in stent occlusion. Prolonging stent patency by using endobiliary radiofrequency ablation (RFA) in combination with metallic stenting was first proposed by Steel et al. (10) and most of the endobiliary RFA experience has been with Habib Endo HPB (EMcision).

ELRA (STARmed) is a novel endobiliary RFA catheter. In contrast with Habib Endo HPB, which uses power-controlled RFA, ELRA applies radiofrequency energy in a temperature-controlled mode. This concept has the potential to decrease the complications related to the RFA procedure and may lead to a more effective ablation by reducing coagulum formation during the RFA procedure. Recent endoscopic studies have demonstrated that ELRA can be safely used in the biliary system with low complication rates (11–13). In this study, we report our single center experience of percutaneous endobiliary RFA with ELRA device and aim to evaluate the safety and effectiveness of percutaneous endobiliary RFA in prolonging SEMS patency.

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Methods

Patient population and study design

This retrospective clinical study was approved by the local ethics committee (Protocol number: 2018/14). Data of 62 consecutive patients who underwent percutaneous treatment in the interventional radiology unit of a university hospital between January 2016 and January 2019 due to MBO were retrospectively evaluated.

All patients were discussed in oncology wards by an interventional radiologist, hepatobiliary surgeon and oncologist at their admission for eligibility to the study. Inclusion criteria were: 1) age, 20–80 years; 2) pathologically proven malignancy causing biliary obstruction; 3) elevated bilirubin levels causing jaundice with or without cholangitis; 4) inoperability of the malignancy; 5) life expectancy exceeding three months. Exclusion criteria were: 1) ECOG performance score >2 (14); 2) serious comorbidity precluding sedation and procedure; 3) surgical operability; and 4) life expectancy less than three months.

All patients were informed about the procedure and signed informed consent before the procedure. Patients eligible for endobiliary RFA and metallic stenting were informed about the potential benefits, risks and additional costs. Thirty patients underwent endobiliary RFA adjuvant to metallic stenting, while 32 patients were treated with only metallic stenting during the study period. Demographic and clinical features of the patients are summarized in Table 1.

Procedure

A multistep treatment protocol was followed. First, patients underwent percutaneous biliary drainage as an on-day procedure and an internal-external drainage catheter was placed. After decompression of the biliary system confirmed by control cholangiography, patients were hospitalized for further treatment.

Main points

- Temperature-controlled endobiliary radiofrequency ablation is a safe and feasible method.
- Endobiliary radiofrequency ablation increases stent patency and survival rates.
- Prospective studies are needed to clarify the role of endobiliary radiofrequency ablation in management of malignant biliary strictures.

In the study group, ELRA (STARmed) RFA catheter was used for endobiliary RFA. ELRA is a bipolar 7 F catheter which uses a 0.035-inch over-the-wire system. The distal end of the probe has two types of configuration: 18 mm and 33 mm length of presumptive ablation. Electrical energy is delivered with a compatible RF generator (VIVA Combo™, VCS10, STARmed). An energy of 400 kHz at 10 W is applied for 90 seconds with a rest period of 30 seconds before moving the catheter. Target temperature for controlled ablation was set to 80°C. Endobiliary RFA was performed through the whole length of the malignant stricture. For strictures exceeding the length of the probe ablation zone, consecutive ablations were done through full length of the stricture. Following ablation of the stricture self-expandable uncovered stents were deployed (Fig. 1). After stent placement control cholangiography was performed and a 40 cm length diagnostic catheter was left inside. Patients were hospitalized for one night and observed for procedure-related complications. The following morning, if normal bile flow was confirmed in control cholangiography, control catheter was withdrawn and patients were discharged.

In the control group, patients underwent stenting on the same day of admission and again a diagnostic catheter was left for control cholangiography. The next day after demonstration of the free flow of bile by cholangiography, control catheter was removed and patients were discharged.

Follow-up

Patients were scheduled for control visits at the end of the first week, first month, third month and then at three-month intervals. Clinical recovery and liver function tests were monitored and patients were evaluated for any sign of biliary obstruction. For patients with suspicion of biliary obstruction further imaging with MRI or CT was performed.

Statistical analysis

Primary outcomes of this study were technical success, complications related to the procedure, stent patency and overall survival.

Complications were evaluated according to the standardized grading system of the Society of Interventional Radiology (SIR) (15). Complications compatible with the definition of Grade A or B according to this grading system were defined as minor complications. Complications were defined as major complications if they were compatible with SIR grade C–F.

NCSS (Number Cruncher Statistical System) 2007 program was used for statistical analysis. Descriptive statistical methods (mean, standard deviation, median, frequency, percentage, minimum, maximum) were used to summarize study data. Shap-

Table 1. Demographic and clinical features of the patients

		ELRA (n=30)	Control (n=32)	*p*
Age (year)	Mean±SD	67.83±12.1	65±7.2	0.24
Sex, n (%)	Male	20 (66.6)	24 (75)	0.47
	Female	10 (33.3)	8 (25)	
Etiology, n (%)	Cholangiocarcinoma	13 (43.3)	17 (53.1)	0.57
	Metastasis	2 (6.7)	1 (3.1)	
	Pancreas carcinoma	11 (36.7)	12 (37.5)	
	Periampullary tumor	1 (3.3)	0 (0)	
	Gastric carcinoma	3 (10)	1 (3.1)	
	Gallbladder carcinoma	0 (0)	1 (3.1)	
Level of obstruction, n (%)	Hilar	11 (36.7)	8 (25)	0.43
	Proximal CBD	7 (23.3)	6 (18.7)	
	Lower CBD	12 (40)	18 (56.2)	
Chemotherapy, n (%)		8 (26.7)	7 (21.9)	0.66
Radiotherapy, n (%)		3 (10)	2 (6.3)	0.29

ELRA, study group with radiofrequency ablation and metallic stenting; Control, metallic stenting only.
SD, standard deviation; CBD, common bile duct.

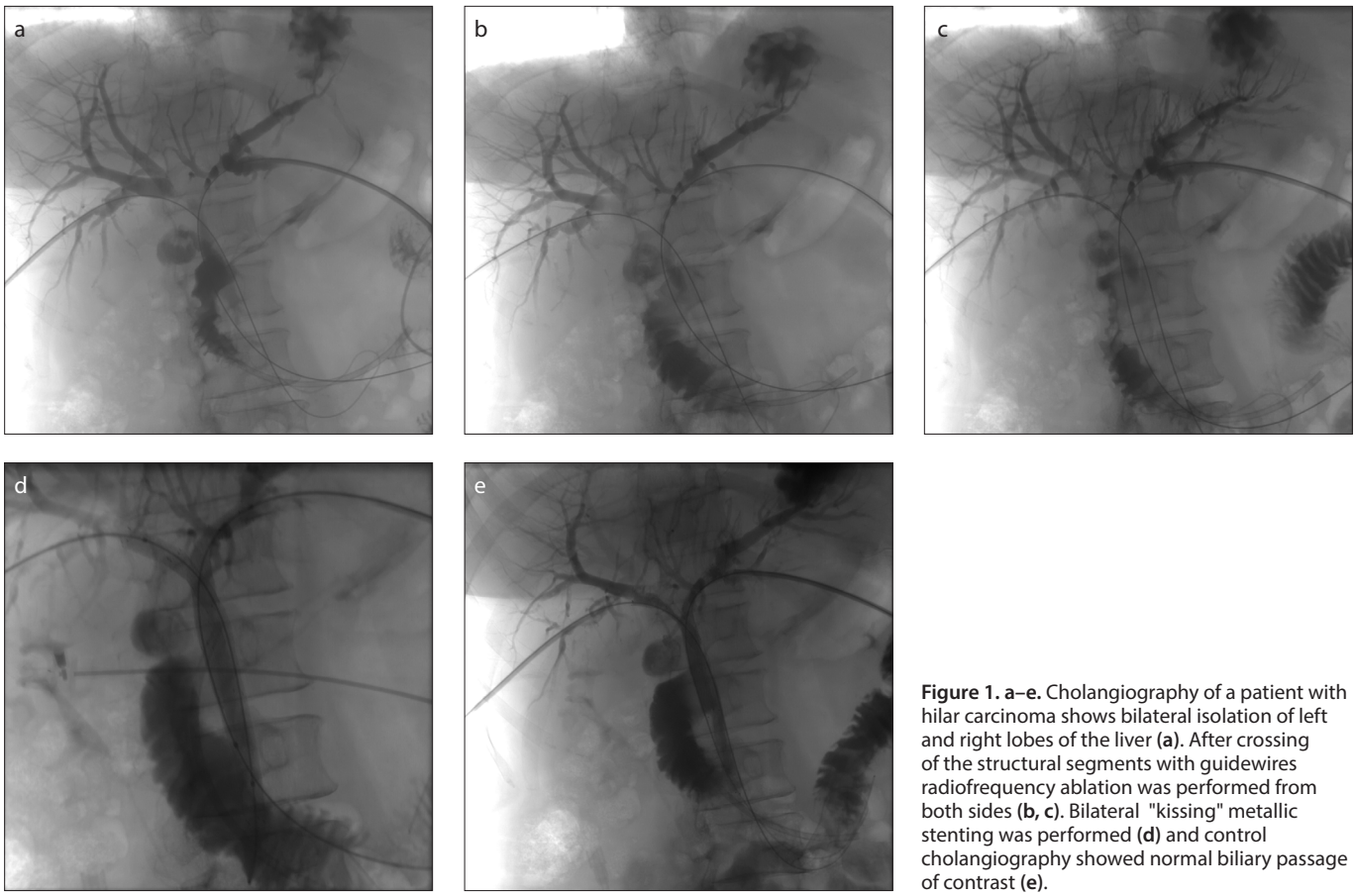

Figure 1. a–e. Cholangiography of a patient with hilar carcinoma shows bilateral isolation of left and right lobes of the liver **(a)**. After crossing of the structural segments with guidewires radiofrequency ablation was performed from both sides **(b, c)**. Bilateral "kissing" metallic stenting was performed **(d)** and control cholangiography showed normal biliary passage of contrast **(e)**.

iro-Wilk test was performed to objectively assess the normality of the underlying distribution of the data within treatment groups and box-plots were used to visually confirm data symmetry. Student t-test was used in the comparison of two groups of quantitative variables with normal distribution. Mann-Whitney U test was used to compare the two groups of quantitative variables without normal distribution. Comparison of qualitative data between study and control groups were done with Pearson's chi-square and Fisher's exact tests. Stent patency and overall survival were estimated using the Kaplan-Meier method and differences were assessed by the log-rank test. A *p* value of less than 0.05 was considered significant.

Results

Both groups were comparable according to age, sex, etiology of malignant biliary obstruction and co-therapies.

All procedures in the study and control groups were performed successfully. Eleven patients in the study group and 8 patients in the control group with hilar obstruction underwent bilateral stenting. Totally, 41 stents were deployed in the study group and 40 stents in the control group.

In the study group, the mean stricture length was 33.37±10.7 mm. Mean pre-procedure luminal diameter was 1.4±0.8 mm and mean post-procedural luminal diameter was 7.3±0.8 mm. A total of 49 ablation cycles were performed through the malignant stricture segments. In the control group, the mean stricture length was 47.94±14.2 mm, which was longer than that of the study group (p = 0.022). Mean luminal diameter was 1.6±0.8 mm and mean post-procedural luminal diameter was 7.6±1.4 mm.

Procedural complications are summarized in Table 3. In the study group, no major complication such as pancreatitis, biliary duct perforation or abdominal hemorrhage was observed following the procedure. Eleven patients had abdominal pain after the procedure; all of them responded to analgesic therapy. One patient presented with minor hemobilia and was treated conservatively since symptoms relieved in one day. Two patients presented with cholangitis following the procedure and both of them recovered after intravenous antibiotic and supportive treatment. Only one of the two patients with cholangitis had positive blood culture and was assumed to have septicemia, but neither patient needed longer hospitalization, so although septicemia was diagnosed, it was still considered as a minor complication.

Similarly there were no pancreatitis, bile duct perforation or abdominal hemorrhage in the control group. Abdominal pain was the most common complication (n=16; 50%). In the control group, four patients presented with cholangitis after the procedure, and all of them responded to conservative and antibiotic therapy. Three patients presented with hemobilia after the procedure. While one of them managed conservatively, two needed endovascular intervention. After endovascular treatment and both patients' condition stabilized, biliary drainage catheters were placed and after resolution of hemobilia, drainage catheters were removed. There was no difference in minor (p = 0.42) and major (p = 0.16) complication rates between study and control groups. Procedural results and complications are summarized in Table 2 and Table 3.

Table 2. Summary of procedural results

		ELRA (n=30)	Control (n=32)	*p*
Stricture diameter (mm)	Min–Max (Median)	1–4 (1)	1–4 (1.4)	0.37
	Mean±SD	1.4±0.8	1.6±0.8	
Stricture length (mm)	Min–Max (Median)	15–56 (32.5)	24–80 (48.5)	0.022*
	Mean±SD	33.37±10.7	47.94±14.2	
Postprocedure diameter (mm)	Min–Max (Median)	5–8 (7.7)	5–11 (7.7)	0.23
	Mean±SD	7.3±0.8	7.6±1.4	
Total bilirubin (mg/dL)	Pre-procedure	9.3±2.8	11.3±3.2	0.021*
	Post-procedure	2.9±1.5	3.1±0.8	0.28
Direct bilirubin (mg/dL)	Pre-procedure	7.3±2.9	8.4±4.2	0.44
	Post-procedure	2.7±0.9	2±0.7	0.41
Survival (days)	Median	246	198	0.004*
Primary stent patency (days)	Median	223	158	0.016*

ELRA, study group with radiofrequency ablation and metallic stenting; Control, metallic stenting only.
SD, standard deviation.
*Statistically significant.

Table 3. Summary of complications

	ELRA (n=30)	Control (n=32)	
	n (%)	n (%)	*p*
Major complications	0 (0)	2 (6.2)	0.16
Minor complications	15 (50.0)	21 (65.6)	0.42
Procedure-related complications			
Pain	11 (36.6)	16 (50)	0.29
Sepsis	1 (3.3)	0	0.29
Cholangitis	2 (6.6)	4 (12.5)	0.43
Hemobilia	1 (3.3)	3 (9.3)	0.33
Abdominal hemorrhage	0	0	-
Bile duct perforation	0	0	-
Hepatic abscess	0	0	-
Pancreatitis	0	0	-
Late complications			
Stent occlusion	9 (30)	18 (50)	0.037*

ELRA, study group with radiofrequency ablation and metallic stenting; Control, metallic stenting only.
* Statistically significant.

In the study group, the mean follow-up time was 9 months (range, 2–24 months). Median survival was 246 days; 25 patients (78.1%) died during the follow-up period. Fifteen patients died because of progression of the primary disease, 3 died due to pneumonia, 4 died from myocardial infarction and 3 died due to septicemia.

In the control group, the mean follow-up time was 7 months (range, 2–11 months). Median survival was 198 days. All patients died during the follow-up period. Twenty-five patients died because of progression of the primary disease, one died due to pneumonia, two died from myocardial infarction, two died due to pulmonary thromboembolism, one due to cerebrovascular accident and one due to cardiac failure.

Survival curves according to Kaplan-Meier analysis are shown in Fig. 2a. Log rank test showed the difference in survival rates between the study group and control group to be statistically significant ($p = 0.004$).

Median stent patency was significantly longer in the study group (223 days vs. 158 days; $p = 0.016$). Stent patency curves according to Kaplan Meier analysis are shown in Fig. 2b. In the study group, 9 stent occlusions were detected during the follow-up. Stent occlusion was due to tumor ingrowth in 7 patients, tumor outgrowth in one patient and sludge formation in one patient. The patient with sludge formation was treated with ERCP successfully. RFA and balloon sweeping was performed in the other patients, with tumor ingrowth and outgrowth. Additional stenting was needed in 4 of these patients to achieve adequate bile flow. In the control group, 18 of the patients presented with biliary obstruction during the follow-up period and stent occlusion. Stent occlusion was due to tumor ingrowth in 9, sludge formation in 7 and tumor outgrowth in 2 patients. Four patients with sludge formation were treated with ERCP and the other 3 patients with sludge formation in whom ERCP failed were treated with percutaneous biliary drainage. Seven patients with tumoral infiltration were treated with additional stent placement and balloon dilation, while the other 4 patients were treated with percutaneous biliary drainage as patients' malignancy progressed and they had low life-expectancy.

Discussion

Metallic stenting is accepted as the most effective palliative treatment in patients with MBO. Stent occlusion is a major problem in management of MBO since it is associated with morbidity and mortality (16). Previous studies regarding the patency of bare SEMS for MBO showed variable results, rarely exceeding 6 months (5, 7–9). The main reasons of stent occlusion and re-intervention were tumor ingrowth and biliary sludge formation.

Previous studies of endobiliary RFA showed the Habib endoPB to be a safe and feasible device for percutaneous usage, as reported complication rates were acceptably low (17–19). It is hypothesized that local ablation and controlled necrosis of the malignant tissue result in delayed tumor ingrowth and outgrowth, thus increasing the patency of the biliary stents. Previous studies on the endoscopic usage of ELRA showed that this novel device is safe and capable of effective ablation in MBO (11–13). In this study, ELRA RFA catheter was used percutaneously. ELRA differs from Habib endoPB by its temperature sensor on the tip such that ablation procedure is done in a temperature-controlled setting, while Habib endoPB does not have

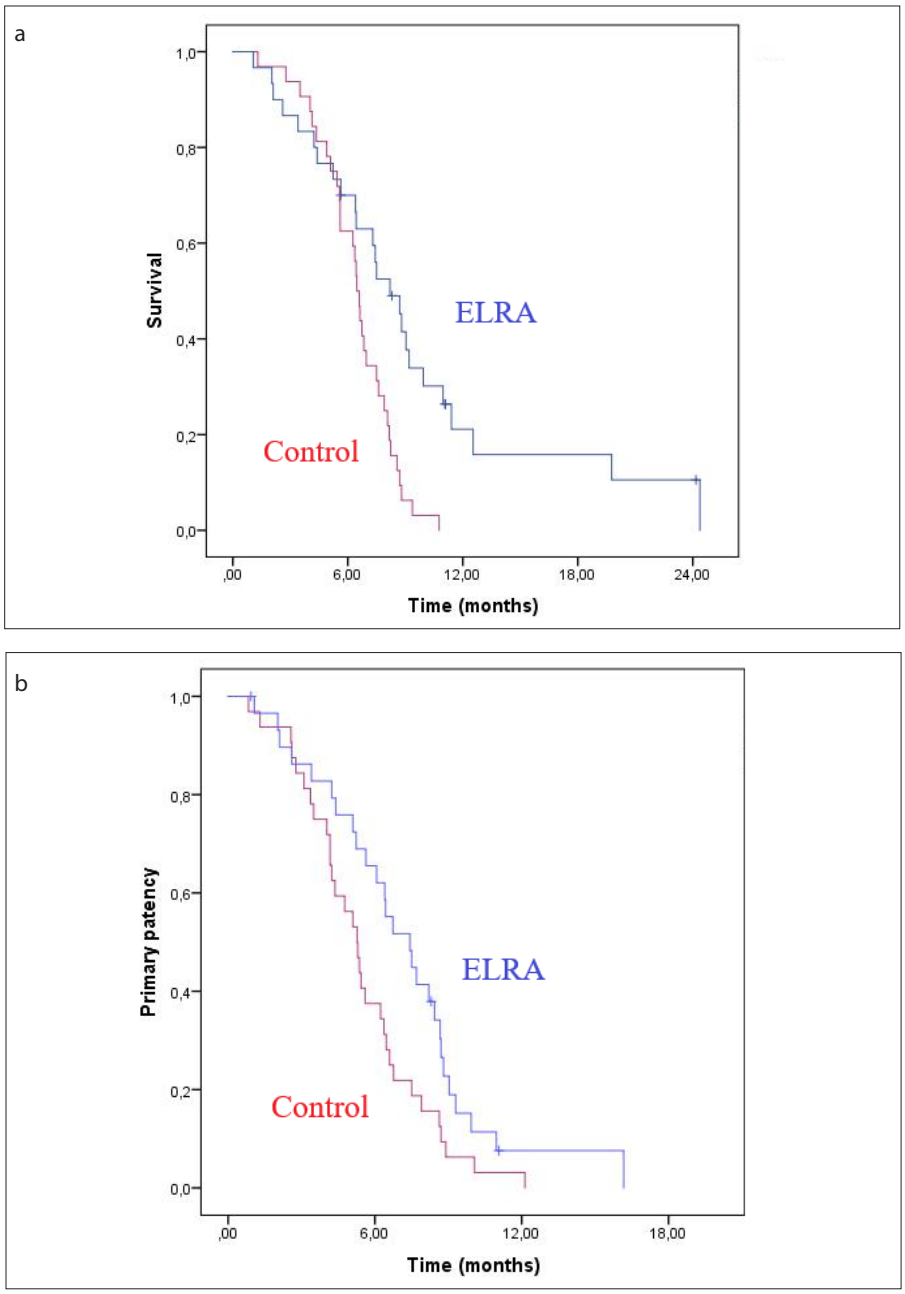

Figure 2. a, b. Kaplan-Meier analysis of survival **(a)** and stent patency **(b)** curves of the patients. ELRA, study group with radiofrequency ablation and metallic stenting; Control, metallic stenting only.

any temperature sensor and ablation is done with a power-controlled setting. Control of temperature levels in the ablation zone offers reduced risk of biliary complications such as perforation and hemobilia. It may also decrease the coagulum formation and increase the chance of achieving an effective ablation zone by reducing the heat sink effect (20, 21).

In this study, procedural complication rates were comparable in both groups. There was no major complication in the study group and the most common minor complication was pain which resolved with analgesic treatment. On the other hand, although statistically not significant, there were two major complications of hemobilia requiring endovascular treatment in the control group. One may expect more biliary tract related complications such as hemobilia, biliary perforation and bile leakage in endobiliary RFA than simple biliary stenting. As a contradiction, Mizandri et al. (17) stated that RFA with low energy delivered "inside" the biliary duct has the advantage of local effect and previous studies of percutaneous endobiliary RFA reported very few biliary complications related to the procedure. However, Zhou et al. (22) reported two cases of biliary perforation one resulting in peritonitis and death. Uncommon complications such as liver infarction, hepatic coma and left bundle branch block have also been reported (23). It can be stated that endobiliary RFA is a safe method but careful planning of the operation, avoiding overlapping ablations and ablation of normal biliary duct is mandatory to reduce the risk of biliary complications. Temperature-controlled nature of the device may have an additional role in our low complication rates. Comparative studies with the power-controlled RFA are still needed to determine its effectiveness in prevention of procedural complications.

In the literature, there are few papers comparing percutaneous endobiliary RFA with bare metallic stenting and most of the studies are designed as retrospective case series (18, 24–26). Reported stent patency in previous studies of percutaneous endobiliary RFA range between 89 days to 241 days. In a retrospective study, Cui et al. (25) showed better primary stent patency and secondary stent patency in the RFA group than in the control group, in patients with cholangiocarcinoma. Interestingly, for other malignancies causing biliary obstruction, primary patency rates did not differ between the groups. The author suggested that cholangiocarcinoma responds better to RFA since the tumor is intraluminal in nature. Wang et al. (24) also stated that RFA use adjunct to stenting prolongs the stent patency. Both studies showed no advantage on overall survival (24, 25). In another retrospective controlled study on patients with distal cholangiocarcinoma, endobiliary RFA showed better patency rates and improvement in quality of life in the RFA group. Again, there was no difference in survival between RFA and control groups. The authors also reported fewer major complications of cholangitis and hemobilia in the RFA group and stated that RFA may play a role in this finding (26). In our study, median stent patency was 223 days, which was compatible with previous reports and longer than the control group. In addition, different from mentioned studies, median survival rates were longer than the control group (17–19, 24–26). Similar to our results, Bokemeyer et al. (27) reported that endoscopic endobiliary RFA improves

survival rates in hilar cholangiocarcinoma in a case-control study. A meta-analysis of previous studies by Sofi et al. (28) also claimed that endobiliary RFA increases survival rates. In a recent prospective study of 65 patients with extrahepatic cholangiocarcinoma, improvement in both stent patency and survival were demonstrated, similar to our results (29). Our results should be interpreted cautiously, since the length of stricture was longer and bilirubin levels were higher in the control group, which may indicate more advanced disease. Although stent patency was significantly higher in the study group, we experienced similar rates of tumor ingrowth and outgrowth, but lower rates of sludge formation. This may be explained by the local effect of endobiliary ablation, which has limited effect on overall tumor burden in the patients. As a result, tumor ingrowth and outgrowth are delayed, but not eliminated. The effect of endobiliary ablation on sludge formation is still unknown and may be clarified in future studies. Prolonging stent patency is expected to increase the overall survival, since stent occlusion is strongly associated with mortality and morbidity. But, endobiliary RFA affects locally with limited tumor necrosis, which results in little decrease in overall tumor burden, so effect of endobiliary RFA on survival is still debatable and should be confirmed with larger prospective studies.

This study has some limitations that need to be mentioned. First of all, our study was designed retrospectively with a limited number of patients which lowers the capability of making general statements. Second, there was no randomization and patient selection bias could not be excluded. Although both control and study groups had similar demographic and clinical features, malignant strictures had different etiologies and the level of obstructions was different which may change the response to the RFA procedure. More homogeneous and specific groups of patients would help us determine the effect of endobiliary ablation more precisely.

In conclusion, endobiliary RFA is a potential solution for prolonging the stent patency, and data concerning endobiliary RFA is still growing. Percutaneous endobiliary RFA with the novel ELRA device seems to be safe and effective for prolonging the patency of metallic stents in malignant biliary obstructions. Although it has been in use since 2013, there is still a need for larger prospective randomized studies to establish the role of percutaneous endobiliary RFA in routine clinical practice.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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