Research Article / Araştırma Makalesi
doi: 10.18678/dtfd.1218573

Duzce Med J, 2023;25(1):78-84
Düzce Tıp Fak Derg, 2023;25(1):78-84

Effect of Percutaneous Endobiliary Radiofrequency Ablation in Malignant Bile Stenosis

Malign Safra Yolu Darlıklarında Perkütan Endobiliyer Radyofrekans Ablasyonun Etkisi

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Received / Geliş Tarihi : 13.12.2022
Accepted / Kabul Tarihi : 29.03.2023
Available Online / Çevrimiçi Yayın Tarihi : 15.04.2023

ABSTRACT

Aim: This study aimed to demonstrate the feasibility of the percutaneous endobiliary radiofrequency ablation (ERFA) method, which is used to increase stent patency in malignant biliary strictures.

Material and Methods: A total of 25 patients, 9 (36%) female and 16 (64%) male, who developed malignant biliary stenosis secondary to various advanced tumors and underwent ERFA and metallic stenting after percutaneous biliary drainage were retrospectively evaluated. The types of malignancies causing obstruction and the follow-up after the procedure were evaluated to demonstrate the median survival and stent patency values of the patients. Stent patency and survival rates were calculated using the Kaplan-Meier method.

Results: The results of the study demonstrated that 17 (68%) out of these 25 patients displayed a significant decrease in their first-week postoperative bilirubin values, with a reduction of greater than 50% compared to the pre-biliary drainage values. The study determined that this treatment approach's overall clinical success rate was 68%. Stent occlusion developed within 180 days in 8 (32%) out of the 25 patients who underwent ERFA and metallic stenting. Additionally, 18 (%72) patients died as a result of malignancy progression. The mortality rates at post-treatment 30 and 180 days were determined to be 24% and 72%, respectively. The median survival and stent patency times were 65 and 70 days, respectively.

Conclusion: Percutaneous ERFA and metallic stenting have the potential to improve survival and stent patency, especially in selected patient groups with distal biliary stenosis. Randomized controlled studies are needed to confirm these results.

Keywords: Malignant biliary obstruction; percutaneous endobiliary radiofrequency ablation; biliary drainage; biliary stenting.

ÖZ

Amaç: Bu çalışmanın amacı, malign biliyer darlıklarda stent açıklığını artırmak için kullanılan perkütan endobiliyer radyofrekans ablasyon (endobiliary radiofrequency ablation, ERFA) yönteminin uygulanabilirliğini ortaya koymaktır.

Gereç ve Yöntemler: Çeşitli ilerlemiş tümörlere sekonder malign biliyer stenoz gelişen ve perkütan biliyer drenaj sonrası ERFA ve metalik stent uygulanan 9 (36%) kadın ve 16 (64%) erkek olmak üzere toplam 25 hasta geriye dönük olarak değerlendirildi. Hastaların ortanca sağkalım ve stent açıklığı değerlerinin gösterilmesi için obstruksiyona sebep olan malignitelerin türleri ile işlem sonrası takipleri değerlendirildi. Stent açıklığı ve sağkalım oranları Kaplan-Meier yöntemi kullanılarak hesaplandı.

Bulgular: Bu çalışmaya dahil edilen 25 hastadan 17'si (%68) işlem sonrası ilk hafta bilirubin değerlerinde pre-biliyer drenaj değerlerine göre %50'den fazla azalma ile anlamlı bir düşüş gösterdi. Bu tedavi yaklaşımının genel klinik başarı oranı %68 olarak tespit edildi. ERFA ve metalik stent uygulanan 25 hastanın 8'inde (%32) 180 gün içinde stent tıkanıklığı gelişti. Ayrıca 18 (%72) hasta malignite progresyonu sonucu hayatını kaybetti. Tedavi sonrası 30 ve 180 gündeki ölüm oranları sırasıyla %24 ve %72 olarak belirlendi. Ortanca hayatta kalma ve stent açık kalma süreleri sırasıyla 65 ve 70 gündü.

Sonuç: Perkütan ERFA ve metalik stentleme, özellikle distal biliyer stenozu olan seçilmiş hasta gruplarında sağkalımı ve stent açıklığını iyileştirme potansiyeline sahiptir. Bu sonuçları doğrulamak için randomize kontrollü çalışmalara ihtiyaç vardır.

Anahtar kelimeler: Malign biliyer darlık; perkütan endobiliyer radyofrekans ablasyon; biliyer drenaj; biliyer stent.

INTRODUCTION

Malignant biliary obstruction may result from a primary tumor of the bile duct epithelium and from metastatic tumors invading these ducts. Palliation is provided through biliary stenting in this patient group with a life expectancy of less than 6-12 months (1). Stenting via percutaneous biliary drainage is an effective and safe treatment method, especially in the patient group where endoscopic access is not possible (2). Metallic stents are more cost-effective and are associated with shorter hospital stays and fewer reinterventions. The most critical factor limiting the effectiveness of stent therapy is stent occlusion due to tumor growth (3). Covered stents have been developed to prevent this complication, but migration problems have developed in these stents, and as a result, sufficient efficacy has not been achieved (4).

The use of endobiliary radiofrequency ablation (ERFA) has recently become more common as a supplemental treatment for alleviating symptoms associated with malignant biliary obstructions. By utilizing radiofrequency energy to generate heat and cause cellular damage, this technique can be carried out through either an endoscopic or a transhepatic method and has the potential to delay stent blockages by reducing tumor load along the obstructed bile duct (5). Recent endoscopic and percutaneous studies have shown that ERFA can be used safely in the biliary system with low complication rates (6-8).

In this study, we reported our single-center experience and aimed to demonstrate the feasibility, safety, and effectiveness of the percutaneous ERFA method and stenting procedure in the palliative treatment of malignant biliary obstructions.

MATERIAL AND METHODS

Study Design and Patient Selection

This retrospective study obtained approval from the local ethics committee (Clinical Research Ethics Committee of Ankara Numune Training and Research Hospital, date: 01.11.2018, number: E-18-2297). Patients who were considered inoperable due to malignant biliary obstruction in general surgery and medical oncology clinics and referred to the interventional radiology clinic for palliative treatment and treated with percutaneous transhepatic ERFA and metallic stenting between April 2017 and April 2018 were included in the study. Between these dates, a total of 28 patients were treated with percutaneous transhepatic ERFA and stenting in our interventional radiology clinic. All patients had hyperbilirubinemia, biliary obstruction symptoms, and pathological diagnoses at admission. None of the patients received radiotherapy. None of the patients had contraindications to the procedure such as irreversible coagulopathy, systemic infection, sepsis, or pregnancy. The follow-ups of two patients could not be accessed, and one patient was excluded from the study due to a Whipple operation in the second month after the procedure. As a result, 25 patients were included in the study.

Patient Demographics

Twenty-five patients with the age range of 44 to 83 (mean 65.0±10.8) years, comprising 9 (36%) females, and 16 (64%) males were evaluated. Etiologies of malignant biliary obstruction were detected radiologically and histopathologically. Evaluation of percutaneous transhepatic cholangiography (PTC) images before the procedure revealed total and near-total stenosis in all of the 25 patients, and the diameter was defined as 0 mm. Patient demographics and tumor characteristics are summarized in Table 1.

Technique

Assessments of complete blood count and biochemical and blood coagulation parameters were performed prior to each procedure. All patients were informed about the details and possible complications of the percutaneous transhepatic ERFA and stenting procedure, and their informed consent was obtained. Operations were planned according to ultrasonographic evaluation. Patients fasted for 8-12 hours before the procedure. Broad-spectrum antibiotics (IV 1 gr 3rd generation cephalosporin) prophylaxis were administered to all patients before the procedure.

Procedures were performed in an angiographic suite with a flat-panel detector-based system (Innova 4100, General Electric Medical Systems, USA). The procedure was performed under standard sterile conditions with the anesthesia team providing sedoanalgesia. ELRA™ (STARmed, Korea) bipolar radiofrequency catheter and radiofrequency generator VIVA Combo™ (STARmed, Korea) were used for the ERFA procedure. The ELRA™ catheter is a disposable catheter with a probe diameter of 7Fr (2.31 mm) and a catheter length of 40 cm for the percutaneous procedure, which can be advanced over a 0.035" guidewire. Four annular electrodes of 3 mm in length with a distance of 2 mm between them after a 7 mm gap at the distal end were placed on the catheter. This RFA catheter can ablate tissue of a length of 18±3 mm and a radius of 2.1±0.3 mm with 7W power and 120 seconds of bipolar activation. In addition, the catheter has a temperature sensor that keeps the tissue at the target temperature (75-80 °C) and provides ablation without carbonization (7).

Table 1. Demographic data and tumor characteristics of the patients

Age (years), mean±SD	65±10.8 (44-83)
Gender, n (%)	
Female	9 (36%)
Male	16 (64%)
Primary tumor, n (%)	
Pancreatic carcinoma	11 (44%)
Cholangiocarcinoma	6 (24%)
*Type 1	1
*Type 2	1
*Type 4	4
Ampulla of Vater tumors	2 (8%)
Gallbladder carcinoma	1 (4%)
Metastases	5 (20%)
Histopathological subtype, n (%)	
Adenocarcinoma	24 (96%)
Squamous cell carcinoma	1 (4%)
Infiltrated bile duct segment, n (%)	
Proximal	9 (36%)
Distal	16 (64%)
Malignant stricture diameter (mm)	0
Malignant stricture length (mm), mean±SD	36.3±11.0

SD: standard deviation

ERFA was performed in a separate session in all patients after internal/external biliary decompression was achieved with the appropriate technique. A hydrophilic 0.035" Amplatz Super Stiff™ (Boston Scientific, USA) guidewire was advanced through the internal/external drainage catheter and fixed, and the catheter was removed. A 7F vascular sheath was placed over the guidewire to facilitate balloon and stent interventions. The level and length of the stenosis segment were determined with cholangiograms obtained by sending contrast material from the side of the vascular sheath. The ELRA™ catheter was placed over the guidewire under the guidance of fluoroscopy. The VIVA Combo™ RF generator was activated by setting it to 7W power and the target ablation temperature value to 80 °C. After every 120 seconds of activation, 60 seconds waited, and washing was done from the vascular sheath. Then, ablation was achieved by moving it proximally to cover the entire stenosis segment. After ablation was completed, a cholangiogram was taken for leakage control and the ERFA catheter was removed. A self-expandable metallic stent was placed over the guidewire to cover the stenosis segment 1-2 cm proximally and distally. Balloon dilatation was performed in cases when the stent patency was insufficient. A follow-up cholangiogram was repeated to evaluate stent placement and biliary drainage. If patency was achieved after the follow-ups, the guidewire and vascular sheath were removed. However, if adequate patency was not achieved, the follow-up catheter was left in place. The catheter was removed after normal bile flow was observed in the follow-up cholangiograms performed a few days after the procedure (Figure 1).

After the procedure, patients' pain medication was arranged, and their follow-up was provided in the relevant clinic. After discharge, the patient's clinic, biochemistry, and imaging were performed at regular intervals according to the oncology protocol. These results were evaluated through the hospital information management system.

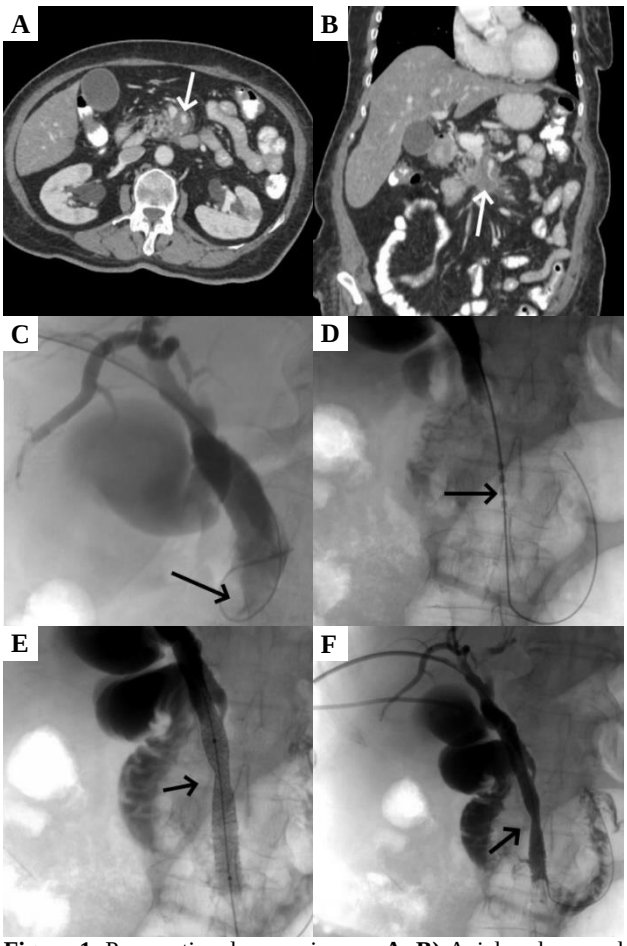

Figure 1. Pancreatic adenocarcinoma. **A, B)** Axial and coronal CT scans show a pancreatic mass surrounding the SMA and SMV in a 77-year-old female patient **C)** The level of stenosis was detected in the PTC obtained with the right approach **D)** ERFA was applied in the next session. **E)** A metallic stent was then applied **F)** The stent was opened in the follow-up cholangiogram

Evaluation of Treatment

Observation of easy transition of the contrast agent into the duodenum after percutaneous ERFA and metallic stent application was interpreted as technically successful. One week after percutaneous ERFA and metallic stenting, a decrease of more than 50% in total bilirubin level compared to before biliary drainage was interpreted as clinically successful. Complications that developed in the first 30 days after the percutaneous ERFA procedure were classified as early complications and those that developed 30 days after the procedure were classified as late complications. The time until death from the percutaneous ERFA procedure was defined as survival. Recurrence of jaundice and a total bilirubin value above 2 mg/dL after percutaneous ERFA procedure were defined as stent occlusion and the elapsed time was determined as stent patency.

Statistical Analysis

Analyzes were performed using the IBM SPSS Statistics v.22.0 (SPSS Inc. USA) statistical analysis program. The Shapiro-Wilk test was used to evaluate the conformity of the data with normal distribution. Normally distributed data were expressed as mean±standard deviation, while data that did not conform to normal distribution were expressed as median (minimum-maximum). Frequencies were presented with percentages. The period between the radiofrequency ablation application time and time of death was recorded in days, and the Kaplan-Meier method was used for survival analysis. The Kaplan-Meier curve was used to determine the relationship between stent patency and survival. Log-rank test was used to compare the survival curves between groups. For both tests, $p<0.05$ was considered statistically significant.

RESULTS

All 25 patients were treated in two separate sessions in our interventional radiology clinic. Percutaneous biliary drainage was applied in the first session, while ERFA and metallic stenting were performed in the second session. The median time between the two sessions was 5 (range, 1-50) days. ERFA and metallic stenting were performed in 4 (16%) of the 25 patients. Balloon dilatation was performed in 21 (84%) patients who did not achieve adequate stent patency. Evaluation of PTC images before ablation revealed nearly complete stenosis in all 25 patients. After ablation, the open bile duct diameter was measured as 5.3±0.7 mm. Follow-up cholangiogram demonstrated the transition of the contrast agent into the duodenum in all 25 patients who underwent ERFA and stenting and the technical success was found to be 100%.

In the 6-month follow-up after the ERFA application, a progressive decrease was detected in patients' total and direct bilirubin values (Figure 2). The slight increase in the second month after the stent procedure observed in the graph was interpreted as the development of stent occlusions. Bilirubin values decreased below 50% of the baseline value before biliary drainage in 17 (%68) of 25 patients one week after ERFA and metallic stenting. Clinical success was determined as 68% (Table 2).

Six (%24) patients died at the end of the first month due to disease progression. The mortality rate in the first 30 days after the procedure was 24%. Bilirubin value decreased below 2 mg/dL in 11 (57.9%) of the remaining 19 patients.

Stent occlusion developed in 1 (%4) patient in the early period (first 30 days) after ERFA and metallic stenting, and the hepatic abscess was observed in also 1 (%4) patient. In the late period (30 days - 6 months following the procedure), stent occlusion developed in 7 (%28) patients, and the hepatic abscess was observed in 2 (%8) patients (Table 3).

As of April 2019, 24 (%96) of the 25 patients included in the study died, accordingly, the median survival time was 65 (95% CI: 32.59-97.40) days (Figure 3). Looking at the stent patency, the median value of stent patency time was 70 (95% CI: 0.27-139.72) days (Figure 4).

Table 2. ERFA success and bilirubin values

Ablation energy (watts)	7-10
Duration of ablation (sec)	90-120
Malignant stricture diameter (mm)	
Before	0
After	5.3±0.7
Technical success, n (%)	25 (100%)
Total/Direct mean bilirubin levels (mg/dL)	
Before PBD	
Total	16.21
Direct	14.07
Before ERFA Day 1	
Total	10.92
Direct	9.48
After ERFA Day 1	
Total	10.27
Direct	8.65
After ERFA Week 1	
Total	7.86
Direct	6.89
After ERFA 1-month	
Total	4.67
Direct	3.97
Clinical success, n (%)	17 (68%)

ERFA: endobiliary radiofrequency ablation, PBD: percutaneous biliary drainage

Table 3. Complications after the procedure, n (%)

Early (0-30 days), n (%)	
Stent occlusion	1 (%4)
Abscess	1 (%4)
Delayed (30 days-6 months), n (%)	
Stent occlusion	7 (%28)
Abscess	2 (%8)

ERFA: endobiliary radiofrequency ablation

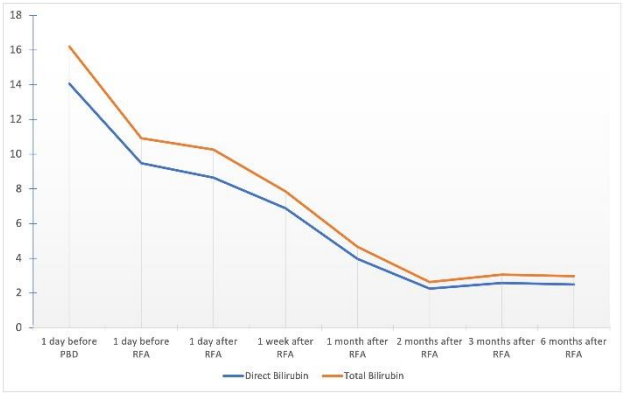

Figure 2. Total and direct bilirubin values after ERFA application in a 6-month period

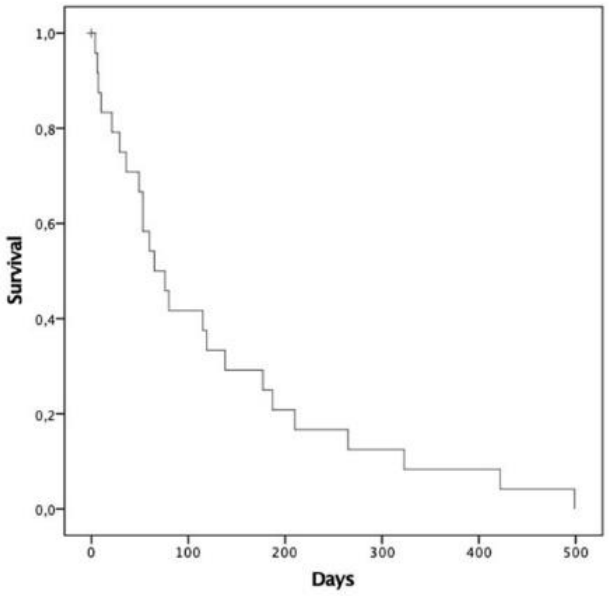

Figure 3. Kaplan-Meier survival curve of the patients

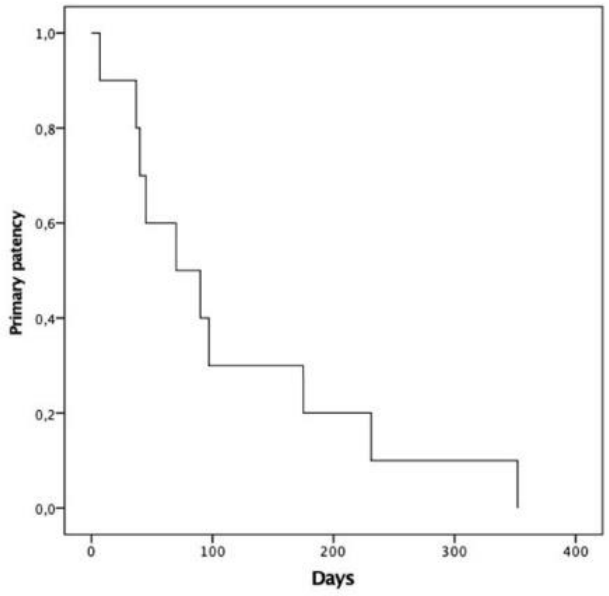

Figure 4. Kaplan-Meier stent patency curve of the patients

There was no statistically significant effect of the gender variable on overall survival (p=0.556). The median survival time of patients diagnosed with cholangiocarcinoma, one of the histopathological variables, was statistically significantly higher than patients with other histopathological diagnoses (p=0.035).

DISCUSSION

In our study, we successfully catheterized 25 patients and performed ERFA followed by metallic stenting. There was an early regression in bilirubin levels. In the first week after ERFA and stenting, total bilirubin regressed to below 50% of the pre-procedural value in 17 of the 25 patients, and clinical success was determined as 68%. In addition, the total bilirubin value decreased below 2 mg/dl in 11 of the 19 patients who were alive and could be followed up in the first month, and our success in the first month was 57.9%. When we look at the literature, nearly 100% of first-month success is observed, and it was found to be significantly lower in our study (6,9). We thought that this was due to inadequate bile duct drainage despite intervention due to complete obstruction of the lumen at the level of the stenosis by advanced tumor invasion.

The mean diameter of the stenosis before the procedure was measured as 1.47±0.17 mm in a study by Acu et al. (9) and as 1.35±0.63 mm in a study by Wu et al. (10), which differs from our study. In our study, the evaluation made with PTC before the procedure revealed almost complete occlusion in the lumen in all patients. The mean diameter of the open lumen after the procedure was 5.23±1.50 mm in Acu et al.'s (9) study and 6.69±2.48 mm in Wu et al's (10) study, which is similar to our present study (5.3±0.73 mm).

The literature demonstrates that two separate sessions are conducted, in which biliary drainage is performed in the first session, followed by ERFA and stenting in the second session (9). Thus, it aims to increase the procedure's success by providing biliary decompression. This method was applied in all cases in our study. After ERFA, self-expanding metallic stents of different sizes were placed, and the transfer of contrast material to the duodenum was evaluated. Technical success was found to be 100%, similar to other studies, and was found to be compatible with the literature.

There are case reports in the literature stating that the biliary perforation develops in the early period after ERFA, and stenting is recommended in the early period of treatment (11). A study by Lee et al. (7) reported that the procedure was performed safely in 30 patients without bile leakage or vascular injury, with the target temperature controlled by an ELRA™ catheter. With this technique, overheating and carbonization are prevented, and thus significant vascular structure or biliary tract injury is avoided. With the ELRA™ catheter, which we also used in our study, no bile leakage or vascular damage was detected after ERFA.

In a study by Akıncı et al. (12), balloon dilation was applied after the ERFA procedure in refractory bilioenteric anastomosis strictures. Although metallic stent was not used in this study, it demonstrated that balloon dilation can be performed safely after RFA. In our study, 24 of 25 patients underwent ERFA and balloon dilation after stenting.

In a study conducted by Acu et al. (9), stent occlusion developed in 3 patients and hepatic abscess in 1 patient within six months out of 20 patients they followed. Our present study observed that 8 out of 25 patients developed stent occlusion, and 3 patients developed a hepatic abscess in a six-month period.

Few publications in the literature have compared ERFA with bare metallic stenting (13-17). Cui et al. (15) reported that stenting with ERFA provides a therapeutic benefit in stent patency compared to stent placement alone, especially in patients with cholangiocarcinoma. The author suggests that cholangiocarcinoma inherently responds better to ERFA because of its intraluminal spread. Similarly, in our study, the median survival time in patients diagnosed with cholangiocarcinoma was statistically significantly higher than the median survival time of patients with other histopathological diagnoses. Cui et al. (15) stated that ERFA and stenting prolong the stent patency. However, no advantage over overall survival has been demonstrated. In studies with control groups conducted by Uyanık et al. (14) and Kallis et al. (16), significant prolongation was observed in stent patency and overall survival.

In the study by Acu et al. (9), the median total survival time was 76 days, and the median stent patency time was 133 days. In the study by Mizandari et al. (6), the median survival was 89.5 days, and the median stent patency was 84.5 days. Wu et al. (10) reported a median survival of 181 days, and median stent patency was 149 days. The patient groups in these studies were mixed, like ours, but the Habib™ was used as the ERFA catheter. In a controlled study by Kallis et al. (16), the Habib™ catheter was used in a selected patient group consisting of only pancreatic carcinomas and it was reported the median survival was 472 days and stent patency was 226 days. Lee et al. (7) conducted a study in a selected group of patients who developed extrahepatic malignant biliary stenosis located 2 cm from the hilum. In the aforementioned study, the median survival was 383 days, and the median stent patency was 236 days. In the study by Uyanık et al. (14), the distribution of patients was mixed, with a median survival of 246 days and median stent patency of 223 days. In these two studies, ELRA™ was used as the ERFA catheter, as in our study. In our study, the median total survival time was 65 days, and the median duration of stent patency was 70 days. In our comparison with the literature, we are significantly behind in stent patency and survival. Although many reports in the literature show that radiofrequency ablation improves stent patency and survival, few studies show that it is ineffective. The study by Oh et al. (18) showed that it did not increase survival and patency.

Evaluation of the results of our present study in the context of the literature, clinical success, stent patency, and survival values were found to be significantly lower. Complete obliteration of the lumen at the level of stenosis and a significantly higher level of total bilirubin before biliary drainage in our patients compared to the literature are thought to affect our results (Table 4). In the context of the literature, we see that the results of ERFA applied in malignancies involving the distal bile ducts are better compared to a mixed patient group, as in our study (7,16). Finally, palliative percutaneous biliary drainage solutions

Table 4. Overview of the available literature on ERFA

Study	Method	Year	n	Catheter	Etiology	Median Stent Patency	Median Survival	Preprocedural Total Bilirubin (mg/dL)
Mizandari et al. (6)	Percutaneous	2013	39	Habib™	Mixed	84.5	89.5	7.54±3.6
Wu et al. (10)	Percutaneous	2015	47	Habib™	Mixed	149	181	14.03±5.8
Kallis et al. (16)	ERCP	2015	23	Habib™	Pancreas	472	226	14.27±2.83
Acu et al. (9)	Percutaneous	2018	21	Habib™	Mixed	133	76	15.09±8.59
Lee et al. (7)	ERCP	2019	30	ELRA™	Distal	236	383	Not reported
Uyanık et al. (14)	Percutaneous	2021	30	ELRA™	Mixed	223	246	9.3±2.8
Oh et al. (18)	ERCP	2022	28	ELRA™	Mixed	140	311	Not reported
Current Study	**Percutaneous**	**2019**	**25**	**ELRA™**	**Mixed**	**70**	**65**	**16.2±8.5**

ERFA: endobiliary radiofrequency ablation, ERCP: endoscopic retrograde cholangiopancreatography

in our interventional radiology clinic are applied in complex patient groups when ERCP is unsuccessful. This situation causes a limitation in selecting patients suitable for ERFA and reduces the procedure's success.

Our study had some limiting factors. The retrospective nature of this study made it difficult for the researcher to master all possible factors that would affect the outcome. In addition, the absence of a control group prevented a comparison of the effect of ERFA on stent patency and survival. Another limitation of our study was the small patient population. The lack of homogeneity among the factors that may affect the results, such as malignancy types and stages, is another limitation of our study.

CONCLUSION

Compared with the literature, the conclusion of our study, we observed that the application of ERFA and metallic stenting before the development of complete obliteration in the lumen, especially in selected patient groups with distal malignant biliary stenosis gives very satisfactory results. In the context of the literature, we observed that the application of ERFA in the patient group with unsuccessful ERCP and relatively low life expectancy does not contribute to stent patency and survival. In order to observe these effects more clearly, homogeneous, randomized controlled prospective clinical studies are required.

Ethics Committee Approval: The study was approved by the Ethics Committee of Ankara Numune Training and Research Hospital (01.11.2018, E-18-2297).

Conflict of Interest: None declared by the authors.

Financial Disclosure: None declared by the authors.

Acknowledgments: None declared by the authors.

Author Contributions: Idea/Concept: HÖ, BS, İA; Design: HÖ, BS, İA; Data Collection/Processing: HÖ, BS, İA; Analysis/Interpretation: HÖ, BS, İA; Literature Review: HÖ, BS, İA; Drafting/Writing: HÖ, BS, İA; Critical Review: HÖ, BS, İA.

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