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Percutaneous Endoluminal Radiofrequency Ablation Combined with Biliary Stenting for Malignant Biliary Obstruction: A Retrospective Single-center Study

Malign Biliyer Obstrüksiyonda Perkütan Endolüminal Radyofrekans Ablasyon ile Birlikte Biliyer Stentleme: Retrospektif Tek Merkezli Çalışma

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ABSTRACT

Objective: To assess the safety and clinical outcomes of combining percutaneous endoluminal radiofrequency ablation (RFA) with biliary stenting for malignant biliary obstruction.

Methods: We retrospectively evaluated 37 consecutive patients treated at a single center between 2013 and 2025 with percutaneous endoluminal RFA followed by metal stent placement for malignant biliary obstruction. Technical success, biochemical response, procedure-related complications, primary stent patency, recurrent biliary obstruction (RBO), and overall survival were evaluated. The 30-day biochemical analysis was restricted to patients who were alive at day 30 and had paired bilirubin measurements available. Kaplan-Meier analysis was used to estimate death-censored primary stent patency and overall survival, and an additional competing-risk analysis was performed for RBO with death without prior RBO treated as a competing event.

Results: Technical success was achieved in all patients (100%). Among the 24 patients who were alive at day 30 and had paired bilirubin measurements available, mean total bilirubin decreased from 7.41 ± 5.84 to 2.04 ± 1.46 mg/dL and mean direct bilirubin from 5.69 ± 4.46 to 1.57 ± 1.15 mg/dL (both $p < 0.001$). Modified CIRSE Grade 3a procedure-related complications occurred in three patients (8.1%), whereas no Grade 4-5 procedure-related complications occurred and there was no procedure-related mortality (Grade 6). RBO developed in three of the 35 patients included in the time-to-event analyses (8.6%). The competing-risk cumulative incidence of RBO was 3.5% at 90 and

ÖZ

Amaç: Malign biliyer obstrüksiyonu olan hastalarda perkütan endolüminal radyofrekans ablasyonun (RFA) biliyer stentleme ile birlikte kullanımının güvenli ve klinik sonuçlarını değerlendirmektir.

Yöntemler: Bu retrospektif, tek merkezli çalışmaya 2013-2025 yılları arasında malign biliyer obstrüksiyon nedeniyle perkütan endolüminal RFA ve ardından metal stent yerleştirilmesi uygulanan ardışık 37 hasta dahil edildi. Teknik başarı, biyokimyasal yanıt, işleme bağlı komplikasyonlar, primer stent açıklığı, rekürren biliyer obstrüksiyon (RBO) ve genel sağkalım değerlendirildi. Otuzuncu gün biyokimyasal analizi, 30. günde hayatta olan ve eşleştirilmiş bilirubin ölçümleri bulunan hastalarla sınırlandırıldı. Ölümle sansürlenmiş primer stent açıklığı ve genel sağkalım Kaplan-Meier yöntemiyle hesaplandı; ayrıca, öncesinde RBO gelişmeden gerçekleşen ölüm rakip olay kabul edilerek RBO için ek bir competing-risk analizi yapıldı.

Bulgular: Tüm hastalarda teknik başarı sağlandı (%100). Otuzuncu günde hayatta olan ve eşleştirilmiş bilirubin ölçümleri bulunan 24 hastada ortalama total bilirubin düzeyi $7,41 \pm 5,84$ mg/dL'den $2,04 \pm 1,46$ mg/dL'ye, ortalama direkt bilirubin düzeyi ise $5,69 \pm 4,46$ mg/dL'den $1,57 \pm 1,15$ mg/dL'ye düştü (her ikisi için $p < 0,001$). Üç hastada (%8,1) modifiye CIRSE Grade 3a işleme bağlı komplikasyon gelişirken, modifiye CIRSE Grade 4-6 işleme bağlı komplikasyon veya işleme bağlı mortalite görülmedi. Zaman-bağımlı analizlere dahil edilen 35 hastanın üçünde (%8,6) RBO gelişti. Competing-risk analizinde RBO'nun kümülatif insidansı 90 ve 180. günlerde %3,5, 365. günde ise %8,9 olarak bulundu. Ölümle sansürlenmiş medyan primer stent açıklığı 367

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ABSTRACT

180 days and 8.9% at 365 days. Median death-censored primary stent patency was 367 days [95% confidence interval (CI), 181 days to not estimable], and median overall survival was 95 days (95% CI, 77-112 days).

Conclusion: Percutaneous biliary drainage followed by endoluminal RFA and SEMS placement was technically feasible and had an acceptable safety profile, with biliary decompression observed among patients evaluable at day 30. The low cumulative incidence of RBO was encouraging, but the small number of events, substantial competing mortality, and lack of a control group limit interpretation and prevent assessment of the independent contribution of RFA.

Keywords: Radiofrequency ablation, stents, cholestasis, extrahepatic, biliary tract neoplasms, radiology, interventional, survival analysis

Öz

gün [%95 güven aralığı (GA), 181 gün-üst sınır hesaplanamadı], medyan genel sağkalım ise 95 gün (%95 GA, 77-112 gün) olarak bulundu.

Sonuç: Perkütan biliyer drenajı takiben endoluminal RFA ve SEMS yerleştirilmesi teknik olarak uygulanabilir olup kabul edilebilir bir güvenlik profiline sahipti; 30. günde değerlendirilebilen hastalarda biliyer dekompresyon gözlemlendi. RBO'nun düşük kümülatif insidansı umut vericiydi; ancak olay sayısının azlığı, ölümün önemli bir rakip olay olması ve kontrol grubunun bulunmaması, bulguların yorumlanmasını sınırlamakta ve RFA'nın bağımsız katkısının değerlendirilmesine olanak vermemektedir.

Anahtar Sözcükler: Radyofrekans ablasyon, kendiliğinden genişleyebilen metalik stentler, kolestaz, safra yolu neoplazmları, girişimsel radyoloji, sağkalım analizi

INTRODUCTION

Malignant biliary obstruction (MBO) can arise from primary biliary tumors or from primary or metastatic malignancies that involve or compress the bile ducts. It is a common and clinically important problem in advanced hepatobiliary and pancreatic malignancies, in which many patients are not candidates for curative surgical resection at the time of diagnosis (1).

Progressive MBO may lead to cholangitis, hepatic dysfunction, and deterioration in quality of life. For these patients, effective biliary decompression and maintenance of biliary patency are central to palliative management (1,2). For palliative biliary drainage, self-expandable metal stents (SEMS) are generally favored over plastic stents because their larger caliber provides more durable patency (2). Nevertheless, recurrent biliary obstruction (RBO) remains an important clinical problem and may result from tumor ingrowth or overgrowth, epithelial hyperplasia, sludge formation, and other causes of stent dysfunction (2).

Several adjunctive local therapies have been investigated to improve biliary drainage and prolong stent patency, including photodynamic therapy, intraluminal brachytherapy, and endobiliary radiofrequency ablation (RFA). Endobiliary RFA delivers controlled thermal energy to malignant tissue within the biliary lumen, producing coagulative necrosis and local tumor debulking. When combined with biliary stenting, RFA may contribute to restoration of the biliary lumen and delay RBO (3-7). Randomized trials and recent meta-analyses have suggested potential benefits in stent patency and/or overall survival (OS); however, these benefits have not been consistent across studies (3-7).

Endobiliary RFA may be delivered through an endoscopic route or by percutaneous transhepatic access. Despite growing experience with endobiliary RFA overall, published evidence on its percutaneous use remains more limited. Early feasibility studies established the technical applicability of percutaneous intraductal RFA, while more recent comparative studies have provided additional evidence regarding its safety and clinical outcomes when combined with SEMS placement (8-11).

At our institution, percutaneous endoluminal RFA combined with biliary stenting has been used as a palliative treatment for MBO in patients who were not candidates for curative surgical resection. We

therefore aimed to evaluate the safety and clinical outcomes of this approach in our clinical practice.

MATERIALS AND METHODS

Study Design and Patient Selection

We retrospectively identified consecutive patients treated at our institution between 2013 and 2025 who had histopathologically confirmed MBO, were not candidates for curative surgical resection, and underwent percutaneous endoluminal RFA followed by SEMS placement. The final study cohort comprised 37 patients.

At our institution, percutaneous endoluminal RFA was not routinely added to SEMS placement in all patients with unresectable MBO, and there was no standardized institutional protocol for selecting patients for adjunctive RFA.

Patients who underwent endoluminal RFA for obstruction of a previously placed biliary stent without primary stent placement, including those treated with balloon dilatation alone or balloon dilatation with additional stent placement, were not included in the present analysis.

Reporting followed the strengthening the reporting of observational studies in epidemiology recommendations (12). The study protocol was reviewed and approved by the Gazi University, Faculty of Medicine Clinical Research Ethics Committee (approval no: 8, date: 08.05.2026). All study procedures were carried out in accordance with the principles of the Declaration of Helsinki. All patients had provided written consent for their interventional treatment. Because the analysis was retrospective, additional study-specific consent was waived.

Procedure

Local anesthesia was used for all procedures, with conscious sedation added when clinically or procedurally required. Before RFA, percutaneous biliary drainage was performed to achieve biliary decompression and establish transhepatic biliary access. The combined RFA and SEMS-placement procedure performed after initial biliary drainage was defined as the index procedure.

A Habib™ EndoHPB RFA catheter (EMcision Ltd, London, UK) connected to a compatible radiofrequency generator was advanced

across the malignant biliary stricture under fluoroscopic guidance. Radiofrequency energy was delivered at 10 W for 90 s per application. According to stricture length, the probe was activated at two treatment levels for lesions measuring ≤ 40 mm and at three treatment levels for lesions >40 mm. At each treatment level, two consecutive 90-s applications were routinely performed, with sufficient overlap between adjacent treatment levels to cover the entire malignant segment and adequately include its proximal and distal margins. Control cholangiography was then performed; if luminal improvement at any treated level was considered inadequate, one or two additional 90-s applications were delivered at that level. The RFA technique and the 10-W/90-s protocol used for the index procedure remained unchanged throughout the study period. Each 90-s period of energy delivery was considered one individual RFA application. For repeat RFA performed during follow-up for in-stent obstruction, a power setting of 12 W was used.

Following RFA, a metallic stent (Wallstent®, Boston Scientific, Natick, MA) was deployed across the treated stricture. Stents measuring 50, 70, or 90 mm in length were used, with length selected according to the longitudinal extent and anatomical location of the obstruction. A 10-mm stent diameter was used in patients not requiring bilateral hilar stenting. In the four patients with hilar obstruction, 8-mm-diameter stents were deployed bilaterally in a side-by-side configuration through separate right and left transhepatic accesses. The two stents were positioned across the hilar obstruction and deployed simultaneously to provide drainage of both hepatic ductal systems. Stent number and configuration were otherwise selected according to the extent and anatomical location of the obstruction.

A procedure was considered technically successful when endoluminal RFA was completed, the intended SEMS configuration covered the treated stricture by at least 1 cm at both margins, and final cholangiography confirmed unobstructed contrast passage into the duodenum. A representative procedural sequence is shown in Figure 1.

Laboratory Assessment and Follow-up

Serum total and direct bilirubin levels were recorded before biliary drainage, immediately before RFA and stent placement, and 30 days after treatment. Early biochemical response at 30 days was assessed only in patients who were alive at day 30 and had paired pre-ablation and 30-day bilirubin measurements available. Of the 13 patients not included in this analysis, 11 died before the 30-day assessment and 2 had no postprocedural follow-up data.

Clinical follow-up was based on available outpatient and hospital records, laboratory findings, and imaging examinations. Imaging was performed when clinically indicated, particularly in patients with suspected RBO.

Complications related to the index procedure were retrospectively classified according to the modified Cardiovascular and Interventional Radiological Society of Europe (CIRSE) classification system (13). Because RFA and SEMS placement were performed as components of the same treatment procedure, adverse events occurring after the intervention were not attributed specifically to either RFA or stent placement. Postprocedural abdominal pain responsive to analgesics was recorded separately and was not assigned a modified CIRSE grade. Adverse events occurring before the index procedure and

attributable to the preceding percutaneous biliary drainage were recorded separately and were not considered procedure-related complications of the index intervention. Procedure-related mortality was defined as death attributable to the RFA and/or stent-placement procedure.

Stent Patency and OS

Primary stent patency was defined as the interval from SEMS placement to the first episode of RBO. RBO was defined as recurrence of obstructive symptoms accompanied by cholestatic laboratory abnormalities and/or imaging evidence of biliary obstruction requiring reintervention (14,15).

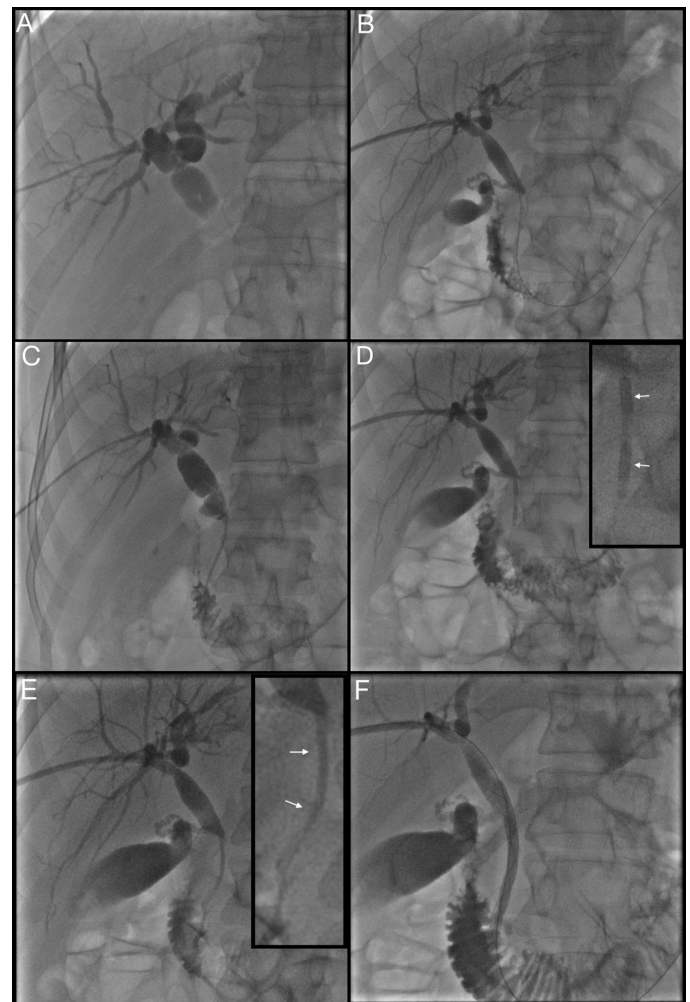


Figure 1. Representative fluoroscopic images of percutaneous endoluminal radiofrequency ablation and biliary stent placement for malignant biliary obstruction. (A) Percutaneous transhepatic cholangiography demonstrates the level of the common bile duct stricture. (B) The stricture is crossed with a guidewire. (C) A biliary drainage catheter is placed during the initial session. (D) During a subsequent session, the RFA catheter is positioned across the stricture and activated (white arrows). (E) Post-ablation cholangiography demonstrates increased luminal caliber at the treated segment before stent placement, consistent with local tumor debulking (white arrows). (F) Final cholangiography after stent placement demonstrates stent patency and free passage of contrast into the duodenum.

RFA: Radiofrequency ablation.

OS was calculated from the date of the index procedure to death from any cause or the last known follow-up. Patients for whom no postprocedural follow-up information was available were considered lost to follow-up and were excluded from the time-to-event analyses.

Statistical Analysis

Continuous data are reported as mean $\pm$ standard deviation and median (range), while categorical data are expressed as number and percentage.

The distribution of within-patient changes in bilirubin was examined before paired testing. As these differences were non-normally distributed, pre-ablation and day-30 bilirubin values were compared with the Wilcoxon signed-rank test. Statistical significance was set at a two-sided $p < 0.05$.

Kaplan-Meier curves were used for analyses of death-censored primary stent patency and OS. Patients who died without RBO were censored for the Kaplan-Meier patency analysis on the date of death (14,15). To account for death as a competing event, the cumulative incidence function (CIF) of RBO was additionally estimated using the Aalen-Johansen approach, with death without prior RBO treated as the competing event. Cumulative RBO incidence was estimated at predefined clinically relevant time points. Numbers at risk were displayed at 0, 100, 200, 300, 400, and 500 days below each time-to-event curve. Medians are presented with 95% confidence intervals (CIs) when calculable. Follow-up duration was summarized by the reverse Kaplan-Meier approach. Statistical analyses were performed using IBM SPSS Statistics, version 23.0 (IBM Corp., Armonk, NY, USA); the CIF was estimated using the survival package (version 3.7-0) in R software (version 4.4.1; R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Patient Characteristics

A total of 37 patients underwent percutaneous endoluminal RFA followed by SEMS placement. The mean age was 66.4 ± 11.7 years (median, 67 years; range, 48-90 years). Twenty-one patients (56.8%) were female and 16 (43.2%) were male.

Pancreatic carcinoma was the most common underlying malignancy (24/37, 64.9%), and the common bile duct was the most frequent level of obstruction (28/37, 75.7%).

The mean length of the malignant biliary stricture was 30.1 ± 10.5 mm, with a median of 29 mm (range, 16-59 mm). In lesions extending separately into the right and left hepatic ductal systems, the lengths of the involved segments were combined to represent the overall extent of the stricture. Detailed patient and lesion characteristics are summarized in Table 1.

Procedural Outcomes

Technical success was achieved in all patients (37/37, 100%). A total of 213 individual 90-s RFA applications were delivered during the 37 index procedures, corresponding to a mean of 5.8 applications per patient.

A total of 43 SEMS were deployed in 37 patients. Six patients received two SEMS, including all four patients with hilar obstruction and two additional patients in whom two stents were required because of stricture length and location.

The median interval between initial percutaneous biliary drainage and the index procedure was 9 days (range, 2-55 days). In 35 of 37 patients, RFA and SEMS placement were performed within 2-15 days after initial drainage. In one patient, the procedure was delayed to 32 days to allow resolution of a drainage-related subcapsular hepatic hematoma. In another patient, the interval was 55 days because of delayed return following an unplanned hospital departure after the initial drainage procedure. Procedural outcomes are summarized in Table 2.

Biochemical Outcomes

Both total and direct bilirubin levels had already fallen between initial biliary drainage and the pre-ablation assessment (Table 2).

Among the 24 patients who were alive at day 30 and had paired bilirubin measurements available, mean total bilirubin decreased from 7.41 ± 5.84 mg/dL before ablation to 2.04 ± 1.46 mg/dL at 30 days. The corresponding median values decreased from 5.48 mg/dL (range, 0.95-23.90 mg/dL) to 1.85 mg/dL (range, 0.75-7.91 mg/dL; $p < 0.001$). Mean direct bilirubin decreased from 5.69 ± 4.46 mg/dL to 1.57 ± 1.15 mg/dL, with corresponding median values decreasing from 4.13 mg/dL (range, 0.75-17.71 mg/dL) to 1.35 mg/dL (range, 0.57-6.22 mg/dL; $p < 0.001$).

The remaining 13 patients were not included in the paired biochemical analysis because 11 died before day 30 and 2 had no postprocedural follow-up data.

Complications

Postprocedural abdominal pain responsive to analgesic treatment occurred in 14 patients (37.8%).

Table 1. Patient and lesion characteristics.

Variable	Value
Total number of patients	37
Age, years, mean $\pm$ SD	66.4 $\pm$ 11.7
Age, years, median (range)	67 (48-90)
Sex, n (%)	
Female	21 (56.8)
Male	16 (43.2)
Underlying malignancy, n (%)	
Pancreatic carcinoma	24 (64.9)
Cholangiocarcinoma	6 (16.2)
Metastatic malignant biliary involvement	3 (8.1)
Gallbladder carcinoma	2 (5.4)
Gastric carcinoma	2 (5.4)
Level of biliary obstruction, n (%)	
Common bile duct	28 (75.7)
Common hepatic duct	5 (13.5)
Hilar	4 (10.8)
Stricture length, mm, mean $\pm$ SD	30.1 $\pm$ 10.5
Stricture length, mm, median (range)	29 (16-59)

Data are shown as mean $\pm$ standard deviation (SD), median (range), or n (%), according to variable type.

Table 2. Procedural, biochemical, and safety outcomes.

Variable	Value/mean $\pm$ SD	Median (range)	p-value
Procedural outcomes			
Technical success, n (%)	37/37 (100)		
Total SEMS deployed, n	43		
Patients receiving two SEMS, n (%)	6 (16.2)		
Bilateral SEMS placement for hilar obstruction, n (%)	4 (10.8)		
Individual 90-s RFA applications, total	213	-	-
RFA applications per patient, mean	5.8	-	-
Interval from biliary drainage to index RFA/SEMS, days	-	9 (2-55)	-
Biochemical parameters			
Before biliary drainage (n = 37)			
Total bilirubin, mg/dL	16.54 $\pm$ 5.91	—	
Direct bilirubin, mg/dL	12.76 $\pm$ 4.54	—	
Before RFA (n = 37)			
Total bilirubin, mg/dL	8.08 $\pm$ 5.17	—	
Direct bilirubin, mg/dL	6.21 $\pm$ 3.96	—	
Paired 30-day assessment (n = 24)			
Total bilirubin, mg/dL			<0.001
Pre-ablation	7.41 $\pm$ 5.84	5.48 (0.95-23.90)	
Day 30	2.04 $\pm$ 1.46	1.85 (0.75-7.91)	
Direct bilirubin, mg/dL			<0.001
Pre-ablation	5.69 $\pm$ 4.46	4.13 (0.75-17.71)	
Day 30	1.57 $\pm$ 1.15	1.35 (0.57-6.22)	
Safety and reintervention outcomes			
Postprocedural abdominal pain responsive to analgesics, n (%)	14 (37.8)		
Modified CIRSE Grade 3a procedure-related complications, n (%)	3 (8.1)		
Cholangitis	2 (5.4)		
Mild pancreatitis	1 (2.7)		
Modified CIRSE Grade 4-5 procedure-related complications	0		
Procedure-related deaths (modified CIRSE Grade 6)	0		
RBO requiring reintervention, n (%)	3/35 (8.6)		

Data are shown as mean $\pm$ standard deviation (SD), median (range), or n (%), as appropriate. Paired pre-ablation and day-30 biochemical values were analyzed with the Wilcoxon signed-rank test. CIRSE: Cardiovascular and Interventional Radiological Society of Europe, RBO: Recurrent biliary obstruction, RFA: Radiofrequency ablation, SEMS: Self-expandable metal stent.

According to the modified CIRSE classification, Grade 3a procedure-related complications occurred in three patients (8.1%), comprising cholangitis in two patients (5.4%) and mild pancreatitis in one patient (2.7%). Both patients with cholangitis recovered with intravenous antibiotic therapy, while the patient with pancreatitis recovered with supportive treatment.

No adverse event with findings suggestive of direct RFA-related thermal injury was identified. No modified CIRSE Grade 4-5 procedure-related complications occurred, and there was no procedure-related mortality (Grade 6).

One additional patient developed abdominal pain and a decrease in hemoglobin level after preprocedural biliary drainage and before undergoing RFA. Imaging demonstrated a subcapsular

hepatic hematoma, and digital subtraction angiography showed no active arterial bleeding. The patient recovered with conservative management, and endoluminal RFA and stent placement were subsequently performed after resolution of the hematoma. Because this event occurred after the preceding biliary drainage procedure and before the index RFA and SEMS-placement procedure, it was classified as drainage-related rather than as a complication of the index intervention.

Follow-up, Primary Stent Patency, and OS

Two patients were lost to follow-up immediately after treatment and were therefore excluded from the time-to-event analyses. The remaining 35 patients were included in the analyses. The median

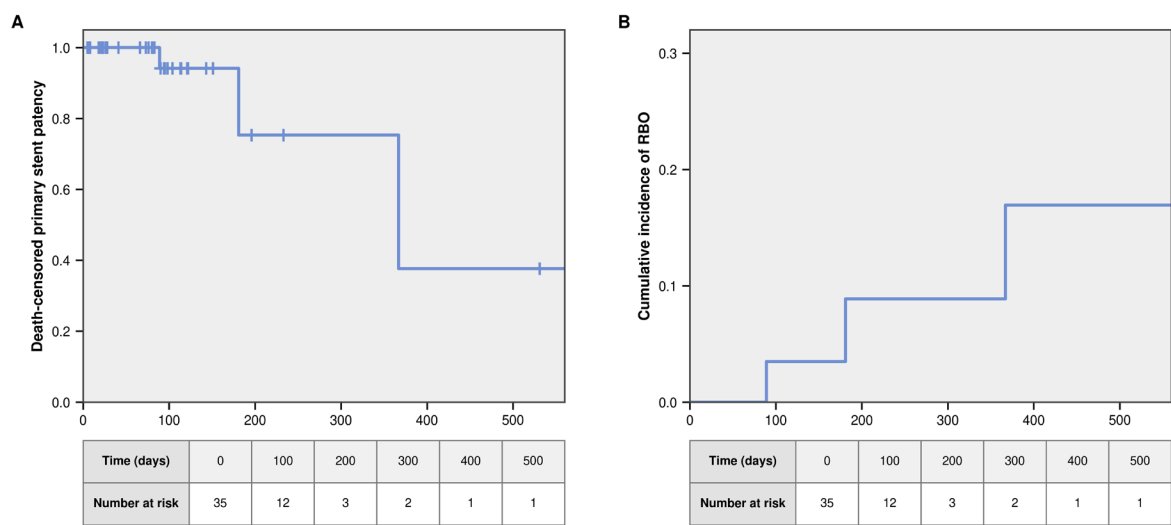


Figure 2. Time-to-event analysis of biliary stent outcomes. (A) Kaplan-Meier estimate of death-censored primary stent patency, with deaths occurring before RBO treated as censored observations. (B) Cumulative incidence of recurrent biliary obstruction estimated using the Aalen-Johansen approach, with death without prior RBO treated as a competing event. Numbers at risk at 0, 100, 200, 300, 400, and 500 days are shown below each panel.

RBO: Recurrent biliary obstruction.

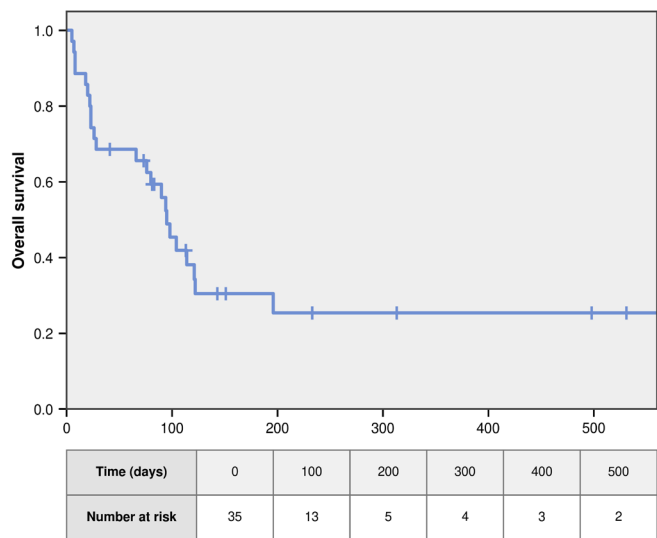


Figure 3. Kaplan-Meier curve showing overall survival after percutaneous endoluminal radiofrequency ablation and biliary stenting. Numbers at risk at 0, 100, 200, 300, 400, and 500 days are shown below the curve.

follow-up duration estimated using the reverse Kaplan-Meier method was 233 days (95% CI, 113-531 days).

RBO requiring reintervention occurred in three of the 35 patients (8.6%), at 89, 181, and 367 days after the index procedure.

In the first two patients, RBO was associated with stent dysfunction due to tumor ingrowth and was successfully managed with repeat endoluminal RFA at 12 W, followed by balloon dilatation and intraluminal sweeping. In the third patient, RBO was associated with stent dysfunction due to tumor ingrowth and overgrowth and was treated with repeat endoluminal RFA at 12 W, balloon dilatation

and intraluminal sweeping, followed by additional SEMS placement, resulting in restoration of biliary patency.

Among the 35 patients, three experienced RBO, 23 died without a preceding RBO event, and nine were censored without RBO at their last available follow-up. In the competing-risk analysis, with death without prior RBO treated as a competing event, the cumulative incidence of RBO was 0% at 30 days, 3.5% at 90 days, 3.5% at 180 days, and 8.9% at 365 days.

In the conventional death-censored Kaplan-Meier analysis, median primary stent patency was 367 days (95% CI, 181 days to not estimable). The estimated death-censored primary stent patency rates at 30, 90, and 180 days were 100%, 94.1%, and 94.1%, respectively (Figure 2A). The competing-risk cumulative incidence curve is shown in Figure 2B. Numbers at risk at 0, 100, 200, 300, 400, and 500 days are displayed below both panels of Figure 2.

Among the 35 patients included in the OS analysis, 23 died during follow-up. The median OS was 95 days (95% CI, 77-112 days). Estimated cumulative survival rates at 30, 90, and 180 days were 68.6%, 55.9%, and 30.5%, respectively (Figure 3). Numbers at risk at the corresponding time points are displayed below the survival curve.

DISCUSSION

In this retrospective single-center series, percutaneous endoluminal RFA followed by SEMS placement was technically successful in all patients. Among patients evaluable at day 30, serum bilirubin levels decreased significantly. Modified CIRSE Grade 3a procedure-related complications occurred in three patients, whereas no modified CIRSE Grade 4-5 procedure-related complications occurred and there was no procedure-related mortality (Grade 6). Only three RBO events were documented during follow-up. The death-censored Kaplan-Meier median primary stent patency was 367 days, whereas competing-risk analysis yielded a cumulative RBO incidence of 8.9%

at 365 days. Median OS was 95 days. All three episodes of RBO were successfully managed with repeat RFA and adjunctive endobiliary treatment. Overall, these findings indicate that percutaneous endoluminal RFA combined with biliary stenting is technically feasible with an acceptable safety profile, but they also highlight that local biliary control and overall prognosis remain distinct in patients with advanced malignancy.

Our 100% technical success rate is in line with previous percutaneous RFA series (8-11,16-19). Cui et al. (17) reported a technical success rate of 98% in a retrospective series of 50 patients undergoing percutaneous intraductal RFA and SEMS placement, whereas other percutaneous series and comparative studies have similarly demonstrated high procedural success rates (18,19). Although available evidence does not establish a technical superiority of percutaneous over endoscopic RFA, direct transhepatic guidewire-based access may offer practical technical advantages in selected patients, particularly in proximal or anatomically complex biliary obstruction. Comparative studies of biliary drainage have reported high technical success with percutaneous access, with a potential advantage over endoscopic access particularly in high-level biliary obstruction (20-22). These studies address biliary drainage rather than RFA itself, so they cannot be taken as evidence that percutaneous RFA is superior to an endoscopic approach. Still, an established transhepatic tract may facilitate device advancement and sequential treatment of long or complex strictures in selected patients. Differences in catheter design, energy-delivery protocols, stent characteristics, obstruction level, and technical definitions across studies should be considered when comparing procedural outcomes.

By day 30, both total and direct bilirubin levels had fallen markedly. Mean total bilirubin decreased from 7.41 to 2.04 mg/dL, while mean direct bilirubin decreased from 5.69 to 1.57 mg/dL. These findings apply only to the 24 patients who were alive at day 30 and had paired laboratory measurements available and should not be extrapolated to the entire cohort. Importantly, bilirubin had already declined after the initial biliary drainage and before RFA. The median interval between drainage and RFA/SEMS placement was 9 days, with most procedures performed within 2-15 days; therefore, the pre-RFA bilirubin values reflect the effect of drainage over this interval. The subsequent biochemical improvement therefore cannot be attributed to RFA alone. RFA-induced coagulative necrosis and local tumor debulking may nevertheless help enlarge the effective biliary lumen before stent deployment and may subsequently contribute to maintenance of luminal caliber and biliary patency (9,23,24). Without a stent-only control group, however, the additional effect of RFA cannot be separated from that of drainage and stenting.

Primary stent patency is one of the most clinically relevant outcomes after endobiliary RFA because tumor ingrowth and overgrowth remain important causes of RBO after SEMS placement. Only three RBO events occurred in the present cohort, yielding a death-censored Kaplan-Meier median primary stent patency of 367 days. The estimated median primary stent patency was numerically longer than that reported in several previous percutaneous series. Cui et al. (17) reported a median stent patency of approximately 7 months in a single-center percutaneous series, while the more recent propensity score-matched study by Cui et al. (9) reported a median primary

stent patency of 8.5 months after percutaneous RFA and stenting compared with 5.1 months after stenting alone. Other contemporary comparative studies and meta-analyses have reported mixed results regarding the effect of RFA on stent patency (18,25-28).

Because a substantial proportion of patients died before experiencing RBO, death represented an important competing event in the evaluation of biliary patency. The competing-risk analysis demonstrated cumulative RBO incidences of 3.5% at 90 and 180 days and 8.9% at 365 days. In contrast, the conventional Kaplan-Meier analysis treats deaths without RBO as censored observations and should therefore be interpreted specifically as death-censored primary stent patency. The divergence between the death-censored Kaplan-Meier estimate and the competing-risk cumulative incidence highlights the substantial impact of competing mortality on interpretation of stent outcomes in this advanced oncologic population.

The 367-day death-censored patency estimate should not, however, be overinterpreted. Only three RBO events occurred, and the upper limit of the 95% CI could not be estimated. Many patients died before a documented episode of RBO. The low number of RBO events is encouraging, but it also makes the late patency estimate imprecise. Direct comparisons with other studies are further complicated by differences in underlying malignancy, obstruction level, stent characteristics, definitions of RBO, follow-up, and the handling of death before RBO. Randomized trials and meta-analyses have likewise not shown a consistent effect of RFA on stent patency (3,4,7,27,28). Thus, the relatively long patency observed in some patients is encouraging, but our data cannot determine whether RFA provides additional benefit over SEMS placement alone.

The three episodes of RBO also provide practical information regarding reintervention. In each case, RBO was associated with stent dysfunction caused by tumor ingrowth, with additional tumor overgrowth in one patient. Repeat RFA at 12 W with balloon dilatation and intraluminal sweeping restored patency in the first two patients, while the third required an additional SEMS. This experience suggests that repeat intraductal RFA can be incorporated into the management of malignant stent dysfunction. Park et al. (29), in a multicenter propensity score-matched study, reported favorable time to RBO after in-stent RFA followed by uncovered SEMS placement for tumor ingrowth or overgrowth causing SEMS occlusion. Although our experience is limited to three cases, biliary drainage was restored in each, suggesting that repeat RFA may be a useful option when local tumor progression compromises an existing SEMS.

From a safety standpoint, the findings were also favorable. Abdominal pain responsive to analgesics was the most frequent postprocedural adverse event. The modified CIRSE Grade 3a procedure-related complications consisted of two cases of cholangitis and one case of mild pancreatitis, all of which resolved without permanent sequelae. Because RFA and SEMS placement were components of the same index intervention, these events could not be reliably attributed to either component individually. No adverse event with findings suggestive of direct RFA-related thermal injury was identified, and no modified CIRSE Grade 4-5 procedure-related complications occurred, and there was no procedure-related mortality (Grade 6). Previous studies and contemporary reviews have reported abdominal pain,

cholangitis, cholecystitis, pancreatitis, and, less frequently, biliary injury among adverse events associated with endobiliary RFA, although reported rates vary according to access route, device, ablation protocol, and complication definition (7,23,24). The subcapsular hepatic hematoma observed in one patient occurred after the preceding percutaneous biliary drainage procedure and before RFA and was accordingly considered a drainage-related event rather than a complication of the index RFA/SEMS intervention.

In contrast to the relatively long estimated stent patency, median OS was only 95 days and was shorter than that reported in several previous percutaneous RFA series (9,17-19). Survival in MBO is influenced by much more than local biliary control, including the biology and extent of the underlying malignancy, performance status, metastatic burden, and access to effective systemic treatment. The predominance of pancreatic carcinoma in our cohort may partly explain the difference from studies composed mainly of patients with cholangiocarcinoma. In the absence of a stent-only control group, our survival data also cannot be used to infer an effect of RFA on OS.

This difference between local control and survival makes patient selection particularly important. The benefit of improved local tumor control or prolonged stent patency is most likely to matter in patients expected to survive long enough to benefit from sustained biliary drainage. For patients with very limited life expectancy, adding an ablative procedure to stenting may offer less clinical value. This concept is supported by recent comparative data demonstrating an association between performance status and OS after treatment for MBO (9). Performance status, disease extent, anticipated survival, and the feasibility of subsequent systemic therapy may therefore all be relevant when considering RFA in addition to stenting. Future studies should focus not only on whether RFA improves biliary outcomes, but also on which patients are most likely to benefit from adding it to stenting.

The broader evidence on survival remains mixed. Several comparative studies and meta-analyses have suggested improved OS with RFA plus stenting (9,27,28), whereas individual randomized trials have reported variable results (3-5). A recent meta-analysis restricted to randomized trials suggested an OS benefit but did not demonstrate a significant improvement in stent patency (7). Differences in tumor type and location, RFA technique, stent choice, systemic treatment, and patient selection probably contribute to these inconsistent findings. Our survival results should therefore be viewed as descriptive of this cohort rather than as evidence for or against a survival benefit from RFA.

One practical strength of this series is the relatively uniform treatment strategy: All included patients underwent primary percutaneous endoluminal RFA followed by SEMS placement. Within the overall pathway of initial biliary drainage followed by RFA and SEMS placement, the procedure achieved high technical success, substantial biochemical improvement among evaluable patients, an acceptable safety profile, and relatively few documented episodes of RBO. Larger prospective, preferably multicenter, controlled studies are needed to determine the incremental value of percutaneous endoluminal RFA over stenting alone and to identify the patients most likely to benefit from durable local biliary control.

Study Limitations

This study has several limitations. Its retrospective, single-center design and small sample size introduce potential selection bias and limit generalizability. The heterogeneity of the underlying malignancies, with pancreatic carcinoma predominating, may also have influenced patency and survival outcomes. RFA was not applied according to a predefined selection algorithm, and its use varied during the study period, creating an additional potential source of treatment-selection bias. Without a contemporaneous stent-only control group, the independent contribution of RFA to biochemical response, primary stent patency, or survival cannot be determined. The 30-day biochemical analysis was limited to 24 surviving patients with paired measurements, while variation in the interval between biliary drainage and RFA/SEMS placement may have influenced bilirubin changes. Although death was accounted for as a competing event in an additional cumulative-incidence analysis, only three RBO events occurred, and the limited number of patients remaining at risk at later time points reduced the precision of both the competing-risk and death-censored Kaplan-Meier estimates. Finally, the study was not designed to identify predictors of early mortality or optimal patient-selection criteria, and changes in systemic oncologic and supportive care over the long study period may have influenced survival.

CONCLUSION

In conclusion, the overall percutaneous treatment strategy, including initial biliary drainage followed by endoluminal RFA and SEMS placement, was technically feasible and was associated with effective biliary decompression and an acceptable safety profile in patients with MBO who were not candidates for curative surgical resection. Because biliary drainage preceded RFA in all patients, the observed biochemical improvement cannot be attributed to RFA alone. However, the local coagulative necrosis and tumor-debulking effect of RFA may provide an adjunctive contribution to maintaining the biliary lumen and prolonging patency after initial decompression. The magnitude of this independent contribution cannot be established in the absence of a control group. The observed primary stent patency was encouraging, but the small number of RBO events and limited OS in this advanced oncologic population require cautious interpretation. Patient selection is likely to be important in determining the clinical value of this treatment. Prospective comparative studies should clarify both the added benefit of RFA and which patients are most likely to benefit from its use.

Ethics

Ethics Committee Approval: The study protocol was reviewed and approved by the Gazi University, Faculty of Medicine Clinical Research Ethics Committee (approval no: 8, date: 08.05.2026). All study procedures were carried out in accordance with the principles of the Declaration of Helsinki.

Informed Consent: All patients provided written consent for the procedure; separate consent for retrospective study participation was waived by the ethics committee.

Footnotes

Authorship Contributions

Surgical and Medical Practices: F.Ö., M.K.A., Concept: F.Ö., M.K.A., E.I., Design: F.Ö., B.Ö., E.I., Data Collection or Processing: F.Ö., B.Ö., Analysis or Interpretation: F.Ö., E.I., Literature Search: F.Ö., Writing: F.Ö.

Conflict of Interest: The authors report no conflicts of interest.

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