Research Article

Pamukkale Medical Journal
doi:https://dx.doi.org/10.31362/patd.1792711

Percutaneous endobiliary ablation (RFA and MWA) prior to stenting: assessing feasibility and outcomes in malignant biliary obstruction

Stentleme öncesi perkütan endobiliyer ablasyon (RFA ve MWA): malign biliyer obstrüksiyonda uygulanabilirliğin ve klinik sonuçların değerlendirilmesi

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Received:29.09.2025 Accepted:10.12.2025

Abstract

Purpose: This study aims to evaluate the feasibility and effectiveness of percutaneous endobiliary Microwave Ablation (MWA) and Radiofrequency Ablation (RFA) prior to metallic stent placement for managing symptomatic, unresectable malignant biliary obstructions (MBOs).

Materials and methods: We conducted a retrospective cohort analysis of 122 patients diagnosed with malignant tumors causing biliary obstructions, comparing outcomes between those receiving stents only and those undergoing prior ablation. Data collected included patient demographics, procedural details, complication rates, stent patency, and overall survival.

Results: Among the 122 patients, 101 received stents alone, while 21 underwent ablation (13 with MWA and 8 with RFA). There was no significant difference in stent patency duration (255.7 days for ablation vs. 219.6 days for stent-only, p=0.282) or overall survival (average of 123 days, p=0.152). The complication rate was significantly higher in the ablation group (p=0.023).

Conclusion: While endobiliary ablative treatments before metallic stenting appear feasible for palliative care of unresectable MBOs, our findings indicate no significant improvement in stent patency or overall survival. Further randomized controlled studies are necessary to clarify the efficacy and necessity of these techniques.

Keywords: Malignant biliary obstruction, endobiliary ablative treatments, microwave ablation (MWA), radiofrequency ablation (RFA), stent patency.

Demirci M, Arslan M, Alver KH, Aslan HS, Vurgun S. Percutaneous endobiliary ablation (RFA and MWA) prior to stenting: assessing feasibility and outcomes in malignant biliary obstruction. Pam Med J 2026;19:331-340.

Öz

Amaç: Bu çalışma, semptomatik ve rezektabl olmayan malign biliyer obstrüksiyonlarının (MBO) palyatif tedavisinde metalik stent yerleştirilmeden önce perkütan endobiliyer Mikrodalga Ablasyon (MDA) ve Radyofrekans Ablasyonun (RFA) uygulanabilirliğini ve etkinliğini değerlendirmeyi amaçlamaktadır.

Gereç ve yöntem: Malign tümörlere bağlı safra yolu obstrüksiyonu tanısı alan 122 hastanın retrospektif kohort analizi yapıldı. Yalnızca stent yerleştirilen hastalar ile stent öncesi ablasyon uygulanan hastaların sonuçları karşılaştırıldı. Çalışmada hasta demografileri, girişimsel ayrıntılar, komplikasyon oranları, stent açıklığı ve genel sağkalım verileri incelendi.

Bulgular: Toplam 122 hastanın 101'ine yalnızca stent yerleştirilirken, 21 hastaya ablasyon uygulandı (13 MDA, 8 RFA). Stent açıklığı süresinde (ablasyon grubu 255,7 gün; yalnız stent grubu 219,6 gün; p=0,282) veya genel sağkalımda (ortalama 123 gün; p=0,152) anlamlı fark saptanmadı. Ablasyon grubunda komplikasyon oranı anlamlı derecede yüksekti (p=0,023).

Sonuç: Rezektabl olmayan MBO'ların palyatif tedavisinde metalik stentleme öncesi endobiliyer ablasyon yöntemleri uygulanabilir görünmekle birlikte, çalışmamız stent açıklığı veya genel sağkalım açısından anlamlı bir iyileşme göstermemektedir. Bu tekniklerin etkinliği ve gerekliliğini netleştirmek için ileriye dönük randomize kontrollü çalışmalara ihtiyaç vardır.

Anahtar kelimeler: Malign biliyer obstrüksiyon, endobiliyer ablatif tedaviler, mikrodalga ablasyon (MDA), radyofrekans ablasyon (RFA), stent açıklığı.

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Demirci M, Arslan M, Alver KH, Aslan HS, Vurğun S. Stentleme öncesi perkütan endobiliyer ablasyon (RFA ve MWA): malign biliyer obstrüksiyonda uygulanabilirliğin ve klinik sonuçların değerlendirilmesi. Pam Tıp Derg 2026;19:331-340.

Introduction

Malignant biliary obstructions (MBO) frequently cause severe symptoms, leading to a significant decline in the quality of life for affected patients. The majority of MBO cases are associated with pancreatic ductal adenocarcinoma and cholangiocarcinoma. Other contributing factors include ampullary carcinoma, gallbladder carcinoma, duodenal adenocarcinoma, lymphoma, and metastatic lymphadenopathy [1]. Palliative treatments for unresectable MBO aim to relieve symptoms of biliary tract obstruction and improve overall well-being [2, 3]. Although stent placement is effective in achieving these goals, the ongoing risk of stent occlusion necessitates the exploration of new techniques. One such approach is the use of percutaneous endobiliary Microwave Ablation (MWA) or Radiofrequency Ablation (RFA) prior to stent insertion, which shows promise in extending stent patency [4-6].

This retrospective study evaluates patients who underwent percutaneous transhepatic endobiliary MWA or RFA before metallic stent placement. The study aims to assess the feasibility and effectiveness of these procedures in managing symptomatic, inoperable MBOs. Key outcomes include technical success, complication rates, stent patency, symptom relief, and overall survival, providing a comprehensive assessment of this combined therapeutic approach. The findings are expected to be valuable in the management of MBO and in guiding clinicians toward more effective patient care strategies.

Materials and methods

Study design and patient selection

This study was approved by the Pamukkale University Non-Invasive Clinical Research Ethics Committee (approval date: 08/12/2020 and approval number: 23). All methods were carried out by relevant guidelines and regulations. This study is a retrospective cohort analysis based on electronic medical records, approved by the Institutional Review Board.

Patients aged 18 to 85 who underwent palliative percutaneous metallic stent placement for pathologically diagnosed malignant tumors causing bile duct narrowing were analyzed in two groups. The first group consisted of patients who received direct metallic stent placement without any prior intervention, while the second group included patients who underwent endobiliary RFA and MWA treatments before stent placement. The enrollment period spanned from September 2014 to December 2020. Collected data included patient demographics, diagnoses, bilirubin levels, procedural details, complications, stent patency, and survival outcomes. Patients who were pregnant, had a life expectancy of less than three months, had uncorrectable coagulopathy, or had undergone endoscopic RFA, MWA, or stent placement were excluded from the study.

Procedure details

A biliary drainage catheter was inserted in all patients prior to the procedure. Stent placement was performed approximately 7 days after catheter insertion. For the first group, the procedure was conducted under sterile conditions with conscious sedation and local anesthesia. For the second group of patients, who underwent RFA or MWA ablation before stenting, the procedure was carried out under general anesthesia.

Radiofrequency Ablation (RFA): The Viva Combo RF Generator VCS10 model, manufactured by STARmed Co. Ltd. (South Korea) and distributed by Taewoong Medical, was used for RFA. The RF probe used was the ELRA™ electrode (Taewoong Medical), a bipolar catheter from the same manufacturer, featuring four electrodes with two length variations: 33 mm and 18 mm. After preparing the patient similarly to the metallic stenting procedure, the vascular sheath guided the RF ablation probe through the wire to the narrowed area. Following confirmation of proper placement of the probe markers connected to the RF generator, the ablation procedure was performed. Subsequently, the RF probe was removed, and the stent was positioned at the level of the constriction using the same wire.

Microwave Ablation (MWA): The MWA system comprised a microwave generator (AveCure Intelligent Controller, MedWaves Inc., CA, USA) and a 14 G, 120 cm microwave antenna (AveCure SuperFlex Smart Catheter, MedWaves Inc., CA, USA). The ablation antenna, which had a flexible 120 cm shaft and no lumen, featured a standard 2.5 cm electrode at its tip that delivered energy for ellipsoid-shaped coagulation. Due to its solid internal structure, the antenna could not operate over a wire but was advanced through a 7F vascular sheath or catheter or guided alongside a guidewire to the treatment area. The size of the ablation zone was adjusted by controlling the temperature and duration on the microwave generator. After performing MWA, the existing drainage catheter was removed using a hydrophilic guidewire, and a vascular sheath was placed over the wire. Cholangiography images then guided the advancement of the MW antenna for ablation. Subsequently, the MW antenna was removed, and a balloon-expanded or self-expandable metallic stent was placed through the vascular sheath in the narrowed area.

The administration of contrast material after ablation facilitated cholangiographic imaging to assess potential complications and evaluate stent patency. A biliary drainage catheter, used temporarily, helped prevent hematomas and stent occlusion caused by debris. The catheter was removed once stent patency was confirmed and normal bile flow was verified in the control cholangiogram.

Postprocedure follow-up

After the procedure, all patients were observed for 24 hours to identify any potential complications. They received intravenous administration of a third-generation cephalosporin one hour before the intervention, and intravenous hydration was maintained until discharge. During the first month, patients underwent weekly physical examinations, laboratory analyses, and ultrasonography. Follow-up continued on a monthly basis thereafter. Throughout the follow-up period, various parameters were carefully recorded, including the patients' general condition, procedural complications, stent patency, survival time, serum bilirubin levels, liver function tests, and other relevant laboratory values. For patients showing progressive bilirubin elevation during follow-up, cholangiography was performed to assess stent occlusion. If needed, interventions were planned during the same session.

Statistical analysis

Statistical analysis was conducted using SPSS 22.0 (IBM SPSS Statistics for Windows, IBM Corp., Armonk, NY, USA) software. Descriptive statistics summarized patient demographics, procedural details, and outcome measures. Continuous variables were analyzed using the Mann–Whitney U test due to non-normal distribution. Differences between categorical variables were analyzed using the Chi-square test or Fisher's exact test where appropriate. Kaplan-Meier curves were used to evaluate patient survival and stent patency durations (Figure 5, 6). A significance level of $p<0.05$ was considered statistically significant for all analyses.

Results

Patient demographics and treatment overview

A cohort of 122 patients with unresectable tumors received palliative treatment through metallic stent insertion for malignant biliary obstruction. Of these, 101 patients underwent stent placement without ablation, while 21 patients received ablation: 13 with MWA and 8 with RFA. Four patients underwent repeat endobiliary ablation due to intrastent occlusion; however, survival and primary stent patency analyses were performed on a per-patient basis. Representative clinical and imaging examples of patients undergoing endobiliary ablation and re-intervention are illustrated in Figures 1-4.

Mann–Whitney U analysis showed no statistically significant differences between groups. At one week, the difference approached statistical significance ($Z=1.93$, $p=0.054$). At one month ($U=607.5$, $Z=1.45$, $p=0.148$) and six months ($U=22.0$, $Z=-0.59$, $p=0.565$), no significant differences were observed.

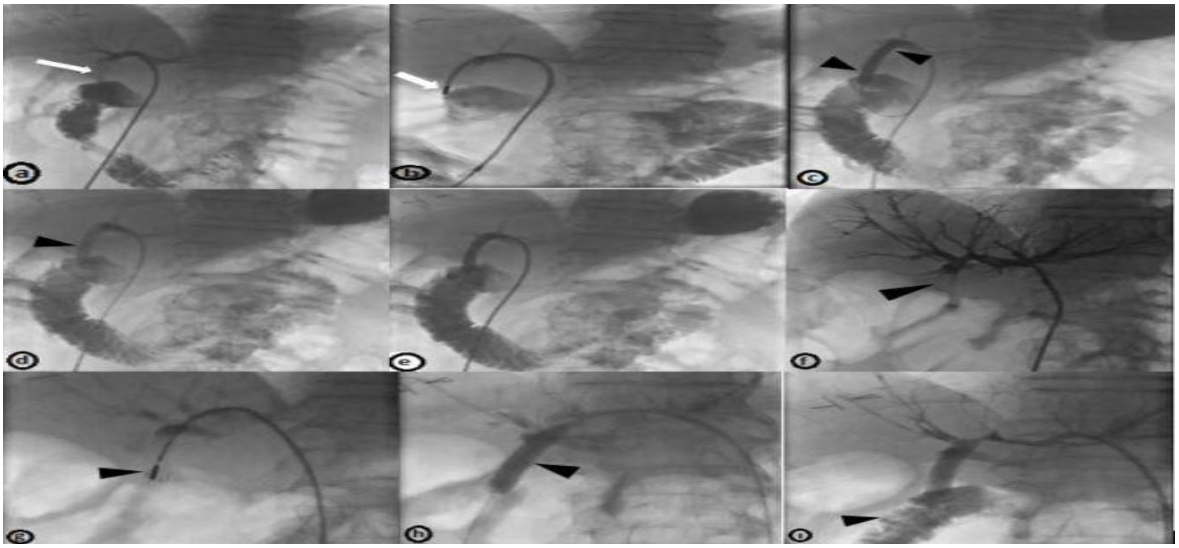

Figure 1. A 69-year-old male patient with primary colon adenocarcinoma and extensive liver metastases was found to have biliary tract dilation and a malignant stricture in the midsection of the common bile duct during his evaluations. The patient was deemed inoperable, and MWA along with stenting was performed in the area of the stricture. Approximately 3.5 months later, due to elevated bilirubin levels, cholangiography revealed stent occlusion. The patient underwent in-stent MWA and re-stenting

a: Percutaneous transhepatic cholangiography showed a stricture in the common bile duct (arrow). b: MWA procedure was applied to the stricture area (arrowhead). c: After the ablation procedure, a balloon was applied to the stricture area (arrowheads). d: A balloon-expandable stent was placed in the ablation area (arrowhead). e: Stent patency was demonstrated with contrast injection. f: During follow-up, stent occlusion was observed (arrowhead). g: MWA was applied inside the stent (arrowhead). h: After ablation, a balloon-expandable re-stenting procedure was performed (arrowhead). ı: Lumen patency was confirmed by contrast injection, with contrast passing into the duodenum (arrowhead)

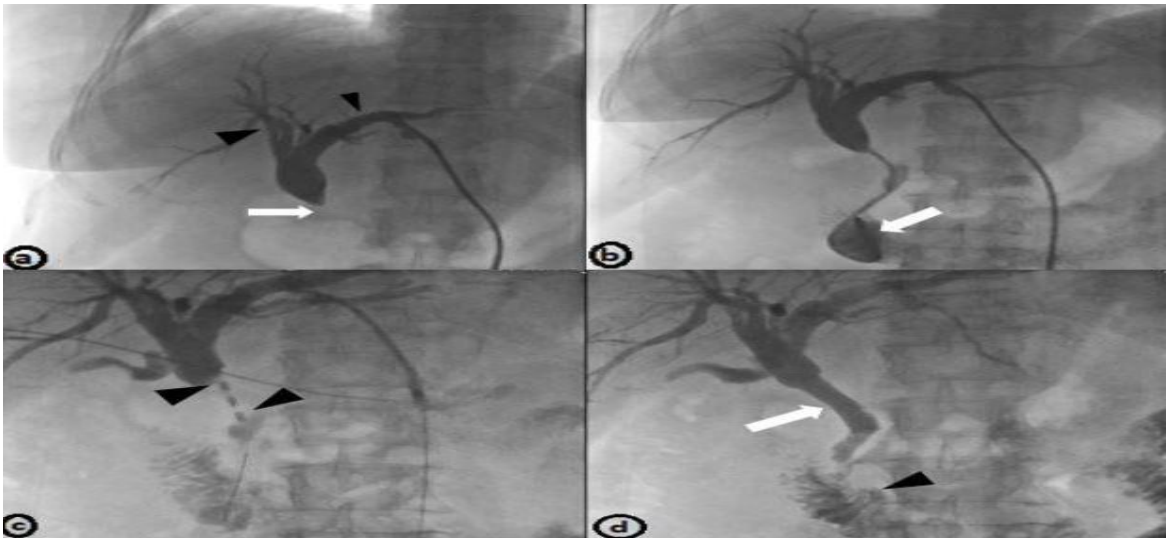

Figure 2. A 70-year-old female patient diagnosed with pancreatic adenocarcinoma had a tumoral obstruction in the distal common bile duct and associated bile duct dilation. Due to her additional comorbidities, high tumor burden, and evidence of invasion, the patient was deemed inoperable. Therefore, for palliative purposes, RFA followed by metallic stenting was performed

a: Percutaneous transhepatic cholangiography shows a stricture in the distal part of the common bile duct (arrow) and dilation of the intrahepatic bile ducts (arrowheads). b: Insertion of an internal-external biliary drainage catheter (arrow) after passing through the stricture. c: Application of radiofrequency ablation to the stricture area (arrowheads). d: Following the ablation, a balloon-expandable stent (arrow) is placed in the stricture region, and the passage of contrast medium (arrowhead) into the duodenum is demonstrated

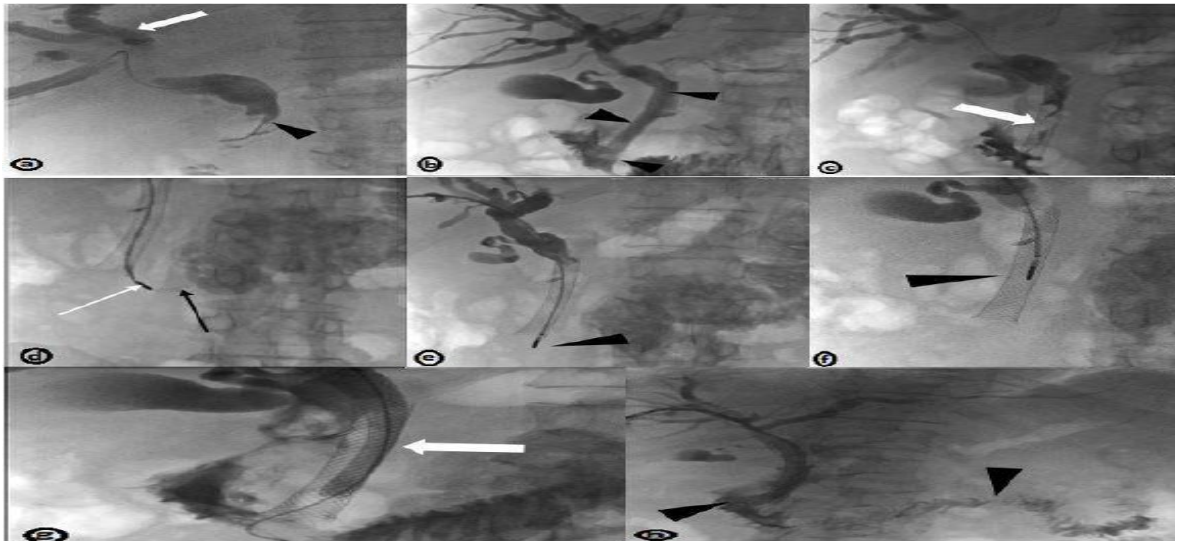

Figure 3. A 71-year-old male patient with colon adenocarcinoma had extensive liver metastases and a stricture in the distal part of the common bile duct due to mass effect. The patient was deemed inoperable and underwent metallic stenting. About one month later, follow-up revealed stent occlusion, and in-stent MWA and re-stenting were performed

a: In percutaneous transhepatic cholangiography, a stricture is observed in the distal part of the common bile duct (black arrow), along with dilation of the intrahepatic bile ducts (white arrow). b: Placement of a self-expanding wall stent in the stricture area (black arrows). c: Follow-up shows occlusion allowing minimal contrast passage within the stent (white arrow). d: The MWA probe (white arrow) is positioned distally to the stent through the catheter (black arrow). e, f: MWA is applied distally to the stent and within the stent (black arrows). g: A self-expanding stent is placed inside the stent after ablation (white arrow). h: Administration of contrast material shows the lumen patency and passage of contrast into the duodenum (black arrows)

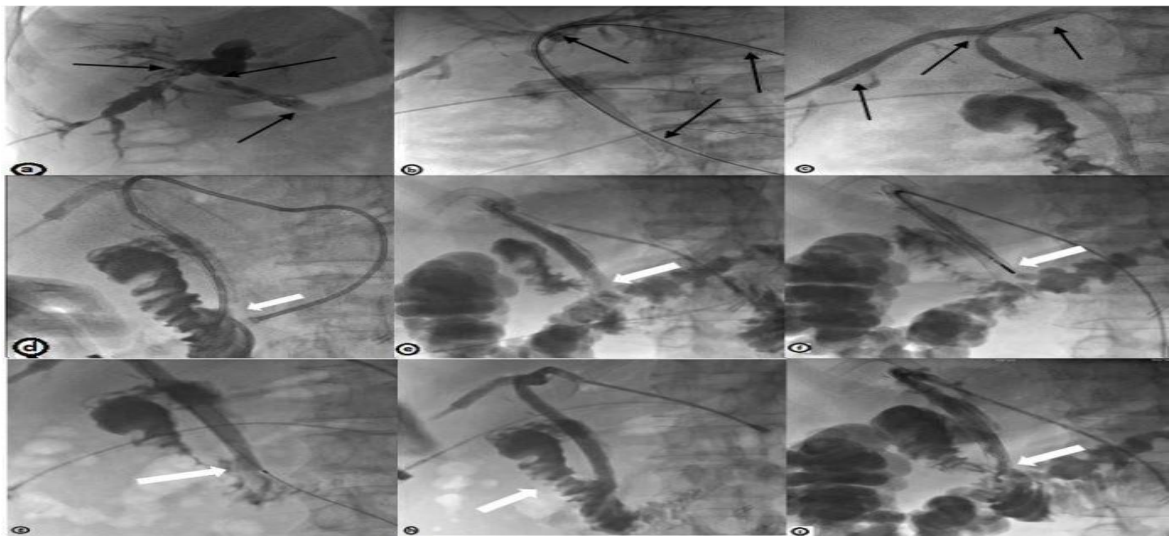

Figure 4. A 62-year-old male patient diagnosed with colon adenocarcinoma had strictures in the intra- and extrahepatic bile ducts due to multiple liver metastases. A T-shaped stent was placed in the patient. Early occlusion and migration towards the proximal side due to tumor overgrowth were observed distal to the stent extending into the duodenum, leading to the performance of instent MWA and re-stenting

a: In percutaneous transhepatic cholangiography, strictures were present at the distal and proximal segments of the common bile duct, as well as at the hepatic canal levels (arrows). b, c: A T-shaped stenting procedure was performed from the left to the duodenum and from the right to the left at the site of the stricture (arrows). d, e: At the distal end of the stent extending into the duodenum, there was a narrowing due to tumor overgrowth and evidence of proximal migration of the stent (arrows). f: Instent microwave ablation was performed at the site of the stricture (arrow). g: A wall stent was placed in the stricture area after the ablation procedure (arrow). h, i: The contrast agent passed through the stent and reached the duodenum (arrows)

Direct bilirubin level trends following stenting

Before biliary stenting, the average direct bilirubin value at admission was 9.53. Direct bilirubin levels showed a progressive decline in both groups after stent placement. At one week, the ablation group exhibited lower bilirubin levels compared to the stent-only group (2.97±3.21 vs. 4.61±4.22). This trend persisted at one month (1.18±1.47 vs. 2.18±3.10). By six months, bilirubin levels were similar between the two groups (0.52±0.64 vs. 0.39±0.39). Despite a trend toward a more rapid decrease in bilirubin levels in the ablation group during the early follow-up period, the differences between groups did not reach statistical significance. The progressive reduction in sample size at later time points, particularly at six months, reflects the high mortality rate in this patient population and may have limited the statistical power of the analysis. There was no statistically significant difference in direct bilirubin levels between the ablation and stent-only groups at 1 week, 1 month, and 6 months (p=0.054, p=0.148, and p=0.565, respectively) (Table 1).

Table 1. Changes in direct bilirubin levels between groups (Mann–Whitney U test)

Timepoint	Ablation (mean ± SD)	Stent only (mean ± SD)	Z Test	*p*
1 week	2.97±3.21 (n=21)	4.61±4.22 (n=78)	1.93	0.054
1 month	1.18±1.47 (n=17)	2.18±3.10 (n=58)	1.45	0.148
6 months	0.52±0.64 (n=6)	0.39±0.39 (n=9)	-0.59	0.565

Z:Mann–Whitney U test, Missing values were not imputed and represent patients who died during follow-up

Procedure-related complications

Among the 101 patients who received metallic stents without ablation, 11 experienced complications, including intraoperative bleeding (n=4), early-onset cholangitis (n=3), liver abscess (n=2), bile leakage leading to abscess formation (n=1), and stent overgrowth due to migration (n=1). In the ablation group of 25 patients, one developed a duodenal fistula, and another had an early-onset cholangitic abscess, resulting in fatal cholangiosepsis. Additional complications noted included subcapsular liver abscess and subcutaneous bile leak collection. Overall, the complication rate was significantly higher in the ablation group compared to the non-ablation group (p=0.023) (Table 2). Severe complications and re-interventions related to stent occlusion and tumor overgrowth are demonstrated in representative cases (Figures 1, 3, and 4).

Table 2. Comparison of complications, survival, and stent patency between groups

Outcome	Ablation (n=21)	Stent only (n=101)	*p*	Test
Complications	4 (19.0%)	11 (10.9%)	0.023	§
Survival (days)	118.4±96.2	124.1±110.5	0.152	††
Stent patency (days)	255.7±30.1	219.6±17.8	0.282	††

§ Fisher's exact test, †† Log-rank test (Kaplan–Meier analysis)

Survival analysis

The average survival time was 123 days (range: 2-1055). Two patients who underwent ablation and three who received stent placement without ablation are still alive. There was no statistically significant difference in survival between the two groups (p=0.152) (Figure 5, Table 2).

Stent patency durations

The average stent patency was 255.7 days (±30.1) in the ablation group and 219.6 days (±17.8) in the stent-only group. There was no statistically significant difference between the two groups (p=0.282) (Figure 6, Table2).

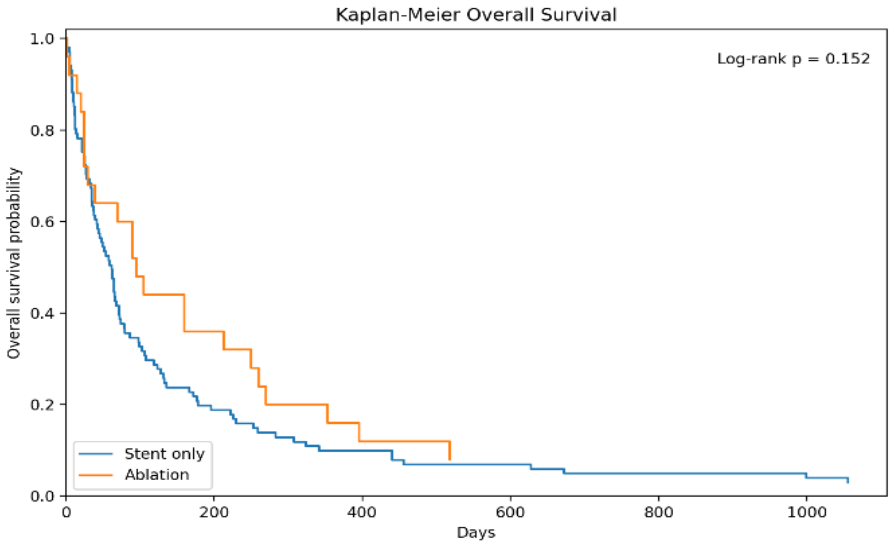

Figure 5. Kaplan–Meier overall survival curves for the ablation and stent-only groups. Survival distributions were compared using the log-rank test

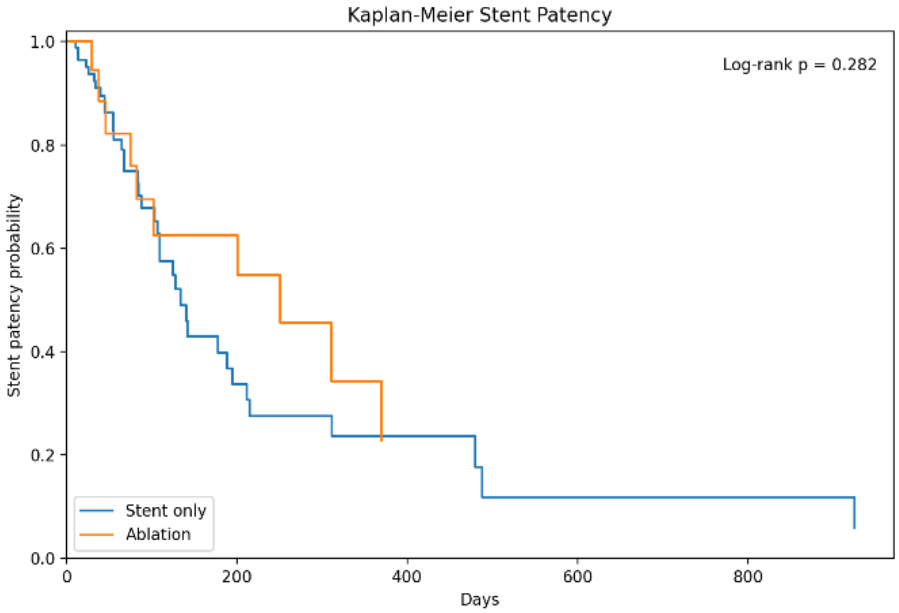

Figure 6. Kaplan–Meier stent patency curves for the ablation and stent-only groups. Patency distributions were compared using the log-rank test

Discussion

The investigation into percutaneous transhepatic endobiliary MWA and RFA as adjunctive therapies prior to metallic stenting for symptomatic, inoperable biliary obstructions has yielded valuable insights. While previous studies have shown that endobiliary RFA may reduce tumoral or epithelial hyperplasia and improve biliary drainage with favorable feasibility, technical success, and safety profiles [7-13], our findings did not demonstrate a significant improvement in stent patency when either RFA or MWA was performed before stent placement (p=0.282). Metallic stents have been shown to reduce the risk of recurrent obstruction more effectively than plastic stents; however, despite their longer patency, many patients still experience stent dysfunction requiring repeat drainage procedures [14, 15]. Various additional strategies—such as polymer-covered stents, intraductal brachytherapy, photodynamic therapy, and endobiliary RFA—have been investigated to prolong patency [16, 17], yet coated stents have not consistently demonstrated superiority over bare-metal stents and may carry higher migration risk [18].

The clinical course and technical challenges encountered in our cohort are further exemplified by the representative cases presented in this study (Figures 1–4), including in-stent tumor overgrowth, occlusion, and the need for repeat ablation and re-stenting.

Endobiliary RFA devices designed specifically for intraductal use have shown potential for reducing epithelial hyperplasia and inhibiting tumor ingrowth [19]. Several studies—including those by Kallis et al. [12], Cui et al. [20], and Li et al. [21] — have reported improved patency and longer survival for patients undergoing RFA combined with stenting compared with stenting alone Studies by Uyanık et al. [9], Pekçevik and Ballı [10], and Wu et al. [22], likewise support the potential benefit of ablative therapies performed before stenting. However, most of the existing evidence is centered around RFA. Published data on endobiliary MWA remain extremely limited, and comparisons between RFA and MWA are not yet conclusive. Technical differences—such as depth of tissue penetration, thermal profile, and ablation geometry—may result in distinct biological effects. Although MWA theoretically enables more uniform and deeper energy deposition, the clinical relevance of these differences for biliary patency and long-term outcomes has not yet been established. Future comparative studies are required to clarify the specific advantages or disadvantages of each modality.

Another important aspect of our findings involves the heterogeneity of the patient population. Tumor types such as pancreatic adenocarcinoma, cholangiocarcinoma, and metastatic disease differ considerably in biological behavior, growth dynamics, and response to local interventions. These variations may contribute to the diverse outcomes observed in stent patency and survival. Subgroup analyses were limited by the small number of patients in the ablation cohort, which also hindered meaningful comparisons between RFA and MWA. Furthermore, the retrospective design introduces potential selection bias, and variations in disease stage, pathological diagnosis, and clinical condition add complexity to the interpretation of results. These challenges are further compounded by the short life expectancy and limited follow-up period of the population, many of whom had failed or were deemed unsuitable for ERCP (Figure 4).

Taken together, although endobiliary RFA and MWA appear technically feasible and safe, the present study reinforces the need for larger, well-designed, prospective trials to determine their true clinical impact. Such studies should adequately account for tumor heterogeneity, disease stage, and modality-specific technical parameters to better define the role of endobiliary ablation in the management of malignant biliary obstruction.

In conclusion, although endobiliary ablative techniques (RFA/MWA) performed prior to metallic stenting demonstrate procedural feasibility and technical safety in the palliative management of unresectable malignant biliary obstructions, their independent impact on stent patency and overall survival remains uncertain. While prior studies have suggested that RFA may reduce epithelial hyperplasia and thereby prolong stent functionality, the consistency of these findings is limited, and evidence regarding MWA remains particularly scarce. In our cohort, the ablation group exhibited a more rapid decline in bilirubin levels and a clinically favorable tendency toward improved stent patency and

survival; however, these differences did not reach statistical significance, underscoring the possibility of a potential yet unconfirmed benefit. To delineate the true therapeutic value of endobiliary ablation, further large-scale, prospective, and ideally randomized studies are required—studies capable of controlling for tumor biology, patient heterogeneity, and modality-specific technical parameters. Such investigations will be essential to clarify the role of endobiliary ablation within biliary drainage strategies and to determine whether these modalities should be incorporated into routine therapeutic algorithms.

Data availability statement: The datasets generated and analyzed during the current study are not publicly available due to none of the data types requiring uploading to a public repository but are available from the corresponding author on reasonable request.

Funding: The authors did not receive support from any organization for the submitted work.

Our study was presented at the Türkrad 2019 congress while it was in the thesis phase.

Authors' contributions: M.D. is the main author of the study; he conducted the thesis work, collected and analyzed the data, and drafted the manuscript. He also actively participated in performing the interventional procedures on the patients included in the study. M.A. supervised the study design, provided scientific guidance, contributed to the final approval of the manuscript, and was also involved in performing the interventional procedures. H.S.A. and S.V. contributed to performing the interventional procedures on the patients and assisted with data collection. K.A. performed the statistical analyses, contributed to summarizing the thesis and transforming it into a manuscript, and carried out the English language revision of the paper.

Conflict of interest: No conflict of interest was declared by the authors.

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