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INTERVENTIONAL RADIOLOGY

ORIGINAL ARTICLE

Managing occluded stents in biliary obstruction using radiofrequency ablation combined with ^{125}I-strand brachytherapy

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PURPOSE
We aimed to assess the effectiveness of percutaneous radiofrequency ablation (PRFA) combined with iodine-125 (^{125}I) seed strand brachytherapy (^{125}I-BT) for treatment of occluded biliary stents.

METHODS
From November 2015 to September 2017, 13 consecutive patients with occluded biliary metal stents, implanted for malignant obstruction, underwent PRFA combined with ^{125}I-BT to reopen the bile duct. Data included clinical and technical success, stent patency, complications, and overall survival.

RESULTS
The clinical and technical success rates were both 100%. One month after treatment, the total serum bilirubin level had decreased significantly ($p < 0.001$). Early complications of cholangitis or hemobilia were experienced by one patient each. Three patients (23.1%) had late complications, including two cases of cholangitis and one case of cholecystitis. During the mean follow-up of 233±82.9 days (range, 88–365 days), the stent patency time was 239±26.5 days (95% CI, 187–291 days), and the 6-month stent patency rate was 68.4%. Five patents died; the mean survival time was 298±30.1 days (95% CI, 239–358 days). The 6-month survival rate was 83%.

CONCLUSION
PRFA therapy combined with ^{125}I-BT is feasible and safe for patients with occluded metal stents placed for malignant biliary obstruction. Nevertheless, randomized controlled trails are needed to confirm the effectiveness of this new approach.

Self-expandable metallic stent (SEMS) placement is an effective treatment for malignant biliary obstruction (1). However, stent restenosis occurs within 6 months in over 50% of patients, due to tumor ingrowth, overgrowth, epithelial hyperplasia, and biliary sludge formation (2, 3). There are no clear recommendations regarding how to reopen SEMS occlusions. Recently, some studies reported the safety and efficacy of a Habib EndoHPB percutaneous radiofrequency ablation (PRFA) catheter for re-opening occluded SEMSs, with a median stent patency time of 102–234 days (4–9).

We previously showed that intraluminal brachytherapy (ILBT) with low dose rate (LDR) iodine-125 (^{125}I) seed strands is effective for treatment of malignant biliary obstruction, prolonging stent patency (10, 11). To the best of our knowledge, there are no reports regarding the use of PRFA and ILBT synchronously to re-open SEMS occlusions. This study assessed the feasibility and effectiveness of PRFA combined with ^{125}I seed strand brachytherapy (^{125}I-BT) for the treatment of malignant biliary occlusion after stenting.

Methods

This study was approved by the Ethics Committee of our hospital (2019-KY-383). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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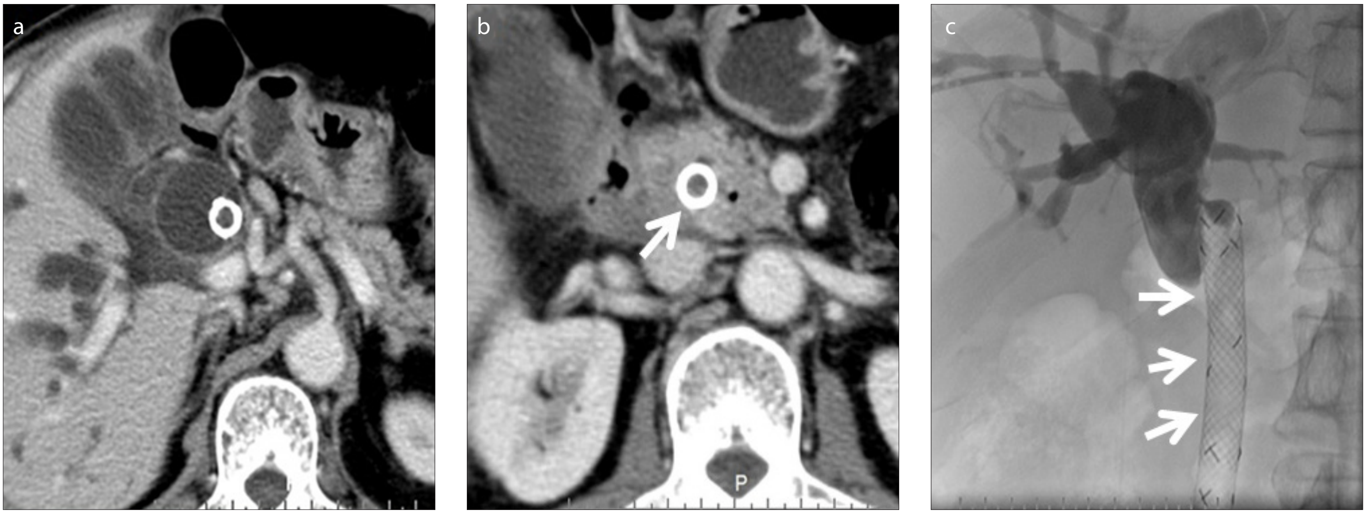

Figure 1. a–c. Axial CT images **(a, b)** reveal biliary dilatation and tumor ingrowth *(arrow)* within the metal biliary stent. Percutaneous transhepatic cholangiography **(c)** shows the occluded biliary stent *(arrows)*.

Patient characteristics

From November 2015 to September 2017, 13 patients with occluded SEMS obstruction underwent PRFA combined with ^{125}I-BT for recanalization of the bile duct. The selected patients met the following eligibility criteria: previous non-coated biliary stent placement; final malignant pathology; refusal to undergo surgery or absence of indications for surgery; and no previous PRFA or ILBT treatment. Exclusion criteria were: tumor volume >70% total liver volume; ECOG (Eastern Cooperative Oncology Group) performance >2; Child-Pugh C status; severe coagulation dysfunction or refractory ascites; or refusal to participate in the study. All patients underwent enhanced magnetic resonance imaging (MRI) or computed tomography (CT, Siemens) before treatments (Table 1; Fig. 1).

Main points

- Percutaneous radiofrequency ablation combined with ^{125}I seed strand brachytherapy is feasible and effective for patients with an occluded self-expandable metallic stent (SEMS) in malignant biliary obstruction.
- A puncture approach from under the diaphragm to the bile duct branch should be coronally flat (avoiding the oblique upward side).
- The ^{125}I strand length should be longer than the occluded portion of the SEMS, to inhibit tumor ingrowth more effectively.
- The dual guidewire technology using an 8 F long sheath can quickly complete the drainage catheter and ^{125}I strand implantation, greatly shortening procedural time.
- Theoretically, endobiliary RFA destroys the tumor within the stent, and continuous ^{125}I-BT inhibits tumor ingrowth and granulation hyperplasia.

Device

An intraductal radiofrequency ablation (RFA) catheter (Habib EndoHPB, EMcision Limited) was connected to a compatible radiofrequency generator (1500X RITA, Fremont). The length depended on the length of the stricture, with overlap of treated areas of approximately 1 cm. LDR-^{125}I seeds (model type 6711 with a half-life of 59.6 days) were made by the Chinese Atomic Energy Science Institution of China. Each seed was 0.8×4.5 mm (radioactivity 25.9 MBq) and emitted 35.5 keV gamma rays. The device included a 3 F catheter (Cook Inc.), with tip parts reduced by the heat shrinkable method 2 cm distal to the catheter tip, to prevent seed displacement into the duodenum. The number of ^{125}I seeds used equaled the stent length in mm divided by 4.5. The ^{125}I seeds were arranged one-by-one within the catheter. There was a hole 1 cm from the tip, for rapid guidewire exchange.

Procedure 1: Intraductal RFA

All procedures were performed under local anesthesia (2% lidocaine) and dezocine (Dezocine Injection, Yangzijiang pharmaceutical co. LTD) by intravenous injection. First, percutaneous transhepatic cholangiography was performed to confirm the location of the biliary SEMS (Micro-Tech) obstruction, under digital subtraction angiography. Second, an Amplatz Super Stiff Guidewire (Boston Scientific) was placed across the metal stent occlusion zone. According to the stricture length, sequential PRFA was applied to treat the entire stricture, with an overlap of treated areas of approximately 1 cm (10 W × 120 s). Balloon ductoplasty (8×60 mm Boston Scientific balloon catheter) was performed by moving the guidewire back and forth within the stent to remove ablated tissue and debris from the occluded SEMS (Fig. 2a).

Procedure 2: ILBT with ^{125}I strand

An 8 F sheath (Cook Inc.) was inserted across the metal stent, and another 0.035-inch guidewire (Glidewire, Terumo) was inserted into the sheath to establish double guidewire approaches. After withdrawing the sheath, the ^{125}I strand was inserted across one guidewire using the rapid exchange technique (the guidewire was inserted from the tip hole to another hole 1 cm from the catheter tip). An 8.5 F drainage catheter (Cook Inc.) was inserted along another guidewire across the occluded SEMS to the duodenum (Fig. 2b, 2c). The 8.5 F drainage catheter and the ^{125}I seed strand were fixed to nearby skin, together.

Evaluation and follow-up

The primary endpoints of the study were technical success, clinical success, and stent patency. Secondary endpoints were complications (early and late) and patient survival. Technical success was defined as completion of both procedures (PRFA and ILBT) and good contrast flow through the stent at the 1-month follow-up. Clinical success was considered a substantial decrease in bilirubin (>75%), relative to the pretreatment

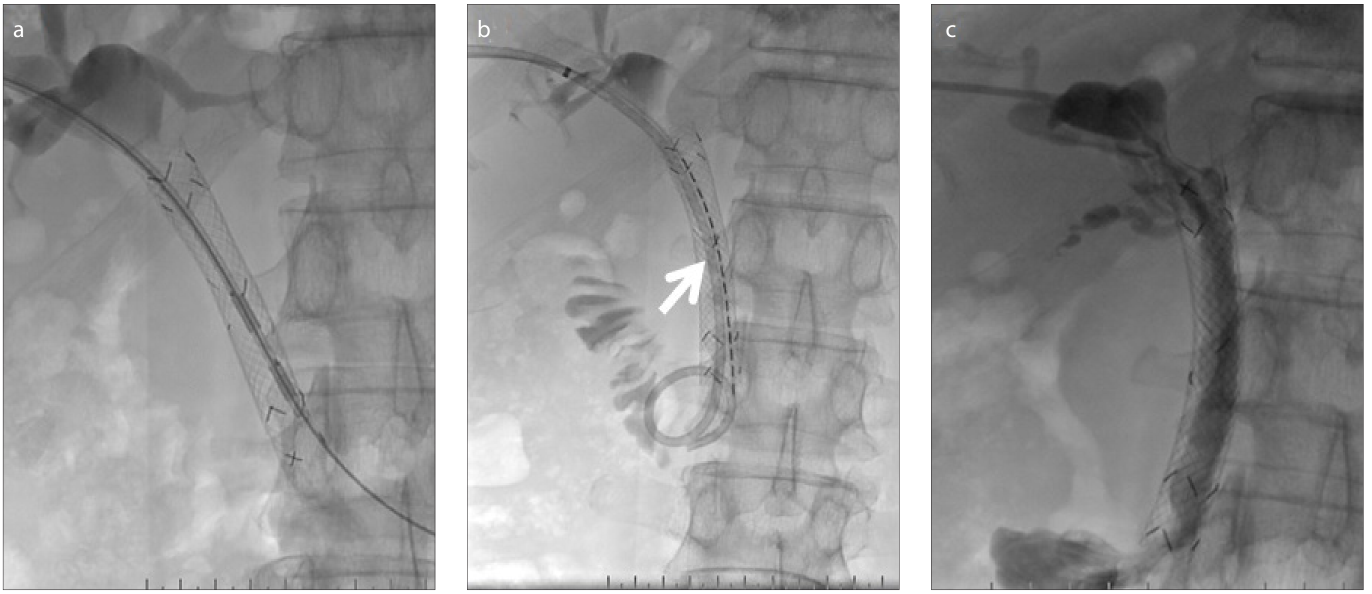

Figure 2. a–c. Percutaneous intraductal radiofrequency (10 W × 120 s) was done within the occluded stent **(a)**. Intraluminal BT with low-dose-rate ^{125}I strand (**b,** *arrow*). Cholangiography **(c)** confirmed the stent patency after combination therapy at 1 month.

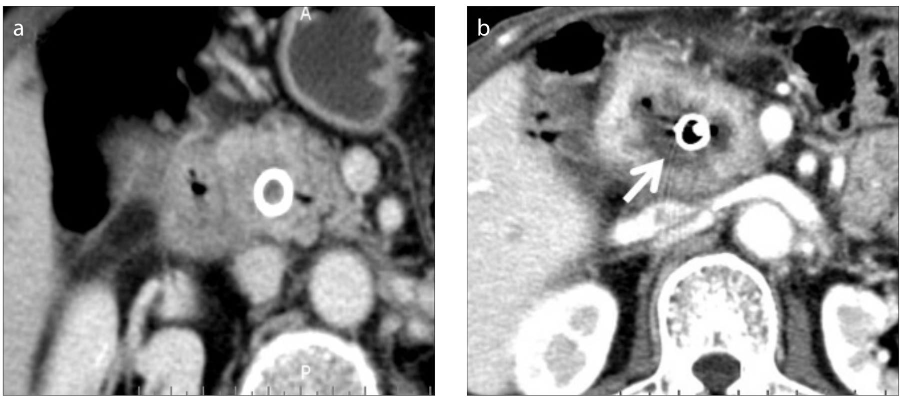

Figure 3. a, b. Axial pretreatment CT image **(a)** shows tumor ingrowth within the metal biliary stent. Axial posttreatment CT image (**b**) shows the stent patency after combination therapy at 1 month, and the low-density area around the stent represents tumor necrosis *(arrow)*.

value, within 1 month. Stent patency was defined as no recurrence of biliary occlusion with increased serum bilirubin (twice the normal level), and biliary dilatation on CT, MRI, or ultrasound (Fig. 3). Early and late complications occurred within or after 30 days of the procedure, respectively (12).

Single-photon emission CT (SPECT)/CT (Siemens) was performed to evaluate the dose distribution of radioactive seeds within 3 days of ^{125}I strand implantation. All patients were followed up every 2 weeks for the first month, and thereafter as per the oncology follow-up protocol. If SEMS reocclusion was suspected, patients underwent repeat PTCD or endoscopic retrograde cholangiopancreatography (ERCP). To provide a precise description of the dose and to compare with related studies, 5 mm from the source axis was set as the dose reference point, from which the dose was calculated by a computerized treatment plan system (TPS, Cancer Physiotherapy Center of Peking University).

Statistical analysis

The data are expressed as the median (range) or mean ± standard deviation, and were analyzed using SPSS 11.0 software. The paired-sample *t*-test was applied to compare the serum bilirubin pre-PRFA (baseline) with the post-PRFA/ILBT treatment at 1 month. Values of $p < 0.05$ were defined as statistically significant.

Results

The study included 13 patients (seven men) with mean age 59.6±11.4 years (range, 45–74 years). Primary diagnoses were gallbladder cancer (n=2), cholangiocarcinoma (n=5), and pancreatic cancer (n=6). Eight patients underwent gemcitabine plus cisplatin chemotherapy, while 5 patients did not undergo any radiotherapy and chemotherapy before stent occlusion. All final malignant pathologies were diagnosed by forceps biopsy via the PTCD approach (n=9) or the ERCP approach (n=4). Seed activity was 25.9 Mbq, with no ^{125}I seeds lost as confirmed by fluoroscopy and SPECT/CT. The estimated radiation dose at the reference point was 27.2±3.3 Gy.

PRFA and ILBT were synchronously completed successfully in all patients, for a technical success rate of 100%. Cholangiograms, MRI, or CT obtained within 1 month after stent placement showed adequate biliary drainage, with decompression of the biliary ducts. Serum bilirubin 1 month after the treatment (57.3±15.4 µmol/L, range 33.3–88.2 µmol/L) was significantly less than at baseline (176.6±60.2 µmol/L, range 98.3–302.1 µmol/L; $p < 0.001$). The drainage catheters and ^{125}I strands were removed from all the patients.

Patient 4 had early complications (bilirubinemia), due to portal vein branch injury, as confirmed by percutaneous cholangiography. After adjusting the position of the drainage tube hole, the bilirubinemia resolved within 3 days. Patient 9 had cholangitis (fever and abdominal pain). These symptoms resolved within 7 days after antibiotics and acid suppression treatment.

Table 1. Characteristics and outcomes of the 13 patients included in the study

	Gender	Age, y	Diagnosis	TNM	SBT, µmol/L		OT, min	Complication		SR (d)	FU, d	Outcome
					Preop	Postop		Early	Late			
1	Male	56	CC	T2N2M0	153.6	52.1	32	NA	NA	NA	207	Alive
2	Male	51	PC	T2N0M0	121.7	43.6	45	NA	NA	NA	165	Death
3	Female	66	CC	T3N1M1	98.3	33.3	24	NA	NA	TI (155)	306	Alive
4	Male	70	CC	T3N2M1	210.5	57.3	42	Hemobilia	NA	TI (176)	200	Death
5	Female	47	PC	T2N0M0	178.2	49.9	57	NA	NA	NA	198	Alive
6	Female	68	PC	T2N0M0	166.6	69.2	34	NA	NA	TI (242)	282	Alive
7	Female	49	CC	T3N2M1	251.5	79.6	26	NA	Cholecystitis	NA	189	Death
8	Male	45	GC	T2N1M1	131.2	45.4	29	No	No	TI (50)	88	Alive
9	Female	74	PC	T3N2M1	145.4	88.2	67	Cholangitis	Cholangitis	TI (100)	131	Death
10	Male	55	CC	T3N1M1	208.9	55.6	37	NA	NA	TI (259)	289	Alive
11	Male	70	GC	T3N1M0	222.1	43.7	62	NA	NA	NA	277	Alive
12	Female	66	PC	T2N1M1	302.1	66.2	44	NA	NA	NA	339	Alive
13	Male	48	PC	T3N1M0	105.2	60.9	51	NA	Cholecystitis	TI (308)	365	Death

STB, serum total bilirubin; y, years; TNM, tumor, node, metastasis stage; OT, operative time; SR, stent reocclusion; d, days; FU, follow-up; CC, cholangiocarcinoma; NA, not available; PC, pancreatic cancer; TI, tumor ingrowth; GC, gallbladder cancer.

Table 2. Recent studies of endobiliary radiofrequency ablation for re-opening the occluded SEMS [a,b]

Author	Year	Study	Pt, n	Pre-RFA (Diameter, mm)	Post-RFA (Diameter, mm)	Success	E Cx [c]	Patency, d	Survival
Mukund (4)	2012	CR	2	NA	NA	100%	NA	6 & 7 mo	NA
Pai (5)	2013	R	9	1.6	8	100%	NA	102.5 d (50–321 d)	3 patients died within 122 d (20–488 d)
Duan (6)	2015	R	14	NA	NA	100%	4 cholangitis	234 d (187–544 d)	6-mo & 12-mo, 100% & 64.3%
Kadayifci (7)	2016	R	50	NA	NA	RFA: 56%	NA	90 d 56%, 119.5 d vs. 24%, 65.3 d [d]	NA
Xia (8)	2017	R	43	1	8	100%	NA	107 d (12–80 d)	80.5 d (30–243 d)
Betgeri (9)	2017	R	8	NA	NA	100%	1 intra-stent H	4 ± 2.1 mo (2–7 mo)	NA

SEMS, self-expandable metallic stent; RFA, radiofrequency ablation; Pt, patients; E Cx, early complication; d, days; CR, case report; NA, not available; R, retrospective; H, hemorrhage.
[a]The approach was PTCD in all studies, except for ERCP in Kadayifci et al. (7); [b]In all studies, RFA power and time was 10W and 120 s, respectively; [c]There was no information on late complications in any study; [d]In RFA and control groups, respectively.

There were three patients (23.1%) with late complications: cholecystitis in Patients 7 and 13, and cholangitis in Patient 9. All these patients received systemic medication, and their symptoms resolved.

During the mean follow-up of 233±82.9 days (range, 88–365), seven patients (Patients 3, 4, 6, 8, 9, 10, and 13) developed stent occlusion caused by tumor ingrowth (detected at days 155, 176, 242, 50, 100, 259, and 308, respectively). Five patients (Patients 3, 4, 8, 9, and 13) underwent plastic stent placement using ERCP. Two patients (Patients 6 and 10) underwent secondary PTCD and biliary SEMS deployment. The mean stent patency time was 239±26.5 days (95% CI, 187–291 days), and the 6- and 9-month patency rates were 68% and 41%, respectively.

Four patients (Patients 2, 4, 9, 13) died of multiple organ failure, and one patient (Patient 7) died of pulmonary embolism. The mean survival time was 298±30.1 days (95% CI, 239–358 days). The 6- and 9-month survival rates were 83% and 65%.

Discussion

Stenting has been the recommended palliative treatment for patients with unresectable malignant biliary obstruction. However, stents (especially non-coated SEMS) tend to occlude because of tumor ingrowth, overgrowth, epithelial hyperplasia, and sludge deposition within 3–6 months (2). Even after the development of advanced technologies such as coated stents, endobiliary photodynamic therapy, locally active endoscopic methods, and ILBT with iridium-192 (^{192}Ir) (13–15), the duration of the metal biliary stent has remained unsatisfactory. Placement of a second SEMS (coated or non-coated) or drainage catheter within the occluded SEMS, via PTCD or ERCP, are considered better options.

RFA generates heat causing immediate tissue necrosis. It has been the preferred minimally invasive method to treat solid

Table 3. Recent studies of ILBT for malignant biliary obstruction with low-dose-rate ^{125}I seeds [a, b]

Author	Year	Study	Pt, n	Complications: Early	Complications: Late	Seed activity	Patency	Survival
Liu (19)	2009	RS	11	18.2% (AST and BR)	18.2% (GOO)	NA	129 d	Median, 150 d
Guo (20)	2010	CR	1	Nil	Nil	NA	NA	30 mo
Zhu (21)	2012	RCT	23	IS, nil; ctrl, 27.2%	IS, 8.3%; ctrl, 45.5%	26.4 Mbq	IS, 7.4 mo; ctrl, 2.5 mo	IS, 7.4 mo; ctrl, 2.5 mo
Chen (22)	2012	RS	34	23.5% (BR, cholangitis)	NA	25.9 Mbq	ILBT, 10.2 mo; ctrl, 7.2 mo	ILBT, 10 mo; ctrl, 8 mo
Yang (23)	2016	PS	18	55.6%	NA	25.9 Mbq	10.6 mo	Mean, 11.91 mo
Jiao (10)	2017	PS	61	BT, 35.5%; ctrl, 14.8%	BT, 70.1%; ctrl, 76.7%	33.67 Mbq	BT, 368 d; ctrl, 220 d	BT, 355 d; ctrl, 209 d
Hasimu (24)	2017	PS	55	ILBT, 14.3%; ctrl, 18.5%	NA	33.3 Mbq	ILBT, 191 d; ctr,l 88 d	ILBT, d; ctrl, 139 d

ILBT; intraluminal brachytherapy; RS, retrospective study; AST, aspartate aminotransferase; BR, bilirubinemia; GOO, gastric outlet obstruction; NA, not available; d, days; CR, case report; mo, months; RCT, randomized controlled trial; IS, irradiation stent; ctrl, control; PS, prospective study.
[a]The approach was PTCD in all studies, except for ERCP in Liu et al. (19) and Guo et al. (20); [b]the technical and clinical success rates were 100% in all studies.

tumors. In recent years, endobiliary RFA (using the Habib EndoHPB radiofrequency ablation catheter) has been used in the bile duct to control local tumor and to reduce the stent obstruction rate (16). Mukund et al. (4) was the first to report endobiliary RFA to clear tumor ingrowth within the SEMS, conducted in two patients. They suggested that this new method was safe and promising, with patency sustained for 6–7 months. Pai et al. (5) reported a prospective study using a bipolar radiofrequency catheter to clear blocked SEMSs in 9 patients, with a median stent patency of 102.5 days. Subsequently, other investigators have reported techniques using PTCD or ERCP to reopen occluded SEMSs, although retrospective designs limited the statistical power of these results (6–9).

It has been demonstrated that the duration of SEMS patency can be prolonged by ILBT using high-dose-rate ^{192}Ir. However, the device is not available in most hospitals in China. Furthermore, the technique predisposes patients to bile duct infection because of repeated instrumentation (17). ^{125}I-BT was invented by a Chinese investigator, and has been extensively applied for vascular thrombi and non-vascular cavity BT, with promising results (18–24). Liu et al. (19) reported a preliminary study to test the feasibility and effectiveness of ILBT using ^{125}I seed strands in 11 patients; the median stent patency time was 129 days. Zhu et al. (21) demonstrated that the 6-month patency rate of the SEMS was substantially longer than that of the control (7.4 vs. 2.5 months) when using the new biliary intraluminal irradiation stent loaded with ^{125}I seeds. Jiao et al. (10) performed a randomized, single-blind controlled study to evaluate the efficacy of SEMS with ^{125}I-BT in malignant biliary obstruction, and found that the median stent patency time in the BT group (368 days) was longer than that of the non-BT control group (220 days). All these studies showed that tumor growth can be inhibited by ^{125}I-BT, and thus prolong stent patency.

In the present study, the Endo RFA was operated under bipolar mode, meaning that both electrodes did not work simultaneously when in contact with the SEMS. Therefore, tumor ingrowth within the stent can be ablated without destroying tumor tissue outside the stent.

We believe that ILBT can be combined with endobiliary RFA. Theoretically, endobiliary RFA destroys the tumor within the stent, and continuous ^{125}I-BT inhibits tumor ingrowth and granulation hyperplasia. Thus, the two treatments are complementary. The present initial study established the safety and efficacy of combined endobiliary RFA and ILBT. The 100% technical and clinical success rates, and the reasonable early complication rate (15.4%) showed that this combination therapy did not decrease clinical success or increase complications, as was seen in other studies (Tables 2 and 3). The mean stent patency time was 239 days (95% CI, 187–291 days) and the 6-month stent patency rate was 68.4%, both rather promising. In the future, randomized controlled trials are needed to confirm the effectiveness of combined endobiliary RFA and ILBT.

To improve this combination therapy for treating an occluded biliary stent, the following three technical aspects must be noted. First, a puncture approach from under the diaphragm to the bile duct branch should be coronally flat (avoiding the oblique upward side), to enable easy manipulation later, and to decrease patient discomfort after subsequent placement of the 8.5 F biliary drainage catheter and ^{125}I seed strand. Second, the ^{125}I strand length should be longer than the occluded portion of the SEMS, to inhibit tumor ingrowth more effectively. Third, the dual guidewire technology using an 8 F long sheath can quickly complete the drainage catheter and ^{125}I strand implantation, greatly shortening procedural time.

Regarding dosimetry, in this study the estimated radiation dose at the reference point was only 27.2 Gy over 1 month, as calculated by the treatment planning system. This was less than the 52.3 Gy reported in our previous study, using single ^{125}I strands (10). The difference is due to the short half-life of the ^{125}I strand within the SEMS. Considering the rapid attenuation of ^{125}I-BT, this study was designed to remove the ^{125}I strand at 1 month. Whether the result would improve with simultaneous double ^{125}I strand BT or replacement after 1 month will be addressed in our next study.

The study had several limitations. First, there was no control group, which potentially confounded the results. Second, patient selection bias may have affected the statistical analysis. Third, it was difficult to evaluate tumor response, which possibly influenced objective evaluation of tumor inhibition by PRFA and ^{125}I-BT.

In conclusion, PRFA combined with ^{125}I-BT is feasible and effective for patients with an occluded SEMS in malignant biliary obstruction. However, randomized controlled trails are needed to confirm the effectiveness of this new approach.

Financial Disclosure

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Conflict of interest disclosure

The authors declared no conflicts of interest.

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