Original Article

Self-expandable metallic stent with ^{125}I seed strand in malignant biliary obstruction: a self-made delivery system and novel implantation method

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Background: Malignant obstructive jaundice (MOJ) has a low immediate surgery rate (10–20%) and a poor post-resection survival rate. Although several clinical results have demonstrated the safety and efficacy of stent placement combined with radioactive seeds, the existing implantation methods are time consuming and prone to error. In this study, we introduced a self-made delivery system and novel implantation method for a self-expandable metallic stent (SEMS) with ^{125}I seed strand and evaluated its feasibility and efficacy in MOJ patients.

Methods: Our self-made delivery system was applied to 61 patients (39 males and 22 females, mean age 66.36±10.73 years) from October 2018 to June 2020 in our center with a novel implantation method. The preparation and manipulation processes were described in detail. Technical and clinical successes were recorded, and stent patency and overall survival (OS) were assessed. A P value of less than 0.05 indicated a significant difference.

Results: Stents with ^{125}I seed strands were successfully placed in all 61 participants with our novel implantation method. The clinical success rate was 96.7%, and no severe procedure-related complications were found except bile leakage through puncture in 1 participant. The median duration of primary stent patency was 120 (37, 233.5) days, and the median OS was 169 (41, 270) days.

Conclusions: Our self-made delivery system with a novel SEMS implantation method with ^{125}I seed strand was feasible and effective for MOJ patients and significantly simplified the current implantation approach.

Keywords: Biliary stent; malignant obstructive jaundice (MOJ); ^{125}I seed strand

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Introduction

Malignant obstructive jaundice (MOJ) is commonly caused by cholangiocarcinoma and various adenocarcinomas. The silent and insidious clinical features of MOJ lead to a low immediate surgery rate (10–20%) and a poor post-resection survival rate (1-5). An unresectable stage with poor prognosis is frequently seen in many patients, and the primary aim is to relieve pruritus, cholangitis,

Table 1 Participant characteristics

Variable	Value
Age (years)	66.36 (10.73)
Gender (M/F)	39/22
Obstruction causes	
Cholangiocarcinoma	26 (42.6%)
Gallbladder cancer	9 (14.8%)
Liver cancer	8 (13.1%)
Pancreatic cancer	13 (21.3%)
Duodenal adenocarcinoma	2 (3.3%)
Metastatic adenocarcinoma	3 (4.9%)
ECOG score	
1	9 (14.8%)
2	5 (8.2%)
3	28 (45.9%)
4	19 (31.1%)
Stent number	
1 stent	60
2 stents	1
Stent size (mm)	
6×40	1
6×60	4
6×80	3
8×40	15
8×60	33
8×80	5
8×100	1
DBIL (μmol/L)	
Before	165.4 (112.3, 225.7)
After	45.6 (11.8, 111.1)
P value	0.00*

Normal distribution represents as mean (SD), non-normal distribution as median (Q1, Q3). *, Wilcoxon matched-pairs signed rank test was used. HCC, hepatocellular carcinoma; ECOG, Eastern Cooperative Oncology Group; DBIL, direct bilirubin.

pain, and jaundice (2,6). Thus, stent implantation in the obstructive biliary duct is the preferred palliation modality for such patients (7-9). For now, two main types of stents including plastic stent and SEMS are equally effective for initial relief of extrahepatic biliary obstruction, with high technical success of >90%, and there is broad consensus that metal stents are preferred for patients expected to survive for >4–6 months and plastic stents are preferred for patients with shorter survival, which is the consequence of taking economic efficiency into consideration (10,11). However, tumor ingrowth, epithelial cell hyperplasia, clot accumulation, and sludge formation lead to a 50% stent restenosis rate within 6 months post stent implantation (12-14). As the stent itself is unable to inhibit tumor progression, the combination of a stent and ^{125}I seed strand brachytherapy, focused on the underlying malignancies instead of simply addressing biliary stenosis, has attracted our attention (15). The ^{125}I seeds are a sustained radiation source that can directly damage tumor cell DNA and inhibit replication (16,17). Although several clinical results have demonstrated the safety and efficacy of stent placement combined with brachytherapy, the existing manipulation approaches are time consuming and error prone. In this study, we introduced a self-made delivery system and a novel stent implantation method with ^{125}I seed strand for MOJ patients to simplify the operation process. We present the following article in accordance with the STROBE reporting checklist (available at https://dx.doi.org/10.21037/atm-21-6392).

Methods

The study was approved by Institutional Review Board, Tangdu Hospital, Fourth Military Medical University (No. TDLL-201809-07) and all patients provided written informed consent. All procedures performed in this study involving human participants were in accordance with the Declaration of Helsinki (as revised in 2013).

Patient data

A total of 61 patients with clinical diagnosis of MOJ were enrolled in our center (Department of Interventional Radiology, Tangdu Hospital, Fourth Military Medical University) from October 2018 to June 2020. The patients' characteristics are shown in *Table 1*.

Inclusion and exclusion criteria

The inclusion criteria were as follows: (I) biliary obstruction caused by pathologically or clinically diagnosed malignant

tumor, unresectable, or patient refused surgery; (II) Karnofsky Performance Scale (KPS) score >40; (III) no previous biliary drainage prior to admission; and (IV) regular follow-up. Patients with the following conditions were excluded: (I) severe cardiovascular and cerebrovascular diseases; (II) uncontrolled infections; and (III) suspicion of benign biliary stricture.

Stents and ^{125}I seeds

Self-expandable stents [E-Luminexx, (C. R. Bard, Inc., Karlsruhe, Germany), Zilver (Cook, Ireland, Ltd., Limerick, Ireland), Epic (Boston Scientific, Galway, Ireland)] with diameters ranging from 6 to 8 mm and lengths of 40–100 mm were used in this study. The ^{125}I seeds (Beijing Atom Hi-Tech Co., Ltd., Beijing, China) with a diameter of 0.8 mm and length of 4.5±0.5 mm were used. The radioactivity of each ^{125}I seed was 0.6 mCi with a half-life of 59.41 days. The principal photon emissions were 27.4 keV and 31.4 keV for X-rays and 35.5 keV for γ-rays, with a 20-mm effective range.

Treatment procedure

Preparation

Percutaneous transhepatic cholangiography was performed to confirm the obstruction and measure the length of the obstructive bile duct. The number of ^{125}I seeds was determined by the formula: n = length of the obstructive segment of the bile duct (mm)/4.5 + 4.

^{125}I seeds delivery device development

A 6-Fr catheter attached to a Y-connector was prepared. The ^{125}I seeds were contained in a 4-Fr catheter sealed at both ends and used to construct the ^{125}I seed strand; then, one end of the strand was threaded with a swedged needle (5-0 polypropylene suture).

ONE STEP delivery procedure

First, the ^{125}I seed strand was delivered through the branch passage of the Y-connector, and the self-expanding stent was then followed from the main passage, right behind the strand in the catheter. Second, the strand was pushed by the stent and then delivered to the target position. The suture (long enough to extend from the obstruction to the Y-connector) from the branch passage of the Y-connector was grasped by the operator in case of translocation. Third, the strand was kept at the target position, then the catheter was retracted to expose the whole stent, and the stent was pushed to the target position parallel to the strand (strand suture was still grasped). Fourth, cholangiography was performed to reconfirm the strand and stent. Then, the stent was released, and the strand was compressed immediately between the stent and the obstructive bile duct wall. Fifth, cholangiography was performed again to evaluate the distribution, and the guide wire and catheter were withdrawn (suture was clipped, and the residual remained in the puncture tract). The *in vitro* delivery process is shown in *Figure 1*, and a schematic diagram is shown in *Figure 2*.

A 59-year-old man with MOJ caused by cholangiocarcinoma was implanted with 2 stents combined with 2 seed strands (shown in *Figure 3*).

Follow-up

All participants were regularly followed up to September 2020 or until patient death. Direct bilirubin was assayed to reflect liver function. Stent patency and patient condition were evaluated every 2 months post stent placement according to laboratory values and clinical complications, including cholangitis, cholecystitis, and hemobilia. Primary stent patency was defined as the time from initial stent placement to the recurrence of jaundice, the last follow-up date, or patient death. Survival was defined from the initial stent placement time to patient death or the last follow-up.

Statistical analysis

Medical records were reviewed and data analyzed using R (version 4.0.4, https://www.rproject.org). Cumulative stent patency and survival rates were determined by Kaplan-Meier survival analyses. The Wilcoxon matched-pairs signed rank test was used to compare the data before and after the operation. A P value <0.05 was considered to indicate statistical significance. Normally distributed data was represented as the mean ± SD, and non-normally distributed data was represented as the median (Q1, Q3).

Results

The baseline characteristics of the participants are shown in *Table 1*. A total of 61 patients (39 males and 22 females) were enrolled with a mean age of 66.36±10.73 years. Among them, the etiologies of MOJ were cholangiocarcinoma (n=26), gallbladder cancer (n=9), liver cancer (n=8),

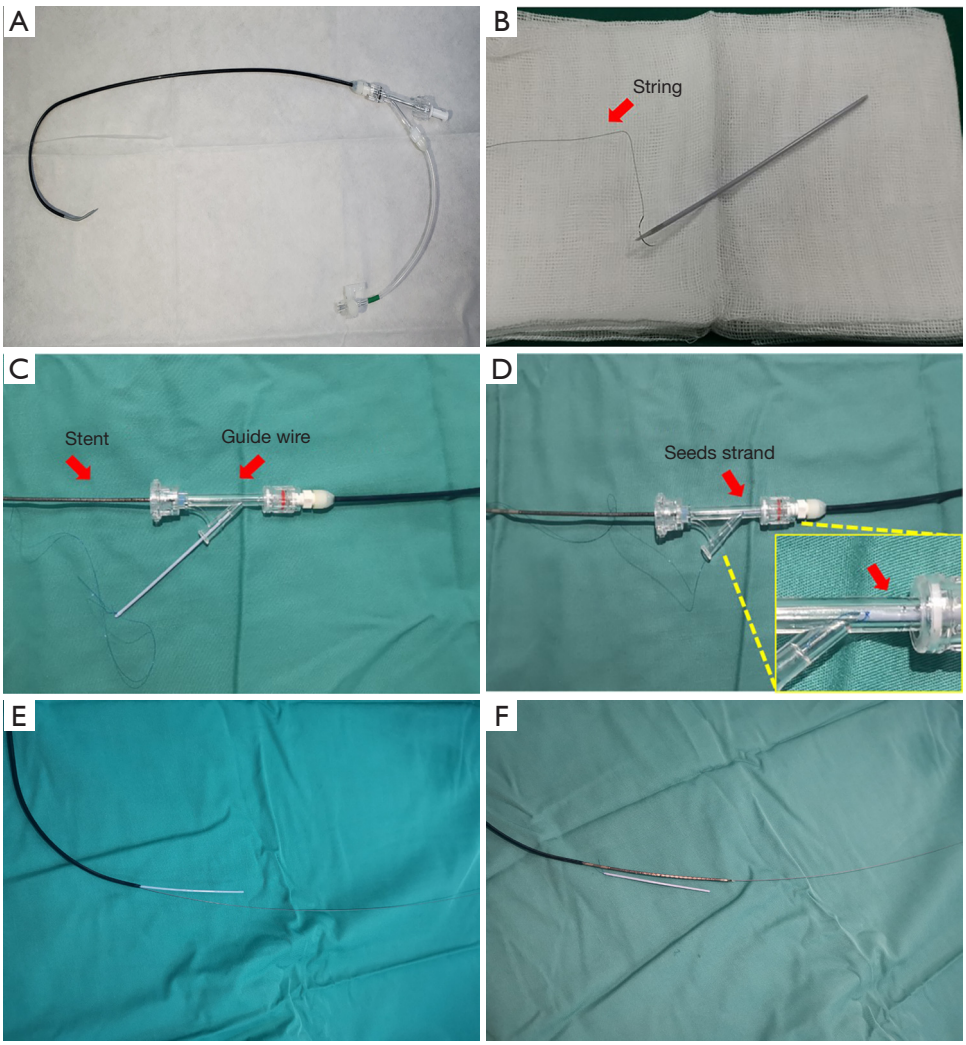

Figure 1 Operation procedure *in vitro*. (A) 6-Fr catheter and Y-connector were prepared; (B) ^{125}I seeds were sealed in a 4-Fr catheter threaded with a swedged needle; (C,D) the ^{125}I seed strand was delivered through the branch passage of the Y-connector, and the self-expanding stent was then followed from the main passage; (E,F) the catheter was retreated to expose the stent, and the ^{125}I seed strand and stent were paralleled in the target obstruction.

pancreatic cancer (n=13), duodenal adenocarcinoma (n=2), and metastatic adenocarcinoma (n=3).

Technical and clinical success

The technical success rate was 100% in all participants. There were 60 (98.4%) patients who received 1 stent and 1 (1.6%) patient received 2 stents. Stents of 8×40 mm (15/62) and 8×60 mm (33/62) were commonly used. An average of 16 seeds (range, 10–32 seeds) were implanted into the bile duct.

The clinical success rate was 96.7% (59/61), 1 patient developed cholangitis, their bilirubin level deceased after medical treatment, and 1 patient received one new stent for occlusion of the previous stent 4 days post-surgery. Direct bilirubin was significantly decreased after stents implantation with ^{125}I seed strands [165.4 (112.3, 225.7) *vs.* 45.6 (11.8, 111.1), P<0.001].

Stent patency and survival rate

Stent patency was determined by biliary obstruction-related clinical findings. The median duration of primary stent

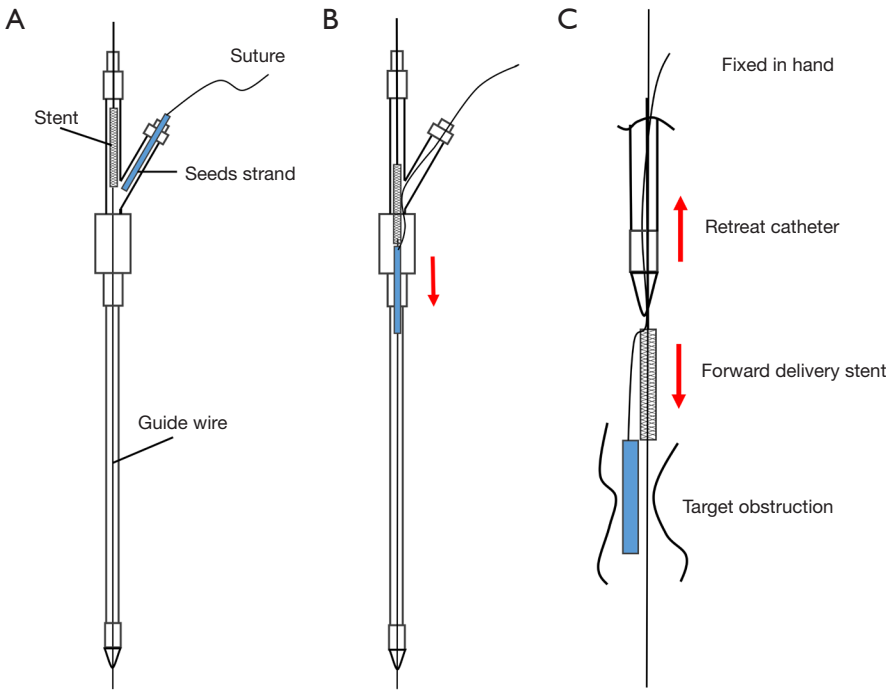

Figure 2 Schematic diagram of delivery procedure. (A) ^{125}I seed strands with sutures and stents were inserted from the branch/main passage; (B) ^{125}I seed strand was pushed forward coaxially by the stent; (C) when the strand reached the target obstruction, the catheter was retreated to expose the stent, then advanced to assume the paralleled position with the suture fixed in hand in case of translocation.

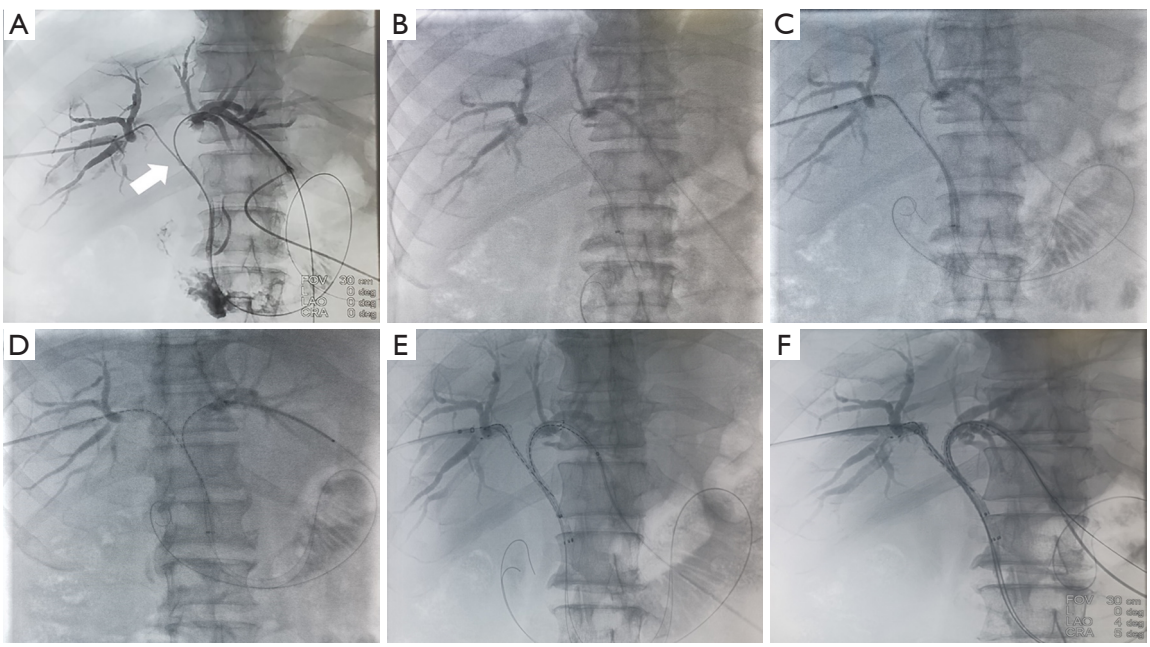

Figure 3 A 59-year-old man with MOJ caused by cholangiocarcinoma was implanted with 2 SEMS combined with 2 seed strands. (A) Cholangiography shows a hilar biliary obstruction (white arrow); (B,C) two guide wires were prepared to deliver seed strands and stents; (D,E) with our implantation method, two stents were deployed simultaneously; (F) cholangiography showed stents were patent. MOJ, malignant obstructive jaundice; SEMS, self-expandable metallic stent.

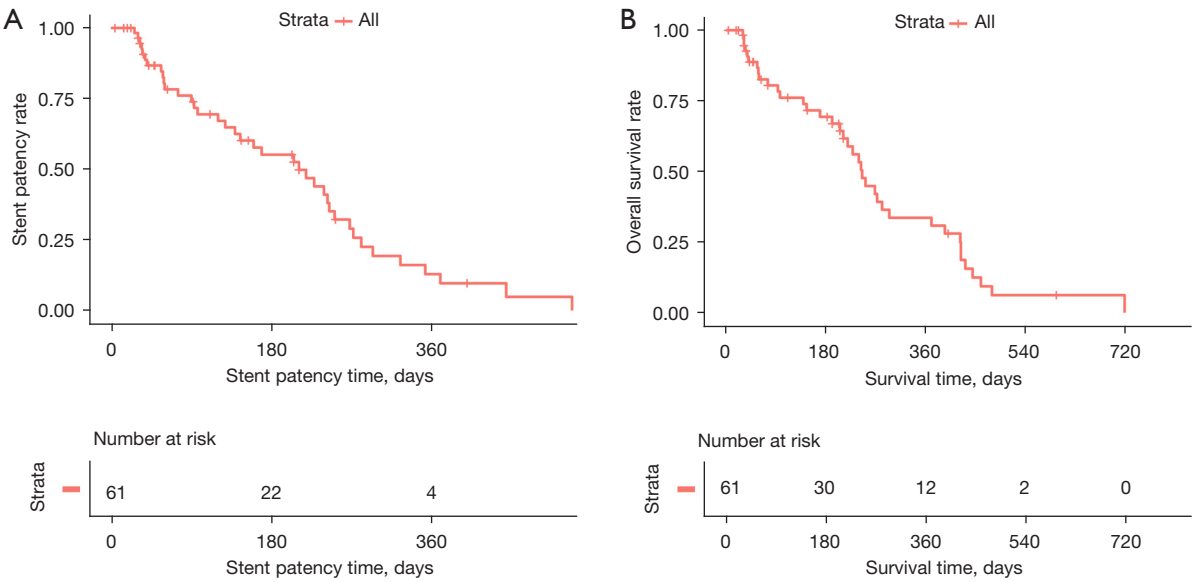

Figure 4 Cumulative stent patency (A) and OS (B) were analyzed by the Kaplan-Meier method. OS, overall survival.

patency was 120 (37, 233.5) days (*Figure 4A*). The median overall survival (OS) was 169 (41, 270) days (*Figure 4B*).

Complications

Bile leakage through puncture was found in one participant. No other significant procedure-related complications occurred.

Discussion

Usually, MOJ is caused by various adenocarcinoma-related bile duct compressions. Unfortunately, the 5-year survival rates of the most common malignancies, such as pancreatic cancer and cholangiocarcinoma, are unfavorable (18,19). Patients with these cancers are frequently diagnosed at an advanced stage and have passed the window of opportunity for surgical therapy. Addressing the obstruction itself to improve liver function and facilitate further radiotherapy, chemotherapy, or other treatments that can prolong patient survival has become an overriding priority.

Over the past 30 years, the implantation of self-expanding metal stents has become widely accepted as a standardized treatment for MOJ patients (20,21). However, the stents have been focused only on the anatomic stenosis of the bile duct, and stent restenosis caused by tumor overgrowth, tissue-reactive hyperplasia, and biliary formation has remained unsolved (20,22-24). According to previous studies, the stent occlusion rate post implantation is relatively high at 25% (25). Although covered stents have appeared to have significantly lower occlusion rates, increased odds of migration and cholecystitis as well as pancreatitis may counteract the benefits (26,27).

The ^{125}I brachytherapy has been widely used in the treatment of prostate carcinoma, lung cancer, and other solid tumors to control local metastasis (28-30). Compared with external irradiation, brachytherapy delivers a higher effective therapeutic dose to carcinomas and a limited dose to adjacent normal organs and tissues (31). Several studies have demonstrated that ^{125}I brachytherapy combined with stents achieves technical success, and this approach represents an effective therapy in MOJ patients, manifesting as extended stent patency time, better malignancy control, and consequently prolonged survival (8,9,32,33). Consistent with these studies, our results showed that the median survival was 169 days, and the median stent patency was 120 days. Moreover, according to our experience, it was suggested that the length of the ^{125}I seed strand for implantation be 1–1.5 cm beyond both ends of the obstructive segment of the bile duct, which can offer a higher radiation dose and may better prevent tumor growth and normal tissue hyperplasia.

Currently, there are various implantation methods for stents combined with ^{125}I seed strands. Specifically, during the process of delivery, 2 stiff guide wires are commonly used for catheter transport with ^{125}I seed strand and stent

insertion. Taking the previous guide wire exchanges into account, guide wires are exchanged at least 3 times, and 2 catheters are frequently used. The process is laborious and thus susceptible to error. Moreover, the whole process requires assistance to fix the guide wire in the case of translocation. With our novel implantation method for a ^{125}I seed strand combined stent (ONE STEP manipulation), 1 catheter, 1 guide wire, and only 1 exchange will be needed; more importantly, 1 operator will be competent for the whole procedure. The reduced operation time (roughly estimated to be 15 min in addition to the percutaneous puncture under ultrasound guidance and seed strand preparation time, not yet statistically analyzed) means reduced radiation doses for both patients and operators, and less contrast agent consumption can minimize damage to patients' kidneys. Furthermore, the novel implantation method can achieve an accurate location preoperatively, adjust the position intraoperatively, and achieve cholangiography postoperatively. In general, our newly designed device and method of implantation are time- and labor-saving and easy to implement.

Since Chen *et al.* first implanted ^{125}I seeds into the porcine bile duct, patients with MOJ treated with ^{125}I seeds experienced a series of improvements such as place ^{125}I seed strands into biliary stenosis through an external drainage tube and then removed them 2 months later, insert the ^{125}I seed strands between the stent and bile duct wall and so on (9,34,35). Li *et al.* reported a novel brachytherapy biliary drainage catheter with two ^{125}I seed strands on both sides, demonstrated prolonged overall stent patency and overall survival in the treatment of advanced perihilar cholangiocarcinoma with MOJ (36). Recently, Zhu *et al.* reported that a newly designed radioactive biliary stent loaded with ^{125}I seeds is safe and technically feasible, facilitates jaundice relief, and seems to prolong survival compared to a conventional biliary stent (25,37). The results are inspiring, and stents loaded with radioactive ^{125}I seeds may be prospectively implemented in many malignancy-induced obstructions, such as bronchial, biliary, and esophageal stenosis. The advantage of radioactive stents is the unified dose distribution and precise dosimetry because the seeds are in direct contact with the circumference of the bile duct. Nonetheless, in our opinion, stent-combined ^{125}I seed strand implantation may still be the mainstream therapy for MOJ patients. As the internal irradiation dose of ^{125}I seed strand is sufficient to inhibit tumor growth: the effective radiation radius was 17–20 mm, the initial dose was 7.7 cGy/h, and the radioactive half-life was 60 days (including 27.4–31.5 keV χ-rays and 35.5 keV γ-rays) (38,39). Moreover, to date, no research has been published investigating the effectiveness of radioactive stents versus ^{125}I seed strands with conventional stents for the treatment of MOJ patients, and further multicenter clinical studies are needed.

In conclusion, we established a novel implantation method for ^{125}I seed strands combined with stents, and the results showed that this ONE STEP manipulation is feasible and convenient for the treatment of MOJ patients.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. https://dx.doi.org/10.21037/atm-21-6392

Data Sharing Statement: Available at https://dx.doi.org/10.21037/atm-21-6392

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://dx.doi.org/10.21037/atm-21-6392). JR was employed by company GE Healthcare China. ZL reports patents pending (China Patent Application No. 202120358478.7). The other authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All procedures performed in this study involving human participants were in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by Institutional Review Board, Tangdu Hospital, Fourth Military Medical University (No. TDLL-201809-07) and informed consent was taken from all the patients.

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