

Outcomes of fluoroscopy guided stent placement for primary and metastatic malignant obstructive jaundice in unresectable tumors

Haiyang Lai

Sixth Affiliated Hospital of Sun Yat-sen University

Ketong Wu

Sixth Affiliated Hospital of Sun Yat-sen University

Yang Liu

Sixth Affiliated Hospital of Sun Yat-sen University

Dan Li

Sixth Affiliated Hospital of Sun Yat-sen University

Tao Peng

Sixth Affiliated Hospital of Sun Yat-sen University

Yuan Wan

Sixth Affiliated Hospital of Sun Yat-sen University

Bo Zhang

zhangb28@mail.sysu.edu.cn

Sixth Affiliated Hospital of Sun Yat-sen University

Research Article

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Abstract

Aim

This study aimed to comprehensively evaluate the clinical outcomes of self-expandable metal stent (SEMS) placement for malignant obstructive jaundice (MOJ), with a specific focus on efficacy, safety, stent patency, and complication rates in patients with either primary or metastatic malignancies.

Methods

We retrospectively analyzed data from 108 consecutive patients with MOJ who underwent fluoroscopy-guided SEMS placement at our institution between February 2013 and December 2024. Patients were stratified into primary (n = 53) and metastatic (n = 55) MOJ cohorts based on the etiology of biliary obstruction. Demographic, pathological, procedural, and outcome variables were collected, including technical success, clinical success, stent patency duration, reintervention rate, and procedure-related complications.

Results

Fluoroscopy-guided SEMS placement achieved 100% technical success in both the primary and metastatic cohorts. The overall clinical success rate was 88.9%, with 90.6% (48/53) in the primary group and 87.3% (48/55) in the metastatic group ($p = 0.590$). The mean stent patency duration was 112.0 ± 227.2 days in the primary group and 86.6 ± 120.1 days in the metastatic group, with no statistically significant difference ($p = 0.470$). Post-procedural fever or infection occurred in 15 (28.3%) patients in the primary group and 18 (32.7%) in the metastatic group, all managed conservatively with antibiotics. No major procedure-related complications (e.g., cholangitis, stent migration, severe bleeding, pancreatitis) were observed. Reintervention rates due to stent occlusion were 20.8% (11/53) in the primary group and 23.6% (13/55) in the metastatic group, respectively ($p = 0.722$). A significantly higher proportion of patients in the metastatic group received subsequent chemotherapy compared to the primary group (56.4% vs. 34.0%, $p = 0.019$), which was associated with prolonged stent patency (123.7 vs. 38.6 days, $p = 0.004$).

Conclusions

Fluoroscopy-guided SEMS placement is a safe and effective palliative intervention for both primary and metastatic MOJ. Stent performance in terms of patency and safety is independent of the underlying tumor etiology. Subsequent chemotherapy significantly improves stent patency in patients with metastatic MOJ. Therefore, a combined strategy of biliary stenting followed by systemic chemotherapy is recommended to optimize palliative outcomes in patients with metastatic disease.

1. Introduction

Malignant obstructive jaundice (MOJ) results from neoplastic involvement of the biliary tree, leading to luminal narrowing, bile flow obstruction, and subsequent hyperbilirubinemia [1]. Primary malignancies of the hepatobiliary-pancreatic system—including pancreatic head carcinoma, cholangiocarcinoma, ampullary carcinoma, and duodenal carcinoma—are the most common etiologies [1]. In contrast, metastatic MOJ, caused by distant tumor spread to the biliary tract or regional lymph nodes, is relatively rare but can arise from a diverse range of primary tumors, ranging from cerebral to pedal neoplasms [2]. MOJ is associated with a cascade of pathophysiological disturbances, including biliary tract infection, pruritus, malnutrition, cachexia, and significant impairment of quality of life [3]. Moreover, severe hyperbilirubinemia often contraindicates potentially life-prolonging anticancer therapies such as chemotherapy and radiotherapy [4], making timely biliary decompression a critical therapeutic priority.

Historically, biliary decompression for MOJ was primarily achieved through endoscopic nasobiliary drainage (ENBD) or percutaneous transhepatic biliary drainage (PTBD) [5]. While ENBD allows assessment of bile characteristics and culture-directed antimicrobial therapy, it is associated with bile loss, impaired nutritional status, pharyngeal inflammation, and patient intolerance during prolonged indwelling [6]. PTBD avoids pharyngeal complications but does not prevent digestive enzyme loss and nutritional deterioration, and requires regular drain replacement with inherent risks of biliary infection [7]. Given that most MOJ patients are diagnosed at advanced, unresectable stages with limited life expectancy—particularly those with metastatic disease—minimally invasive and effective palliative interventions are paramount [8].

Self-expandable metal stents (SEMS) have emerged as a well-validated minimally invasive option for biliary decompression in MOJ, offering superior safety and efficacy profiles compared to PTBD [9]. SEMS are associated with reduced mortality, shorter hospital stays, and faster symptom relief, making them the first-line palliative intervention for advanced MOJ—especially in patients with comorbidities or limited prognosis [10].

While the efficacy of SEMS in primary MOJ is well established, data on their performance in metastatic MOJ remain sparse. Early biliary decompression is critical to enable subsequent anticancer therapy, which may improve quality of life and survival. Therefore, this study aimed to comparatively analyze the clinical outcomes of fluoroscopy-guided SEMS placement in patients with primary versus metastatic MOJ, focusing on efficacy, safety, stent patency, and complication rates.

2. Materials and Methods

2.1 Study Population

Consecutive patients with unresectable MOJ who underwent fluoroscopy-guided SEMS placement at our institution between February 2013 and December 2024 were retrospectively enrolled. The diagnosis of MOJ was confirmed by a combination of clinical manifestations (jaundice, pruritus, dark urine, clay-

colored stools), laboratory tests (elevated serum bilirubin, alkaline phosphatase, gamma-glutamyl transferase), and imaging studies (abdominal computed tomography [CT], magnetic resonance cholangiopancreatography [MRCP], abdominal ultrasonography [US]). Histopathological confirmation of malignancy was obtained whenever possible.

Inclusion criteria were: (1) age ≥ 18 years; (2) confirmed unresectable primary or recurrent malignancy causing MOJ; (3) no contraindications to interventional procedures; (4) complete clinical and follow-up data available. Exclusion criteria included: (1) severe coagulation dysfunction (international normalized ratio > 1.5 , platelet count $< 50 \times 10^9/L$); (2) extensive liver tumor replacement with no functional hepatic parenchyma; (3) severe cardiac, hepatic, or pulmonary insufficiency incompatible with the procedure; (4) active bleeding or infection; (5) refusal to participate in follow-up.

All patients provided written informed consent prior to the procedure. This retrospective study was conducted in accordance with the Declaration of Helsinki and utilized anonymized pre-existing medical records. Per local Institutional Review Board (IRB) policy, formal ethics approval was exempt due to the de-identified nature of the data.

2.2 Interventional Devices and Procedures

All procedures were performed by two experienced interventional radiologists with ≥ 10 years of clinical experience. The devices used included 8 mm or 10 mm diameter self-expandable metal stents (Bard, Karlsruhe, Germany; Cook Medical, Limerick, Ireland) with lengths of 6 cm or 8 cm, 0.90-mm diameter Terumo guidewire (150 cm length; Terumo Corporation, Tokyo, Japan), 5-Fr KMP catheter (Cook Medical, Bloomington, IN, USA), 8.5-Fr pigtail external drainage catheter, liquid paraffin lubricant, and GE flat-panel or Philips digital subtraction angiography (DSA) systems.

A standardized two-stage procedure was adopted: (1) Initial decompression via PTBD was performed under ultrasound or DSA guidance to relieve acute cholestasis. (2) Definitive SEMS placement was performed after clinical stabilization and a decline in serum bilirubin levels (typically 3–7 days after PTBD). During the stenting procedure, the patient was placed in the supine position. Contrast medium was injected through the indwelling PTBD catheter to delineate the extent and location of the biliary stricture. A guidewire and 5-Fr KMP catheter were advanced through the 8.5-Fr sheath across the stricture to its distal end. The guidewire was retained, and the KMP catheter was used to inject contrast medium to confirm the stricture length and adjacent biliary anatomy. An appropriately sized SEMS was then deployed over the guidewire to cover the entire stricture. Balloon dilatation was performed if stent expansion was suboptimal. For restenosis during follow-up, a stent-in-stent technique was employed.

2.3 Outcome Measures and Follow-Up

Data collected included demographic parameters (age, sex), pathological characteristics (tumor type, location of obstruction), procedural details (stent size, procedure duration), and outcome variables. The primary outcome measures were technical success, clinical success, and stent patency duration.

Secondary outcomes included reintervention rate, complication rate, and post-procedural management (palliative care vs. chemotherapy).

Definitions

(1) Technical success: Successful deployment of the SEMS across the biliary stricture in a single session, with contrast medium passing freely through the stent into the duodenum. (2) Clinical success: A $\geq 50\%$ reduction in total serum bilirubin level within two weeks post-SEMS placement compared to the pre-procedural baseline. (3) Stent patency duration: The time from stent placement to the first occurrence of stent occlusion (defined by recurrent jaundice, elevated serum bilirubin, or imaging evidence of biliary dilatation above the stent) or death, whichever occurred first. (4) Complications: Procedure-related adverse events were classified according to the Society of Interventional Radiology (SIR) complication classification system. Major complications included cholangitis requiring hospitalization, severe bleeding, pancreatitis, stent migration, and liver abscess; minor complications included post-procedural fever ($< 38.5^{\circ}\text{C}$) responsive to conservative treatment.

Follow-up was conducted at 1, 3, 6, and 12 months post-procedure, or more frequently if clinical symptoms occurred. Follow-up evaluations included physical examination, laboratory tests (serum bilirubin, liver function tests), and imaging studies (abdominal US or CT) as needed to assess stent patency.

2.4 Statistical Analysis

Statistical analysis was performed using SPSS version 29.0 (IBM Corp, Armonk, NY, USA). Continuous variables were presented as mean $\pm$ standard deviation ($\bar{x} \pm s$) with range, and categorical variables as counts and percentages. Comparisons of continuous variables between groups were performed using the independent samples t-test or Mann-Whitney U test, as appropriate. Categorical variables were compared using the χ^2 test or Fisher's exact test. Stent patency was analyzed using the Kaplan-Meier method, with differences between groups assessed by the log-rank test. A p-value < 0.05 was considered statistically significant.

3. Results

3.1 Baseline Clinical Characteristics

A total of 108 patients (67 males [62.0%], 41 females [38.0%]) with a mean age of 59.2 ± 14.1 years (range: 25–85 years) were included. Based on the etiology of MOJ, patients were stratified into the primary group (n = 53) and metastatic group (n = 55). The primary group included tumors of pancreatic (n = 15), gastric (n = 15), cholangiocarcinoma (n = 11), hepatocellular (n = 6), duodenal (n = 5), and gallbladder (n = 1) origin (Fig. 1). The metastatic group had primary tumors of colorectal (n = 46, 83.6%), esophageal (n = 2), jejunal (n = 2), and other sites (n = 5: appendiceal, cervical, pulmonary, melanoma, bladder), with biliary obstruction caused by lymph node metastasis or direct tumor invasion (Fig. 2). The

location of biliary obstruction was the hilar biliary confluence (n = 15), common hepatic duct (n = 4), and common bile duct (n = 89). The baseline clinical characteristics of the two groups are summarized in Table 1.

Table 1
Baseline Clinical Characteristics of the Study Population

Clinical Data	Primary Group (n = 53)	Metastatic Group (n = 55)	p-value	Total (n = 108)
Age (years), $\bar{x} \pm s$ (range)	61.8 $\pm$ 12.8 (29.0–85.0)	56.7 $\pm$ 14.8 (25.0–84.0)	0.060	59.2 $\pm$ 14.1 (25.0–85.0)
Sex (male/female), n (%)	30 (56.6)/23 (43.4)	37 (67.3)/18 (32.7)	0.258	67 (62.0)/41 (38.0)
Obstruction site, n (%)	-	-	0.201	-
Hilar biliary confluence	5 (9.4)	10 (18.2)	-	15 (13.9)
Common hepatic duct	2 (3.8)	2 (3.6)	-	4 (3.7)
Common bile duct	46 (86.8)	43 (78.2)	-	89 (82.4)
Stent patency duration (days), $\bar{x} \pm s$ (range)	112.0 $\pm$ 227.2 (3.0-1233.0)	86.6 $\pm$ 120.1 (1.0- 648.0)	0.470	99.1 $\pm$ 181.2 (1.0-1233.0)
Stent malfunction, n (%)	11 (20.8)	13 (23.6)	0.722	24 (22.2)
Stent-in-stent, n (%)	6 (11.3)	6 (10.9)	0.946	12 (11.1)
Repeat PTBD drainage, n (%)	5 (9.4)	7 (12.7)	0.590	12 (11.1)
Treatment after SEMS placement, n (%)	-	-	0.019	-
Palliative treatment	35 (66.0)	24 (43.6)	-	59 (54.6)
Chemotherapy	18 (34.0)	31 (56.4)	-	49 (45.4)
Post-procedural fever, n (%)	15 (28.3)	18 (32.7)	0.622	33 (30.6)
Technical success rate, n (%)	53 (100.0)	55 (100.0)	-	108 (100.0)
Clinical success rate, n (%)	48 (90.6)	48 (87.3)	0.590	96 (88.9)
PTBD removal rate, n (%)	45 (84.9)	48 (87.3)	0.725	93 (86.1)
Abbreviations: SEMS, self-expandable metal stent; PTBD, percutaneous transhepatic biliary drainage; $\bar{x} \pm s$, mean $\pm$ standard deviation.				

3.2 Technical and Clinical Success

Fluoroscopy-guided SEMS placement achieved 100% technical success in both the primary (53/53) and metastatic (55/55) groups. The overall clinical success rate was 88.9% (96/108). In the primary group, 48 of 53 patients (90.6%) achieved clinical success, with 5 patients (9.4%) having persistent hyperbilirubinemia (> 50% of baseline) requiring long-term external biliary drainage. In the metastatic group, clinical success was achieved in 48 of 55 patients (87.3%), with 7 patients (12.7%) requiring permanent external drainage due to inadequate biliary decompression. There was no statistically significant difference in clinical success rate between the two groups ($p = 0.590$). The PTBD removal rate was 84.9% (45/53) in the primary group and 87.3% (48/55) in the metastatic group ($p = 0.725$).

3.3 Stent Patency and Reintervention

The mean stent patency duration was 112.0 ± 227.2 days (range: 3-1233 days) in the primary group and 86.6 ± 120.1 days (range: 1-648 days) in the metastatic group, with no statistically significant difference (log-rank test, $p = 0.470$) (Fig. 3). During follow-up, stent occlusion due to tumor progression occurred in 11 patients (20.8%) in the primary group (all > 3 months post-procedure) and 13 patients (23.6%) in the metastatic group (all > 90 days post-procedure). Among these, 6 patients in the primary group and 6 patients in the metastatic group underwent successful fluoroscopy-guided re-stenting (stent-in-stent technique), while 5 patients in the primary group and 7 patients in the metastatic group opted for palliative external drainage alone. The reintervention rate did not differ significantly between the two groups ($p = 0.722$).

A significantly higher proportion of patients in the metastatic group received subsequent systemic chemotherapy compared to the primary group (56.4% [31/55] vs. 34.0% [18/53], $p = 0.019$). In the metastatic group, patients who received chemotherapy had a significantly longer mean stent patency duration than those who received palliative care alone (123.7 ± 135.4 days vs. 38.6 ± 45.2 days, $p = 0.004$).

3.4 Complications

No major procedure-related complications (SIR grade ≥ 3) were observed in either group. Post-procedural fever and infection (SIR grade 1–2) occurred in 15 patients (28.3%) in the primary group and 18 patients (32.7%) in the metastatic group within the first week post-procedure. All cases were managed conservatively with broad-spectrum antibiotics, and symptoms resolved within 3–5 days. During the follow-up period, 6 deaths occurred in the primary group and 5 deaths in the metastatic group. Causes of death in the primary group included sepsis ($n = 2$), respiratory failure ($n = 1$), cardiopulmonary collapse ($n = 1$), multi-organ failure ($n = 1$), and hemorrhage ($n = 1$). In the metastatic group, deaths were attributed to sepsis ($n = 2$), multi-organ failure ($n = 1$), acute hepatic failure ($n = 1$), and hemorrhage ($n = 1$). None of the deaths were directly attributable to the SEMS placement procedure.

4. Discussion

Malignant obstructive jaundice is a devastating complication of advanced malignancies, with primary hepatobiliary-pancreatic tumors being the most common etiology [1]. Metastatic MOJ, though less frequent, arises from diverse primary tumors and poses similar therapeutic challenges [2]. The primary goal of treatment is to achieve effective biliary decompression to relieve symptoms, improve quality of life, and enable subsequent anticancer therapy [3]. In this study, we demonstrated that fluoroscopy-guided SEMS placement is a safe and effective palliative intervention for both primary and metastatic MOJ, with high technical and clinical success rates and a favorable safety profile.

The 100% technical success rate in our study is consistent with previous reports [7, 9], highlighting the reliability of fluoroscopy-guided SEMS placement in traversing and stenting biliary strictures. The overall clinical success rate of 88.9% indicates that SEMS effectively relieves biliary obstruction in most patients, regardless of whether the obstruction is primary or metastatic. The slightly higher clinical success rate in the primary group (90.6% vs. 87.3%) was not statistically significant, suggesting that the etiological origin of MOJ does not affect the biochemical response to stenting. The overall PTBD removal rate of 86.1% reflects the successful transition from external to internal drainage, which is associated with improved patient comfort, reduced infection risk, and better nutritional status compared to long-term external drainage [10, 17].

Stent patency is a critical outcome measure for palliative biliary stenting, as occlusion leads to recurrent jaundice and compromised quality of life. In our study, the mean stent patency duration was longer in the primary group than in the metastatic group (112.0 vs. 86.6 days), but this difference was not statistically significant. This finding aligns with existing literature [20], suggesting that the fundamental mechanism of stent occlusion—primarily tumor progression—is common to both primary and metastatic MOJ, making etiology a less important determinant of patency than initially hypothesized. Notably, we found that subsequent chemotherapy was a key modifier of stent patency in metastatic MOJ patients, with those receiving chemotherapy having significantly longer patency (123.7 vs. 38.6 days, $p = 0.004$). This indicates a synergistic relationship between biliary stenting and chemotherapy: stenting enables chemotherapy by relieving hyperbilirubinemia, and chemotherapy controls tumor progression, thereby preventing stent occlusion. This "virtuous cycle" underscores that SEMS placement is not merely a palliative endpoint but a critical enabler of life-prolonging anticancer therapy [6], particularly in metastatic disease where systemic treatment is often indicated.

The safety profile of SEMS placement in our study was excellent, with no major procedure-related complications observed. Post-procedural fever, the most common minor complication, occurred in 28.3% and 32.7% of the primary and metastatic groups, respectively, and was effectively managed with antibiotics. This incidence falls within the reported range of 10%-30% for biliary stenting [10], and the absence of major complications (e.g., cholangitis, stent migration, severe bleeding) highlights the safety of the procedure when performed by experienced interventional radiologists. The overall reintervention rate of 22.2% is comparable to previous studies [8, 20], and the successful management of stent occlusion with the stent-in-stent technique further supports the utility of SEMS in long-term palliation.

A notable finding in our metastatic cohort was the predominance of colorectal cancer (83.6%) as the primary tumor. Colorectal cancer frequently metastasizes to the liver and regional lymph nodes, and hepatic hilar lymphatic spread leading to common bile duct infiltration is the primary mechanism of biliary obstruction in these patients [16]. This highlights the need for heightened awareness of MOJ as a potential complication in advanced colorectal cancer. Additionally, the higher rate of subsequent chemotherapy in the metastatic group (56.4% vs. 34.0%, $p = 0.019$) likely reflects the greater feasibility of systemic treatment in metastatic colorectal cancer compared to some primary hepatobiliary malignancies (e.g., advanced cholangiocarcinoma), where treatment options may be more limited [19].

This study has several limitations inherent to its retrospective design. First, the retrospective nature precluded standardized assessment of symptomatic outcomes (e.g., pruritus relief, quality of life) using validated tools. Second, incomplete tumor staging data for some patients may have affected the analysis of prognostic factors. Third, the absence of a comparative cohort (e.g., patients managed with ENBD or plastic stents) prevents definitive conclusions regarding the relative advantages of SEMS over alternative drainage modalities. Fourth, the long study period (2013–2024) may have introduced variability in stent technology and clinical practice, though a standardized procedural protocol was maintained. Future prospective, multicenter studies with larger sample sizes and standardized outcome assessments are needed to validate these findings.

5. Conclusions

Fluoroscopy-guided SEMS placement is a safe and effective palliative intervention for both primary and metastatic malignant obstructive jaundice, with high technical and clinical success rates. Stent patency and safety are independent of the underlying tumor etiology. Subsequent chemotherapy significantly improves stent patency in patients with metastatic MOJ. Therefore, a combined strategy of biliary stenting followed by systemic chemotherapy is recommended to optimize palliative outcomes in patients with metastatic disease.

Abbreviations

SEMS = Self-Expandable Metal Stent

MOJ = Malignant Obstructive Jaundice

ENBD = Endoscopic Nasobiliary Drainage

PTBD = Percutaneous Transhepatic Biliary Drainage

CT = Computed Tomography

MRCP = Magnetic Resonance Cholangiopancreatography

US = Ultrasonography

DSA = Digital Subtraction Angiograph

SIR = Society of Interventional Radiology

Declarations

***Ethical Approval and Consent to Participate**

The requirement of ethical approval for this study was waived by the Institutional Review Board of The Sixth Affiliated Hospital, Sun Yat-sen University in accordance with the relevant policies of the hospital for research involving fully anonymized, pre-existing medical records and with the ethical principles outlined in the Declaration of Helsinki.

***Consent for Publication**

Written informed consent for publication was obtained from all participants.

***Availability of data and materials**

The original contributions presented in the study are included in the article/supplementary material. Further inquiries can be directed to the corresponding author

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Author Contribution

HL, KW, YL, and BZ performed SEMS implantation. HL, KW, YL, DL, TP, YW and BZ conducted the acquisition of data, analysis, and interpretation of data, drafting of the manuscript, and statistical analysis; HL, KW, and BZ performed the study concept and design, critical revision of the manuscript for important intellectual content, and study supervision.

Data Availability

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Figures

Figure 1.

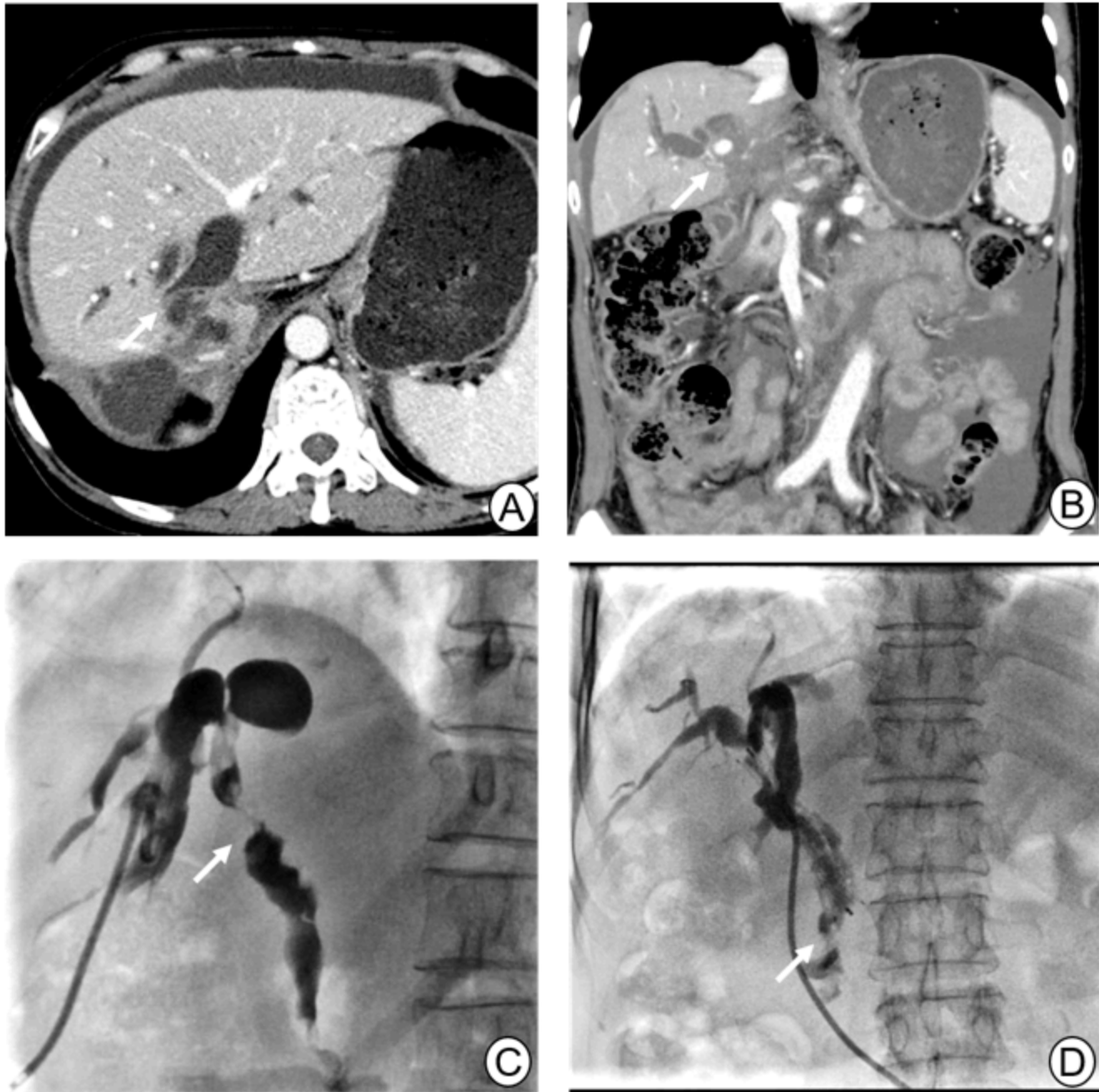


Figure 1

A 63-year-old woman with hilar cholangiocarcinoma (primary MOJ). (A, B) Abdominal contrast-enhanced CT scan showing a tumor (arrow) invading the common bile duct, causing local luminal stenosis and intrahepatic bile duct dilatation. (C) Fluoroscopic image during SEMS placement: iodinated contrast medium was injected to confirm the stenosis site, and the stent was deployed across the occluded segment (arrow). (D) Follow-up cholangiography at a week post-procedure confirmed stent patency and resolution of biliary dilatation.

Figure 2.

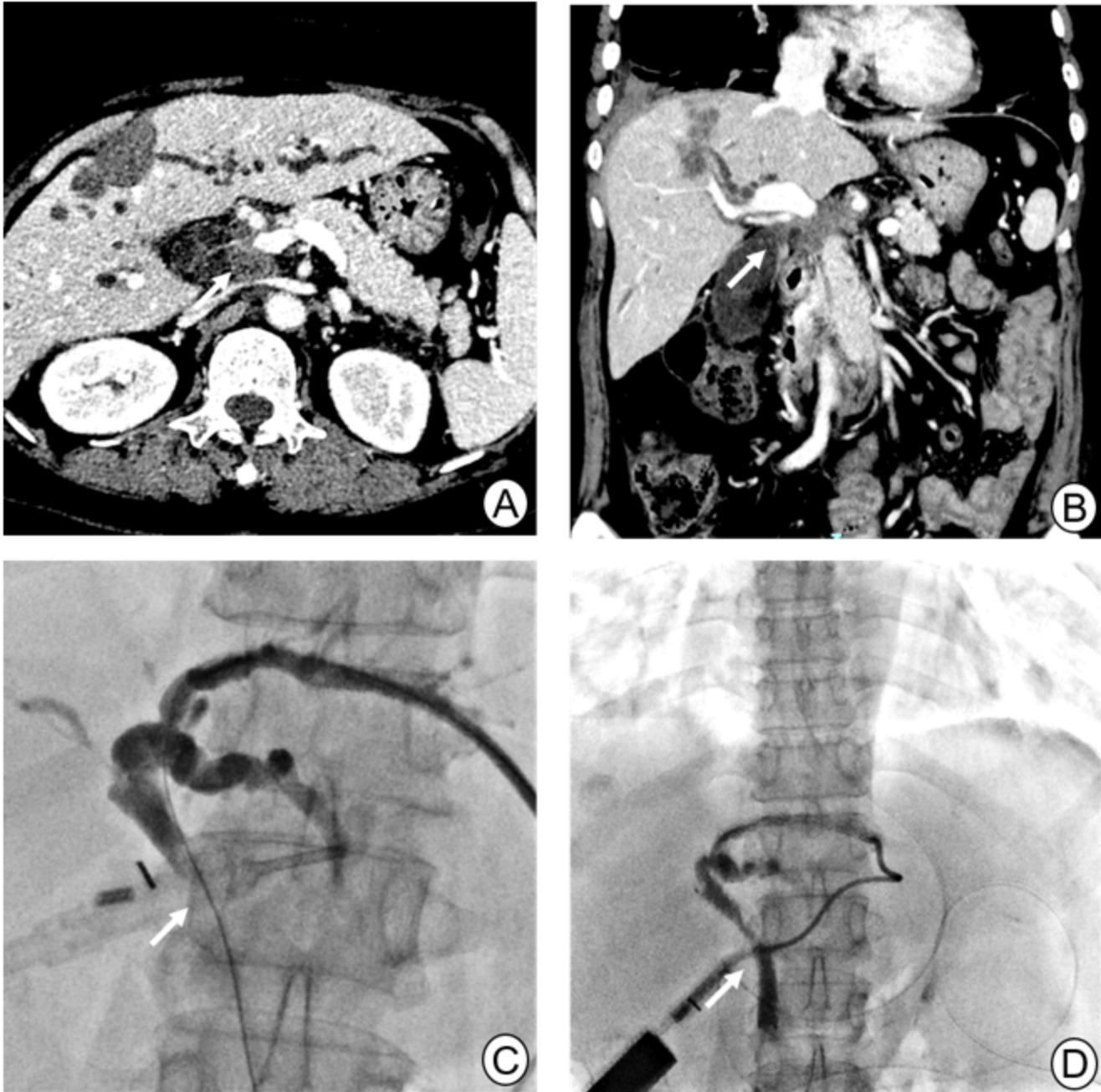


Figure 2

A 64-year-old woman with rectal cancer metastatic to hilar lymph nodes (metastatic MOJ). (A, B) Abdominal coronal contrast-enhanced CT scan showing a tumor (arrow) invading the common bile duct, resulting in local luminal stenosis and intrahepatic bile duct dilatation. (C) Fluoroscopic image during SEMS placement: contrast medium injection confirming the stenosis site, with stent deployment across the occluded segment (arrow). (D) Follow-up cholangiography at a week post-procedure confirmed stent patency and resolution of biliary dilatation.

Figure 3.

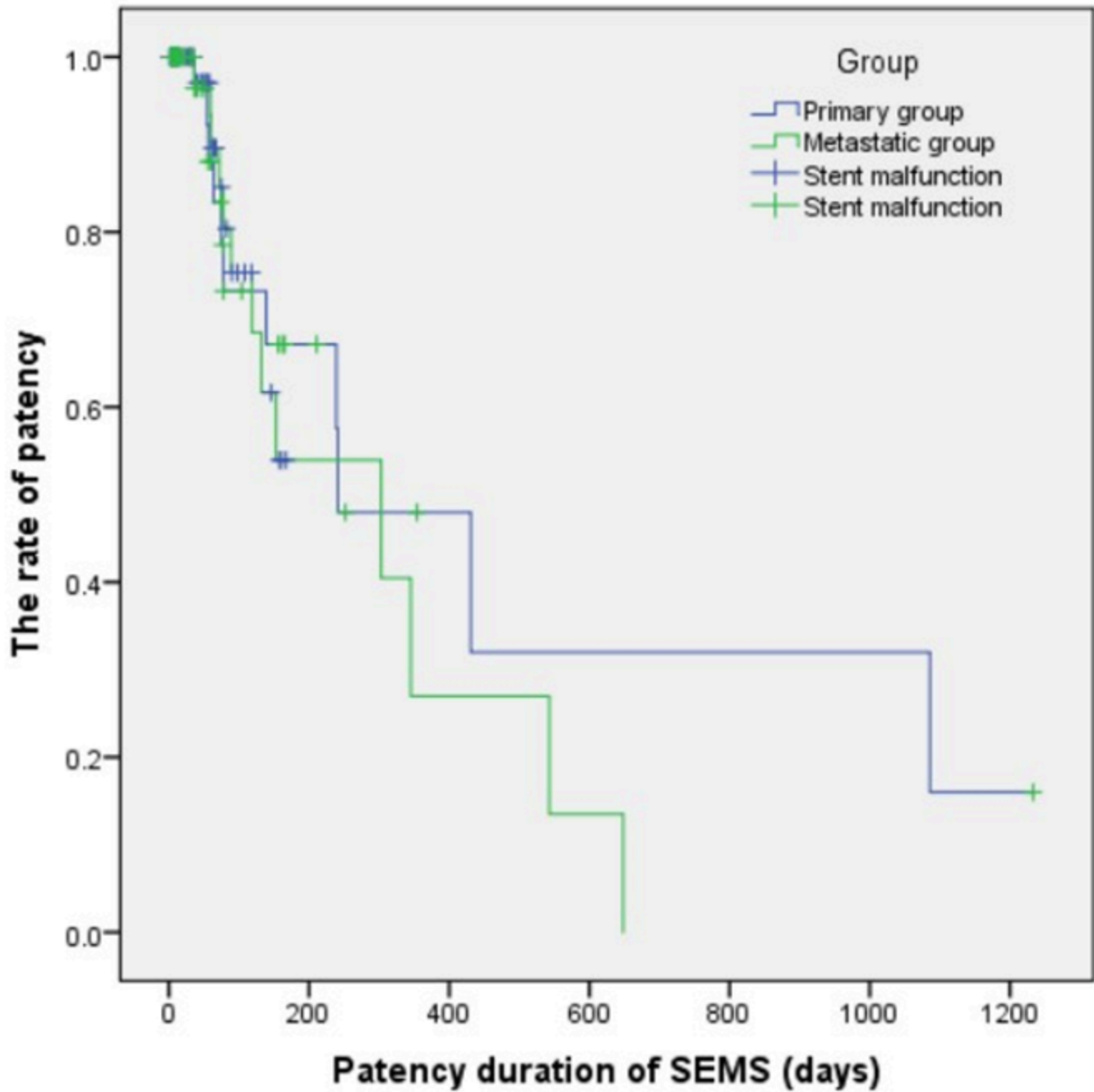


Figure 3

Kaplan-Meier curve for stent patency in primary versus metastatic malignant obstructive jaundice (MOJ) groups. The mean stent patency duration was 112.0 ± 227.2 days in the primary group and 86.6 ± 120.1 days in the metastatic group, with no statistically significant difference (log-rank test, $p=0.470$).