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Retrospective Study

Uncovered Self-Expanding Metal Stent Placement for Unresectable Malignant Biliary Obstruction: Hope or Hype?

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Abstract

Background: Biliary drainage is recommended for unresectable malignant Extrahepatic Biliary Obstruction (EHBO) to palliate jaundice, pruritus, and cholangitis, yet real-world data from India on uncovered Self-Expanding Metal Stents (SEMS) remain limited.

Methods: This single-center retrospective analysis of prospectively collected data from GB Pant Hospital, New Delhi, evaluated stent patency and survival after uncovered biliary SEMS insertion in biopsy-proven unresectable malignant EHBO (Bismuth types 1-3 and distal obstruction) between September 1st, 2023, and December 31st, 2024, with biweekly follow-up until March 13th, 2025, or death. The primary outcome was stent patency at 3 months; secondary outcomes included clinical success at 2 weeks, 6-month survival, and adverse events.

Results: Forty-nine patients were included, most commonly with gallbladder carcinoma (67%); 95.8% had ECOG performance status ≤ 2. Technical success was 100% and clinical success 86%. ERCP-related adverse events occurred in five patients (Three perforation: managed as two conservative, one surgical; one post-sphincterotomy bleed; one aspiration pneumonia), with two procedure-related deaths (aspiration pneumonia and surgically managed perforation). Only 24% initiated chemotherapy post-stenting. Median survival was 89 days, with 20.7% alive at 6 months and most deaths attributable to disease progression.

Conclusion: Uncovered SEMS showed high technical success and acceptable short-term clinical efficacy, but a very high 6-month mortality rate, due to limited access to chemotherapy and aggressive gallbladder cancer, which may lessen the practical benefit of SEMS compared to plastic stents in settings with limited palliative oncological therapy.

Keywords: Uncovered SEMS; Biliary cancer; Cholangitis; Jaundice; Pruritus

Introduction

Biliary drainage is indicated for unresectable malignant Extrahepatic Biliary Obstruction (EHBO) to palliate jaundice and pruritus. The use of biliary Self-Expanding Metal Stents (SEMS) in unresectable EHBO is increasing; however, data on the safety and efficacy of uncovered biliary SEMS in India remains limited. The study aimed to assess whether uncovered SEMS are associated with meaningful improvements in stent patency, complication rates and survival in patients with unresectable malignant EHBO.

Methodology

This study is a single-center retrospective analysis of prospectively collected data from September 1st, 2023, to December 31st, 2024, at the GB Pant Hospital, New Delhi. Patients with unresectable biopsy-proven malignant EHBO with Bismuth classification types 1,2,3, and distal biliary obstruction were included. Covered SEMS and SEMS placed for benign causes of extrahepatic biliary obstruction during the study period were excluded (Figure 1A). The Institutional Ethics Committee granted a waiver of ethical clearance considering the retrospective nature of the study.

The patients were admitted pre-procedure and received IV antibiotics on admission. ERCP indications included pre-chemotherapy palliation of jaundice, pruritus, and cholangitis. The procedure was performed using a standard duodenoscope (TJF-Q190V Duodenoscope, Olympus®, Tokyo, Japan).

After successful biliary cannulation, bile aspiration and air cholangiography were performed to confirm the position, and endoscopic sphincterotomy was performed. EGISTM (S&G Biotech Inc., Gyeonggi-do, Republic of Korea) single bare metallic SEMSs were placed in all patients, with 10 mm diameter and 8 cm or 10 cm length stents, except for the Bismuth Type 3 block, where bilateral SEMS were placed (Figure 1B-1D). Complications were managed according to standard protocols. Patients were referred for chemotherapy after successful ERCP stenting and followed up biweekly for complications until March 13th, 2025, or mortality.

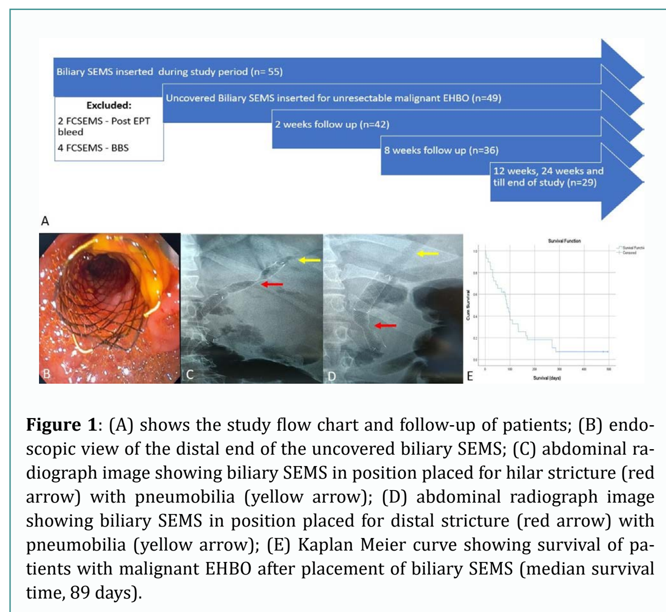

Figure 1: (A) shows the study flow chart and follow-up of patients; (B) endoscopic view of the distal end of the uncovered biliary SEMS; (C) abdominal radiograph image showing biliary SEMS in position placed for hilar stricture (red arrow) with pneumobilia (yellow arrow); (D) abdominal radiograph image showing biliary SEMS in position placed for distal stricture (red arrow) with pneumobilia (yellow arrow); (E) Kaplan Meier curve showing survival of patients with malignant EHBO after placement of biliary SEMS (median survival time, 89 days).

The primary outcome of this study was the frequency of stent patency at 3 months. Secondary outcomes included clinical success at 2 weeks, overall survival at 6 months, and adverse events. Various study definitions and definitions of complications are provided in Supplementary Table 1.

Statistical analysis

Data were entered into an MS Excel spreadsheet, and statistical analysis was performed using SPSS v. 25. Categorical data were expressed as frequencies and percentages. Continuous data was expressed as mean +/standard deviation for normal distribution and median +/IQR for skewed distribution. Kaplan Meier analysis was used to assess survival and stent patency. Cox regression analysis was done for various predictors of survival and stent patency. $p<0.05$ was considered statistically significant.

Results

This study included 49 patients with biopsy-proven malignant EHBO who underwent placement of uncovered biliary SEMS. The most common malignancy was gallbladder carcinoma (67%). Baseline characteristics are shown in Table 1. Technical and clinical success rates were 100% and 86 %, respectively.

The median stent patency could not be reached owing to high mortality before stent placement. Three patients had developed stent block, with two managed by placement of plastic stents and one by another SEMS. ERCP-related complications occurred in five patients: Three perforations (two managed conservatively and one surgically), one post-sphincterotomy bleeding, and one aspiration pneumonia post-ERCP. Of these five patients, one with aspiration pneumonia and one who underwent surgery for perforation had succumbed to the respective complication. Chemotherapy was initiated only in 24% of patients after biliary SEMS placement. The median survival was 89 days, with six of 29 (20.7%) patients still alive at the 6-month follow-up. Most deaths occurred due to disease progression. This is shown in the Kaplan–Meier survival analysis in Figure 1E.

On univariable analysis, none of the evaluated factors demonstrated a significant association with stent patency or overall survival (Tables 2 and 3). Consequently, multivariable analysis was not performed, as no variables met criteria for inclusion based on univariable results.

Table 1: Baseline demographic, clinical, laboratory and imaging characteristics of the study.

Parameter	n = 49
Demographic Data	
Age, yrs, mean (SD)	54.24 ± 12.6
Sex, male, n (%)	25 (51%)
Comorbidities	
Hypertension	7 (14.2 %)
Diabetes	5 (10.2 %)
Disease characteristics; n (%)	
Etiology	
Carcinoma Gall Bladder	33 (67.3%)
Carcinoma of the head of the pancreas	6 (12.2%)
Cholangiocarcinoma	6 (12.2%)
Periampullary carcinoma	4 (8.2%)
ECOG Status	
1	6 (12.2%)
2	41 (83.6%)
3	2 (4.1%)
Hematological and biochemical parameters (Mean ± SD)	
Haemoglobin (g/dL)	10.4 ± 1.6
Total Leucocyte count (cells/uL)	12128 ± 7020
Platelets (cells/uL)	304936 ± 131733
Total Bilirubin (mg/dL)	14.3 ± 6.9
Aspartate Transaminase (U/L)	119.6 ± 69.5
Alanine Transaminase (U/L)	70.2 ± 34.0
Alkaline Phosphatase (U/L)	759.9 ± 582.8
International Normalised Ratio	1.12 ± 0.43
Blood Urea (mg/dL)	35.61 ± 31.81
Serum Creatinine (mg/dL)	0.87 ± 0.47
Total Protein (g/dL)	6.5 ± 0.82
Serum Albumin (g/dL)	2.89 ± 0.6
Level of block based on MRCP Findings; n(%)	
Hilar Block as per Bismuth-Corlette Classification	
Type 1	9 (18.4%)
Type 2	19 (38.8%)
Type 3	10 (20.4%)
Distal Block	11 (22.4%)
Indications for stenting; n (%)	
Pre chemotherapy	18 (36.7%)
Pruritus	5 (10.2%)
Both	26 (53.1%)
Stent characteristics; n (%)	
Single SEMS	39
Bilateral SEMS	10
Length of stent (cm); mean (SD)	9 ± 1.09

cm: centimeters; ECOG: Eastern Cooperative Oncology Group; MRCP: Magnetic Resonance Cholangiopancreatography; SD: Standard Deviation; SEMS: Self-Expandable Metal Stent

Table 2: Univariate cox proportional hazards analysis for survival.

Parameter	HR	Lower CI	Upper CI	p value
Age >50 years	0.022	0.000	386322.378	0.655
Male sex	297.491	0.000	455100686635.310	0.598
Comorbidities present	33.552	0.000	3690760904.748	0.710
Etiology:				
CaGB	1.612	0.093	27.911	0.743
CaHOP	24.045	0.000	17700294263592.918	0.820
PACA	0.354	0.015	8.291	0.518
Cholangiocarcinoma	21.902	0.000	644731834710147070.000	0.873
ECOG prior to stenting	50.075	0.000	19637714.587	0.551
Non-hilar (distal) block	0.798	0.049	12.982	0.874
Distant metastasis present	0.019	0.000	209992.700	0.631
Number of SEMS placed	24.045	0.000	17700294263593.105	0.820
Length of stent (cm)	0.893	0.221	3.603	0.874
Complications occurred	21.902	0.000	644731834710174590.000	0.873
Stent obstruction	0.038	0.000	292628903.407	0.778
Received chemotherapy	1.254	0.077	20.400	0.874
Total Bilirubin (mg/dl)	0.724	0.447	1.174	0.190
ALP (IU/L)	0.999	0.994	1.004	0.829
INR	0.172	0.000	400.246	0.656

Table 3: Univariate cox proportional hazards analysis for stent patency.

Parameter	HR	Lower CI	Upper CI	p value
Age >50 years	0.531	0.225	1.253	0.149
Male sex	2.094	0.895	4.898	0.088
Comorbidities present	0.480	0.180	1.285	0.144
Etiology:				
CaGB	0.942	0.397	2.233	0.892
CaHOP	0.486	0.131	1.799	0.280
PACA	1.939	0.535	7.022	0.313
Cholangiocarcinoma	0.872	0.201	3.773	0.854
ECOG prior to stenting	0.475	0.204	1.110	0.085
Non-hilar (distal) block	1.025	0.455	2.309	0.953
Distant metastasis present	0.630	0.270	1.467	0.284
Number of SEMS placed	0.40	0.138	1.162	0.092
Length of stent (cm)	1.118	0.742	1.685	0.594
Complications occurred	0.214	0.073	0.626	0.070
Received chemotherapy	0.446	0.166	1.199	0.110
Total Bilirubin (mg/dl)	1.005	0.945	1.069	0.873
ALP (IU/L)	1.000	1.000	1.001	0.258
INR	4.456	1.433	13.856	0.100

Discussion

This study describes a real-world scenario involving patients with unresectable malignant EHBO. The etiology of malignant EHBO was similar to that reported in previous studies from northern India [1,2]. Most patients had an ECOG performance status ≤ 2 (95.8%) at the time of SEMS placement, indicating that they were eligible for chemotherapy [3-5]. However, only 24% of patients received chemotherapy, which is possible due to the denial of chemotherapy, poor socioeconomic status, and rapid progression of the disease before the bilirubin level reached a suitable level for chemotherapy.

The high mortality rate (80 %) in this study can be attributed to the lack of chemotherapy and the predominance of rapidly progressive GB carcinoma. A meta-analysis revealed that plastic stents had a median patency of 36 days to 173 days, whereas metallic stents had a median patency of 76 to 276 days [6]. The European Society of Gastrointestinal Endoscopy recommends SEMS for malignant EHBO [7]. A study in Jaipur reported a mean stent patency of 109 days for unresectable malignant EHBO, with greater efficacy in distal strictures than in hilar strictures [8]. Owing to the high mortality rate, median stent patency could not be achieved. While SEMS placement was effective for biliary decompression, survival outcomes were primarily influenced by advanced malignancy and limited treatment options.

None of the factors on showed a significant association with survival or stent patency univariable analysis. This may be attributable to the relatively small sample size, high attrition rate, and predominance of advanced, aggressive malignancies with poor overall survival, which could have limited the ability to detect statistically significant differences between subgroups.

The choice between covered and uncovered SEMS in malignant EHBO also remains controversial. Several meta-analyses have demonstrated no consistent superiority of covered SEMS over uncovered SEMS with respect to overall stent patency or patient survival. Almadi et al. reported in their meta-analysis with 1061 patients that although covered SEMS reduced tumor ingrowth, they were associated with significantly higher migration rates and did not demonstrate clear long-term patency benefits compared with uncovered SEMS [6]. Similarly, Li et al., in a meta-analysis of 14 trials involving 1417 patients, found no significant differences between covered and uncovered SEMS regarding cumulative stent patency, survival, or overall complication rates. They found that tumor ingrowth was more common with uncovered SEMS compared with more tumor overgrowth in covered SEMS as the cause for loss of stent patency [9]. Randomized studies have also shown conflicting findings, with some reporting longer patency for uncovered SEMS due to lower migration rates compared to covered SEMS (541 days *vs* 240 days) [10], whereas others demonstrated reduced tumor ingrowth with covered SEMS but without improvement in survival outcomes [11].

While uncovered SEMS are generally considered more cost-effective because of longer patency and fewer reinterventions, this advantage is most relevant in patients with an expected survival beyond 3 months. In our cohort, the high early mortality likely attenuated the practical benefit of prolonged stent patency, underscoring the need to individualize stent selection according to anticipated survival and feasibility of repeat interventions [12].

A major limitation of the present study was the high attrition rate, with approximately 40.8% of patients lost to follow-up. Given the retrospective design, outcome assessment depended on the availability of hospital records and follow-up documentation, which may have contributed to incomplete long-term data capture. In addition, many patients had advanced malignancy, belonged to lower socioeconomic strata, and were referred from distant regions, making continued follow-up challenging. This may have introduced follow-up bias and affected the assessment of long-term outcomes such as stent patency, reintervention rates, and survival. Patients lost to follow-up may have undergone subsequent interventions or experienced disease progression or death outside our institution. Therefore, the long-term efficacy outcomes should be interpreted with caution. At the same time, the high attrition rate reflects the practical difficulties of maintaining longitudinal follow-up in patients with advanced hepatobiliary malignancies in resource-limited settings.

Conclusion

SEMS placement appears to be a safe and effective modality for palliation of malignant EHBO, providing biliary decompression and symptomatic relief in patients with unresectable disease. However, the high six-month mortality rate (~80%) underscores the aggressive underlying disease biology and limited impact of currently available palliative chemoradiotherapy on overall survival. Therefore, the potential advantages of metallic over plastic stents should be interpreted within the framework of expected survival and individual patient prognosis.

Declaration

Ethical Approval and Consent to participate – Waived in view of retrospective data analysis

Human Ethics - NA

Consent for publication - Written consent taken from all patients

Authors' Contributions

Venkatesh Vaithiyam, Barjesh Chander Sharma, Ashok Dalal, and Siddharth Srivastava are involved in the patient's care and data collection. Siddharth Srivastava, Lalit Chandra Kummetha, Ujjwal Sonika and Venkatesh Vaithiyam - conceptualization and original draft of manuscript, Siddharth Srivastava, Sanjeev Sachdeva - Supervision and final review of the manuscript.

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Supplementary Table 1: Various study definitions.

Technical Success	
Distal block	Successful placement of biliary SEMS with proximal end above the level of block, with free flow of bile.
Hilar block	Successful placement of biliary SEMS with proximal end above the level of block in both right and left systems, with free flow of bile.
Clinical Success	A fall in bilirubin by >50% from baseline 2 weeks after SEMS placement
Complication	
Post ERCP Perforation	Defined and classified as by Stapfer et al., 2000
Post ERCP Pancreatitis	New or worsened abdominal pain combined with elevated pancreatic enzymes (amylase or lipase ≥ 3 times upper limit of normal), thus prolonging a planned hospital admission or necessitating hospitalization after an ERCP
Post-ERCP Sphincterotomy Bleeding	Immediate bleeding requiring endoscopic or other intervention within 24 hr, or delayed bleeding recognised based on clinical evidence (such as melena, haematochezia, and hematemesis), with a decrease in haemoglobin level >2 g/dL or the need for blood transfusion within 10 days after ERCP
Cholangitis	Defined as per the Tokyo criteria, TG18