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Comparison of Stent Patency, Biochemical and Clinical Improvement in Plastic Versus Metallic Biliary Stent for Palliation in Malignant Biliary Obstruction in a Developing Country Tertiary Hospital

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ABSTRACT

Objective: To compare stent patency, biochemical, and clinical outcomes between partially covered self-expandable metal stents (SEMS) and plastic stents (PS) in patients with malignant biliary obstruction.

Methodology: A prospective observational study was conducted at Faisalabad Teaching Hospital from January to June 2024. Sixty patients with malignant biliary obstruction confirmed by imaging and elevated bilirubin (≥1.75 mg/dL) were included. Patients were allocated to PS or SEMS groups based on clinical judgment. ERCP was performed by experienced gastroenterologists. Outcomes assessed included stent patency, biochemical improvement, complications, and reintervention rates. Data were analyzed using SPSS v20 with t-test and Chi-square; $p < 0.05$ was considered significant.

Results: The PS group included 30 patients (60% male; mean age 57.9 ± 7.9 years), and the SEMS group included 30 patients (66.7% male; mean age 55.7 ± 6.9 years). Pancreatic cancer was the most frequent diagnosis, followed by gallbladder cancer and cholangiocarcinoma. Post-procedural cholangitis was significantly higher in the PS group (80.0%) compared to SEMS (43.3%; $p = 0.003$). Stent dysfunction occurred in 63.3% of PS versus 33.3% of SEMS ($p = 0.021$). Mean stent patency was significantly longer with SEMS (190.5 ± 98.7 days) than PS (128.7 ± 54.3 days; $p = 0.004$). Biochemical improvement and symptom relief were superior in the SEMS group, with fewer reinterventions and shorter hospital stays.

Conclusion: SEMS demonstrated better patency, lower complication rates, and improved clinical outcomes compared to PS, supporting their use as a more effective palliative option in malignant biliary obstruction, especially for patients with longer life expectancy.

Keywords: Malignant biliary obstruction, self-expandable metal stents, plastic stents, stent patency, palliation.

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Introduction

Malignant biliary obstruction is a serious and often late-stage complication of various abdominal malignancies. Pancreatic adenocarcinoma is the most prevalent cause in the West, but gallbladder cancer (GBC) is the primary cause in India and Pakistan. Cholangiocarcinoma, ampullary carcinoma, metastatic illness, and malignant lymphadenopathy are other causes. GBC, the most common biliary tract malignancy, is common across the Indo-Gangetic region and portions of Pakistan. Approximately half of all GBC patients present with jaundice, which typically indicates advanced, inoperable disease.[1] The prognosis of pancreato-biliary malignancies remains poor, with up to 85% of patients presenting at a stage where curative therapy is no longer feasible.[2]. Even with surgical resection, the median survival is around 25–

34 months; for unresectable cases, it drops significantly to about 4.7 months.[3, 4,5]

Obstructive jaundice in these patients leads to a spectrum of debilitating complications, including pruritus, malabsorption, coagulopathy, cholangitis, and biliary sepsis, potentially culminating in multi-organ failure and death.[6] In unresectable cases, palliative biliary drainage becomes the cornerstone of management to relieve symptoms and prevent complications.

Endoscopic retrograde cholangiopancreatography (ERCP) with PS or SEMS stent implantation is recommended for malignant distal common bile duct blockage palliation. The choice of stent traditionally depends on the patient's clinical condition, expected survival, and local expertise. PS are less expensive and more familiar to many healthcare teams, but require replacement every 3–4 months due to higher rates of occlusion and migration. In contrast, SEMS offer significantly longer patency and may offset their higher initial cost with fewer interventions over time.[7, 8]

Given the limited life expectancy of these patients, cost-effectiveness and quality-of-life considerations are essential in guiding stent selection.[9, 10] While multiple studies have shown longer patency and lower re-intervention rates with SEMS, findings are inconsistent, and there is limited data particularly from low-resource settings comparing biochemical and clinical outcomes between plastic and metal stents.[11] The aim of this study is to compare stent patency, biochemical improvement, and clinical outcomes between plastic and metallic stents used in the palliative management of malignant biliary obstruction in a tertiary care hospital in a developing country.

Methodology

This observational cohort study was conducted at Faisalabad Teaching Hospital, Faisalabad from 1.01.2024 to 30.06.2024 after obtaining approval from the ERC vide letter no.48-ERC/FMU/2022-23/336. Written informed consent was obtained from all participants. Patients age>18year, both genders, diagnosed with malignant biliary obstruction confirmed by abdominal CT scan and/or MRCP, had clinical symptoms of obstructive jaundice (e.g., icterus, pruritus, dark urine, pale stools), serum total bilirubin ≥1.75 mg/dL at the time of presentation, and not undergone prior biliary surgery or stenting were included in study. Sample size 60 was calculated using WHO sample size calculator at 5% level of significance, taking anticipated proportion of CBD as 10%[12] and margin of error 8%. Patients with previous surgery of the bile ducts, Benign causes of biliary obstruction, Severe coagulopathy precluding ERCP and patient refusal or inability to provide informed consent were excluded. Patients were not randomized. The choice between PS or SEMS was made by the attending endoscopist based on clinical judgment, stent availability, life expectancy, and anatomical considerations. All ERCP procedures were performed by an assistant professor or senior consultant gastroenterologist. Baseline liver function tests LFTs were recorded prior to ERCP.

Follow-up LFTs were obtained 6 months post-procedure. Patients were followed clinically and biochemically at 1, 3, and 6 months. Imaging was done when clinically indicated to assess stent position and patency. The primary outcomes assessed in this study included stent patency was defined as the duration (in days) from the time of stent placement during ERCP to the first documented evidence of stent dysfunction, patient death, or last follow-up occurred first) duration defined as the time from stent placement to stent occlusion or the need for re-intervention, and biochemical improvement, measured by serial reductions in serum bilirubin and liver enzyme levels over time. Stent dysfunction was defined as the clinical and/or radiological evidence of stent failure, indicated by recurrence of obstructive symptoms, elevated liver function tests, or imaging evidence requiring re-intervention or stent replacement. Clinical improvement was evaluated based on the resolution of symptoms such as jaundice, pruritus, and abdominal discomfort. The study also recorded procedure-related complications, including stent migration, occlusion, and episodes of cholangitis. Lastly, overall survival was measured from the date of stent insertion to the last follow-up or death. All data were analyzed with SPSS for Windows version 20.0. The independent samples t-test was used to evaluate continuous variables (mean ± SD). Categorical variables were reported as frequencies and percentages and examined with the Chi-square test. A p-value of <0.05 was judged statistically significant.

Results

Study comprised of total 60 patients randomly divided into two groups (30 in plastic and 30 in SEMS). There were 18 (60.0%) males and 12(40.0%) females in plastic group and 20 (66.7%) males and 10(33.3%) females in group SEMS. Mean age of the patients was57.87±7.90 years in plastic and 55.70±6.87years in SEMS group. There were 17 (56.7%) patients in plastic and 21(70.0%)

in SEMS group that were <60 years age and 13 (43.3%) in plastic and 9(30.0%) in SEMS group that were ≥ 60 years age. Residence of most the patients was urban (66.7% in plastic and 56.7% in SEMS group. Diagnosis of the patients showed that hepatocellular carcinoma was most common in both groups (9(30.0%) in plastic and 7(23.3%) in group SEMS followed by pancreatic, ampullary and Cholangiocarcinoma. Initial albumin level was < 3.5 g/dl in 24 (80.0%) in plastic and 25(83.3%) in SEMS group and ≥ 3.5 g/dl in 6(20.0%) patients of plastic and 5(16.7%). 24 (80.0%) patients in plastic and 13(43.3%) in SEMS group has Cholangitis after stent implant (Table I).

Table I: Demographic and clinical Characters of Patient. (n=60)

	Group		P Value
	Plastic	SEMS	
Gender			
Male	18 (60.0%)	20 (66.7%)	0.287
Female	12 (40.0%)	10(33.3%)	
Age			
< 60 Years	17 (56.7%)	21(70.0%)	0.284
≥60 Years	13 (43.3%)	9 (30.0%)	
Residence			
Rural	10 (33.3%)	13 (43.3%)	
Urban	20 (66.7%)	17 (56.7%)	0.426
Diagnosis			
Pancreatic cancer	9 (30.0%)	10(33.3%)	
Cholangiocarcinoma	5(16.7%)	5 (16.7%)	
Gallbladder cancer	8 (26.7%)	10(33.3%)	
Hepatocellular carcinoma	4(13.3%)	3(10.0%)	0.897
Other	4(13.3%)	2(6.7%)	
Liver metastasis			
Yes	7(23.3%)	6(20.0%)	0.765
No	23 (76.7%)	24 (80.0%)	
Initial albumin level			
< 3.5 g/dl	24 (80.0%)	25(83.3%)	0.739
> 3.5 g/dl	6(20.0%)	5(16.7%)	
Cholangitis			
Yes	24 (80.0%)	13 (43.3%)	0.003
No	6 (20.0%)	17 (56.7%)	
Total	30(100.0%)	30(100.0%)	

Biochemical parameters such as ALT, AST and Bilirubin were noted at start, 7th, 14th day, 01**,** 03 and 06 months. Total number of interventions in 6 months period was higher in plastic group as compared to SEMS. Stent Dysfunction was higher (19(63.3%) in plastic group as compared to SEMS group and there was a significant difference in two groups (0.021) as shown in table II.

Patients' subjective well-being was assessed using a predesigned, five-item questionnaire developed for this study. The questionnaire evaluated common symptoms associated with malignant biliary obstruction, including appetite, pain, shortness of breath, nausea, and vomiting. Each symptom was rated on a Likert-type scale with responses ranging from "not at all" to "very much." Over the 6-month follow-up period following stent placement, a noticeable improvement was observed across all assessed symptoms, indicating enhanced symptom control and better perceived well-being among patients.

Table II: Biochemical parameters at start and 6 months period.

	Plastic	SEMS	P Value
ALT			
At start	191.63±52.86	218.83±71.69	0.100
6 months	35.80±6.97	38.93±9.46	0.149
AST			
At start	179.97±63.96	200.10±86.13	0.308
6 months	45.13±13.25	49.80±21.99	0.324
Bilirubin			
At Start	13.22±2.25	14.48±1.40	0.069
6 months	1.783±.735	1.880±.64	0.589
Number of interventions in 6 months			
Once	24 (80.0%)	20 (66.7%)	
Twice	7 (23.3%)	4 (13.3%)	0.501
>Twice	3 (10.0%)	2 (6.7%)	
Stent Dysfunction			
Yes	19 (63.3%)	10 (33.3%)	0.021
No	11 (36.7%)	20 (66.7%)	
Total	30 (100.0%)	30(100.0%)	
Length of stay	14.70±1.93	12.63±1.92	0.000
Stent Patency	128.66±54.31	190.50±98.7	0.004

Table III: Patient-Reported Symptom Profile Following Stent Insertion.

Symptom	Response	Plastic N(%)	SEMS N(%)	Total	P Value
Have you lacked appetite?	Quite a bit	10(33.3)	9(30.0)	19(31.7)	0.077
	Very much	20(66.7)	21(70.0)	41(68.3)	
Have you had pain?	Quite a bit	12(40.0)	10(33.3)	22(36.7)	0.287
	Very much	18(60.0)	20(66.7)	38(63.3)	
Were you short of breath?	Quite a bit	7(23.3)	6(20.0)	13(21.7)	0.098
	Very much	23(76.7)	24(80.0)	47(78.3)	
Have you felt nauseated?	Quite a bit	9(30.0)	7(23.3)	16(26.7)	0.341
	Very much	21(70.0)	23(76.7)	44(73.3)	
Have you vomited?	Quite a bit	9(30.0)	6(20.0)	15(25.0)	0.371
	Very much	21(70.0)	24(80.0)	45(75.0)	
Total		**30(100.0)**	**30(100.0)**	**60(100.0)**	

Table IV: Improvement in Patient-Reported Symptoms After 6 Months.

Symptom	Response	Plastic N(%)	SEMS N(%)	Total N(%)	P Value
Appetite	Not at all	10(33.3)	9(30.0)	19(31.7)	0.077
	A little	20(66.7)	21(70.0)	41(68.3)	
Pain	A little	18(60.0)	20(66.7)	38(63.3)	0.287
	Quite a bit	12(40.0)	10(33.3)	22(36.7)	
Short breath	A little	23(76.7)	24(80.0)	47(78.3)	0.098
	Quite a bit	7(23.3)	6(20.0)	13(21.7)	
Nauseated	A little	21(70.0)	23(76.7)	44(73.3)	0.341
	Quite a bit	9(30.0)	7(23.3)	16(26.7)	
Vomited	A little	21(70.0)	24(80.0)	45(75.0)	0.276
	Quite a bit	9(30.0)	6(20.0)	15(25.0)	
Total		**30(100.0)**	**30(100.0)**	**60(100.0)**	

Discussion

Malignant obstructive jaundice is a severe illness that often leads to anorexia, pruritus, steatorrhea, and a gradual deterioration in quality of life. ERCP with biliary stenting has become the standard palliative method for inoperable malignant distal biliary blockage, offering significant symptom alleviation and enhanced biliary outflow.[13] The selection of plastic stents PS against SEMS is determined by patient prognosis, life expectancy, and financial factors, particularly in resource-constrained environments. SEMS are often favored for patients with a longer expected lifespan, owing to their enhanced patency relative to plastic stents.[14]

This comparative study was conducted at a tertiary care hospital in a developing country to evaluate stent patency, biochemical response, and clinical outcomes in patients receiving either PS or SEMS for malignant

obstruction. In the PS group, there were 18 (60.0%) males and 12 (40.0%) females, while in the SEMS group, 20 (66.7%) were male and 10 (33.3%) females. Mean age was 57.87 ± 7.90 years in the PS group and 55.70 ± 6.87 years in the SEMS group. Most patients were under 60 years of age: 17 (56.7%) in the plastic group and 21 (70.0%) in the SEMS group. These demographic patterns are comparable to findings from similar studies.[14] For example, Cabral et al. reported a cohort of 20 males and 38 women, with a median age of 64.5 years.[15]

In both groups, hepatocellular carcinoma was the most common diagnosis—9 (30.0%) in the plastic group and 7 (23.3%) in the SEMS group—followed by pancreatic, ampullary, and cholangiocarcinoma. Baseline serum albumin levels were <3.5 g/dL in 24 (80.0%) patients in the plastic group and 25 (83.3%) in the SEMS group. The remaining patients had albumin levels ≥3.5 g/dL. Notably, post-procedural cholangitis was more frequent in the plastic group (24 patients, 80.0%) compared to the SEMS group (13 patients, 43.3%), consistent with other reports in the literature.[16]

Rate of reintervention was higher in the PS group, not solely due to stent patency but also other clinical variables, a finding consistent with previously published studies.[17,18] The mean stent patency duration was significantly longer in the SEMS group (190.50 ± 98.7 days) compared to the plastic group (128.66 ± 54.31 days).

These findings align with previous literature, which reports average plastic stent patency around 123 days and metal stents at approximately 149 days.[16] Other studies have shown that median patency for plastic stents ranges from 35-165 days and for metallic stents from 80–273 days, reinforcing the superior durability of SEMS.[10, 19]

Conclusion

This study demonstrates that SEMS offer significant advantages over plastic stents in the palliative management of malignant biliary obstruction. Although demographic and clinical characteristics were largely comparable between groups, patients who received SEMS showed better clinical outcomes, including significantly longer stent patency (190.5 vs. 128.7 days, $p = 0.004$), reduced stent dysfunction rates (33.3% vs. 63.3%, $p = 0.021$), and fewer complications such as cholangitis ($p = 0.003$). SEMS were also associated with greater biochemical improvement, enhanced symptom control, and fewer reinterventions, supporting their long-term clinical and economic benefits.

Limitations: This study was limited by its single-center design and relatively small sample size, which may restrict the generalizability of the findings. The follow-up period was confined to six months. Additionally, quality-of-life assessments were based on a non-validated symptom questionnaire developed for this study, which may introduce response bias.

Recommendations: SEMS should be considered the preferred stenting option in patients with inoperable malignant biliary obstruction. In resource-constrained settings, SEMS offer a cost-effective strategy by minimizing the need for repeated interventions and hospital visits. Future multicenter studies with longer follow-up, and standardized quality-of-life tools are recommended to confirm these results and further evaluate survival benefits and patient satisfaction across different types of hepatobiliary malignancies.

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