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## Original Article

# Are self-expandable metal stents superior to plastic stents in palliating malignant distal biliary strictures? A meta-analysis and systematic review



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## ABSTRACT

**Background:** Palliation for inoperable malignant distal biliary strictures can be achieved with self-expandable metal stents (SEMS) and plastic stents (PS). This is a meta-analysis to compare PS and SEMS. The aim of the study is to compare clinical outcomes in patients with SEMS and PS.

**Methods:** Study selection criteria were studied using SEMS and PS for palliation in patients with malignant distal biliary stricture. For data collection and extraction, articles were searched in Ovid journals, Medline, Cochrane database, and Pubmed. Pooled proportions were calculated using both Mantel–Haenszel method and DerSimonian Laird method for statistical analysis.

**Results:** Initial search identified 1376 reference articles, of which 112 were selected and 11 studies ( $N = 947$ ) were included in this analysis. Pooled analysis showed SEMS patency to be 167.7 days (95% CI = 159.2–176.3) compared to 73.3 days (95% CI = 69.8–76.9) in PS. SEMS have lower odds of occlusion when compared to PS with an odds ratio of 0.48 (95% CI = 0.34–0.67). SEMS has a lower odds of cholangitis compared to PS, with an odds ratio of 0.46 (95% CI = 0.30–0.69).

**Conclusion:** SEMS seem to be superior to PS with better patency periods and survival duration. SEMS have lower occlusion rates, re-intervention rates, and cholangitis.

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## Introduction

Malignant distal biliary obstruction occurs as a result of primary neoplasms of pancreato-biliary tract and other local cancers (gall bladder and liver malignancies) that can compress the biliary tract. The local tumors manifest as strictures occluding the biliary tract.<sup>1</sup> The 5 year survival rate of most of these malignancies is less than 5%.<sup>2</sup> These malignancies are often unresectable at the time of presentation, thus making palliation with biliary stents a widely accepted management option.<sup>3-6</sup> Biliary obstruction causes jaundice, malabsorption, pruritus, anorexia, or cholangitis.<sup>4,5</sup> Endoscopic retrograde biliary drainage with decompression and placement of biliary stents can relieve obstructive symptoms and improve quality of life.<sup>7</sup> Furthermore, biliary stents have lower morbidity than bypass surgery and are often the best method for palliation.<sup>8-10</sup>

Biliary stents can broadly be classified into self-expandable metal stents (SEMS) and plastic stents (PS). Biliary stenting has shown to improve the quality of life of these patients and relieve jaundice.<sup>7</sup> Bore size of the stent plays a key role in stent patency. Smaller bore size leads to early blockade of stent from accumulation of biliary sludge.<sup>5</sup> Diameter of the PS is approximately 10-14 Fr compared to the diameter of the SEMS which is approximately 30 Fr after stent deployment. For a long time, PS have been used for palliation, however due to the short patency period, they had to be changed every few months. It is presumed that PS have significantly shorter patency period compared to uncovered self-expandable metal stents (USEMS).<sup>8-11</sup>

Previous retrospective studies, randomized control trials (RCTs), reviews and meta-analyses comparing the efficacy of PS and SEMS showed wide heterogeneity of results.<sup>8-18</sup> On comparison, there have been mixed outcomes in regards to stent patency periods, stent occlusion rates, stent migration, survival benefit, pancreatitis, cholecystitis, and cholangitis. There have also been recent studies published that were not included in the prior meta-analyses. In our meta-analysis, we sought to include all the available studies including RCTs and retrospective cohort studies comparing the efficacy of PS and SEMS in palliation of malignant distal biliary obstruction. Primary outcomes are stent patency periods (number of days the stent is patent) and occlusion rates of PS versus metal stents in managing malignant distal biliary strictures. Secondary outcomes include survival benefit, overall complications, stent migration, pancreatitis, cholangitis, and cholecystitis in both groups.

## Material and Methods

### Inclusion criteria

Studies using SEMS and PS for palliation in patients with malignant distal biliary stricture/obstruction. Studies comparing the two wings were included in this analysis. Studies should have looked at a minimum of two variables that must include stent patency days and adverse events. Patients in the studies should have had a malignant distal biliary stricture

that is either non-resectable (probably due to extensive distant metastasis or vascular invasion) or inoperable (due to other comorbidities).

### Exclusion criteria

Studies without a comparison arm (non-comparison studies) were excluded. Studies performed on biliary strictures in hilar or middle portion of biliary tree were excluded. Studies that looked at patients with prior radiological biliary procedures, prior biliary surgical procedures, and prior biliary stent placement were also excluded. Patients with American Society of Anesthesiologists (ASA) grade 4 or 5, inability to follow up, duodenal obstruction, potentially benign biliary obstruction were all excluded.

### Data collection and extraction

Articles were searched in Cochrane Central Register of Controlled Trials (CENTRAL), PubMed, Medline, Cumulative Index for Nursing & Allied Health Literature, EMBASE, ACP journal club, Medline nonindexed citations, Ovid journals, old Medline, DARE, International Pharmaceutical Abstracts, and OVID Healthstar. The search was performed for the years 1966 to December 2015. Major gastroenterology journals from the past 3 years were searched manually and relevant abstracts. Study authors for the abstracts included in this analysis were contacted when the required data for the outcome measures could not be determined from the publications. The search terms used were SEMS, PS, malignant distal biliary stricture, patency, occlusion rate, stent migration, mortality, morbidity, complications, systematic review and meta-analysis. Data was extracted and searched by two authors independently (HM and SP) into an abstraction form. Cohen's  $\kappa$  was used to quantify the agreement among the reviewers for the data collected.<sup>19</sup> Co-authors have resolved any differences in the study process by mutual agreement.

### Definitions

Stent patency is defined as the interval between stent insertion and stent occlusion or stent replacement. Stent occlusion is defined as development of jaundice with biochemical evidence of cholestasis, worsening transaminasemia and/or cholestasis with episodes of fever suggestive of cholangitis. Follow up period for all the studies included in this analysis was either till patient's death or stent occlusion or 12 months after first stent placement; whichever ever occurred first. Time till death is defined as the number of days the patient was alive since the first biliary stent placement as a palliative attempt.

### Quality of the studies

Quality of a study was assessed by many criteria (e.g. blinding of outcome, randomization, concealment of allocation, selection bias of the arms in the study).<sup>20,21</sup> Quality of the study could be assessed in RCTs or prospective studies with a treatment and control arm. In studies with no control arms, there is no clear consensus regarding how to assess them.

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