Self-expandable metal stents versus plastic stents for malignant biliary obstruction: a meta-analysis

Tarek Sawas, MD,[1] Shadi Al Halabi, MD, MPH,[2] Mansour A. Parsi, MD,[2] John J. Vargo, MD, MPH[2]

Milwaukee, Wisconsin; Cleveland, Ohio, USA

Background: Malignant biliary obstruction frequently portends a poor prognosis. Palliative treatment with stenting is often required to alleviate symptoms and potentially prevent adverse events.

Objectives: The aims of our study were (1) to evaluate the clinical difference between self-expandable metal stents (SEMSs) and plastic stents (PSs) in both hilar and distal malignant biliary obstruction on occlusion rate and 30-day mortality rate (primary outcomes) and stent insertion success rate, therapeutic failure, reintervention rate, and adverse events (secondary outcomes); (2) to compare unilateral stenting with bilateral stenting in hilar malignant obstruction in terms of occlusion rate and 30-day mortality rate (primary outcomes) and insertion success rate, therapeutic failure, and adverse events (secondary outcomes).

Methods: PubMed, Embase, and Cochrane databases were searched for studies that provided data about malignant biliary obstruction and stent therapy. We included randomized, controlled trials (RCT), prospective observational cohort, and retrospective case-control studies. The quality of each included RCT study was assessed by the Jadad scale. Mantel-Haenszel odds ratios (ORs) and mean differences were calculated by using a random-effects model.

Results: Nineteen studies involving 1989 patients (1045 SEMSs and 944 PSs) were included for the comparison of SEMSs and PSs. We also included 7 studies that compared unilateral with bilateral stenting involving 634 patients (346 unilateral and 268 bilateral). Our meta-analysis confirmed that SEMSs are associated with a statistically significant lower risk of occlusion compared with PSs in the short term (OR 0.27; 95% confidence interval [CI], 0.13-0.60) and long term (OR 0.38; 95% CI, 0.28-0.53). SEMSs had a lower 30-day occlusion rate than PSs in both hilar malignant obstruction (OR 0.16; 95% CI, 0.04-0.62) and distal malignant obstruction (OR 0.36; 95% CI, 0.14-0.93). SEMSs had a lower long-term occlusion rate compared with PSs in hilar malignant obstruction (OR 0.28; 95% CI, 0.19-0.39) and distal malignant obstruction (OR 0.42; 95% CI, 0.27-0.64). The 30-day mortality rate was similar with SEMSs and PSs (OR 0.74; 95% CI, 0.47-1.17). Therapeutic failure was more likely when using PSs (13%) compared with SEMSs (7%) (OR 0.43; 95% CI, 0.27-0.67). SEMSs required fewer reinterventions compared with PSs (mean difference, -0.49; 95% CI, -0.8 to -0.19). The incidence of cholangitis was statistically lower with SEMSs (8% vs 21%) (OR 0.41; 95% CI, 0.22-0.76). Bilateral stenting for hilar obstruction was not associated with a lower obstruction rate than unilateral stenting (OR 1.49; 95% CI, 0.77-2.89) or a lower 30-day mortality rate (OR 0.73; 95% CI, 0.29-1.79). There was no statistical difference in therapeutic failure (OR 1.47; 95% CI, 0.77-2.89) or cholangitis incidence (OR 0.61; 95% CI, 0.27-1.38).

Conclusion: SEMSs are associated with a statistically significantly lower occlusion rate, less therapeutic failure, less need for reintervention, and lower cholangitis incidence. There was no statistically significant difference in occlusion rate, therapeutic failure, and cholangitis incidence with bilateral stenting. Guideline recommendations may need to be modified to reflect clear and compelling data demonstrating the benefit of SEMSs in patients with malignant biliary obstruction. Bilateral stenting should be avoided because it has no benefit over unilateral stenting in terms of occlusion rate or therapeutic failure. (Gastrointest Endosc 2015;82:256-67.)

(footnotes appear on last page of article)

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Malignant biliary obstruction results from different types of tumors including pancreatic cancer, cholangiocarcinoma, gallbladder, and hepatocellular carcinoma. Obstructive jaundice is usually a marker that the malignancy is not amenable to surgical intervention,[1] and at this stage of the disease, palliative treatment with biliary stenting is the key step to alleviate symptoms and potentially prevent adverse events.[2]

The current approach to relieve malignant biliary obstruction is either through percutaneous or endoscopic stenting. The latter approach is more popular because it is less invasive and more comfortable for the patients.[3] Biliary stenting in malignant biliary obstruction improves cholestatic symptoms (jaundice, pruritus), anorexia, and overall quality of life.[4,5] The current choice for endoscopic stenting is either self-expandable metal stents (SEMSs) or plastic stents (PSs). PSs are composed of polyethylene, polyurethane, or Teflon,[6] whereas SEMSs are made of various metal alloys that are constructed to achieve adequate radial expandable force without sacrificing flexibility and conformability to the duct.[7] SEMSs can be either uncovered or covered with material to prevent tumor ingrowth. The current guidelines from the American Society for Gastrointestinal Endoscopy[8] for distal malignant biliary obstruction recommend either SEMSs or PSs, with PSs preferred in cases of distant metastasis and short life expectancy. However, studies have shown that although PSs are less expensive, metal stents have better drainage and longer patency,[9] with recent data showing they are more cost-effective.[10,11] In hilar malignant obstruction, both types of stent can be inserted, but there are not enough data to support the use of one over the other.[8] There is also a debate about whether unilateral stenting should be done versus bilateral stenting in hilar obstruction. We aimed to do a meta-analysis to provide evidence-based recommendations and detect differences between SEMSs and PSs in both hilar and distal malignant biliary obstruction on the occlusion rate and 30-day mortality rate (primary outcomes) and stent insertion success rate, therapeutic failure, reintervention rate, and adverse events (secondary outcomes). We also sought to determine the preferred method of stenting (unilateral vs bilateral) in hilar malignant obstruction in terms of occlusion rate and 30-day mortality rate (primary outcomes) and stent insertion success rate, therapeutic failure, and adverse events (secondary outcomes).

METHODS

Search strategy and study selection

PUBMED, Embase, and Cochrane Central Register of Controlled Trials were queried to identify all studies that assessed stenting for malignant biliary obstruction in humans published until September 2014. The following search terms were used: cholestasis, biliary malignancy, hilar obstruction, biliary tract neoplasia, biliary obstruction, stent, SEMSs, and PSs. Reference lists from relevant original papers, guidelines, and review articles were examined without a language or date restriction. Data stemming from animal and in vitro studies as well as those reports without original data were excluded. We excluded studies that did not compare SEMSs with PSs or only evaluated patients with nonmalignant biliary obstruction. Thus, studies were included in the systematic review and meta-analysis if they were randomized clinical trials, prospective or retrospective control studies comparing SEMSs with PSs in both hilar and distal malignant biliary obstruction or comparing unilateral with bilateral stenting for hilar malignant obstruction.

Data abstraction

Two investigators (T.S. and S.A.) performed an independent review of identified abstracts. Similarly, the selected papers for full review were also assessed. Discrepancies were resolved by a third reviewer (M.P.). For those selected studies, characteristics were abstracted including publication year, country, and study design. In addition, participant characteristics (age, sex, underlying malignancy, and the location of obstruction), type of the stent, occlusion rate, 30-day mortality rate, insertion success rate, therapeutic failure, reintervention rate, and adverse events (Supplementary Table 1, available online at www.giejournal.org) were also extracted. The Jadad score was used to assess the quality of the randomized, controlled trials (RCTs).[12] A Jadad score of 2 or higher was considered high quality. Non-RCTs were not given a score. Studies were included regardless of their quality. However, a sensitivity analysis was performed later based on the quality. The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guideline was used.[13] The primary clinical outcomes for the comparison between SEMSs and PSs were the occlusion rate and 30-day mortality rate. Secondary outcomes were stent insertion success rate, therapeutic failure, reintervention rate, and adverse events. The primary outcomes for the unilateral and bilateral stenting comparison were the occlusion rate and 30-day mortality rate. The secondary outcomes were the stent insertion success rate, therapeutic failure, and adverse events.

Stent occlusion was considered when patients experienced recurrent jaundice, an increase in liver enzymes, or bile duct dilation, as seen on imaging studies. Stent insertion success was defined as successful passage and deployment of the stent through the biliary stricture. Therapeutic failure was defined as the lack of resolution of cholestasis symptoms or failure of bilirubin to decrease after stent placement. Cholangitis was defined as a new onset of fever (temperature 38°C) without sources of infection outside the biliary tract and persisting for longer than 24 hours after ERCP.[14,15]

Statistical methods

For clinical outcomes, an intention-to-treat analysis was used. An odds ratio (OR) was calculated for dichotomous variables for each study. The pooled estimate and 95% confidence interval (CI) was estimated by using a Mantel-Haenszel random-effects model. For continuous outcomes, the mean difference was calculated with 95% CIs by using the inverse variance random-effects model. Heterogeneity among studies was assessed with the inconsistency index (I^2) statistic, which ranges from 0%