Comparison of plastic stents with self-expandable metal stents in palliative treatment of malignant biliary obstruction: a meta-analysis

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Abstract. – OBJECTIVE: The present study is to compare plastic stents (PS) with self-expandable metal stents (SEMS) in patients with malignant bile duct obstruction.

PATIENTS AND METHODS: Literature search in PubMed (Medline) and Embase databases was performed for all prospective randomized trials that compared SEMS with PS for the treatment of malignant biliary obstruction between January 1966 and January 2015. Research studies were included in the present meta-analysis if they met the inclusion criteria. In the meta-analysis, summary risk ratio estimates for major outcome were calculated. Forest plots were used to assess overall risk estimate, and funnel plots were used to assess overall publication bias. Meta-analysis was performed using STATA 11.0 software.

RESULTS: Ten articles with 810 patients were eligible for inclusion in the present meta-analysis. SEMS is not significantly associated with complications or 30-day mortality when compared with PS (p = 0.069 and 0.167, respectively). Further stratified analysis showed similar results. For other therapeutic effects, SEMS offered 2.27-fold 6-month stent patency rate (95% CI = 1.30-3.95), and 36% reduction in a recurrent obstruction (95% CI = 0.17-0.51), as compared with PS. In addition, SEMS was associated with fewer hospitalization days than PS (p = 0.023) in a random model. With fixed model, the corresponding p-value was less than 0.001.

CONCLUSIONS: The present meta-analysis demonstrates that SEMS cannot result in lower risks of complications and mortality, but can provide a lower risk of recurrent obstruction and longer stent patency for the palliation of malignant bile duct obstruction when compared with PS.

Key Words:

Self-expandable metal stents, Plastic stents, Palliative treatment, Malignant biliary obstruction.

Introduction

Malignant tumors, such as pancreatic cancer, gallbladder cancer, and cholangiocarcinoma, are among the most morbid and lethal diseases in elderly people worldwide, although therapies for these cancers have already had great developments^{1,2}. One important reason is that these specific cancers are commonly associated with bile obstruction. The curative operation is the only therapy, but few patients have respectable lesions at the time of diagnosis³.

Biliary stent placement is considered a good palliative treatment for patients with malignant biliary strictures. It plays an important role in maintaining disease condition, improving the quality of life, and reducing complications and mortality^{4,5}. Since the late 1970s, plastic stents (PS) have been used in biliary stent placement, but self-expandable metallic stents (SEMS) are becoming more and more popular in recent years⁶. Several groups of researchers have compared the efficacy of PS with that of SEMS in patients with bile obstruction, but their results do not agree with each other^{5,7,8}. Two prospective randomized controlled trials show that endoscopic metal stents provide longer survival than endoscopic plastic stents in patients with hilar and common malignant biliary obstruction^{5,7}. However, one meta-analysis shows that there are no significant differences in complications and mortality between metal and plastic stents⁸. These differences may be explained by the confounding of the position of bile obstruction⁹. However, there are few data that compare SEMS with PS in patients with different malignant biliary obstruction positions. For these reasons, we conduct a meta-analysis of prospective randomized trials to compare SEMS with PS in the palliative management of malignant biliary obstruction.

Patients and Methods

Search Strategy

We conducted a literature search in PubMed (Medline) and Embase databases for all prospective randomized trials that compared SEMS with PS for the treatment of malignant biliary obstruction between January 1966 and January 2016. The key search terms utilized in this process were: "biliary obstruction", "distal biliary obstruction", "hilar biliary obstruction", "bile duct obstruction", "stent", "biliary stent", and "palliative therapy" in combination with "tumor", "ampullary tumor", "cancer", "pancreatic cancer", "gallbladder cancer", "cholangiocarcinoma", and "hepatic carcinoma". Also, we scrutinized references of retrieved literature to identify further relevant studies.

Study Selection

Research studies were included in the present meta-analysis if they met the following criteria: (1) the study design was prospective and randomized; (2) comparison was carried out between SEMS and PS; and (3) the article included a description of specified number of patients with malignant biliary obstruction. In contrast, articles that involved or were focused on non-human studies, conference abstracts, editorials, comments, and unpublished articles were excluded from the present meta-analysis. If a study had been reported for more than once, we used the most recently published results.

Data Extraction

For each study, the following information was extracted: name of first author, year of publication, study location, study design, age and gender of participants, number of participants, stent type, technical success of the procedures, complications, mortality, and recurrence of biliary obstruction.

Data Analysis

In the meta-analysis, summary risk ratio (RR) estimates for major outcome were calculated using the method published previously¹⁰. Heterogeneity among studies was assessed using I² statistic, which described the proportion of total variation

in point estimate caused by heterogeneity. For I² metric, I² values of 25%, 50%, and 75% were considered as cut-off points for low, moderate, and high degrees of heterogeneity, respectively. When heterogeneity was significant, we used a random effects model; otherwise, we used a fixed effects model. Forest plots were used to assess the overall risk estimate, and funnel plots were used to assess the overall publication bias. The meta-analysis was performed using STATA 11.0 software (StataCorp LP, College Station, TX, USA).

Results

Study Search

A total of 1,763 research articles from PubMed and Embase databases were obtained using the keywords previously outlined. After applying the inclusion criteria, only 12 research articles satisfied the criteria. Further critical evaluation of the selected 12 articles showed that two articles still failed to meet the inclusion criteria^{5,11}, one article's design was retrospective⁵, and one article's study was not only for malignant bile obstruction but also for benign bile obstruction¹¹. Therefore, after evaluation of all research articles, only 10 were included in the present meta-analysis (Figure 1).

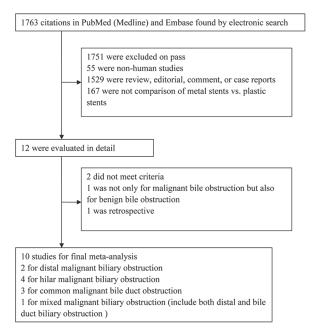


Figure 1. Literature search procedure. A literature search was conducted in PubMed (Medline) and Embase databases for all prospective randomized trials that compared SEMS versus PS for the treatment of malignant biliary obstruction between January 1966 and January 2016.

Study Characteristics

General characteristics of the included studies showed that the 10 studies included 810 patients with malignant biliary obstruction (Table I). Among all studies, two studies compared SEMS with PS for distal malignant biliary obstruction¹²⁻¹³, four studies compared the two for hilar malignant biliary obstruction¹⁴⁻¹⁷, three studies compared the two for common malignant bile duct obstruction^{7,18-19}, and one study compared the two for mixed malignant biliary obstruction (distal and bile duct biliary obstruction)²⁰. In addition, one trial by Prat et al19 divided patients into three treatment groups: group 1 (polyethylene stent to be exchanged in case of dysfunction), group 2 (polyethylene stent to be exchanged every 3 months), and group 3 (SEMS). Because group 1 and group 2 may have deistical treatment effect, we divided this trial into two studies: one study comprised groups 1 and 3, and the other comprised groups 2 and 3.

Technical Success

Overall analysis of all studies revealed that, when compared with PS, SEMS had no significantly lower technical success [RR (95% CI) = 0.97 (0.94-1.01), p = 0.104]. Further stratified analysis showed similar results. The two stents had essentially equal technical success rates for patients with distal malignant biliary obstruction [RR (95% CI) = 0.98 (0.93-1.03), p = 0.436], hilar malignant biliary obstruction [RR (95% CI) = 0.99 (0.91-1.06), p = 0.697, common malignant bile duct obstruction [RR (95% CI) = 0.96 (0.92-1.01), p = 0.101, and mixed distal and bile duct malignant obstruction [RR (95% CI) = 0.96 (0.92-1.01), p = 0.190]. Overall, hilar and common bile duct obstruction groups were not heterogeneous in terms of technical success ($I^2 = 0$ for all; p =0.513, 0.623, and 0.945, respectively). In distal malignant biliary obstruction group, we excluded a trial because of its 100% technical success rate in both stents. Therefore, we could not conclude its heterogeneity. In mixed group, we could not conclude the heterogeneity for only one trial (Figure 2).

Complications and Mortality

The RR of major complications and 30-day mortality for each trial and 95% CI are shown in Figures 2 and 3, respectively. According to Figure 2, SEMS had a marginal statistically significant reduction (34%) in the RR of complication rates than PS for patients with hilar malignant biliary

Table 1. Characteristics of included studies.

\uthors	Year	z	Location	Design	Biliary obstruction types	Metal stent type	Plastic stent type
Oavids P	1992	105	Netherlands	Randomized	Distal malignant biliary	Endoscopic SEMS	Endoscopic polyethylene
/agner H	1993	20	Germany	Randomized	Hilar malignant biliary	SEMS	Large-bore plastic
ımer J		101	Austria	Randomized	Common malignant bile duct	Transhepatic SEMS	Transhepatic endoprostheses
<u>H</u>		105	France	Randomized	Common malignant bile duct	Endoscopic SEMS	Endoscopic polyethylene
Piñol V	2002	54	Spain	Randomized	Mixed malignant biliary	Percutaneous SEMS	Endoscopic polyethylene
erlund C	٠,	100	Sweden	Randomized controlled	Common malignant bile duct	Endoscopic SEMS	Endoscopic polyethylene
gchan A		108	Thailand	Randomized controlled	Hilar malignant biliary	Endoscopic SEMS	Endoscopic polyethylene
ses P		120	North American	Randomized	Hilar malignant biliary	Endoscopic SEMS	Endoscopic polyethylene
kai T		09	o Japan	Randomized controlled	Hilar malignant biliary	Endoscopic SEMS	Endoscopic polyethylene
Schmidt A	2014	37	Germany	Randomized trial	Distal malignant biliary	Endoscopic SEMS	Endoscopic wing-shaped plastic

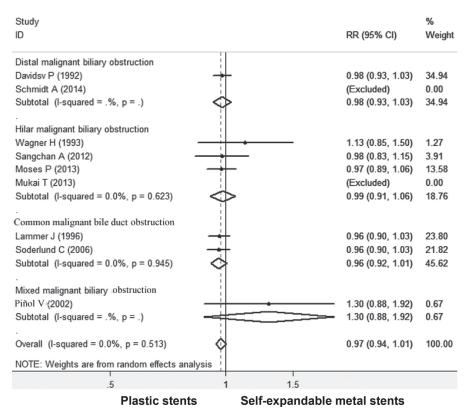


Figure 2. Forest plot for the association between SEMS and technical success. The meta-analysis was performed using STATA 11.0. RR, risk ratio; I² statistic, the proportion of total variation in point estimate caused by heterogeneity.

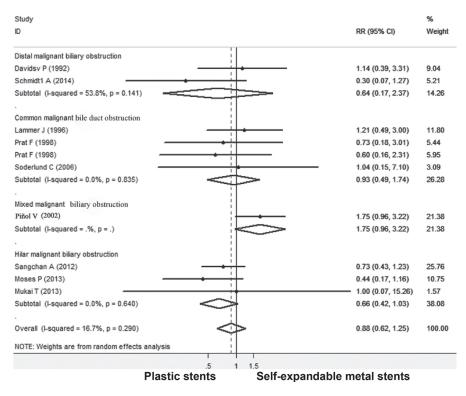


Figure 3. Forest plot for the association between SEMS and major complications. The meta-analysis was performed using STATA 11.0. RR, risk ratio; I² statistic, the proportion of total variation in point estimate caused by heterogeneity.

obstruction (p = 0.069). For patients with mixed bile obstruction, SEMS had a marginal statistically significant increase (75%) in mixed bile than PS (p = 0.069). No significant result was observed when comparing SEMS with PS in other groups. Except for distal malignant biliary obstruction, PS and SEMS had no statistically significant difference in the incidence of severe complications (overall: $I^2 = 16.7$, p = 0.290; common: $I^2 = 0$, p= 0.835; hilar: $I^2 = 0$, p = 0.640). Among distal malignant biliary obstruction patients, there was moderate and insignificant heterogeneity in terms of major complications ($I^2 = 53.8$, p = 0.141) (Figure 3). In the present meta-analysis, seven studies evaluated 30-day mortality as an outcome measure. Overall, about 32% (97/300) of patients with SEMS died in 30 days, whereas 37% (110/295) of patients with PS died in 30 days [RR (95% CI) = 0.89 (0.76-1.05), p = 0.167]. The 30-days mortality of patients with SEMS was not significantly lower than that of patients with PS in common malignant bile duct obstruction group (RR = 0.89, p = 0.243), hilar malignant biliary obstruction group (RR = 0.72, p = 0.620), and mixed malignant biliary obstruction group (RR = 0.84, p =0.292), respectively. Of note, the 30-day mortality of patients with SEMS in common malignant bile duct obstruction group was insignificantly higher than that of patients with PS (RR = 0.357, p = 0.101). No heterogeneity of effect estimates on RR was observed in terms of 30-day mortality in the seven trials ($I^2 = 19.0$, p = 0.285) (Figure 4).

Stent Patency and Recurrent Obstruction

The present meta-analysis of 6-month patency involved 5 studies. The pooled estimates for stent patency in random model showed that the 6-month patency rate for SEMS was 2.27-fold of that for PS (95% CI = 1.30-3.95, p = 0.004). The result in fixed model is similar [SEMS versus PS: RR (95% CI) = 2.24 (1.69-2.97), p < 0.001]. The five studies were moderately heterogeneous in terms of 6-month patency ($I^2 = 62.3$, p =0.031) (Figure 5). Further stratified analysis by random model consistently showed that patients with SEMS were in favor of significantly or marginally significantly higher patency rate in all groups, as compared with patients with PS (p was less than 0.05 or near 0.05 for all) (Figure 6). By fixed model, patients with SEMS were in favor of significantly higher patency rate in all groups than patients with PS (p < 0.01 for

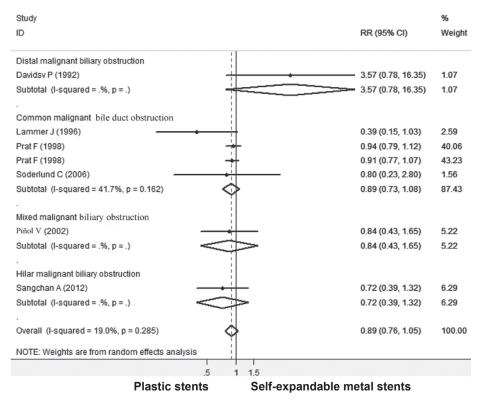


Figure 4. Forest plot for the association between SEMS and 30-days mortality. RR, risk ratio; I² statistic, the proportion of total variation in point estimate caused by heterogeneity.

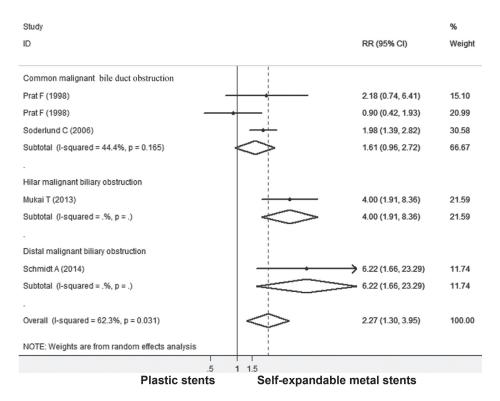


Figure 5. Forest plot for the association between SEMS and 6-month patency. RR, risk ratio; I² statistic, the proportion of total variation in point estimate caused by heterogeneity.

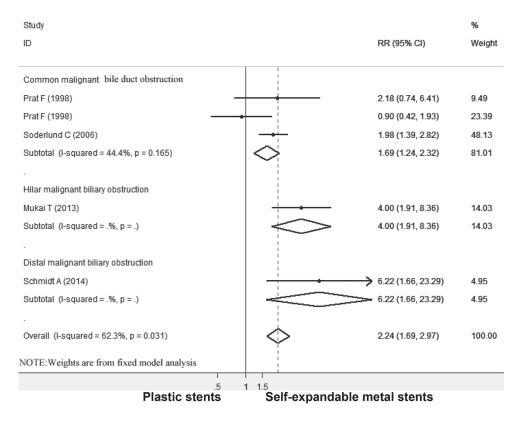


Figure 6. Forest plot for the association between SEMS and recurrent bile obstruction (*random model*). RR, risk ratio; I² statistic, the proportion of total variation in point estimate caused by heterogeneity.0

all). Of the four included studies, two studies demonstrated that recurrent bile obstruction after SEMS placement was less frequent than that after PS placement; the other two studies showed no difference (Figure 7). The overall RR (SEMS vs. PS) was 0.64 (95% CI = 0.49-0.83, p = 0.001). No heterogeneity was observed in terms of recurrent obstruction among the four included studies ($I^2 = 0$, p = 0.760). In the present meta-analysis, about 31% (50/159) of patients with SEMS had recurrent bile obstruction, while 50% (78/157) of patients with PS had recurrent bile obstruction (Figure 7).

Hospitalization Days

A total of five studies included hospitalization days. Results by random model showed that patients with SEMS had an average of 1.13-day reduction in hospitalization days compared to patients with PS (95% CI = 0.15-2.11, p = 0.023) (Figure 8). By fixed model, the reduction of hospitalization days was 1.03 (95% CI = 0.77-1.29, p < 0.001). Except for mixed malignant biliary obstruction group, we recorded a reduction of more than 0.69 day in hospitalization days when comparing SEMS with PS in different bile obstruction position groups (p < 0.05 in both random and fixed model for all). In mixed malignant biliary

obstruction group, we observed an insignificant increase in hospitalization days (0.32) in patients with SEMS, as compared with patients with PS, in both random model and fixed model (all p = 0.375) (Figure 9).

Discussion

The present meta-analysis has identified no significant association between stent types and patient survival. SEMS placement is not associated with fewer complications and mortality than PS placement. Similar results are observed in stratified analysis based on bile obstruction position. However, SEMS placement is associated with a higher long-time stent patency rate and less frequent recurrence of obstruction when compared with PS placement in malignant biliary obstruction patients. Furthermore, patients after SEMS placement have shorter hospitalization days as compared with patients after PS placement.

To date, most random clinical trials have shown no significant difference between metal stents and plastic stents in late complication and mortality among malignant biliary obstruction

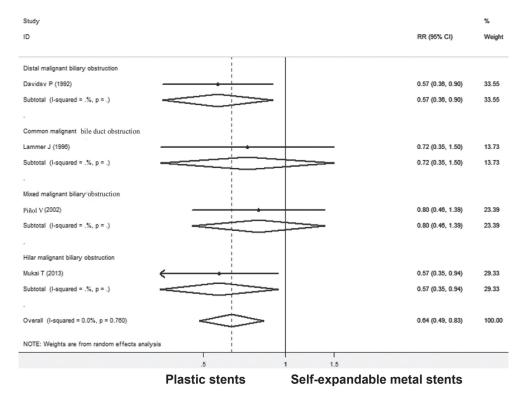


Figure 7. Forest plot for the association between SEMS and recurrent bile obstruction (*fixed model*). RR, risk ratio; I² statistic, the proportion of total variation in point estimate caused by heterogeneity.

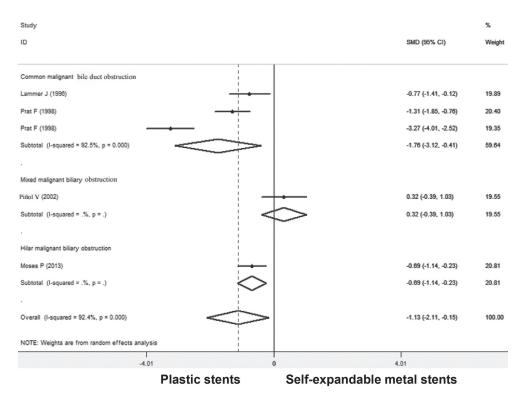


Figure 8. Forest plot for the association between SEMS and hospitalization days analyzed by random model. RR, risk ratio; I^2 statistic, the proportion of total variation in point estimate caused by heterogeneity.

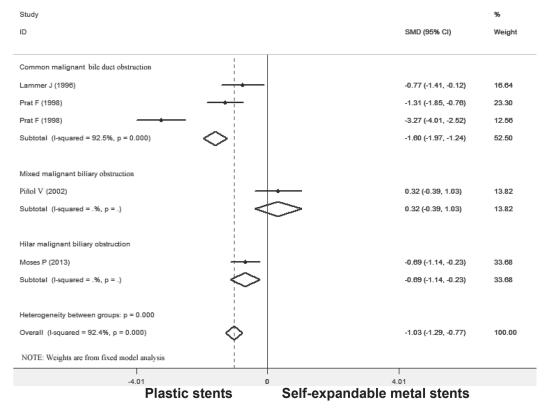


Figure 9. Forest plot for the association between SEMS and hospitalization days analyzed by fixed model. RR, risk ratio; I² statistic, the proportion of total variation in point estimate caused by heterogeneity.

patients²¹⁻²⁵. However, Liberato et al²⁶ discover that SEMS insertion for the palliation of hilar cholangiocarcinoma provides lower early and late complication rates as compared with PS placement. However, this trial is retrospective and has not analyzed other malignant bile obstruction types. A single-center, open-label, randomized controlled trial from Southeast Asia shows 50% reduction in hazard risk of death in unrespectable hilar cholangiocarcinoma patients receiving metal stents compared with plastic stents¹⁵. A randomized trial from Austria discovers that use of SEMS is significantly associated with lower 30-day mortality rate than use of PS among patients with common malignancy bile duct obstruction¹⁸. Although stent type influences early complication rate, stent placement is still not a cure measure for malignant biliary strictures^{6,27}. In addition, the majority of patients with stent placement have advanced cancer, and their long-time mortality is high, although they have received high-quality treatments. Moreover, location difference in response to different types of stents varies greatly and may affect the association between SEMS and complication or mortality rate⁹.

Except for complication and mortality, SEMS is a good measure for other efficacies, such as stent patency and recurrent obstruction. Several studies show that metal stents are associated with longer stent patency compared to conventional PS^{3,5,7}. In a random controlled trial, PS placement is still unable to offer equivalent 6-month patency compared to SEMS even after improvement¹². Similarly, this trial shows that SEMS results in more reduction in obstruction recurrence frequency compared to PS after improvement12. This phenomenon may be attributed to higher frequency in bacterial formation in plastic stent than in metal stent, which usually results in stent clogging²⁸. Another difference is that SEMS is associated with fewer hospitalization days when compared with PS. This difference may be explained by lower possibility of developing stent dysfunction in SEMS than in PS²⁹.

The present study has some advantages. First, the meta-analysis has included prospective random trials with a large sample size and long follow-up time, which have greatly increased the power to detect potential differences between SEMS and PS in the treatment of bile obstruction caused by cancer. Then, location-specific meta-analysis is carried out in the present study, because different loca-

tions of bile obstruction can result in different stent type responses. However, the number of high-quality clinical trials in different locations of bile obstruction is still too small to evaluate the association between location-specific stent type and efficacy of treatment. More high-quality clinical trials, especially prospective random controlled trials with large sample sizes are needed to validate the association between stent type and the effect of conservative treatment in the future.

Conclusions

SEMS cannot offer lower risks of complications and mortality than PS, but can provide lower risk of recurrent obstruction and longer stent patency for the palliation of malignant bile duct obstruction.

Acknowledgements

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Conflict of Interest

The Authors declare that they have no conflict of interests.

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