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REVIEW ARTICLE – PANCREATIC TUMORS

Comparison Between Plastic and Metallic Biliary Stent Placement for Preoperative Patients with Pancreatic Head Cancer: A Systematic Review and Meta-Analysis

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ABSTRACT

Background. Optimal preoperative biliary drainage for patients with pancreatic cancer before pancreatoduodenectomy remains unclear. This study aimed to investigate the comparison of efficacy and safety between a metallic stent (MS) and a plastic stent (PS).

Methods. Comparative studies on the use of MS and PS for pancreatic cancer before pancreatoduodenectomy were systematically searched using the MEDLINE and Web of Science databases. Pre- and postoperative data also were extracted. Random-effects meta-analyses were performed to compare post-endoscopic retrograde cholangiopancreatography (ERCP) complications as well as intra- and postoperative outcomes between the two arms of the study, and pooled odds ratios (ORs) or mean differences (MDs) were calculated with 95 percent confidence intervals (CIs).

Results. The study analyzed 12 studies involving 683 patients. Insertion of MS was associated with a lower incidence of re-intervention (OR, 0.06; 95% CI 0.03–0.15; $P < 0.001$), increased post-ERCP adverse events (OR, 2.22; 95% CI 1.13–4.36; $P = 0.02$), and similar operation time (MD, 18.0 min; 95% CI –29.1 to 65.6 min; $P = 0.46$), amount of blood loss (MD, 43.0 ml; 95% CI –207.1 to 288.2 ml; $P = 0.73$), and surgical complication rate (OR, 0.78; 95% CI 0.53–1.15; $P = 0.21$). The cumulative stent patency rate after 3 months was higher in the MS group than in the PS group (70–100 % vs 30.0–45.0 %).

Conclusion. For biliary drainage in patients with pancreatic cancer during this era of multidisciplinary treatment, MS use might be the first choice because MS provides a more durable biliary drainage and a similar risk of postoperative outcomes compared with PS.

Pancreatic cancer (PC) is a devastating disease and one of the major causes of cancer-related death.[1] To improve survival outcomes, the role of neoadjuvant treatment (NAT) for patients with borderline resectable or locally advanced PC has evolved.[2] Because obstructive jaundice should be ameliorated before NAT is initiated,[3] durable and secure preoperative biliary drainage (PBD) is needed. With the increasing use of NAT for patients with resectable PC, the role of PBD has increased in recent decades.[4]

According to previous studies on unresectable PC,[5] endoscopic biliary drainage (EBD) is commonly used for biliary drainage.[6] Two types of implantable devices are used for EBD: plastic stent (PS) and metal stent (MS). Plastic stents are 7 to 10 Fr in size and can easily be removed and replaced with fewer incidences of endoscopic retrograde cholangiopancreatography (ERCP)-related pancreatitis and cholecystitis.[7,8]

On the other hand, metal stents usually are larger than 10 mm and have a self-expanding force, a longer patency period than plastic stents and less need for re-intervention. However, use of MS has disadvantages. Previous studies have shown that the post-ERCP adverse event rate was higher after MS insertion than after PS insertion, and that self-expanding pressure led to inflammatory changes in

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the surrounding tissue.[5,9–11] Therefore, selecting a stent in the preoperative setting has been a trade-off, especially for patients treated with NAT. A longer MS patency period (4–12 weeks) is required before surgery for patients undergoing upfront surgery and a much longer waiting time for patients receiving NAT,[12] while local inflammation should be avoided to minimize surgical risk.

To identify which types of stents are optimal in the preoperative setting, several studies have compared MS with PS for resectable and borderline resectable PC.[13–24] However, the patient populations in these studies were small, and the studies were retrospective and performed mostly at a single center. Little is known about the optimal stents for resectable and borderline resectable PC with obstructive jaundice in a preoperative setting. Therefore, this study aimed to investigate the comparison between MS and PS in terms of endoscopic re-intervention and perioperative complication rates for patients with PC who underwent subsequent surgery.

METHODS

Search Strategy

This systematic review and meta-analysis were reported in accordance with PRISMA guidelines (Table S1).[25] A systematic literature survey was conducted according to the recommendations of the Cochrane Collaboration.[26] Searches were performed to identify all studies referring to preoperative decompression of the bile duct for PC. The MEDLINE and Web of Science databases were searched for eligible articles published between January 1989 and October 2022.

In 1989, the first clinical trial of MS deployment was reported.[27] The following search terms were used: ((pancreatic neoplasm*) OR (pancreatic cancer) OR (pancreatic ductal adenocarcinoma) OR (pancreatic head cancer) OR (head of pancreas)) AND ((metal*) or (plastic)). The final electronic search was performed on 15 November 2022. No language restrictions were imposed in any of the searches. In addition, the reference lists of all articles fulfilling the eligibility criteria and other relevant articles missed in the electronic searches were examined through manual searches.

Selection Criteria

Two independent investigators (Y.E. and M.T.) reviewed all records identified in the literature search. The inclusion criteria specified only studies that compared MS with PS in terms of re-intervention, stent potency, and postoperative outcomes. The exclusion criteria ruled out reports that did not include a surgical description, reports that did not include at least two of the four components of the intra- and postoperative findings (blood loss, operation time, morbidity, and mortality), and review articles without original data and those that dealt with cell lines or animals. If the abstract was relevant, the full article was assessed for eligibility. For overlapping cohorts, the most recent or relevant publication was selected.

Data Extraction

Data were extracted independently by two authors (Y.E. and M.T.) according to a pre-specified protocol. A third reviewer (M.K.) resolved all disagreements. From each included study, the first-author information, year of publication, study type (e.g., retrospective study, prospective study, or randomized control trial), study design (e.g., single-center or multi-center study), country of origin, number of patients, types of neoadjuvant therapy, regimen of neoadjuvant chemotherapy, resectability classification (e.g., resectable, borderline resectable, and locally advanced PC) according to national comprehensive cancer network (NCCN) guidelines (version 1, 2022), periods between stent insertion and operation, stent types, rates and reasons for re-intervention, cumulative stent patency rate, and intra- and postoperative characteristics (e.g., blood loss, operation time, morbidity, and mortality) were recorded.

Re-intervention was defined as biliary drainage necessitated by the appearance of elevated hepatobiliary enzyme and total bilirubin levels (stent occlusion), concomitant cholangitis, or dislocated stents (stent migration). The study defined ERCP-related adverse effects, including cholecystitis, pancreatitis, perforation, and bleeding, as local inflammation or bleeding after ERCP. Surgical complications included all grades of the Clavien–Dindo (CD) classification.[28] Two-by-two contingency tables were constructed to perform a meta-analysis. Data were extracted independently by two authors (Y.E. and M.T.) according to the pre-specified protocol.

Quality Assessment

The methodologic quality of the included studies was assessed by two authors (Y.E. and M.T.) using the Risk of Bias in Nonrandomized Studies of Interventions (ROBINS-I). The ROBINS-I includes seven potential risks of bias (confounding, selection of participants, classification of interventions, deviations from intended interventions, missing data, measurement of outcomes, and selective reporting). Each domain was assessed as low, moderate, serious, critical, or not assessable, and the overall risk of bias was evaluated for each study. Two authors (Y.E. and M.T.) independently assessed the methodologic quality of the included studies and the overall quality of evidence. In case of disagreement, a consensus was reached through discussion with a third reviewer (M.K.).

Data Synthesis and Statistical Analysis

Outcomes were either presented as originally reported or, if possible, calculated from published raw data. Quantitative analyses of at least three studies were performed. The sample mean and standard deviation were calculated using the sample median, size, and minimum and maximum values.[29] Pooled odds ratios (ORs) and 95 percent confidence intervals (CIs) were calculated to compare the rates of re-intervention, surgical complications, and mortality between the MS and PS groups. Pooled weighted mean differences (MDs) and 95 % CIs were calculated for blood loss and operative times.

A random-effects model was used for the meta-analysis. A P value lower than 0.050 was considered statistically significant. The I^2 and Q tests were used to assess study heterogeneity. K-mean cluster analysis was used to identify a potential subset of patients relative to 3 months stent patency and postoperative complication rates.[30] Potential publication bias was assessed by visual inspection of funnel plots and application of the Harbord test if more than nine studies were analyzed.[31] For statistical analysis, R version 4.2.0 (R Project for Statistical Computing, Vienna, Austria) and the meta-analysis package (Meta 5.1.1 and estmeansd 0.2.1) were used.

RESULTS

Overview of Literature Search

The electronic database search identified 5300 articles. From these articles 742 duplicates were removed, after which 4370 articles were excluded after screening of the titles and abstracts. The remaining 188 studies met the prespecified inclusion criteria and were evaluated using full-text analysis. The analysis included 12 studies (Fig. 1).[13–23]

Characteristics of Included Studies

The included studies were conducted in three countries (Table 1). Nine studies were conducted in a single center, and two studies were multi-center investigations. The studies included two randomized controlled trials,[21,22] one prospective cohort study,[15] and nine retrospective cohort studies.[13,14,16–20,23,24] Nine studies, all from Japan, referred to NAT and resectability. Of the 683 participants assessed, 286 were treated with MS, and 397 were treated with PS. The stent types in the MS group were uncovered self-expandable metal stents (UCSEMS),[17] full-covered SEMS (FCSEMS),[15,16,20–23] partially covered SEMS (PCSEMS),[14,19] and unspecified stents,[13,18] whereas those in the PS group were 7 to 10 Fr in diameter and 5 to 9 cm in length.

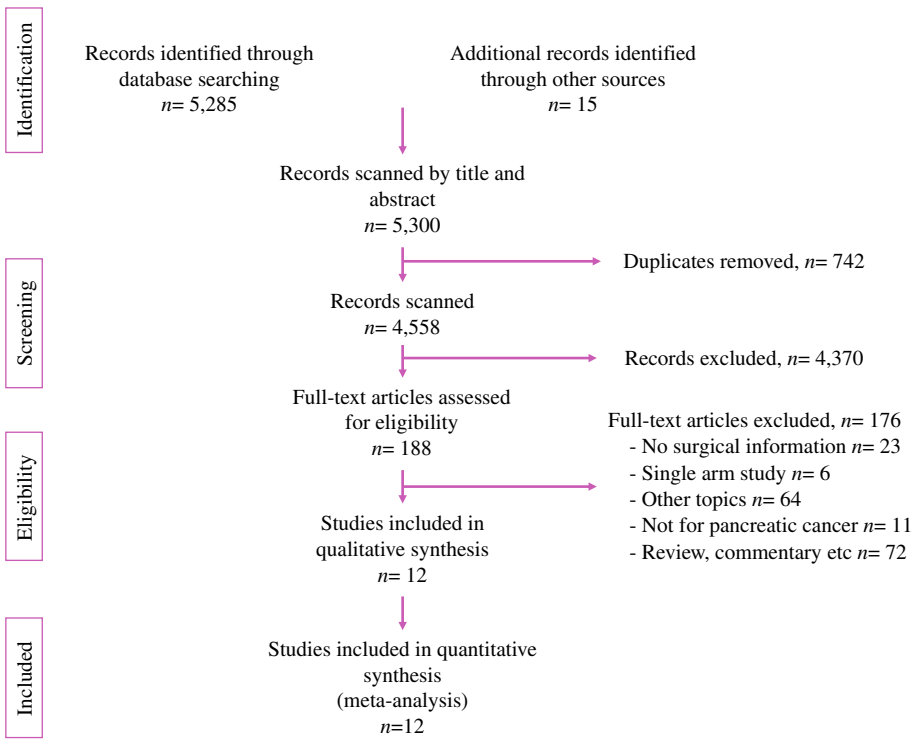

FIG. 1 PRISMA diagram showing a selection of articles for review

TABLE 1 Characteristics of the included studies

References	Country	Year	Neoadjuvant therapy	Resectability	No. of patients (MS/PS)	Median surgery waiting time: days (IQR)		Stent characteristics	
						MS	PS	MS	PS
Decker et al[13]	USA	2011	NR	NR	11/18	n.r	n.r	10 mm, 6 cm	10 Fr, 7–9 cm
Kubota et al[14]	Japan	2014	NAC and/or NACRT, GEM + TS-1 (+30 Gy)	BR	17/21	120 (51–230)	102 (55–180)	10 mm, 6 cm PCSEMS	7–8.5 Fr, 5–7 cm
Tol et al[15]	Netherlands	2016	NR	n.r	49/102	n.r	n.r	FCSEMS	10 Fr
Tsuboi et al[16]	Japan	2015	NAC gem-citabine + TS-1	BR	9/11	n.r	n.r	10 mm, 6 cm FCSEMS	7 Fr, 7 cm straight type
Nakamura et al[17]	Japan	2019	Gemcitabine + 54 Gy	R/BR	17/26	72 (55–107)	79 (54–115)	Covered or uncovered SEMS with a diameter of 8 or 10 mm	diameter from 7 to 8.5 Fr
Kuwatani et al[18]	Japan	2020	TS-1 or TS-1 + RT	R/BR	17/12	n.r	n.r	n.r	n.r
Hasegawa et al[19]	Japan	2021	NAC/ NACRT, GEM or TS-1 + RT, FOL-FIRINOX, or GnP	R/BR/LA	27/40	n.r	n.r	10 mm, FCSEMS or PCSEMS	7–8.5 Fr
Ichikawa et al[23]	Japan	2021	TS-1, gem-citabine plus TS-1, gemcitabine + nab-pacli-taxel, FOL-FIRINOX	n.r	45/75	37 (12–499)	34 (12–257)	8–12 mm, 5–8 cm, FCSEMS	8–8.5 Fr, 5–10 cm
Tamura et al[21]	Japan	2021	Gnp	BR	11/11	104 (89–111)	107 (64–111)	10 mm, 6–8 cm FCSEMS	10Fr, 5–7cm straight type
Mandai et al[22]	Japan	2021	No	R	36/34	28 (22–37)	24.5 (18.3–38)	10 mm FCSEMS	10 Fr straight type
Kobayashi et al[20]	Japan	2021	TS-1 + RT (30 Gy)	R/BR	21/22	79 (42–122)	73 (47–131)	8 mm, 8 cm FCSEMS	7 Fr, 7 cm straight type, both-end pigtail-type
Kataoka et al[24]	Japan	2021	GEM + TS1, GnP	R	26/25	38.5 (13–138)	33.0 (16–112)	6 mm FCSEMS	n.r

IQR, interquartile range; MS, metallic stent; PS, plastic stent; NR, not resectable; n.r., not reported; NAC, neoadjuvant chemotherapy; NACRT, neoadjuvant chemoradiotherapy; GEM, gemcitabine; TS-1, Tegafur/Gimeracil/Oteracil; BR, borderline resectable; PCSEMS, partially covered self-expandable metallic stent; FCSEMS, fully covered self-expandable metallic stent; R, resectable; SEMS, self-expandable metallic stent; RT, radiotherapy; LA, locally advanced; GnP, gemcitabine + nab-paclitaxel

Risk of Re-Intervention During Waiting Periods

The waiting period was 72.5 days (range, 8.2–136.9 days) in the MS group and 62.0 days (range, 10.5–113.4 days) in the PS group. During that time, the MS group was less likely to undergo intervention during the follow-up period (OR, 0.06; 95% CI 0.03–0.15; $P < 0.001$; $I^2 = 64.1$ %; Fig. 2). The reasons for intervention were as follows: stent occlusion, stent migration, retrograde cholangitis, and unspecified conditions.

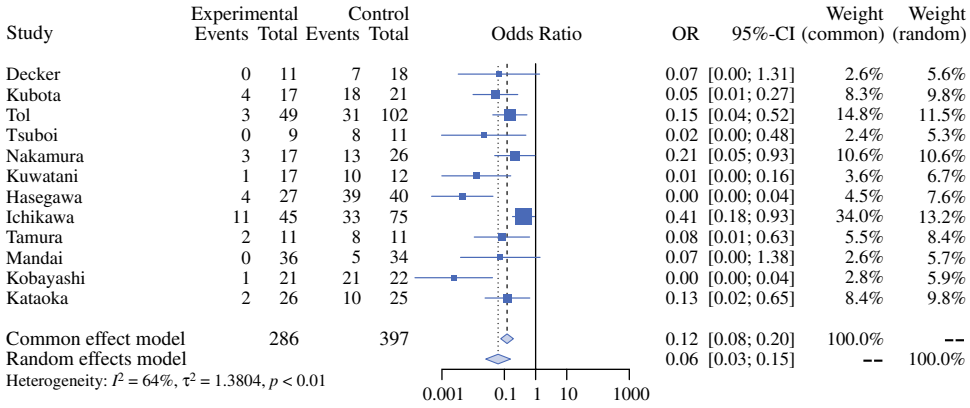

FIG. 2 Forest plot of studies examining the re-intervention rate

Risk of ERCP-Related Complications

Nine studies reported on ERCP-related complications. Overall, 582 patients (MS [n= 243] vs PS [n = 339]) were analyzed. The ERCP-related adverse event rate was significantly higher in the MS group than in the PS group during the follow-up period (OR, 2.22; 95% CI 1.13–4.36; P = 0.02; I^2= 24.0 %; Fig. S1). Post-ERCP pancreatitis was observed in 10.7 % of the MS group, whereas it was observed in 4.7 % of the PS group (OR, 3.01; 95% CI 1.48–6.11; P = 0.002; I^2= 0 %). The rate of cholecystitis after ERCP was 4.1 % in the MS group, whereas it was 1.5 % in the PS group (OR, 1.56; 95% CI 0.53–4.62, P = 0.42; I^2= 0 %).

Postoperative Outcomes

Figure S2A–D shows a forest plot of the studies examining postoperative outcomes. Between the MS and PS groups, no significant differences in blood loss (MD, 43.0 ml 95% CI –202.1 to 288.2 ml; P = 0.73; I^2 = 22.4 %) or operation time (MD, 18.0 min; 95% CI –29.4 to 65.5 min; P = 0.46; I^2 = 64.3 %) were observed among 458 patients (MS [n = 205] vs PS [n = 253]; Fig. S2A and B). In addition, according to the 11 studies that included 571 patients (MS [n = 238] vs PS [n = 333]), no statistically significant difference between the two groups was found in the incidence of surgical complication (OR, 0.78; 95% CI 0.53–1.15; P = 0.21; I^2 = 0 %; Fig. S2C). The surgical mortality rate was reported in six studies involving 315 patients (MS [n = 126] vs PS [n = 189]), and it was similar in the MS and PS groups (OR, 0.59; 95% CI 0.10–3.60; P = 0.57; I^2 = 19.1 %; Fig. S2D).

Stent Patency

In the analysis of the stent patency rate 1, 2, and 3 months after insertion relative to stent type, the patients with PS had a lower rate of stent patency than those with MS (1 month: MS [94.0 %] vs PS [75.6 %], P = 0.006; 2 months: MS [91.1 %] vs PS [48.1 %], P < 0.001; 3 months: MS [87.0 %] vs PS [26.8 %], P < 0.001). Figure 3 shows a scatter plot of the surgical complication and cumulative stent patency rates 3 months after insertion. The cumulative stent patency rate

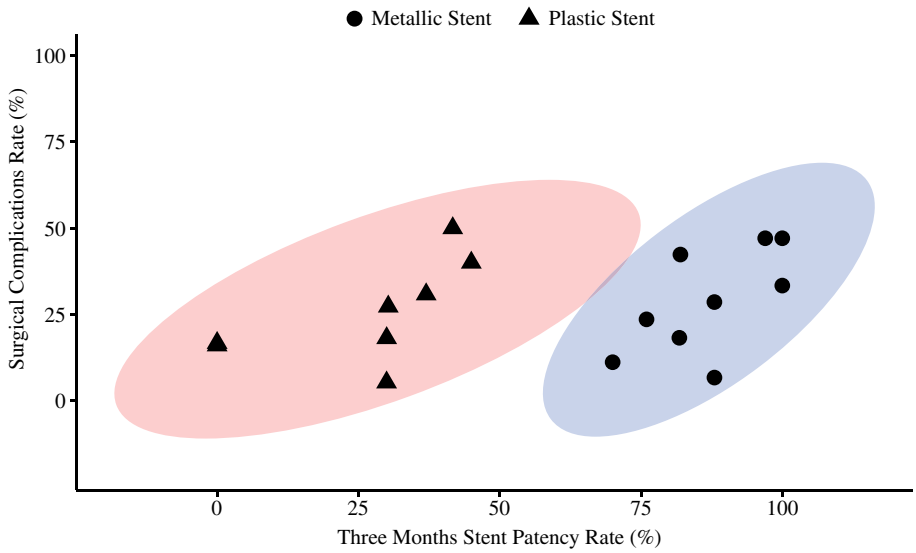

FIG. 3 Scatter diagram of cumulative stent patency and surgical complication rate. Each ellipse means 95 % confidence interval ellipses (blue: metallic stent; red: plastic stent)

varied from 70 % to 100 % in the MS group and from 30.0 % to 45.0 % in the PS group. *K*-mean clustering identified two subgroups of patients that corresponded to the stent type. This indicated that the distribution of stent patency and complication rates were distinct between the MS and PS groups.

Quality Assessment

The results of the quality assessment are presented in Table S2. Two clinical trials were graded as having a low risk of all biases, whereas other trials were referenced as having a moderate risk. In five studies, classification of intervention was described in detail. In addition, the funnel plots were symmetric and insignificant in the Harbord test (Figs. 4 and S3A–E).

DISCUSSION

This meta-analysis assessed the superiority of MS over PS for potentially resectable PC in terms of pre- and postoperative outcomes. Deployment of MS was associated with a lower rate of re-intervention. The study showed no significant differences between the two groups in lengths of operation time, amounts of blood loss, surgical complication rates, or mortality rates. In contrast, MS insertion was correlated with an increased risk of post-ERCP complications (e.g., cholecystitis and pancreatitis).

Preoperative biliary drainage has become increasingly endorsed as a treatment choice for pancreatic head cancer since neoadjuvant chemotherapy has been widely accepted for patients with potentially resectable PC.[2] Whereas several studies have examined the superiority of MS over PS in unresectable PC, the efficacy and safety of MS compared with PS as PBD for resectable and borderline resectable PC have not been well investigated, and few guideline recommendations have been available regarding this topic.[5,9]

To date, an increasing number of patients with PC have been treated with NAT. In NAT settings, the preoperative waiting period can be extended to 3 to 6 months according to recent clinical trials of NAT for resectable and borderline PC.[32–36] Recent meta-analyses have demonstrated that patients with PC who received NAT and treatment with MS had a lower rate of re-intervention and NAT cessation without a greater incidence of postoperative outcomes than those treated with PS.[37,38] However, these meta-analyses are limited to patients with NAT, making the application of this result to a broader population of patients with PC impossible. Furthermore, almost one–fourth of the patients treated with upfront surgery for PC underwent surgery 4 to 12 weeks after diagnosis.[12,39] Therefore, PBD is important even for individuals who have undergone upfront surgery.

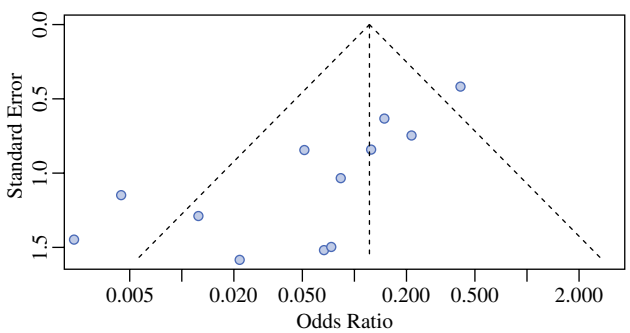

FIG. 4 Funnel plot for the publication bias test of the re-intervention rate ($P = 0.13$, Harbord test)

One advantage of using MS over PS is the longer period of stent patency due to the larger caliber of the lumen and its self-expansion force.[40,41] In contrast, PS has generally been selected for PBD because the waiting period before surgery for resectable PC is relatively short.[42] It is unclear whether the incidence of re-intervention needed after PS insertion is comparable with that after MS in the preoperative setting.

In the current study, the MS group was less likely to undergo re-intervention than the PS group. In addition, this study showed that the cumulative stent patency rates of the MS and PS groups differed significantly 1, 2, and 3 months after insertion. These results indicate that even in a limited period, biliary obstruction or cholangitis that needs re-intervention would often occur in patients treated with PS. Secured stent patency is more likely to be exhibited by MS for 3 or more months than by PS, assisting in MS deployment, especially in patients treated with NAT.[43,44] Re-intervention would require repeated hospitalization and subsequently delay the planned curative resection, resulting in increased total cost and impaired survival.[14,21,45] In summary, these results support the recommendation for MS insertion in the preoperative setting.

Previous investigators have demonstrated that the use of MS is a negative risk factor for post-ERCP pancreatitis or cholecystitis in patients with biliary obstruction due to unresectable periampullary malignancy.[7,8] According to these previous studies, patients in whom an MS was inserted had more than five times higher rates of ERCP-related pancreatitis.[7] The rate of cholecystitis after stent insertion was more than three times higher for patients treated with MS than for those treated with PS. However, whether the rate of cholecystitis and pancreatitis after MS insertion differs from that of PS for potentially resectable PC is poorly documented.[8]

In the current study, the ERCP-related adverse event rate was significantly higher in the MS group. This suggests that post-ERCP events should be meticulously observed and managed appropriately if adverse events occur after MS insertion because post-ERCP complication would prevent the receipt of NAC. Further studies are needed to investigate whether the increased ERCP-related adverse effects after MS insertion affect the cessation or delay of NAT administration

and to identify which cases are more prone to post-ERCP complications.

Previously, there were concerns that MS insertion led to fibrotic changes in the surrounding bile duct due to stent-related inflammation, resulting in greater operative and postoperative complications and creating technical difficulties such as fibrotic adhesion of the portal vein and arteries, which may compromise R0 resection and interfere with biliary reconstruction.[10,46,47] Although some patients who experienced ERCP-related pancreatitis or cholecystitis suffered from increased local inflammation, this meta-analysis demonstrated no significant difference in surgical outcomes (blood loss, operation time, surgical complications, and mortality). The fact that the two stent types had comparable effects on surgical outcomes could be attributable to the lower rates of obstructive cholangitis in patients treated with MS, which has a significant impact on surgical difficulties and mortality.[48,49] The effect from a lower frequency of cholangitis would offset stent-related local inflammation. These results support the idea that MS deployment does not harm the subsequent pancreatoduodenectomy for resectable and borderline resectable PC. Previous studies have shown that postoperative complications precluded adjuvant chemotherapy for patients with PC, leading to poor survival. Therefore, MS deployment is an important therapeutic option for PC.[50]

Our study differed from previous meta-analysis on this topic for several reasons.[37,38,42] First, in the meta-analysis by Crippa et al.,[42] the patient population encompassed "periampullary cancer," which includes not only pancreatic cancer but also distal cholangiocarcinoma and ampullary cancer. Although distal cholangiocarcinoma and ampullary cancer may share some anatomic similarities, they diverge from pancreatic cancer in terms of oncologic management. For instance, NAT is strongly recommended for pancreatic cancer, whereas no established, effective neoadjuvant treatment exists for distal cholangiocarcinoma and ampullary cancer.[51,52] Therefore, we distinguish between pancreatic cancer and other periampullary cancers.

Second, Du et al.[37] and Kumar et al.[38] focused on patients with pancreatic cancer who underwent NAT. Although NAT is recommended for all pancreatic cancer cases, the rate of NAT administration was approximately 40 %.[53] The underutilization of NAT was more pronounced among older patients treated at non-academic facilities.[53] Given the low rate of NAT implementation, it may be more reflective of real-world practice to encompass both patients who receive NAT and those who do not. As such, we included the entire pancreatic cancer population. We contend that our study could contribute to expanding the existing evidence, thus strengthening the case for MS insertion efficacy for pancreatic cancer patients.

This meta-analysis had some limitations. First, most of the studies included in this analysis had relatively small samples. In addition, most of the included published papers were from Japan. This may have led to a decreased heterogeneity of the patient' population, affecting the generalizability of this analysis.

Second, no comparison between full-covered and uncovered types of MS was performed in this analysis due to the scarcity of data. Therefore, further studies on this topic are needed.

Third, this study did not include a cost-effectiveness analysis between MS and PS. However, recent studies have demonstrated that patients treated with MS had a lower rate of cholangitis or occlusion that required hospitalization than patients treated with PS, and the total cost was equivalent with regard to stent type.[14,21,45]

Fourth, the patient population varied across studies, resulting in the heterogeneity of this meta-analysis. Moreover, this meta-analysis included nine retrospective studies, which might have been linked to selection bias, heterogeneity of study designs, disparities in data reporting, and unadjusted confounding factors.

Finally, data on stent latency were extracted from the graphs of the original studies. This method may have caused measurement bias.

In conclusion, use of MS was superior to use of PS postoperatively for resectable and borderline resectable PC regarding the incidence of re-intervention, stent-related adverse events, and short-term outcomes after surgery. The increased likelihood of avoiding re-intervention and obstructive cholangitis would facilitate neoadjuvant chemotherapy and prevent inflammation around the bile duct. As the optimal EBD for resectable or borderline resectable PC, MS is preferred over PS.

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