Pancreatic stents for prophylaxis against post-ERCP pancreatitis: a meta-analysis and systematic review CME

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Background: Acute pancreatitis is a common complication of ERCP. Several randomized, controlled trials (RCTs) have evaluated the use of pancreatic stents in the prevention of post-ERCP pancreatitis with varying results.

Objective: We conducted a meta-analysis and systematic review to assess the role of prophylactic pancreatic stents for prevention of post-ERCP pancreatitis.

Design: MEDLINE, Cochrane Central Register of Controlled Trials and Database of Systematic Reviews, PubMed, and recent abstracts from major conference proceedings were searched. RCTs and retrospective or prospective, nonrandomized studies comparing prophylactic stent with placebo or no stent for post-ERCP pancreatitis were included for the meta-analysis and systematic review. Standard forms were used to extract data by 2 independent reviewers. The effect of stents (for RCTs) was analyzed by calculating pooled estimates of post-ERCP pancreatitis, hyperamylasemia, and grade of pancreatitis. Separate analyses were performed for each outcome by using the odds ratio (OR) or weighted mean difference. Random- or fixed-effects models were used. Publication bias was assessed by funnel plots. Heterogeneity among studies was assessed by calculating I^2 measure of inconsistency.

Setting: Systematic review and meta-analysis of patients undergoing pancreatic stent placement for prophylaxis against post-ERCP pancreatitis.

Patients: Adult patients undergoing ERCP.

Interventions: Pancreatic stent placement for the prevention of post-ERCP pancreatitis.

Main Outcome Measurements: Post-ERCP pancreatitis, hyperamylasemia, and complications after pancreatic stent placement.

Results: Eight RCTs (656 subjects) and 10 nonrandomized studies met the inclusion criteria (4904 subjects). Meta-analysis of the RCTs showed that prophylactic pancreatic stents decreased the odds of post-ERCP pancreatitis (odds ratio, 0.22; 95% CI, 0.12-0.38; $P < .01$). The absolute risk difference was 13.3% (95% CI, 8.8%-17.8%). The number needed to treat was 8 (95% CI, 6-11). Stents also decreased the level of hyperamylasemia (WMD, −309.22; 95% CI, −350.95 to −267.49; $P \leq .01$). Similar findings were also noted from the nonrandomized studies.

Limitations: Small sample size of some trials, different types of stents used, inclusion of low-risk patients in some studies, and lack of adequate study of long-term complications of pancreatic stent placement.

Conclusions: Pancreatic stent placement decreases the risk of post-ERCP pancreatitis and hyperamylasemia in high-risk patients. (Gastrointest Endosc 2011;73:275-82.)

Abbreviations: CI, confidence interval; OR, odds ratio; RCT, randomized, controlled trial.

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Pancreatitis is a common and potentially preventable complication of ERCP. Post-ERCP pancreatitis leads to a significant increase in morbidity and mortality, depending on the severity and associated complications. Likewise, it may lead to prolonged hospitalization with substantial economic impact. The reported incidence of pancreatitis occurring after ERCP varies from 5% to 32%.[1-3] The wide variation in the rates of post-ERCP pancreatitis is attributable to differences in patient selection and procedure-related risk factors.

Several mechanisms have been postulated for the induction of post-ERCP pancreatitis. Injury to the papilla, pancreatic sphincter, and pancreatic duct can result from instrumentation, pancreatic manipulation, and contrast injection. Outflow tract edema and disruption caused by trauma may cause obstruction to the flow of pancreatic secretions. Impaired pancreatic duct drainage can initiate the trigger mechanisms for pancreatitis.[3]

Several strategies have been proposed to prevent or reduce the severity of post-ERCP pancreatitis. These include careful patient selection, improved technical maneuvers (such as minimizing traumatic manipulation of the ampulla, selective use of contrast injection, and use of a guidewire for cannulation), and specific endoscopic interventions including temporary pancreatic stent placement.[4] Placement of pancreatic stents is one of the common and favored prophylactic approaches used to reduce the risk of post-ERCP pancreatitis.[5-12] Theoretically, a stent placed across the injured outflow tract helps to maintain the flow of pancreatic secretions.

Several studies of small sample sizes have evaluated the efficacy of temporary stent placement for the prevention of post-ERCP pancreatitis with varying results.[5,7,9,11-13] Two previous meta-analyses favored prophylactic stent placement as a method to reduce the risk of post-ERCP pancreatitis.[10,14] Since the publication of these meta-analyses, 2 additional clinical trials with large sample sizes have been published[11,15] along with additional nonrandomized studies.[16,17] The previous meta-analyses did not review the nonrandomized studies. In light of the additional data, we conducted a systematic review and meta-analysis with the inclusion of the newly published trials. We also performed a subgroup analysis to determine the role of pancreatic stent characteristics (stent size and flanges) in the prevention of post-ERCP pancreatitis.

Take-home Message

- The role of pancreatic stents in the prevention of post-ERCP pancreatitis has been evaluated by several studies.
- This was a meta-analysis and systematic review of both randomized, controlled trials and nonrandomized studies evaluating the role of pancreatic stents in the prevention of post-ERCP pancreatitis. Overall, pancreatic stents decrease the risk of post-ERCP pancreatitis in high-risk patients. However, several unanswered questions remain in this area.

METHODS

Study selection

Articles and abstracts comparing pancreatic stents with placebo or no treatment were selected. Exclusion criteria were those studies not involving post-ERCP pancreatitis as a study endpoint or studies comparing stents with other drugs or other stents or drains. The search was restricted to adult patients. There were no language restrictions. Both full-length publications and abstract publications were selected.

Literature search and identification of primary studies

Articles were searched on pancreatic stent placement in the prevention of post-ERCP pancreatitis in adults. All articles were searched irrespective of language, publication status (articles or abstracts), or results. A 3-stage search strategy was adopted and implemented. First was a search of MEDLINE, EMBASE, and the Cochrane Central Register of Controlled Trials using PubMed and Ovid as search engines (1966 to January 2010). The search terms used were "prophylactic stent placement," "pancreatic stents," "hyperamylasemia," "ERCP," "post-ERCP pancreatitis," and "ERCP pancreatitis." Second, references, lists of retrieved articles, reviews, and meta-analyses were scanned for additional articles. Third, a manual search of abstracts submitted to Digestive Disease Week, American College of Gastroenterology, and United European Gastroenterology Week (2000-2009) was performed.

Data extraction

Data extraction was independently performed by 2 investigators (A.C., M.L.B.) and reviewed by a third for agreement. The 2 independent investigators extracted data from each study using a common data extraction form. Details of study design (randomization/blinding/concealment), number of subjects and dropouts, sizes and diameter of stents, and outcomes of post-ERCP pancreatitis and hyperamylasemia were evaluated. All randomized, controlled trials (RCTs) were assigned a quality score based on the Jadad scale, with 5 being of high quality and 0 being of poor quality.[18] Disagreements were discussed by the authors and resolved by consensus.

Data analysis of RCTs

Statistical pooling of the data by using meta-analytical techniques was done for RCTs. Data from nonrandomized studies were excluded from the statistical pooling. Primary outcome was the incidence of post-ERCP pancreatitis. Secondary outcomes were the incidence of hyperamylasemia; incidence of mild, moderate, or severe pancreatitis; and

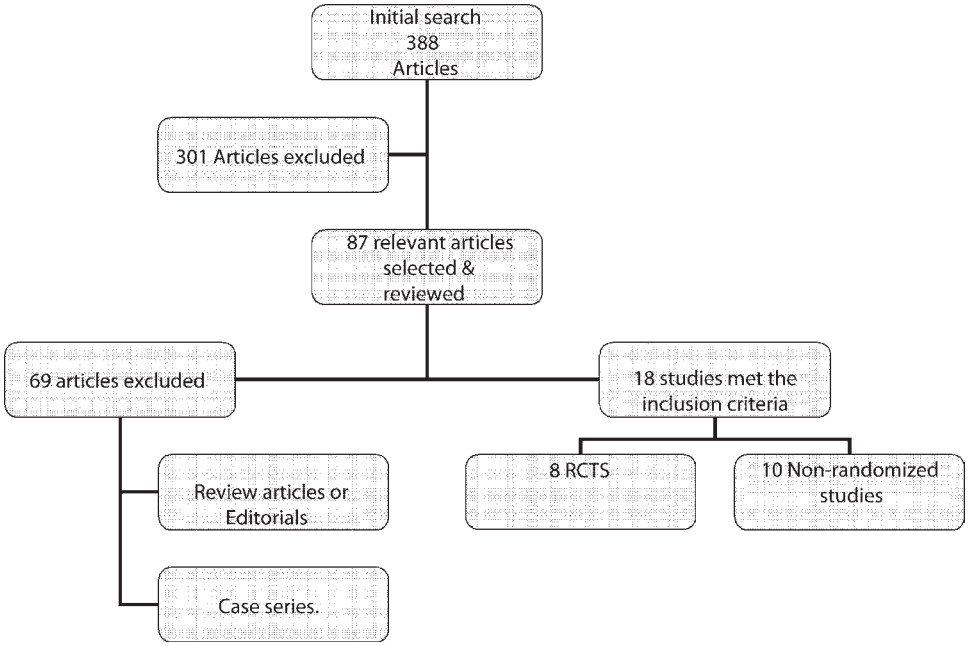

Figure 1. Article identification and selection algorithm.

possible adverse effects from stent placement. All data were analyzed according to both per-protocol and intent-to-treat analyses. All the clinical trials reported their results on a per-protocol analysis. For intent-to-treat analysis, patients with a failed attempt at pancreatic stent placement were assumed to have had pancreatitis develop if no data were provided in the clinical trials. The effects of pancreatic stent placement were analyzed by calculating pooled estimates of post-ERCP pancreatitis, hyperamylasemia, and severity of pancreatitis. Separate analyses were performed for each outcome by using odds ratio (OR) or weighted mean difference. Random- or fixed-effects models were used as appropriate. A statistically significant result was observed with a 95% confidence interval (CI) and a P value of $<.05$. Whenever statistical significance was detected, an absolute risk reduction with 95% CI and the number needed to treat with 95% CI were calculated. Rev Man 4.2 and Comprehensive Meta-analysis (Biostat Inc, Englewood, NJ) software were used for statistical analysis of the data. Subgroup analysis was performed to assess the effect of stent size and the presence or absence of flanges on post-ERCP pancreatitis. Publication bias was assessed by funnel plot. Sensitivity analysis was also performed after restricting the studies to high quality, nature of publication (full-length publications or abstracts), per-protocol analysis, or intent-to-treat analysis. Heterogeneity among studies was assessed by calculating I^2 measure of inconsistency. Generally, an I^2 of 0% to 40% excludes heterogeneity, I^2 of 30% to 60% may represent moderate heterogeneity, I^2 of 50% to 90% may represent substantial heterogeneity, and I^2 of 75% to 100% represents considerable heterogeneity.

Nonrandomized studies

Data from the nonrandomized studies were also extracted as described previously. Retrospective studies or prospective nonrandomized studies were included. Case series were excluded from the analysis. Primary and secondary outcomes analyzed were similar, as stated previously.

RESULTS

Meta-analysis of RCTs

The initial search identified 388 articles. Of these, 87 relevant articles were selected and reviewed by 3 independent authors (A.C., M.L.B., P.K.R.). Eight RCTs (656 subjects) and 10 nonrandomized studies (4904 subjects) met the inclusion criteria and were selected for final review and analysis (Fig. 1). Both the RCTs and nonrandomized studies were analyzed separately. Analysis of the RCTs is presented first. Table 1 shows the details and Jadad scores for the selected RCTs (5 = excellent quality, 0 = poor quality). Two studies[6,13] published in abstract form were not assigned any quality scores because there were insufficient data. All the other studies were of adequate quality (Jadad scores ≥3). All RCTs were published from 1993 to 2009. None of the studies performed an intent-to-treat analysis.

Six studies were conducted in the United States and 2 in Japan. A summary of the studies is presented in Table 1. The percentage of female subjects varied from 36% to 84.2% among the studies. All trials used stents sizes of size 5F[9,11,13,15,19] or 5F to 7F.[6,7,12] Four trials used stents 2 to 2.5 cm in length,[6,7,9,12] whereas 3 trials used stents 3 cm or longer.[11,15,19] One trial did not report the length of the stent

TABLE 1. Summary of randomized, controlled trials included in the meta-analysis

Study	Jadad score	Age, y (mean) C	Age, y (mean) S	Indication/procedures	% Females	Type of stent	No. of patients	Pancreatitis, % No stents	Pancreatitis, % Stents
Smithline et al,[12] 1993	3	47	46	Precut biliary ES, SOD, small duct size	79.6	Flanged, polyethylene 5F/7F and 2-2.5 cm long	98	18	14
Sherman et al,[6] 1996	—	NR	NR	Precut biliary ES	NR	5F-7F and 2-2.5 cm long	104	21	2
Tarnasky et al,[7] 1998	2	45.7	46.4	Biliary ES for SOD	73.8	5F or 7F, 2/2.5 cm long	82	26	7
Patel,[13] 1999	—	44	47	Pancreatic ES for SOD	61.1	5F stent	36	33	11
Fazel et al,[9] 2003	3	45	43.6	Difficult cannulation, biliary ES, SOD	84.2	Flanged, 5F, 2 cm long	67	28	5
Harewood et al,[19] 2005	3	44*	53.5*	Endoscopic ampullectomy	63.2	Flanged, polyethylene, 5F, 3-5 cm long	19	33	0
Tsuchiya et al,[11] 2007	3	69	65	All consecutive ERCP irrespective of risk factors	36	Unflanged, polyethylene 5F, 3 or 4 cm	64	12.5	3.1
Sofuni et al,[15] 2007	3	66	67	All consecutive ERCP irrespective of risk factors	36	Flanged, polyethylene stent 5F, 3 cm long	211	13.6	3.2

ES, Endoscopic sphincterotomy; *SOD,* sphincter of Oddi dysfunction; *NR,* not reported.
*Age reported as median.

used.[13] Flanged stents were used in 4 trials,[9,12,15,19] whereas 1 trial[11] used unflanged stents. In 5 trials, the stents used were made of polyethylene, whereas other trials did not provide information about the stent material. The indications for ERCP varied among the studies. Few studies included high-risk ERCP procedures as inclusion for stent placement, such as biliary sphincterotomy for sphincter of Oddi dysfunction, difficult cannulation, precut sphincterotomy, pancreatic sphincterotomy, and endoscopic ampullectomy. Two Japanese studies used gabexate for prophylaxis against pancreatitis because it is considered the standard of care in Japan. In 1 study, intravenous antibiotics were administered before the procedure. In 2 trials, stents were kept for more than 7 days, whereas in the others, the stents were removed within 7 days. Repeat endoscopy was required less frequently in trials using unflanged stents.

Publication bias was evaluated by funnel plot with no significant publication bias identified (Fig. 2).

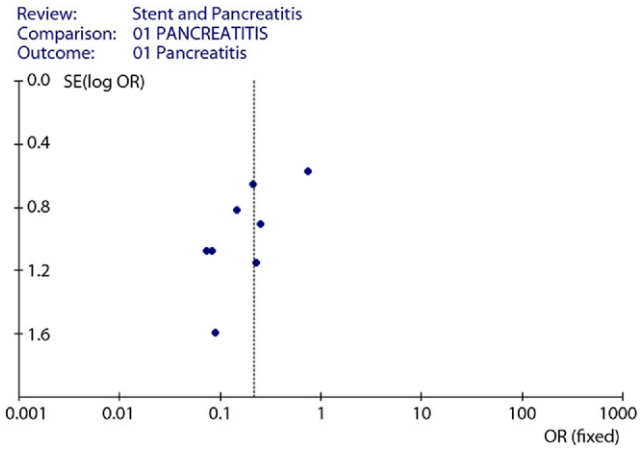

Figure 2. Funnel plot assessing for publication bias. No publication bias was noted. SE, standard error.

Post-ERCP pancreatitis. All trials except 1 reported using the consensus definition (1991) for defining post-ERCP pancreatitis.[20] The study by Sherman et al, published in abstract form, did not specify the definition of post-ERCP pancreatitis. However, we assumed that they used the consensus definition of post-ERCP pancreatitis. Post-ERCP pancreatitis was documented in 16 of 322 patients (4.96%) with a pancreatic stent placed, compared with 66 of 334 patients (19.76%) without a pancreatic stent placed. Pooled analysis showed a significant OR reduction with stent placement (OR, 0.22; 95% CI, 0.12-0.38; $P < .01$) (Fig. 3). The absolute risk difference was 13.3% (95% CI, 8.8%-17.8%). The number needed to treat was 8 (95% CI, 6-11). There was no significant heterogeneity among the studies. Subgroup analysis was performed to evaluate the effect of the presence of flanges and the length of the stents on post-ERCP pancreatitis. In the studies analyzed, the number of patients with post-ERCP pancreatitis was lower with shorter stents (<3 cm); however, this observed difference was not statistically significant.

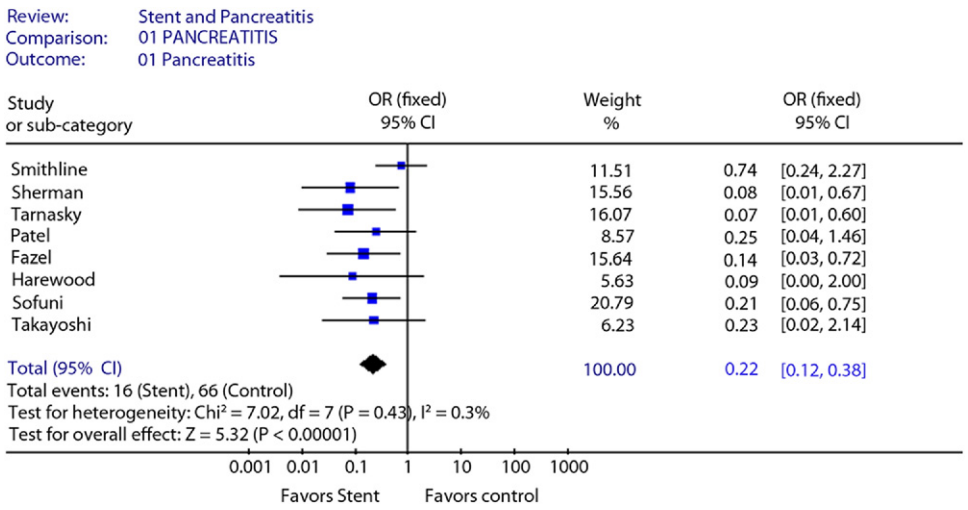

Figure 3. Forrest plot demonstrating the effect of pancreatic stents on overall risk of post-ERCP pancreatitis.

Similarly, 4 trials used flanged stents, whereas 1 trial used flanged stents. Pooled analysis did not demonstrate a statistically significant difference in the risk of post-ERCP pancreatitis.

Hyperamylasemia. Four trials provided data on post-procedure hyperamylasemia. Pancreatic stent placement significantly reduced the mean levels of amylase compared with control (WMD, 309.22; 95% CI, −350.95 to −267.49; $P \leq .01$). No significant heterogeneity was present ($P = .11$).

Severity of pancreatitis. All studies used the Cotton et al[20] criteria for assessing the severity of pancreatitis. Seven trials provided data on the severity of pancreatitis. Stents significantly decreased the odds of mild (OR, 0.39; 95% CI, 0.20-0.76; $P = .005$; $I^2 = 0\%$) as well as moderate pancreatitis (OR, 0.19; 95% CI, 0.07-0.51; $P = .0009$; $I^2 = 0\%$). However, although a trend was noted, stent placement did not significantly decrease the odds of severe pancreatitis (OR, 0.22; 95% CI, 0.05-1.01; $P = .05$; $I^2 = 0\%$).

Complications. Only 2 studies provided data on the complications with pancreatic stents.[7,15] One study reported 1 patient with cholangitis, 2 with pancreatitis after stent removal, and 1 with guidewire perforation (graded as severe).[7] The other study did not find any complication.[15]

Intent-to-treat analysis. Information on the success of pancreatic stent placement was provided in 5 studies.[9,11,12,15,19] One study[7] did not seem to have any patients with unsuccessful stent placement; however, this was not clearly stated in the results section, and therefore we excluded this study from our intent-to-treat analysis. Unsuccessful stent placement was reported in a total of 12 patients. Acute pancreatitis developed in 2 (out of 7) patients. Data were not provided for 5 patients. For the intent-to-treat analysis, we assumed that post-ERCP pancreatitis developed in these 5 patients. Analysis of the 5 studies revealed an absolute risk difference of 10.6% (95% CI, 5.1-16.1); the number needed to treat was 11.

Sensitivity analysis. We conducted a sensitivity analysis after restricting the studies to full-length publications, high-quality studies (Jadad score >3), studies with high-risk patients, and studies conducted in the United States only (2 Japanese studies using gabexate were excluded). Restricting the studies to these parameters did not alter the results. Data were also analyzed by random effects, and similar results were obtained. We also conducted a cumulative meta-analysis by publication date for the 8 studies. The efficacy of pancreatic stent placement for the prevention of post-ERCP pancreatitis was established by the publication of the second study. The efficacy of the stents remained constant over time with subsequent publications.

Systematic review of nonrandomized studies

We also analyzed the data from nonrandomized studies (Table 2). Ten studies met the inclusion criteria (4904 subjects). All studies except 1 included high-risk patients. Sample size varied from 28 to 2861 patients. A statistically significant reduction in the incidence of post-ERCP pancreatitis was noted in 5 studies. Studies were reported from the United States, Canada, and Japan. The indications for ERCP varied among the studies. The incidence of pancreatitis in the control group varied widely (range 6%-66.7%). Overall, fewer cases of severe pancreatitis were also reported with use of pancreatic stents (range 0%-20%).

DISCUSSION

Our meta-analysis and systematic review demonstrated that pancreatic stent placement after ERCP significantly decreased the odds of post-ERCP pancreatitis. Pancreatic stents lowered the risk of both mild and moderate post-ERCP pancreatitis. In the studies analyzed, the number of patients with severe pancreatitis was also lower those who had pancreatic stents. Our findings are similar to the 2 previous meta-analyses published on this topic.[10,14] The

TABLE 2. Summary of nonrandomized studies

Study	Country	Age, y	% Female	Procedures	No.	Pancreatitis		*P* value
						No stents	Stents	
Elton et al,[26] 1998	U.S.	60.2 (mean)	57.5	Pancreatic ES	194	12.5	0.7	<.003
Vandervoort et al,[27] 1999	U.S.	63 (28-93)	46.6	Pancreatic and biliary brush cytology	42	28.1	0	.08
Aizawa and Ueno,[8] 2001	Japan	68.4	43.1	Biliary balloon dilation for stones	40	6	0	.11
Fogel et al,[28] 2002	U.S.	NR	NR	SOD	436	28.6	13.5	<.05
Norton et al,[29] 2002	U.S.	60	46	Endoscopic ampullectomy	28	11.1	20	.05
Freeman et al,[30] 2004	U.S.	73% <55 y	77.4	Consecutive high-risk patients	225	66.7	14.4	.06
Catalano et al,[31] 2004	U.S.	Range 24-93	51.5	Endoscopic ampullectomy	103	16.7	3.3	.10
Cotton et al,[17] 2005	U.S.	NR	NR	All patients undergoing manometry	2861	8.1	5.3	.002
Hookey et al,[32] 2006	Canada	NR	NR	Pancreatic ES	572	19.3	8.8	.001
Saad et al,[16] 2008	U.S.	40.2	74.9	Suspected SOD and normal manometry	403	9	2.4	.006

ES, Endoscopic sphincterotomy; *SOD,* sphincter of Oddi dysfunction; *NR,* not reported.

previous meta-analyses included 5 studies[10] and 6 studies,[14] respectively. In contrast to our study, one of the previous meta-analysis showed a reduction in severe post-ERCP pancreatitis with pancreatic stents.[14] The previous meta-analyses also included nonrandomized studies in the statistical analysis. We only included RCTs in the statistical pooling. Three additional randomized studies were included in this study.[11,13,15] One of the RCTs published as an abstract was excluded from the previous meta-analyses, thus increasing the chance of introducing publication bias.[13] We also conducted a systematic review of nonrandomized studies to better explore the evidence regarding the role of pancreatic stents in the prevention of post-ERCP pancreatitis.

In the current study, we also explored whether the size or characteristics of the pancreatic stent had an impact on the outcome. On subgroup-analysis, we did not find any significant difference in outcome between unflanged stents and flanged stents or smaller (<3 cm) and longer stents (≥3 cm). However, these results are based on studies with small numbers of subjects. Short, unflanged stents can fall off prematurely and thus may not protect against post-ERCP pancreatitis in high-risk patients. Previous studies demonstrated that longer and inner flanges may be injurious to the duct lining, including injury during stent removal, because most flanged stents need to be removed by repeat endoscopy compared with smaller stents, which have a higher rate of spontaneous passage.[7] A recent study also found that unflanged 3F stents were associated with a slightly lower rate of post-ERCP pancreatitis compared with a 5F or 6F stent.[21] However, another study comparing long 3F stents with short 5F stents did not find any difference in the rates of post-ERCP pancreatitis.[22]

Although there was no statistical heterogeneity among the studies, there were significant differences among the studies. The indications for ERCP varied among the studies. The majority of the studies in this meta-analysis/systematic review included patients at high risk of post-ERCP pancreatitis. Two RCTs from Japan included consecutive patients for ERCP, with most patients being at low risk of post-ERCP pancreatitis. The number of female patients also varied among the studies. The Japanese studies included older patients compared with the U.S. studies. The experience of the endoscopists was not described in detail in most of the studies. All the studies were conducted at a teaching hospital, and thus it can be assumed that all were experienced operators in ERCP. Two studies from Japan added gabexate.[11,15] This is not the current practice in the United States or Europe. The duration that stents were left in situ varied among the studies.

Although we found that pancreatic stents decreased the odds of getting post-ERCP pancreatitis, there are several unanswered questions. It is still unclear who should get a pancreatic stent. A survey of the therapeutic endoscopists in the United States revealed variations in their practice patterns.[23] Almost all the respondents to the survey used pancreatic stents in their practice. However, there was disagreement over the indications for pancreatic stents. Based on the current data and a recent cost-effective analysis,[24] high-risk patients are the group of patients who will

benefit the most from pancreatic stents. The time of placement is also unclear. It is unclear whether the stents should be placed after or before therapy, ie, before performing sphincterotomy or after.[5] Interestingly, a recent case series explored the role of rescue ERCP a few hours after the initial procedure to prevent post-ERCP pancreatitis.[25] Several pharmacological agents have also been investigated for the prevention of post-ERCP pancreatitis. The role of pharmacological agents in combination with pancreatic stents has not been adequately studied. Two studies from Japan in this meta-analysis used gabexate along with stents. Other pharmacological agents (such as nonsteroidal agents, octreotide, somatostatin) could be studied in the future. It is unclear how long the stents need to remain in place. Too long a duration may lead to pancreatic injury, whereas too short a duration may not be protective against ERCP. In 1 study, removal of the stents at the end of ERCP was not protective against post-ERCP pancreatitis.[6] The ideal characteristics of a stent are not well-known. Current evidence suggests that shorter, unflanged stents may be better. Most of the studies used polyethylene stents, which tend to be stiff. Stents made from softer material could be less injurious to the ducts.[5] The short- and long-term consequences of a pancreatic stent also need to be studied in detail. The studies included in this analysis did not evaluate the complications of stent placement in a systematic manner.

In conclusion, this meta-analysis and systematic review demonstrate that pancreatic stent placement in high-risk individuals for the prevention of post-ERCP pancreatitis is beneficial.

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