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META-ANALYSIS

Updated meta-analysis of pancreatic stent placement in preventing post-endoscopic retrograde cholangiopancreatography pancreatitis

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Abstract

AIM: To investigate the efficacy and safety profile of pancreatic duct (PD) stent placement for prevention of post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis (PEP).

METHODS: We performed a search of MEDLINE, EMBASE, and Cochrane Library to identify randomized controlled clinical trials of prophylactic PD stent placement after ERCP. RevMan 5 software provided by Cochrane was used for the heterogeneity and efficacy analyses, and a meta-analysis was performed for the data that showed homogeneity. Categorical data are presented as relative risks and 95% confidence intervals (CIs), and measurement data are presented as weighted mean differences and 95%CIs.

RESULTS: The incidence rates of severe pancreatitis, operation failure, complications and patient pain severity were analyzed. Data on pancreatitis incidence were reported in 14 of 15 trials. There was no significant heterogeneity between the trials (I^2 = 0%, P = 0.93). In the stent group, 49 of the 1233 patients suffered from PEP, compared to 133 of the 1277 patients in the no-stent group. The results of this meta-analysis indicate that it may be possible to prevent PEP by placing a PD stent.

CONCLUSION: PD stent placement can reduce postoperative hyperamylasemia and might be an effective and safe option to prevent PEP if the operation indications are well controlled.

Key words: Pancreatic stent placement; Pancreatitis; Endoscopic retrograde cholangiopancreatography; Post-endoscopic retrograde cholangiopancreatography pancreatitis

Core tip: Pancreatitis is one of the most common and severe complications after endoscopic retrograde

cholangiopancreatography (ERCP). The reported incidence of post-ERCP pancreatitis (PEP) varies between 2% and 7% in prospective trials and may be as high as 30%-50% in high-risk patients. Although a previous meta-analysis has indicated that pancreatic duct stent placement can prevent PEP, particularly in high-risk patients, there is a lack of high-quality evidence-based studies based on appropriate numbers of well-validated publications. Therefore, an updated meta-analysis was conducted to investigate stents in preventing PEP.

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INTRODUCTION

Pancreatitis is one of the most common and severe complications after endoscopic retrograde cholangiopancreatography (ERCP). The reported incidence of post-ERCP pancreatitis (PEP) varies between 2% and 7% in prospective trials of non-selective studies[1-4] but may be as high as 30%-50% in high-risk patients. Andriullin *et al*[5] studied 16855 patients who underwent ERCP between 1977 and 2006 and found that the incidence of PEP was 3.47% (585 patients). Although most patients experienced mild PEP, 10% of patients developed severe PEP, which led to prolonged hospital stays, increased medical costs, and life threatening symptoms[6].

The precise mechanisms of PEP remain unclear. It was demonstrated by Chahal *et al*[7] that a substitute drainage pathway could prevent PEP, confirming the hypothesis that pancreatic drainage blockage as a result of Oddi sphincter spasms or papillary edema might be a major reason for PEP. Therefore, it is reasonable that pancreatic stent placement could improve pancreatic drainage and reduce the enzymatic reactions of tryptic enzymes.

Although a previous meta-analysis[8] has indicated that PD stent placement can prevent PEP, particularly in high-risk patients, there is a lack of high-quality evidence-based studies based on appropriate numbers of well-validated publications. For instance, low-quality retrospective studies were retrieved for a meta-analysis conducted by Singh *et al*[9], which might have led to a less confident conclusion. Another example is a study by Pan *et al*[10]; although it included six retrospective clinical trials, only abstracts were available for three of these studies. In addition, because of the limitations of the literature, the incidence rates of PEP and severe PEP from PD stent placement require a specific technique due to the unique anatomical structure of the pancreas duct. PD stenting might increase post-ECRP complications if there are any manipulation accidents during placement. Therefore, safety remains an important concern during prophylactic PD stent placement. Here, we analyzed the efficacy and safety of PD stent placement to prevent PEP by performing a meta-analysis of randomized controlled studies.

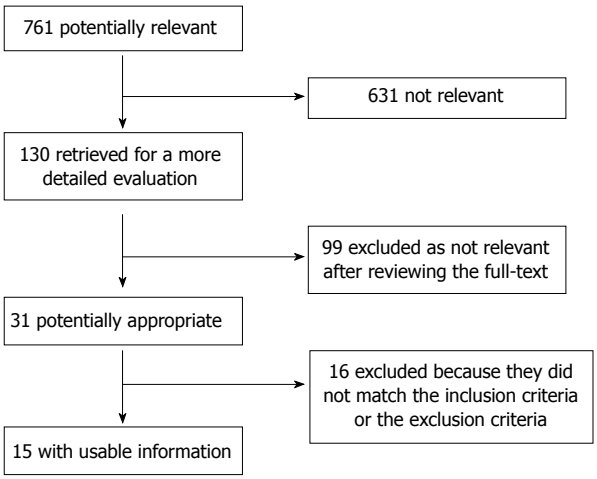


Figure 1 Publication retrieval flow chart. A flow chart depicting the step-by-step search process with respect to the eligibility criteria and the retrieval of published literature of the randomized controlled trials.

MATERIALS AND METHODS

Inclusion and exclusion criteria

We retrieved randomized controlled clinical trials of PD stent placement that were published in English or Chinese and contained full texts or abstracts. Patients who underwent prophylactic PD stent placement were included in a PD stent group, and patients who did not undergo stent placement were included in a control group. The medication strategies were not included in the analysis.

The clinical trials with pre-operative PD stents were excluded, as were publications with incomplete datasets or repeated data.

Publication retrieval

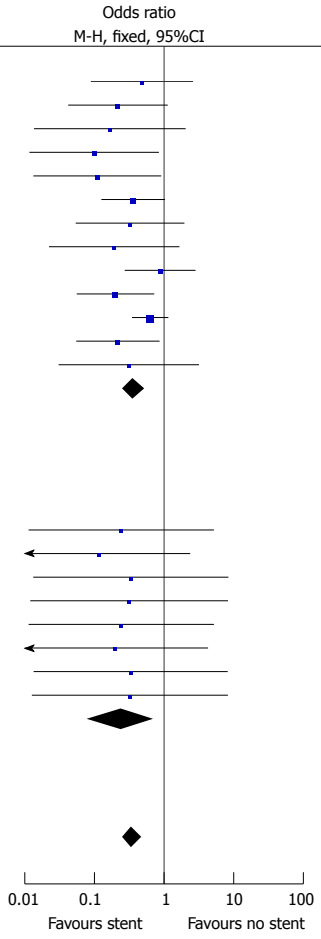
Published clinical trials on prophylactic PD stents to prevent PEP were retrieved from MEDLINE (between 1980 and May 2013), EMBASE (between 1980 and May 2013), and Cochrane clinical trial databases. Using PubMed as an example, the retrieval strategy included the keyword, subject heading, or the combination, such as "pancreatic* AND stent* AND (ERCP OR Endoscopic retrograde cholangiopancreatography) AND (PEP OR pancreatitis)."

Publication quality evaluation

The full-text publications were read, and relevant information was independently extracted by two researchers. The assessments included the risk of bias, information integrity, selectiveness, and other potential

A

Study or subgroup	Stent Events	Stent Total	No stent Events	No stent Total	Weight	Odds ratio M-H, fixed, 95%CI
1.1.1 Mild						
Cha 2012	2	46	5	58	3.30%	0.48 [0.09, 2.61]
Fazel 2003	2	40	7	36	5.50%	0.22 [0.04, 1.13]
Harewood 2005	1	11	3	8	2.50%	0.17 [0.01, 2.04]
Ito 2010	1	35	8	35	6.10%	0.10 [0.01, 0.84]
Karaguchi 2012	1	60	8	60	6.20%	0.11 [0.01, 0.91]
Lee 2012	6	50	14	51	9.60%	0.36 [0.13, 1.03]
Patel 1999	2	18	5	18	3.50%	0.33 [0.05, 1.96]
Sherman 1996	1	46	6	58	4.10%	0.19 [0.02, 1.66]
Smithline 1993	6	48	7	50	4.70%	0.88 [0.27, 2.83]
Sofuni 2007	3	98	14	103	10.40%	0.20 [0.06, 0.72]
Sofuni 2011	20	213	30	213	21.40%	0.63 [0.35, 1.15]
Thanasky 1998	3	43	10	39	7.70%	0.22 [0.05, 0.86]
Tsuchiya 2007	1	32	3	32	2.30%	0.31 [0.03, 3.17]
Subtotal (95%CI)		740		761	87.20%	0.37 [0.26, 0.52]
Total events	49		120			
Heterogeneity: χ^2 = 10.62, *df* = 12 (*P* = 0.56); I^2 = 0%						
Test for overall effect: *Z* = 5.59 (*P* < 0.00001)						
1.1.2 Severe						
Cha 2012	0	46	2	58	1.70%	0.24 [0.01, 5.19]
Fazel 2003	0	40	3	36	2.90%	0.12 [0.01, 2.37]
Lee 2012	0	50	1	51	1.20%	0.33 [0.01, 8.38]
Patel 1999	0	18	1	18	1.10%	0.32 [0.01, 8.27]
Sherman 1996	0	46	2	58	1.70%	0.24 [0.01, 5.19]
Smithline 1993	0	48	2	50	1.90%	0.20 [0.01, 4.28]
Sofuni 2011	0	213	1	213	1.20%	0.33 [0.01, 8.19]
Tsuchiya 2007	0	32	1	32	1.20%	0.32 [0.01, 8.23]
Subtotal (95%CI)		493		516	12.80%	0.24 [0.08, 0.72]
Total events	0		13			
Heterogeneity: χ^2 = 0.37, *df* = 7 (*P* = 1.00); I^2 = 0%						
Test for overall effect: *Z* = 2.55 (*P* = 0.01)						
Total (95%CI)		1233		1277	100.00%	0.35 [0.25, 0.49]
Total events	49		133			
Heterogeneity: χ^2 = 11.61, *df* = 20 (*P* = 0.93); I^2 = 0%						
Test for overall effect: *Z* = 6.15 (*P* < 0.00001)						
Test for subgroup differences: χ^2 = 0.53, *df* = 1 (*P* = 0.47); I^2 = 0%						



B

Study or subgroup	Stent Events	Stent Total	No stent Events	No stent Total	Weight	Odds ratio M-H, fixed, 95%CI
2.1.1 Mild						
Cha 2012	2	46	5	58	3.70%	0.48 [0.09, 2.61]
Fazel 2003	2	40	7	36	6.10%	0.22 [0.04, 1.13]
Harewood 2005	1	11	3	8	2.80%	0.17 [0.01, 2.04]
Ito 2010	1	35	8	35	6.80%	0.10 [0.01, 0.84]
Karaguchi 2012	1	60	8	60	6.90%	0.11 [0.01, 0.91]
Lee 2012	6	50	14	51	10.70%	0.36 [0.13, 1.03]
Smithline 1993	6	48	7	50	5.30%	0.88 [0.27, 2.83]
Sofuni 2007	3	98	14	103	11.60%	0.20 [0.06, 0.72]
Sofuni 2011	20	213	30	213	23.80%	0.63 [0.35, 1.15]
Thanasky 1998	3	43	10	39	8.60%	0.22 [0.05, 0.86]
Tsuchiya 2007	1	32	3	32	2.50%	0.31 [0.03, 3.17]
Subtotal (95%CI)		676		685	88.90%	0.38 [0.26, 0.54]
Total events	46		109			
Heterogeneity: χ^2 = 10.13, *df* = 10 (*P* = 0.43); I^2 = 1%						
Test for overall effect: *Z* = 5.24 (*P* < 0.00001)						
2.1.2 Severe						
Cha 2012	0	46	2	58	1.90%	0.24 [0.01, 5.19]
Fazel 2003	0	40	3	36	3.20%	0.12 [0.01, 2.37]
Lee 2012	0	50	1	51	1.30%	0.33 [0.01, 8.38]
Smithline 1993	0	48	2	50	2.10%	0.20 [0.01, 4.28]
Sofuni 2011	0	213	1	213	1.30%	0.33 [0.01, 8.19]
Tsuchiya 2007	0	32	1	32	1.30%	0.32 [0.01, 8.23]
Subtotal (95%CI)		429		440	11.10%	0.23 [0.06, 0.81]
Total events	0		10			
Heterogeneity: χ^2 = 0.34, *df* = 5 (*P* = 1.00); I^2 = 0%						
Test for overall effect: *Z* = 2.28 (*P* = 0.02)						
Total (95%CI)		1105		1125	100.00%	0.36 [0.25, 0.51]
Total events	46		119			
Heterogeneity: χ^2 = 11.10, *df* = 16 (*P* = 0.80); I^2 = 0%						
Test for overall effect: *Z* = 5.72 (*P* < 0.00001)						
Test for subgroup differences: χ^2 = 0.55, *df* = 1 (*P* = 0.46); I^2 = 0%						

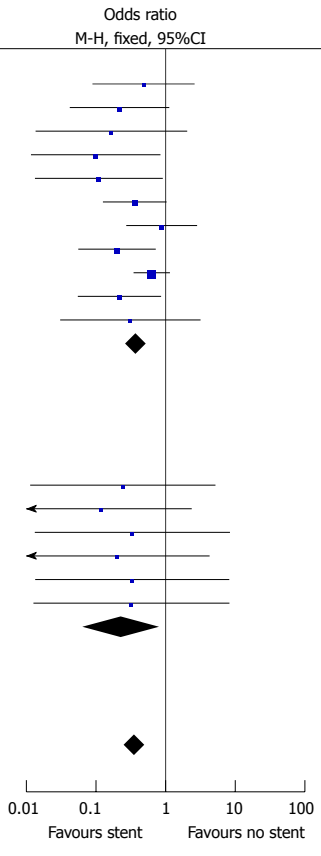


Figure 2 Forest plots. A: A forest plot depicting the incidence of post-endoscopic retrograde cholangiopancreatography pancreatitis (PEP) in the analyzed studies; data from both articles and abstracts were included; B: A forest plot depicting the incidence of PEP in the analyzed studies; data from the abstracts were excluded.

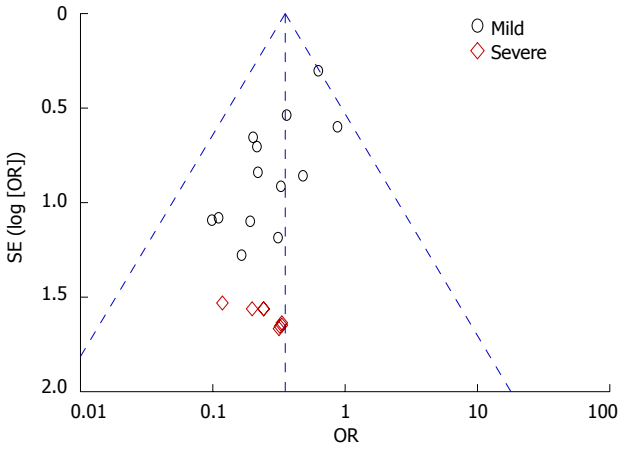


Figure 3 Publication bias funnel plot. A funnel plot depicting the assessment of publication bias of the eligible studies included in this meta-analysis.

biases. When a discrepancy occurred between the two researchers with regard to the extracted information or the publication quality, the original publications were re-reviewed until an agreement was achieved. Because of the difficulties of PD stent placement, most of the studies did not include a sham group. Therefore, a sensitivity analysis of the surgery outcome was conducted instead of an evaluation on blindness grouping.

Statistical analysis

RevMan 5 software provided by Cochrane was used for the heterogeneity and efficacy analyses, and a meta-analysis was performed for the data that showed homogeneity. Categorical data are presented as relative risks (RRs) and 95% confidence interval (CIs), and measurement data are presented as weighted mean differences (WMDs) and 95%CIs. The differences among the published studies were analyzed using the χ^2 test ($P < 0.1$ as a test level), and I^2 was used to determine the significance of the difference ($I^2 > 50\%$ indicated significant or substantial differences; $I^2 > 75\%$ indicated no need for a merged analysis). The fixed-coefficient model was used if there were no significant differences; otherwise, the random coefficient model was used. Descriptive analyses were performed for data that could not be used for the merged analysis. If there was statistical significance between the PD stent and control groups in terms of PEP prevention by meta-analysis, a funnel plot was used for bias analysis.

RESULTS

Publication retrieval

The flow chart in Figure 1 depicts the publication retrieval process.

Study characteristics

Of the 15 studies published between 1990 and 2013, 12 were published articles and 3 were abstracts (Table 1). All the studies included various high-risk groups, such as patients with sphincter of Oddi dysfunctions (SODs), difficult cannulation, pre-cut sphincterotomy, pancreatic sphincterotomy, biliary balloon dilation of intact papilla for stone extraction, endoscopic ampullectomy, and pancreatic brush cytology.

Quality assessment of the included studies

The conditions of randomization, double-blinding, and the risk of missing data from each study were evaluated. Nine studies reported randomization concealment, but none of the studies were double-blinded. Half of the studies used statistics from the intent-to-treat group, and the other half assessed the loss of data. The results are shown in Table 2.

Pancreatitis incidence analysis

Data on pancreatitis incidence were reported in 14 (12 in articles and 2 in abstracts) of 15 trials. There was no significant heterogeneity between the trials ($I^2 = 0\%$, $P = 0.93$); therefore, a fixed effects model was used to pool the results. In the stent group, 49 of the 1233 patients suffered from PEP, compared to 133 of 1277 patients in the no-stent group. The meta-analysis (Figure 2) showed that the stent group had a significantly ($P < 0.00001$) lower incidence of PEP (OR = 0.35; 95%CI: 0.25-0.49). Subgroup analyses were performed to examine the incidence of different degrees of PEP. These results are shown in Figure 2A. Because the data from the abstracts were not comprehensive, which may lead to bias and affect the reliability of the results, we also conducted an analysis in which data from abstracts were excluded (Figure 2B). The results (OR = 0.36; 95%CI: 0.25-0.51, $P < 0.00001$) showed no significant difference from the pooled results that included all the data.

Publication bias assessment

Possible publication bias was assessed using Begg's funnel plot and Egger's test. No evidence of publication bias was detected (Figure 3).

Sensitivity analysis

Each study was excluded from the analysis one by one to assess how its exclusion would affect the pooled estimate. Our results for PEP incidence in the entire study and each subgroup were robust.

DISCUSSION

Papillary balloon dilation, incision, and pre-incision are usually required during diagnostic and therapeutic ERCP operations. Surgical manipulation in combination with concurrent superoxide dismutase disease can result in pancreatic duct drainage blockage and intracellular proteolytic enzyme activation[11]. Bacterial contamination during endoscopic surgery can result

Table 1 Characteristics of the included studies

Ref.	Type	Study type	Intervention	Stent	Patients	*n* (stent)	*n* (control)
Smithline *et al*[16], 1993	Article	RCT	Biliary ES	5-7F, 2-2.5 cm	SOD	43	50
Sherman *et al*[17], 1996	Abstract	RCT	Precut biliary ES	5-7F, 2-2.5 cm		46	58
Tarnasky *et al*[12], 1998	Article	RCT	Biliary ES	5-7F, 2-2.5 cm	SOD	41	39
Tarnasky *et al*[12], 1998	Abstract	RCT	Biliary ES	5F, 2 cm		36	38
Patel *et al*[18], 1999	Abstract	RCT	Pancreatic ES	5-7F, 2-2.5 cm	SOD	18	18
Fazel *et al*[19], 2003	Article	RCT	ERCP	5F, 2 cm	Difficult cannulation	38	36
Harewood *et al*[20], 2005	Article	RCT	Endoscopic ampullectomy	5F, 3-5 cm	Ampullary adenoma	11	8
Sofuni *et al*[21], 2007	Article	RCT	ERCP, *etc.*	5F, 3 cm	Various	98	103
Tsuchiya *et al*[22], 2007	Article	RCT	ERCP, *etc.*	5F, 3-4 cm	Various	32	32
Ito *et al*[23], 2010	Article	RCT	ES, IDUS	5F, 4 cm	With high-risk factors	35	35
Pan *et al*[24], 2011	Article	RCT	ERCP	5F	With high-risk factors	20	20
Sofuni *et al*[25], 2011	Article	RCT	ERCP, *etc.*	5F, 3 cm	With high-risk factors	213	213
Kawaguchi *et al*[26], 2012	Article	RCT	ERCP, ES, IDUS	5F, 3 cm	With high-risk factors	60	60
Cha *et al*[27], 2012	Article	RCT	ES	5-7F, 2-2.5 cm	Difficult cannulation	46	58
Lee *et al*[28], 2012	Article	RCT	ES, IDUS, *etc.*	3, 4, 6, 8F	Difficult cannulation	50	51

RCT: Randomized controlled trial; ES: Endoscopic sphincterotomy; IDUS: Intraductal ultrasonography.

Table 2 Quality of included studies

Ref.	Concealment of randomization	Double-blinding	Risk of losing data
Smithline *et al*[16], 1993	-	-	-
Sherman *et al*[17], 1996	-	-	NK
Tarnasky *et al*[12], 1998	+	-	NK
Patel *et al*[18], 1999	-	-	NK
Fazel *et al*[19], 2003	+	-	+
Harewood *et al*[20], 2005	+	-	+
Sofuni *et al*[21], 2007	+	-	+
Tsuchiya *et al*[22], 2007	+	-	-
Ito *et al*[23], 2010	+	-	-
Pan *et al*[24], 2011	-	-	-
Sofuni *et al*[25], 2011	+	-	-
Kawaguchi *et al*[26], 2012	+	-	-
Cha *et al*[27], 2012	-	-	-
Lee *et al*[28], 2012	+	-	-

+: Reported or used with relatively lower risk; -: Not reported or not used with potential risk; UK: Unknown.

in chemical or allergic injuries to the pancreas and subsequent local inflammatory cascading, which can eventually lead to pancreatitis. PEP is one of the most common and severe complications after ERCP, and effective prophylactic intervention is of great clinical significance. Tarnasky *et al*[12] found that patients with accessory papilla usually had a lower PEP incidence when the pancreatic papilla was blocked, indicating that improved pancreatic drainage might effectively decrease the incidence of PEP. In addition, Bourke *et al*[13] reported that although the incidence of pancreatitis after sphincterotomy was higher than that after diagnostic ERCP, the rate of severe PEP was significantly reduced, implying that sphincterotomy might be able to reduce PEP severity. Because PD stent placement can prevent pancreatic duct drainage impairment as a result of papillary edema or sphincter spasms, it might be an effective option to prevent PEP.

All the 15 published studies used in the current analysis were RCTs and included 1606 patients, making this analysis larger than a previous similar study. We also analyzed the association between PD stent length and PEP occurrence. Therefore, our study had more validated methods and comprehensive data compared to the previous publication. PEP risk factors include difficulty with intubation, sphincter pre-incision, pancreatic duct opacification, and a previous history of PEP. When there is difficulty in pancreatic duct intubation, pancreatic duct stent-assisted bile duct intubation, pancreatic duct guidewire-assisted bile duct intubation, or pre-incision technology is usually conducted to improve the success rate of bile duct intubation. The cases included in the current study were all cases with intubation difficulty; PD stent placement-assisted intubation was employed in the PD stent group, and if that failed, biliary duct deep intubation by fenestration was performed. Pancreatic duct guidewire-assisted bile duct intubation was conducted in the control group, but biliary duct deep intubation by fenestration was performed if the guidewire-assisted procedure failed. Our analysis showed that the proportions of bile duct deep intubation, pancreatic duct opacification, and pancreatic duct guidewire-assisted bile duct intubation

were similar between the PD stent placement and control groups. It was reported by Fogel *et al*[14] that the pre-incision of the biliary sphincter combined with PD stent placement could improve the success rate of selective bile duct intubation and reduce the frequency of repeated intubation. Similarly, the success rate of selective bile duct intubation was 97.4% in a study by Goldberg *et al*[15], who used PD stent-assisted intubation and reported mild pancreatitis in just two patients, indicating a satisfactory safety profile of the technique. In the current study, there were 49 patients with mild PEP and no patients with severe PEP in the PD stent placement group compared to 120 and 13 patients in the control group, respectively. There was a significant difference between the two groups in terms of the incidence of complications.

Although pancreatic stenting decreases the incidence of PEP, potential problems remain that may cause PEP in the stent group. Stent placement following biliary interventions can be difficult. Failure usually occurs because the pancreatic orifice cannot be identified or a guidewire cannot be advanced deeply into the duct. Likewise, an additional endoscopy is often needed for stent removal.

In conclusion, the results of this meta-analysis indicate that it may be possible to prevent PEP by placing a PD stent. This procedure can reduce postoperative hyperamylasemia and might be an effective and safe option to prevent PEP if the operation indications are well controlled.

COMMENTS

Background

Pancreatitis is one of the most common and severe complications after endoscopic retrograde cholangiopancreatography (ERCP). The reported incidence of post-ERCP pancreatitis (PEP) varies between 2% and 7% in prospective trials and may be as high as 30%-50% in high-risk patients.

Research frontiers

The precise mechanisms of PEP remain unclear. It was demonstrated by Chahal *et al* that a substitute drainage pathway could prevent PEP, confirming the hypothesis that pancreatic drainage blockage as a result of Oddi sphincter spasms or papillary edema might be a major reason for PEP. Therefore, it is reasonable that pancreatic stent placement could improve pancreatic drainage and reduce the enzymatic reactions of tryptic enzymes. Although a previous meta-analysis has indicated that pancreatic duct (PD) stent placement can prevent PEP, particularly in high-risk patients, there is a lack of high-quality evidence-based studies based on appropriate numbers of well-validated publications.

Innovations and breakthroughs

All the 15 published studies used in the current analysis were randomized controlled trials and included 1606 patients, making this analysis larger than a previous similar study.

Applications

The results of this meta-analysis indicate that it may be possible to prevent PEP by placing a PD stent. This procedure can reduce postoperative hyperamylasemia and might be an effective and safe option to prevent PEP if the operation indications are well controlled.

Peer-review

The authors in this manuscript evaluate the existing literature on this topic. The quality standards for inclusion are high, and their methodology is sound. This is an interesting and valuable contribution.

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