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MINIREVIEWS

Prevention of post-endoscopic retrograde cholangiopancreatography pancreatitis using pancreatic stents: A review of efficacy, diameter and length

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Abstract

Although endoscopic retrograde cholangiopancreatography (ERCP) is an important procedure for the diagnosis and treatment of pancreaticobiliary diseases, post-ERCP pancreatitis (PEP) is the most frequent adverse event that can sometimes be fatal. However, prophylactic pancreatic stent (PS) insertion has been performed to prevent PEP in high-risk patients. In some randomized controlled trials (RCTs) and meta-analyses, the efficacy of prophylactic PS insertion has been shown to prevent PEP. In addition, several types of stents have been used to decrease PEP. In this review, we introduce the details of these RCTs and meta-analyses and reveal the specifications for stent placement, for example, the stent diameter and length and the pancreatic region into which the stent should be inserted.

Key Words: Endoscopic retrograde cholangiopancreatography; Post-endoscopic retrograde cholangiopancreatography pancreatitis; Prophylactic pancreatic stent

Core tip: Post-endoscopic retrograde cholangiopancreatography pancreatitis (PEP) is the most frequent adverse event that can sometimes be fatal. Pancreatic stent (PS) insertion is recommended to prevent PEP based on some randomized controlled trials (RCTs) and meta-analyses. Currently, several types of PS have been used. In this review, we introduce these RCTs and meta-analyses and reveal what stent should be used.

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INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is an important procedure for the diagnosis and treatment of pancreaticobiliary diseases but is sometimes a dangerous procedure. Several adverse events related to ERCP have been reported (duodenal perforation, bleeding, *etc*)[1-4]. Among them, post-ERCP pancreatitis (PEP) is the most frequent adverse event and is sometimes fatal. According to past reports, PEP occurs in 0.4%-5.6% of patients[5-12], and the mortality rate of PEP is 0-0.1%[8,10-12]. The risk factors of PEP that have been specified in past reports were history of previous PEP, more than two contrast injections into the pancreatic duct, sphincter of Oddi dysfunction (SOD), age less than 50 years, female gender, difficult biliary duct cannulation, biliary sphincter balloon dilation, precut sphincterotomy, and a history of previous pancreatitis[11-19]. As prophylaxis for PEP in high-risk patients with these risk factors, pancreatic stent (PS) insertion is a preventative option. In this review, we present our investigations on the efficacy of PS placement for preventing PEP, and we disclose what stent should be selected and how the PS should be inserted.

SEARCH STRATEGY

The studies included in this review were retrieved from PubMed using the following keywords: "Post-ERCP pancreatitis" and "pancreatic stent". Furthermore, studies written in English were selected. Only randomized controlled trials (RCTs) and meta-analyses that examined the efficacy of PS for preventing PEP were selected for further analysis. Studies that compared different stents (flanged or unflanged, diameter, length) were analyzed to determine which PSs should be used.

ADAPTATION OF PROPHYLACTIC PS INSERTION

As mentioned above, patients with high risk factors become candidates for pro-phylactic PS insertion. The patients recommended PS insertion had a history of previous PEP, SOD, difficult biliary duct cannulation, biliary sphincter balloon dilation, precut sphincterotomy or sphincterotomy, pancreatic duct cannulation or contrast agent injection to the pancreatic duct, or endoscopic ampullectomy[20].

RCTs

In an RCT in 1993, Smithline *et al*[21] reported first prophylactic PS insertion for preventing PEP. In the report, the risk factors of PEP were acinarization, precutting, and a history of pancreatitis. The report could not prove the efficacy of PS insertion and did not recommend PS for PEP (PEP rate: Stent group 14% (6/43) *vs* 18% (9/50), $P = 0.299$). However, several additional RCTs were performed, and the total number of RCTs on this topic increased to eleven from 1993 to 2016[21-31] (Table 1). Except for the first report written by Smithline, all reports indicated the efficacy of PS insertion for preventing PEP, and severe PEP did not occur in patients who received a PS[22-31]. Although a significant difference was not observed, the PEP rate was lower in the stent group than in the no stent group in the report written by Tsuchiya *et al*[25] [stent group 1/32 (3.1%) *vs* no stent group 4/32 (12.5%), $P > 0.05$].

Table 1 Randomized controlled trials of prophylactic pancreatic stent insertion for preventing post-endoscopic retrograde cholangiopancreatography pancreatitis

Author	Yr	Country	Sample number		Risk factors	PEP *n* (%)	Criteria for PEP
			Stent	No stent		Stent/no stent	
Smithline *et al* [21]	1993	United States	43	50	Acinarization, pre-cutting, history of pancreatitis	Total 6 (14)/9 (18), P = 0.299; Mild 5 (12)/5 (10), P = NA; Moderate 1 (2)/2 (4) P = NA; Severe 0 (0)/2 (4), P = 0.264	Cotton
Tarnasky *et al* [22]	1998	United States	41	39	SOD	Total 1 (2)/10 (26), P = 0.003; Mild 0 (0)/5 (13), P = NA; Moderate 0 (0)/5 (13), P = NA; Severe 0 (0)/0 (0), P = NA	Cotton
Fazel *et al*[23]	2003	United States	38	36	Difficult cannulation SOD	Total 2 (5.3)/10 (28), P < 0.05; Mild 2 (5.3)/5 (14), P = NA; Moderate 0 (0)/2(6), P = NA; Severe 0 (0)/3 (8), P = NA	Cotton
Sofuni *et al* [24]	2007	Japan	98	103	IDUS, biopsy, EPBD, SOD, POCS, Duodenal diverticulum, acinarization, initial pancreato-graphy, difficulty of cannulation	Total 3 (3)/14 (13.6), P = 0.019; Mild 2 (2)/8 (7.8), P = 0.139; Moderate 1 (1)/6 (4.6), P = 0.156; Severe 0 (0)/0(0), P = NA	Cotton
Tsuchiya *et al* [25]	2007	Japan	32	32	EST, IDUS, EPBD, SOD, pancreatic duct cannulation	Total 1 (3.1)/4 (12.5), P > 0.05; Mild 1 (3.1)/2 (6.3), P = NA; Moderate 0 (0)/1 (3.1), P = NA; Severe 0 (0)/1 (3.1), P = NA	Cotton
Ito *et al*[26]	2010	Japan	35	35	History of pancreatitis, history of PEP, pancreatic duct opacification, EST, IDUS, EPBD, cytology of pancreatic juice, biopsy of pancreatic duct	Total 1 (2.9)/8 (23) (per-protocol) 0 (0)/9 (24), P = 0.0096; Mild 1 (2.9)/8 (23); Moderate and severe 0	Cotton
Sofuni *et al* [28]	2011	Japan	213	213	History of pancreatitis, SOD, pancreato-graphy, EST, precut sphincter-otomy, EPBD, CBD tissue sampling, pancreatic duct tissue sampling, biliary drainage without EST, ENBD without EST, IDUS, difficulty of cannulation, long procedural time	(Intention to treat) Total 20 (9.4)/31 (14.6), P = 0.076; Mild 16 (7.5)/22 (10.3), P = 0.24; Moderate 4 (1.9)/8 (3.8), P = 389; Severe 0 (0)/1 (0.5), P = 1.00; (Full analysis set) Total 16 (7.9)/31 (15.2), P = 0.021; Moderate 12 (5.9)/22 (10.8), P = 0.77; Mild 4 (1.97)/8 (3.92), P = 0.952; Severe 0 (0)/1 (0.5), P = 1.00	Cotton
Pan *et al*[27]	2011	China	20	20	History of pancreatitis, pancreatic duct cannulation, pancreato-graphy, difficult cannulation, hyperamyla-semia	Total 4 (20)/14 (70), P < 0.01; Mild, moderate, severe NA	Cotton
Kawaguchi *et al*[29]	2012	Japan	60	60	History of PEP, SOD, difficult cannulation, pre-cutting, pancreatic duct biopsy, IDUS of pancreatic duct	Total 1 (1.7)/8 (13.3), P = 0.032; Mild 1 (1.7)/8 (13.3), P = 0.032	Modified Cotton
Lee *et al*[30]	2012	Korea	50	51	Difficult biliary cannulation, pancreatic cannulation	Total 6 (12)/15 (29.4), P = 0.031; Mild 5 (10)/12 (23.5), P = NA; Moderate 1 (2)/2 (3.9), P = NA; Severe 0 (0)/1 (2), P = NA	Cotton
Yin *et al*[31]	2016	China	104	102	History of PEP, cannulation difficulty, periampullary diverticulum	Total 8 (7.7)/18 (17.7), P = 0.031, Mild, Moderate, severe NA	NA

RCT: Randomized controlled trial; PEP: Post-endoscopic retrograde cholangiopancreatography pancreatitis; SOD: Sphincter of Oddi dysfunction; IDUS: Intraductal ultrasonography; EPBD: Endoscopic papillary balloon dilation; POCS: Peroral cholangioscopy; EST: Endoscopic sphincterotomy; CBD: Common bile duct; ENBD: Endoscopic nasobiliary drainage; NA: Not available.

PS FOR AMPULLECTOMY

In 2005, Harewood *et al*[32] reported on prophylactic PS placement for endoscopic snare excision of the duodenal ampulla. In this study, 19 patients were enrolled, and 10 received a PS. Although the number of participants was small, postprocedure pancreatitis was significantly higher in patients without PS than in patients with PS [33% (3/9) *vs* 0% (0/10), P = 0.02].

META-ANALYSES

Among the eleven RCTs, PEP occurred more in patients without PS than in patients with PS. PS insertion was recommended for preventing PEP. Additionally, severe PEP did not occur in any patient who received a PS in all eleven RCTs. However, the frequency of severe PEP was not significantly different between the stent group and the no stent group in any of the RCTs. The results of severe PEP referred to the small sample size in each RCT and far fewer patients with severe PEP. These facts indicated that prophylactic PS might prevent not only total PEP but also severe PEP.

The usefulness of prophylactic PS placement for preventing severe PEP was not statistically recognized within each RCT. However, six meta-analyses were previously performed on prophylactic PS placement to prevent PEP[33-38] (Table 2). Among them, two of the six meta-analyses reported that prophylactic PS insertion did not statistic-ally prevent severe PEP[33,35]. As more cases of prophylactic PS were reported, the second-most recent meta-analysis was conducted by Shi *et al*[37]; however, the efficacy of prophylactic PS for preventing severe PEP could not be proven. As a cause, the meta-analysis involved only full text articles and excluded articles with only abstracts, and the number of cases became small. On the other hand, two meta-analyses written by Mazaki *et al*[34,36] involved both full-text articles and articles with only abstracts; therefore, the number of cases was large. In the two meta-analyses written by Mazaki *et al*[34,36], the efficacy of prophylactic PS insertion for preventing severe PEP was indicated (2010: Stent group 0/336 *vs* no stent group 7/344, $P < 0.04$, 2014: Stent group 0/694 *vs* no stent group 13/718, $P = 0.01$). Furthermore, in the most recent meta-analysis written by Fan *et al* [38], severe PEP was significantly lower in patients with a PS than in patients without a PS (stent group 0/493 *vs* no stent group 13/516, $P < 0.01$).

From a meta-analysis, it became apparent that prophylactic PS might be efficient for preventing not only PEP but also severe PEP.

WHAT STENT SHOULD BE USED?

As described above, PEP is reduced by PS insertion. However, several forms, diameters, and lengths of PSs exist. What stent should we use (Table 3)?

Internal flanged or unflanged

In 2018, He *et al*[39] compared 5-Fr 3 cm internal unflanged stents with a single pigtail on the duodenal side and 5-Fr 3 cm internal flanged stents with a single pigtail on the duodenal side. The PEP rates were not different between the two types of stents [unflanged stents 5.07% (7/138) *vs* flanged stents 7.97% (11/138), $P = 0.329$]. However, spontaneous PS displacement at 5 d was significantly higher in the internal unflanged stent group than in the internal flanged stent group [unflanged stent 47.72% (63/138) *vs* flanged stent 15.67% (21/134), $P < 0.001$]. Furthermore, spontaneous PS displacement at 14 d was significantly higher in the internal unflanged stent group than in the internal flanged stent group [unflanged stent 84.21% (112/133) *vs* flanged stent 42.65% (58/136), $P < 0.001$]. When the internal unflanged stent with a single pigtail on the duodenal side was used, an additional endoscope insertion to remove the PS was avoided.

PS diameter

In past reports, the diameter of the PS makes a difference not only in the occurrence of PEP but also in usability. In 2004, Rashdan *et al*[40] wrote a retrospective study about prophylactic PS placement in 2940 cases. They described that small-diameter stents (*i.e.*, 3-4-Fr) were more effective than were 5-Fr or 6-Fr stents in preventing PEP [PEP rate: 3-4-Fr stent 8.7% (213/2447) *vs* 5-6-Fr stent 11.0 % (54/493), $P = 0.0471$]. However, Zolotarevsky *et al*[42] reported that there was no significant difference in the PEP rate between patients who received a 3-Fr PS and patients who received a 5-Fr PS. However, insertion of a 5-Fr stent was faster (9.2 min *vs* 11.1 min, $P = 0.355$), easier [mean modified 5-point Likert scale[41,42]: 1.8 (5-Fr) *vs* 3.4 (3-Fr), $P < 0.01$], and required fewer wires [1.5 (5-Fr) *vs* 1.9 (6-Fr), $P = 0.002$] than insertion of a 3-Fr PS[43]. Pahk *et al*[44] reported that spontaneous passage was more frequent with 4-Fr PSs than with 5-Fr PSs [95.8% (115/137) *vs* 68.7% (134/209), $P < 0.001$ (by log-rank test)]; therefore, the need for additional endoscopy to retrieve the PS was reduced by using a 4-Fr PS. However, the incidence of PEP was not significantly different between the 4-Fr PS group and the 5-Fr PS group. An additional report stated that insertion of a PS with a diameter > 5-Fr was effective in preventing PEP (PEP rate: > 5-Fr > 5 cm 1.4% *vs* ≤ 5-Fr ≤ 5 cm 9.4%, $P = 0.0252$)[45].

Based on the above results, whether the diameter of PS influences the occurrence of PEP remains controversial. According to past reports, thin stents (*i.e.*, 3-Fr or 4-Fr) should be used with the expectation of spontaneous dislodgment, and a 5-Fr stent should be used in cases that were difficult to insert PS.

Table 2 Meta-analyses of prophylactic pancreatic stent insertion for preventing post-endoscopic retrograde cholangiopancreatography pancreatitis

Author	Yr	Number of included studies	Type of included studies	PEP rateStent/no stent	PS insertion for preventing PEP
Singh *et al*[33]	2004	5	Full text	n = 206/275	Recommended
			Abstract	Total 12/43, P = 0.001 Mild to moderate 12/36, P = 0.001; Severe 0/7, P = 0.15	
Mazaki *et al*[34]	2010	8	Full text	n = 336/344	Recommended
			Abstract	Total 19/64, P < 0.001; Mild to moderate 19/55, P < 0.001; Severe 0/7, P < 0.04	
Choudhary *et al*[35]	2011	8	Full text	n = 322/334	Recommended
			Abstract	Total 16/66, P < 0.00001	
Mazaki *et al*[36]	2014	14	Full text	n = 751/781	Recommended
			Abstract	Total 49/133, P < 0.001; Mild to moderate 49/120, P < 0.001; Severe 0/13, P = 0.01	
Shi *et al*[37]	2014	10	Full text	n = 561/584; Total 34/117, P < 0.001; Mild 24/70, P < 0.001; Moderate 6/24, P = 0.004; Severe 0/6, P = 0.077	Recommended
Fan *et al*[38]	2015	15	Full text	n = 1233/1277	Recommended
			Abstract	Total 49/133, P < 0.00001; Mild 49/120, P < 0.00001; Severe 0/13, P < 0.00001	

PS: Pancreatic stent; PEP: Post-endoscopic retrograde cholangiopancreatography pancreatitis.

PS length

Few reports have described the length of PSs (Table 3). In 2009, Chahal *et al*[46] compared the occurrence of PEP between 5-Fr, 3 cm long unflanged PSs and 3-Fr, 8 cm or longer unflanged PSs. PEP was less frequent in the 5-Fr, 3 cm stent group than in the 3-Fr, long-stent group [PEP rate: 3-Fr 8 cm 14% (18/133) *vs* 5-Fr 3 cm 9% (11/116), P = 0.30]. However, significant differences between these two groups were not observed. Fujisawa *et al*[47] compared PS lengths (unflanged straight stent, 5-Fr at 3 cm *vs* 5-Fr at 5 cm) and reported that the PEP rate and the median time until stent dislodgement were both lower in the 3 cm group than in the 5 cm group (PEP rate: 3 cm 2.0% *vs* 5 cm 8.8%, P = 0.035, median period until spontaneous PS dislodgement: 3 cm 2 d *vs* 5 cm 4 d, P < 0.001). In this report, earlier stent dislodgement of the 3 cm PS might contribute to preventing PS obstruction-induced PEP. However, Olsson *et al*[45] reported that a PS with a length > 5 cm and a diameter > 5 Fr is the most effective in preventing PEP. In this report, the frequency of PEP was not significantly different between patients who received a PS ≤ 5 cm and patients who received a PS > 5 cm.

These results regarding the influence of PS length on PEP varied, and we propose two explanations for these inconsistencies. Perhaps the diameters of PS were not matched, except for in the second report written by Fujisawa *et al*[47]; although in this report the pancreatic region into which the PS was inserted was not investigated, and only PS length was investigated. Pancreas size differs among people; therefore, both a 3 cm and 5 cm stent can be inserted into the pancreatic head depending on the patient. However, spontaneous dislodgement could contribute to preventing PEP if both a 3 cm and 5 cm PS were inserted in or near to the pancreatic head.

Location in the pancreas of PS insertion

As described in the previous section, the PEP rate was compared between patients who received a PS ≤ 5 cm and patients who received a PS > 5 cm in a report written by Olsson *et al*[45]. In comparison, the PEP rate was not significantly different between the two groups. In patients who received a PS > 5 cm, the stent might reach the pancreatic body or the tail. However, the pancreatic regions into which the stents were inserted were not described.

However, Sugimoto *et al*[48] compared hyperamylasemia and the PEP rate between patients who had a PS inserted into the pancreatic head (the head group) and patients who had a PS inserted into the pancreatic body or tail (the body/tail group). Although a significant difference was not observed, the PEP rate was lower in the body/tail group than in the head group [0% (0/16) *vs* 9.2% (12/131), P = 0.363]; PEP was not observed in the body/tail group. Furthermore, after ERCP, the level of the pancreatic isozyme of serum amylase was significantly higher in the head group than in the body/tail group [138.5 (7.0-2086) IU/L *vs* 78.5 (5.0-1266.5) IU/L, P = 0.03]. Proteinase activation, which exacerbates pancreatitis, is induced by difficult pancreatic duct drainage[49]; therefore, stent placement

Table 3 Comparison of stent type

Author, yr	Stent type	*n*	Results
Flanged or unflanged			
He *et al*[39], 2018	Internal unflanged 5-Fr 3 cm stent with a single pigtail on the duodenal side *vs* internal flanged 5-Fr 3 cm stent with a single pigtail on the duodenal side	138/138	Spontaneous migration was more frequent with the internal unflanged stent (migration at five days: 47.72% *vs* 15.67%, $P < 0.001$, migration at 14 d 84.21% *vs* 42.65%, $P < 0.001$)
Comparison of stent diameter			
Rashdan *et al*[40], 2004	3-4-Fr, 3-8 cm without internal flange *vs* 5-6-Fr, NA, with internal flange	2447/493	The 3-4-Fr stent was more effective in preventing PEP than the 5-6-Fr stent (PEP rate: 3-4-Fr stent 8.7% (213/2447) *vs* 5-6Fr 11.0% (54/493), $P = 0.0471$)
Zolotarevsky *et al*[43], 2011	5-Fr 5 cm *vs* 3-Fr 6 cm	38/40	PEP rates did not differ. 5-Fr PS placement was easier [mean modified 5-point Likert scale[40,41]: 1.8 (5-Fr) *vs* 3.4 (3-Fr), $P < 0.01$)], faster [9.2 (5-Fr) *vs* 11.1 minutes (3-Fr), $P = 0.355$], and required fewer wires [1.5 (5-Fr) *vs* 1.9 (6-Fr), $P = 0.002$]
Pahk *et al*[44], 2011	4-Fr *vs* 5-Fr, both stents were 2 to 11 cm, unflanged	137/209	PEP rates did not differ. Spontaneous migration was more frequent with the 4-Fr stent [95.8% (115/137) *vs* 68.7% (134/209), $P < 0.001$ (by log-rank test)]
Olsson *et al*[45], 2016	≤ 5-Fr, ≤ 5 cm *vs* > 5-Fr, > 5 cm	241 (≤ 5-Fr)/135 (> 5-Fr)	The > 5-Fr, > 5 cm stent was more effective in preventing PEP (> 5-Fr, > 5 cm 1.4% *vs* ≤ 5-Fr, ≤ 5 cm 9.4%, $P = 0.0252$)
Comparison of stent length			
Chahal *et al*[46], 2009	5-Fr 3 cm, unflanged *vs* 3-Fr 8 cm or longer, unflanged	116/133	Spontaneous migration was more frequent with the 5-Fr 3 cm stent (5-Fr 98% *vs* 3-Fr 88%, $P = 0.0001$). Failure of PS placement was observed more often in the longer 3-Fr stent group (5-Fr 0/116 *vs* 3-Fr 11/133, $P = 0.0003$). PEP rates did not differ
Fujisawa *et al*[47], 2016	5-Fr 3 cm *vs* 5-Fr 5 cm, both stents were unflanged and straight	98/102	The 5-Fr 3 cm stent was more efficient for preventing PEP (3 cm 2.0% *vs* 5 cm 8.8%, $P = 0.035$). The period until spontaneous dislodgement was significantly shorter for the 3 cm stent than for the 5 cm stent (3 cm 2 d *vs* 5 cm 4 d, $P < 0.001$)
Part of the pancreas in which the stent was inserted			
Sugimoto *et al*[48], 2018	Pancreatic head *vs* pancreatic body or tail	131/16	After ERCP, the level of the pancreatic isozyme of serum amylase was higher in the head group than in the body/tail group [head group 138.5 (7.0-2086) IU/L *vs* body/tail group 78.5 (5.0-1266.5) IU/L, $P < 0.03$]

ERCP: Endoscopic retrograde cholangiopancreatography; PEP: Post-ERCP pancreatitis.

up to the pancreatic body or tail contributes to greater pancreatic drainage than stent placement in the pancreatic head does.

CONCLUSION

The results of several RCTs and meta-analyses have revealed that PS is efficient for preventing PEP. However, PEP can occur in patients who underwent stent placement. Currently, the main argument is

which PS should be used. Additional endoscopic insertion to remove the PS could be avoided by using an internal unflanged PS. The diameter of PS is controversial because thin stents easily migrate, and thick stents are easily inserted in some cases. With respect to the length of the stent, a 3 cm stent may be more efficient than a 5 cm stent in preventing PEP. However, the risk of PEP may be altered according to the pancreatic region into which the PS is inserted.

Overall, there remain few cases in which a prophylactic PS was utilized; therefore, the accumulation of additional cases is necessary.

FOOTNOTES

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