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Into which Region Should a Prophylactic Pancreatic Stent Be Inserted? A Propensity Score Matching Analysis

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ABSTRACT

Background & Aims: Endoscopic retrograde cholangiopancreatography (ERCP) is an important procedure for the diagnosis and treatment of pancreaticobiliary diseases. However, post-ERCP pancreatitis (PEP) is sometimes a mortal adverse event. Though pancreatic stent (PS) insertion has proven to be a useful prophylaxis for PEP in several past reports, the region of the pancreas into which the PS should be inserted is unknown. Therefore, this study investigated where a prophylactic PS for PEP should be inserted.

Methods: In this retrospective study, we targeted 282 patients without past history of abdominal surgery and who underwent initial ERCP and insertion of prophylactic PS to prevent PEP between January 2007 and April 2019. Patients with PS insertion to the pancreatic head (head group) were compared with patients with PS insertion into the pancreatic body or tail (body/tail group) using propensity score matching for patient characteristics, ERCP procedures, and post-ERCP adverse events.

Results: After propensity score matching and removing the cases with the PS passing spontaneously for ERCP procedures, 52 head group patients and 54 body/tail group patients were selected. The PEP rate was significantly higher in the head group than in the body/tail group (9.6% vs. 0%, p=0.026).

Conclusion: Pancreatic stent insertion in the pancreatic body/tail was more effective for preventing PEP than PS insertion in the pancreatic head.

Key words: ERCP – post-ERCP pancreatitis – pancreatic stent.

Abbreviations: EPBD: endoscopic papillary balloon dilation; ERCP: endoscopic retrograde cholangiopancreatography; EST: endoscopic sphincterotomy; MPD: main pancreatic duct; pAMY: pancreatic isozyme of serum amylase; PEP: post-ERCP pancreatitis; PS: pancreatic stent; RCT: randomized controlled trial.

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is an important procedure for the diagnosis and treatment of pancreaticobiliary diseases. However, there are several adverse events of ERCP, such as duodenal perforation or bleeding, after endoscopic sphincterotomy (EST) [1-4]. Among them, post-ERCP pancreatitis (PEP) is the most frequent and sometimes fatal adverse event. The frequency of PEP occurrence was reported to be 0.4-5.6% in patients who underwent ERCP [5-12]. Moreover, the reported mortality rate of PEP was 0–0.1% [8, 10-12]. The risk factors for PEP are history of previous PEP or pancreatitis, repeated contrast injections into the pancreatic duct, brush cytology of the main pancreatic duct (MPD), sphincter of Oddi dysfunction, age < 50 years old, female gender, difficulty with biliary duct cannulation, endoscopic papillary balloon dilation (EPBD), and precut sphincterotomy [11-20]. Among these risk factors, certain issues related to the pancreatic duct were selected as a matter of course. Therefore, the efficacy of prophylactic pancreatic stent (PS) insertion to prevent PEP has been reported in several reports. Many randomized controlled trials (RCTs) have been performed on prophylactic PS for PEP [21-31], and mostly achieved good results. In some meta-analyses, the efficacy of prophylactic PS has been shown [32-38].

On the other hand, PEP occurs in some patients who underwent insertion of PS to prevent PEP, and the region into which the PS should be inserted remains unknown. There is no consensus about the diameter of the stent [39-43]. Regarding

the length of the stent, Fujisawa et al. [44] reported that a 5-Fr 3 cm stent was more effective for preventing PEP than a 5-Fr 5 cm stent. However, 3 cm and 5 cm PSs are inserted into the pancreatic head in most cases. Regarding the pancreatic region where prophylactic PSs should be inserted, Sugimoto et al. [45] reported that prophylactic PSs inserted up to the pancreatic body or tail were more effective for preventing post-ERCP hyperamylasemia than PSs inserted in the pancreatic head. In this study, PEP occurrence was not observed in patients in whom a PS was inserted into the pancreatic body or tail. However, this report was limited to patients who underwent the double guide wire method for biliary cannulation.

Therefore, the appropriate region into which a prophylactic PS should be inserted is still unknown in high-risk patients. In this study, the aim was to establish the appropriate region into which a PS should be inserted.

METHODS

Study design and ethics

In this retrospective study with propensity score matching, we compared the pancreatic regions into which a prophylactic PS was inserted to prevent PEP. This study was approved by the Institutional Review Board of Fukushima Medical University.

Patients

A total of 282 patients who did not have past history of abdominal surgery underwent initial ERCP and insertion with a prophylactic PS to prevent PEP at Fukushima Medical University between January 2007 and April 2019 (Fig. 1). Among them, 18 patients with an ampullary tumor, 12 patients without data on pancreatic isozyme of serum amylase available, and 11 patients showing serum hyperamylasemia before ERCP were removed. In addition, 10 patients who underwent insertion of 4-Fr or 7-Fr PSs were removed because a 5-Fr PS was usually used to prevent PEP. Finally, 231 patients with a 5-Fr prophylactic PS were enrolled in this study. The length of the PS was determined randomly by each endoscopist.

A total of 174 patients underwent insertion of a PS in the pancreatic head (head cases). Fifty-seven patients underwent insertion of a PS in the pancreatic body or tail (body/tail cases).

ERCP procedures

All patients underwent insertion with a side view duodenoscope after they were sedated sufficiently with intravenous injection of midazolam. Before ERCP, 300 mg of gabexate mesylate was administered. If biliary cannulation was successful for cholangiography without pancreatic duct procedures, prophylactic PS was not needed. However, if only

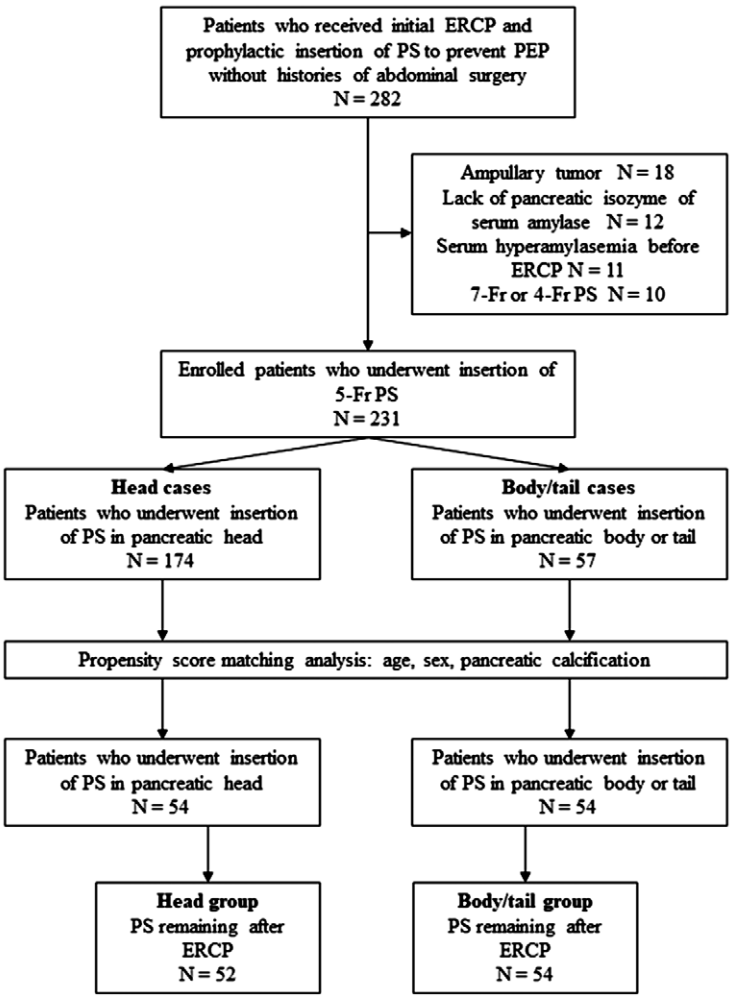

Fig. 1. Flow chart of patients who were involved in this study.

guidewire insertion to the MPD or pancreatography could be performed, a double guidewire method was performed. After a guidewire was inserted into the pancreatic duct as deep as possible, biliary cannulation was started. If biliary cannulation was achieved, a prophylactic PS was inserted into the MPD (Fig. 2). If biliary cannulation was still difficult, PS was inserted into the MPD and precut of Vater papilla was performed.

The main investigation of the pancreatic duct was performed. After pancreatography, pancreatic juice sampling for cytology or pancreatic brush cytology was performed as necessary. For the high-risk patients described above, PSs were finally inserted.

Pancreatic stents without flanges on the pancreatic ductal side were not removed after ERCP. On the other hand, PSs with flanges on the pancreatic ductal side were usually removed two or three days after ERCP. If a patient was diagnosed with PEP or hyperamylasemia, the PS was removed one day after ERCP.

The duodenoscopes used were: JF240, TJF240, and JF260V ERCP (Olympus, Tokyo, Japan). The ERCP catheters used in this study were a Tandem XL (Boston Scientific Japan, Tokyo, Japan), MTW ERCP catheter taper (MTW Endoskopie, Wesel, Germany), or PR-233Q (Olympus). The EST knife used in this study was a CleverCut 3V (Boston Scientific Japan). Another EST knife used to precut Vater's papilla was an RX Needle Knife (Boston Scientific Japan, Tokyo, Japan). The PSs used in this study was a Geenen 5-Fr, 3-cm stent that has two flanges at the duodenal end and without any flanges at the pancreatic ductal end (Cook Japan), or a Geenen 5-Fr, 5, 7, or 9-cm stent that has two flanges at the duodenal end and two flanges at the pancreatic ductal end, a Zimmon 5-Fr, 2-cm unflanged single pigtail stent at the duodenal end (Cook Japan, Tokyo, Japan), a Zimmon 5-Fr, 4-cm unflanged single pigtail stent at the duodenal end (Cook Japan).

Outcomes of this study

The primary outcome of this study was the PEP rate. Post ERCP pancreatitis and the severity of PEP were diagnosed according to Cotton et al.'s [46] criteria. The definition of PEP was elevated serum amylase more than three times the normal upper limit with abdominal pain at more than 24 hours after ERCP. Furthermore, all PEP cases were confirmed to have peripancreatic inflammation by contrast-enhanced CT. The severity of PEP was determined as follows (mild: extended hospitalization for 2-3 days, moderate: extended hospitalization for 4-10 days, severe: extended hospitalization more than 10 days, or hemorrhagic pancreatitis, or pseudocyst that needs, or necessity of intervention).

In addition, patient characteristics (age, gender, peripapillary diverticulum, pancreatic calcification), ERCP procedures influencing PEP (EST, EPBD, brush cytology, precut Vater's papilla, procedure time, spontaneous PS dislodgment within a week after ERCP), and serum pancreatic isozyme of serum amylase (pAMY) after ERCP were compared between the head cases and body/tail cases. Pancreatic stent migration within a week was confirmed by X-ray or computed tomography. The selected values of serum amylase and pAMY were the highest within one week after ERCP. Serum amylase and pAMY were measured three hours after and 24 hours after ERCP. If hyperamylasemia was observed, serum amylase and pAMY were measured every day until serum amylase decreased to a normal level or was no more than two times the normal upper limit.

Propensity score matching

This study was not a prospective randomized controlled trial; therefore, several selection biases or confounding factors existed. To negate biases and confounding factors, propensity score matching was performed. Matching items were selected from the factors before ERCP procedures that could affect the risk of PEP. In past reports, young age, female gender, acute pancreatitis, and absence of chronic pancreatitis were risk factors for PEP [9, 17, 47-49]. Therefore, age, gender, and pancreatic calcification were selected as matching items in this study. Pancreatic calcification was used as a factor in chronic pancreatitis [50]. The calculation of propensity scores was performed by logistic regression analysis. Caliper was determined as 0.2 times a standard deviation of all patients' propensity scores.

Statistical analyses

Student's t test or Welch's t test were used for the comparison of continuous variables. Fisher's exact test was used for the comparison of nominal variables. A p value <0.05 was considered to indicate a significant difference.

All of the statistical analyses were performed using the EZR platform (Saitama Medical Center, Jichi Medical University, Saitama, Japan) [51].

RESULTS

Selected patients and diseases

After propensity score matching, 54 patients were selected for both head cases and body/tail cases (Fig. 1). The 54 patients among body/tail cases after propensity score matching analysis

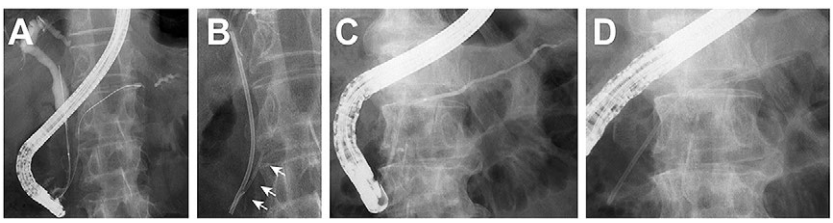

Fig. 2. Two patients underwent insertion of prophylactic PS for PEP. (A) A patient in the head group who was cannulated in the biliary duct by the double guidewire method and (B) underwent insertion of a PS (5-Fr 3 cm) in the pancreatic head (arrow: PS). (C) A patient in the body/tail group who underwent pancreatography, and (D) a PS (5-Fr 9 cm) was inserted into the pancreatic body or tail.

were defined as the body/tail group. For two patients among the head cases after propensity score matching analysis, PS were missing from the MPD during the ERCP procedure. Therefore, 52 patients were defined as the head group.

Diseases of all patients are shown in Table I.

Table I. Diseases in each group

	Head cases (n = 174)	Body/tail cases (n = 57)
Diagnosis, n		
Biliary tract extension	2	
Biliary stricture		
Benign	6	
Malignant		
Pancreatic cancer	19	16
Biliary tract cancer	44	10
Hepatocellular carcinoma	3	
Obstructive jaundice by metastatic cancer		
Barrett's esophageal cancer		1
Colon cancer	4	
Gastric cancer	2	
Uterine cancer	1	
Bladder cancer	1	
Ovarian cancer	1	
Breast cancer	1	
Lung cancer		1
Malignant lymphoma		1
Suppression of lymph node swelling	1	
Common bile duct stone	49	8
Primary sclerosing cholangitis	1	1
Biliary tract varix	1	
Gallbladder adenomyosis	3	
Intraductal papillary neoplasm of bile duct	1	
Sphincter of Oddi dysfunction	1	
Biliary cysts	1	
Lemmel syndrome	1	
Chronic pancreatitis	12	11
Intraductal papillary mucinous neoplasm	9	5
Autoimmune pancreatitis	5	2
Mucinous cystic neoplasm	2	
Pancreatic neuroendocrine tumor	2	1
Serous cyst adenoma	1	

Patient characteristics and outcome before propensity score matching

The results of the comparison of patient characteristics and the factors related to ERCP between head cases and body/tail cases are shown in Table II. Brush cytology of the MPD was performed more frequently in the body/tail cases than in the head cases (12.3% vs 2.3%, p <0.01). Pancreatic stent spontaneous dislodgment within a week after ERCP occurred more frequently in the head cases than in the body/tail cases (21.3% vs 0%, p<0.01). The pAMY after ERCP was significantly higher in the head cases than in the body/tail cases (311.0±381.6 U/L vs 166.3±200.4 U/L, p<0.01). Post-ERCP pancreatitis occurred more frequently in the head cases than in the body/tail cases (9.2% vs 0%, p=0.014).

Table II. The comparison of patient characteristics, ERCP procedures and outcomes before propensity score matching

	Head cases (N = 174)	Body/tail cases (N = 57)	p value
Patient characteristics			
Age (years, mean ± SD)	68.0 ± 13.3	66.1 ± 12.1	0.34
Sex (male/female)	92/ 82	35/ 22	0.286
Pancreatic calcification (%)	11 (6.3)	7 (12.3)	0.16
Peripapillary diverticulum (%)	47 (27.0)	16 (28.1)	0.87
ERCP procedures and outcomes			
EST (%)	112 (64.4)	35 (61.4)	0.75
Precut of Vater papilla (%)	40 (23.0)	8 (14.0)	0.19
EPBD (%)	7 (4.0)	2 (3.5)	1.0
Brush cytology of MPD (%)	4 (2.3)	7 (12.3)	< 0.01
Procedural time of ERCP (min, mean ± SD)	61.4 ± 22.3	56.6 ± 27.6	0.24
PS spontaneous dislodgment within a week after ERCP (%)	37 (21.3)	0 (0)	< 0.01
P AMY after ERCP (U/L, mean ± SD)	311.0 ± 381.6	166.3 ± 200.4	< 0.01
PEP (%)	16 (9.2)	0 (0)	0.014
Mild	4		
Moderate	10		
Severe	2		

ERCP: pndoscopic retrograde cholangiopancreatography; EST: endoscopic sphincterotomy; EPBD: endoscopic papillary balloon dilation; MPD: main pancreatic duct; PS: pancreatic stent; pAMY: pancreatic isozyme of serum amylase; PEP: post-ERCP pancreatitis

Patient characteristics and outcome after propensity score matching

The results of the comparison of patient characteristics and the factors related to ERCP between the head group and body/tail group after propensity score matching are shown in Table III. Pancreatic stent spontaneous dislodgment within a week after ERCP occurred more frequently in the head group than in the body/tail group (13.5% vs 0%, p<0.01). The pAMY after ERCP was significantly higher in the head group than in the body/tail group (347.5±442.3 U/L vs 157.5±196.8 U/L, p<0.01). Post-ERCP pancreatitis occurred more frequently in the head group than in the body/tail group (9.6% vs 0%, p=0.026). Post ERCP pancreatitis occurrence was not significantly different between the patients whose PSs spontaneously dislodged and the patients whose PSs did not (Table IV).

DISCUSSION

In this study, the appropriate region into which a PS should be inserted was investigated. In the results, PEP occurred more frequently in the head group than in the body/tail group. The

Table III. The comparison of patient characteristics, ERCP procedures and outcomes after propensity score matching

	Head group (N = 52)	Body/tail group (N = 54)	p value
Patient characteristics			
Age (years, mean ± SD)	67.2 ± 12.0	66.6 ± 12.1	0.82
Sex (male/female)	33/19	32/22	0.69
Pancreatic calcification (%)	4 (7.7)	4 (7.4)	1.0
Peripapillary diverticulum (%)	15 (28.8)	16 (29.6)	1.0
ERCP procedures and outcomes			
EST (%)	33 (63.5)	34 (63.0)	1.0
Precut of Vater papilla (%)	8 (15.4)	7 (13.0)	0.79
EPBD (%)	4 (7.7)	2 (3.7)	0.43
Brush cytology of MPD (%)	2 (3.8)	6 (11.1)	0.27
Procedural time of ERCP (min, mean ± SD)	62.7 ± 22.1	57.5 ± 28.0	0.30
PS spontaneous dislodgment within a week after ERCP (%)	7 (13.5)	0 (0)	< 0.01
P AMY after ERCP (U/L, mean ± SD)	347.5 ± 442.3	157.5 ± 196.8	< 0.01
PEP (%)	5 (9.6)	0 (0)	0.026
Mild	2		
Moderate	2		
Severe	1		

ERCP: Endoscopic retrograde cholangiopancreatography; EST: Endoscopic sphincterotomy; EPBD: Endoscopic papillary balloon dilation; MPD: Main pancreatic duct; PS: Pancreatic stent; P AMY: Pancreatic isozyme of serum amylase; PEP: Post-ERCP pancreatitis

Table IV. The relationship between PS spontaneous dislodgment and PEP after propensity score matching

	PS spontaneous dislodgment within a week after ERCP		p value
	Yes (N = 7)	No (N = 99)	
PEP (%)	0 (0)	5 (5.1)	1

PS: Pancreatic stent; ERCP: Endoscopic retrograde cholangiopancreatography; PEP: Post-ERCP pancreatitis

pAMY after ERCP was significantly higher in the head group than in the body/tail group.

As mentioned in the background section, the efficacy of PS for preventing PEP has already been proven in previous RCTs and meta-analyses [21-38]. Currently, which PS should be used is becoming the main issue, and the debate among studies comparing stent diameters was lively. In 2004, Rashdan et al. [41] reported that the 3-4 Fr PS was more effective in preventing PEP than the 5-6 Fr PS (PEP rate: 8.7% vs 11.0%, p=0.0471). However, Zolotarevsky et al. [43] and Pahk et al. [40] showed that the difference in PS diameter did not influence PEP occurrence. Olsson et al. [52] reported that the PS > 5-Fr, > 5 cm stent was more effective in preventing PEP than the PS ≤ 5-Fr, ≤ 5 cm (PEP rate: 1.4% vs 9.4%, p=0.0252). From these past reports, it has been unclear whether PS diameter influences PEP occurrence. Regarding the PS length, Chahal et al. [53] compared 5-Fr 3 cm PS and 3-fr 8 cm PS for preventing PEP. In this report, PEP occurrence did not differ. In the report written by Fujisawa et al. [44], the 5-Fr 3 cm PS was more effective for preventing PEP than the 5-Fr 5 cm PS (PEP rate: 2.0% vs 8.8% p = 0.035). As described above, Olsson et al. [52] insisted that > 5-Fr, > 5 cm PS was effective in preventing PEP. Regarding stent length, fixed results have not been obtained with the diameter of the stent. However, the size of the pancreas varies in each person. Therefore, the pancreatic region that the PS was inserted into should be taken into consideration. In fact, the PEP rate decreased in the body/tail group than in the head group in this study.

Regarding the mechanism of PEP, there are many unclear points. However, in past reports, the mechanism was explained [28, 54]. Stimulation by cannulation or contrast media infusion of the pancreatic duct causes edema of Vater papilla, sphincter of Oddi spasm, and blockage of the pancreatic juice stream. Therefore, elevated MPD pressure, vascular insufficiency of the pancreatic parenchyma, injury to the epithelium of the pancreatic duct, pancreatic acinar, and trypsin are activated. Finally, several chemical mediators destroy the defense mechanism of the pancreas. The drainage of MPD by PS maintains the flow of pancreatic juice and prevents PEP. In the PEP cases in this study, malposition of PS was observed by CT. In PEP cases, PS penetrated the branch of the pancreatic duct, or the tip of PS contacted the side of the MPD at the curve of the MPD between the pancreatic head and body. Pancreatic drainage was not adequately performed in these PEP cases. Therefore, PEP occurrence was believed to be observed more in the head cases than in the body/tail cases.

There were some limitations in this study. First, this study was retrospective and performed in a single institution. The PEP rate was decreased by prophylactic PS; therefore, a prospective study that compared two different stents and that aimed at PEP prevention would be difficult in a single institution. In the future, a multicenter prospective RCT on this topic is desirable. Second, ERCP procedures were not performed by a single endoscopist. However, if a trainee performs ERCP, the specialists of pancreaticobiliary endoscopy guide the trainee and sometimes perform the procedure on behalf of the trainee. Therefore, the ERCP procedures were kept at a certain quality. Third, PS without internal flange was used in only the head group. Hence, spontaneous dislodgment of the PS within a week after ERCP was significantly more common in the head group than in the body/tail group. However, past reports described that PS spontaneous dislodgment did not contribute to PEP occurrence [39] but prevented PEP [44]. Pancreatic stent without an internal flange was not thought to be a disadvantage in the head group. In fact, PEP occurrence was not significantly different between the patients with PS spontaneous dislodgment and the patients without PS spontaneous dislodgment (Table IV). Fourth, brush cytology of the MPD was performed more frequently in the body/tail cases than in the head cases. Although brush cytology of the MPD is a risk factor for PEP [20], PEP occurrence was significantly lower in the body/tail cases than in the head cases. Accordingly, PS insertion into the pancreatic body or tail might overcome this disadvantage.

CONCLUSION

Prophylactic PS should be inserted into the pancreatic body or tail to prevent PEP.

Conflicts of interest: None to declare.

Authors' contributions: M.S. wrote the paper, designed and performed the research. T.T. wrote the paper, designed and supervised the research. R.S., N.K., H.A., J.N., M.T., Y.S., H.I., M.H., and T.K. provided clinical advice. T.H. supervised the study. H.O. supervised the study and the writing of the paper. All authors have read and approved the final version of the manuscript.

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