

## Need for pancreatic stenting after sphincterotomy in patients with difficult cannulation

Kazunari Nakahara, Chiaki Okuse, Keigo Suetani, Yosuke Michikawa, Shinjiro Kobayashi, Takehito Otsubo, Fumio Itoh

Kazunari Nakahara, Chiaki Okuse, Keigo Suetani, Yosuke Michikawa, Fumio Itoh, Department of Gastroenterology and Hepatology, St. Marianna University School of Medicine, Kawasaki 216-8511, Japan

Shinjiro Kobayashi, Takehito Otsubo, Department of Gastroenterological and General Surgery, St. Marianna University School of Medicine, Kawasaki 216-8511, Japan

Author contributions: Nakahara K and Okuse C contributed equally to this work; Nakahara K and Okuse C designed the report; Nakahara K, Suetani K, Michikawa Y, and Kobayashi S were attending doctors for the patients; Otsubo T and Itoh F organized the report; and Nakahara K wrote the paper.

Correspondence to: Kazunari Nakahara, PhD, Department of Gastroenterology and Hepatology, St. Marianna University School of Medicine, 2-16-1, Sugao, Miyamae-ku, Kawasaki 216-8511, Japan. [nakahara@marianna-u.ac.jp](mailto:nakahara@marianna-u.ac.jp)

Telephone: +81-44-9778111 Fax: +81-44-9765805

Received: January 11, 2014 Revised: March 10, 2014

Accepted: April 21, 2014

Published online: July 14, 2014

### Abstract

**AIM:** To investigate the need for pancreatic stenting after endoscopic sphincterotomy (EST) in patients with difficult biliary cannulation.

**METHODS:** Between April 2008 and August 2013, 2136 patients underwent endoscopic retrograde cholangiopancreatography (ERCP)-related procedures. Among them, 55 patients with difficult biliary cannulation who underwent EST after bile duct cannulation using the pancreatic duct guidewire placement method (P-GW) were divided into two groups: a stent group ( $n = 24$ ; pancreatic stent placed) and a no-stent group ( $n = 31$ ; no pancreatic stenting). We retrospectively compared the two groups to examine the need for pancreatic stenting to prevent post-ERCP pancreatitis (PEP) in patients undergoing EST after biliary cannulation by P-GW.

**RESULTS:** No differences in patient characteristics or endoscopic procedures were observed between the two groups. The incidence of PEP was 4.2% (1/24) and 29.0% (9/31) in the Stent and no-stent groups, respectively, with the no-stent group having a significantly higher incidence ( $P = 0.031$ ). The PEP severity was mild for all the patients in the stent group. In contrast, 8 had mild PEP and 1 had moderate PEP in the no-stent group. The mean serum amylase levels (means  $\pm$  SD) 3 h after ERCP ( $183.1 \pm 136.7$  vs  $463.6 \pm 510.4$  IU/L,  $P = 0.006$ ) and on the day after ERCP ( $209.5 \pm 208.7$  vs  $684.4 \pm 759.3$  IU/L,  $P = 0.002$ ) were significantly higher in the no-stent group. A multivariate analysis identified the absence of pancreatic stenting ( $P = 0.045$ ; odds ratio, 9.7; 95%CI: 1.1-90) as a significant risk factor for PEP.

**CONCLUSION:** In patients with difficult cannulation in whom the bile duct is cannulated using P-GW, a pancreatic stent should be placed even if EST has been performed.

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**Key words:** Pancreatic stenting; Pancreatic guidewire placement; Post-endoscopic retrograde cholangiopancreatography pancreatitis; Endoscopic sphincterotomy; Endoscopic retrograde cholangiopancreatography

**Core tip:** We retrospectively examined the need for pancreatic stenting after endoscopic sphincterotomy (EST) in patients with difficult biliary cannulation in whom the bile duct was cannulated using the pancreatic duct guidewire placement method (P-GW). The incidences of post-endoscopic retrograde cholangiopancreatography pancreatitis (PEP) were 4.2% and 29.0% in the Stent and no-stent groups, respectively, with the no-stent group having a significantly higher incidence ( $P = 0.031$ ). A multivariate analysis identified the absence of pancreatic stenting as a significant risk factor

for PEP. Therefore, in patients with difficult cannulation in whom the bile duct is cannulated using P-GW, a pancreatic stent should be placed even if EST has been performed.

Nakahara K, Okuse C, Suetani K, Michikawa Y, Kobayashi S, Otsubo T, Itoh F. Need for pancreatic stenting after sphincterotomy in patients with difficult cannulation. *World J Gastroenterol* 2014; 20(26): 8617-8623 Available from: URL: <http://www.wjg-net.com/1007-9327/full/v20/i26/8617.htm> DOI: <http://dx.doi.org/10.3748/wjg.v20.i26.8617>

## INTRODUCTION

While various causes of post-endoscopic retrograde cholangiopancreatography pancreatitis (PEP) have been noted, the most common cause is obstruction to the outflow of pancreatic juice due to edema of the papilla of Vater<sup>[1,2]</sup>. In recent years, many randomized controlled trials have shown the usefulness of pancreatic stenting for preventing the development of PEP<sup>[1-5]</sup>.

Endoscopic sphincterotomy (EST) is also considered an effective procedure for preventing PEP because it enables the outflow of pancreatic juice<sup>[6-8]</sup>. Thus, it is still unclear whether there is an additional need for pancreatic stenting to prevent PEP in patients who undergo EST. Because the pancreatic duct orifice remains patent after EST, the placement of a pancreatic spontaneous dislodgement stent without flaps for the prevention of PEP often results in the premature dislodgement of the stent.

Thus, in this study, we examined the additional need for pancreatic stenting to prevent PEP in patients undergoing EST. Patients with difficult biliary cannulation who underwent EST after selective biliary cannulation by the pancreatic duct guidewire placement method (P-GW)<sup>[9-11]</sup> were divided into two groups according to whether pancreatic stenting had occurred, and we compared the treatment outcomes and incidence of complications between the two groups. A multivariate analysis was performed to identify risk factors for the development of PEP in patients undergoing EST after biliary cannulation by P-GW.

## MATERIALS AND METHODS

### Patients

Endoscopic retrograde cholangiopancreatography (ERCP)-related procedures were performed in 2136 cases at the Division of Gastroenterology and Hepatology of the St. Marianna University School of Medicine Hospital between April 2008 and August 2013. In our department, biliary cannulation is first attempted using the conventional contrast-assisted cannulation (CC) method. However, in cases where bile duct cannulation

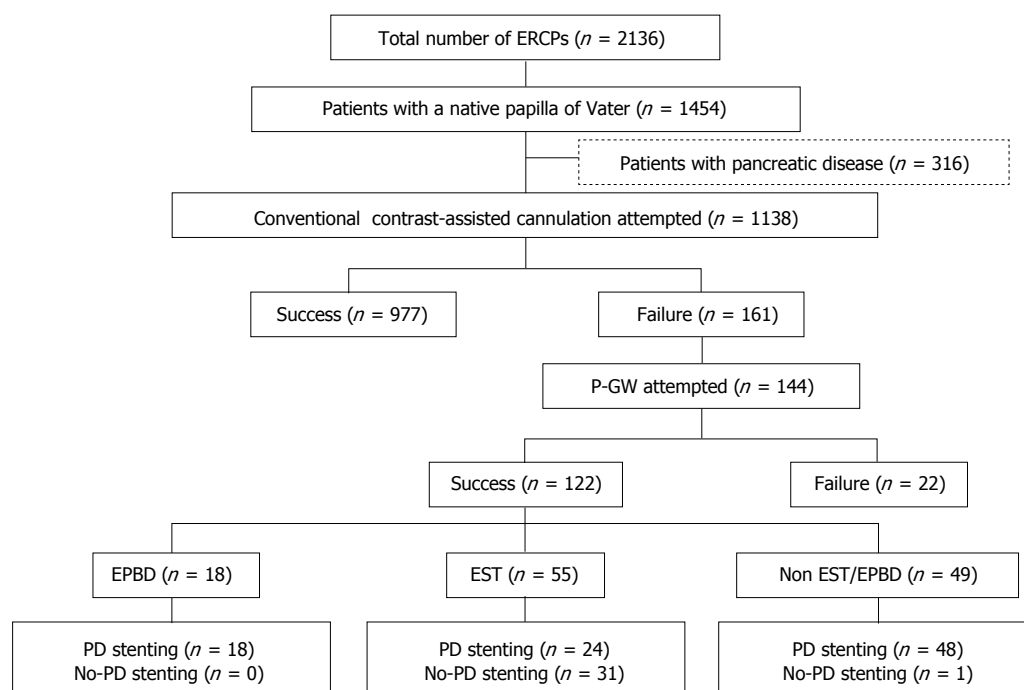
is difficult to perform using CC but in which a guidewire can be placed in the pancreatic duct, P-GW is employed as the procedure of first choice to achieve biliary cannulation. A second cannula was passed into the same working channel of the scope alongside the guidewire using the two-devices-in-one-channel method<sup>[12]</sup>, and biliary cannulation was attempted.

Of the 2136 patients who underwent ERCP-related procedures during the study period, 1454 had a native papilla. After 316 patients who did not undergo biliary cannulation or who had pancreatic diseases were excluded, 1138 patients remained. Biliary cannulation was achieved using CC in 977 of these patients. Then, among the 161 patients who experienced difficult biliary cannulation using CC, P-GW was attempted in 144, and successful biliary cannulation was achieved in 122 patients. Among these 122 patients with successful biliary cannulation using P-GW, EST was performed in 55, endoscopic papillary balloon dilation (EPBD) was performed in 18, and no papillary procedure was performed in 49 patients. EST was performed using an electrosurgical generator in the 120-Watt Endocut mode (ICC 200: ERBE Corp., Tuebingen, Germany). Following EST, a pancreatic duct stent was placed in 24 patients (stent group), whereas no pancreatic stenting was performed in the remaining 31 cases (no-stent group) (Figure 1). The pancreatic duct stents used were all 5-Fr, 3-cm-long spontaneous dislodgement stents with a single duodenal pigtail (Pit-stent, Gadelius Medical, Tokyo, Japan).

Decisions regarding whether pancreatic stenting was necessary were left to the discretion of the endoscopist performing each procedure. All the procedures were supervised by a single expert, who performs approximately 500-600 ERCPs per year. Because our hospital is an educational institution, trainees performed approximately half of the procedures. However, when deep cannulation of the bile duct was not achieved within 15 min, the expert took over the procedure. In all cases, 600 mg of gabexate mesilate was administered on the day of the procedure to prevent PEP. The patients' serum amylase levels (normal range: 37-124 IU/L) were measured prior to, 3 h after, and 1 d after the ERCP procedure.

### Measurements

The stent group ( $n = 24$ ), in which pancreatic stenting was performed after EST, and the no-stent group ( $n = 31$ ), in which no pancreatic duct stent was placed after EST, were retrospectively compared in terms of patient characteristics (age, sex, primary disease, history of pancreatitis, and peripapillary diverticulum), endoscopic procedures (diameter of the pancreatic duct guidewire, range of EST incision, biliary maneuver, and procedure time), incidence of PEP, complication rate, and serum amylase levels. Moreover, univariate and multivariate logistic regression analyses were performed to identify the risk factors for PEP in patients undergoing EST after biliary cannulation by P-GW.



**Figure 1** Flow chart showing the clinical courses of the patients. EST: Endoscopic sphincterotomy; P-GW: Pancreatic duct guidewire placement; ERCP: Endoscopic retrograde cholangiopancreatography; PD: Pancreatic duct; EPBD: Endoscopic papillary balloon dilation.

**Table 1** Comparison of patient characteristics and diagnoses between the stent and no-stent groups

	Stent group (n = 24)	No-stent group (n = 31)	P-value
Age (mean ± SD)	70.8 ± 12.8	72.4 ± 10.0	0.631
Sex (male/female)	11/13	16/15	0.788
History of pancreatitis	0	0	
Periampullary diverticulum	10	13	1.000
Choledocholithiasis	15	21	0.778
Cholangiocarcinoma	4	7	0.739
Acute cholecystitis	3	3	1.000
Lymph node metastasis	2	0	0.186
Gallbladder carcinoma	1	1	1.000
Sphincter of Oddi dysfunction	1	1	1.000
Liver metastasis	0	1	1.000

The ranges of the EST incisions were defined as follows: an incision up to the hooding fold was considered a small incision, an incision up to the upper border of the oral protrusion was a large incision, and an incision with a range between those of small and large incisions was an intermediate incision. The diagnosis of pancreatitis and the determination of its severity were based on consensus guidelines proposed by Cotton *et al.*<sup>[13]</sup>. Moreover, complications, such as bleeding, perforation, and cholangitis, were also diagnosed according to the consensus guidelines proposed by Cotton *et al.*<sup>[13]</sup>.

### Statistical analysis

The statistical analysis was performed using Fisher's exact test or Welch's *t*-test, as appropriate. To identify risk factors for post-ERCP pancreatitis, variables found

to be possibly significant ( $P < 0.2$ ) by univariate analysis were entered into a multiple logistic regression model. *P* values  $< 0.05$  were regarded as denoting significance. The statistical analysis was performed using the Prism 5 program (GraphPad Software, Inc., CA, United States) and SPSS (version 19; SPSS, Chicago, IL, United States).

## RESULTS

### Patient characteristics and endoscopic procedures

No significant differences in age, sex, distribution of primary diseases, history of pancreatitis, or presence/absence of peripapillary diverticulum were observed between the Stent and no-stent groups (Table 1). Moreover, the analysis of endoscopic procedure-related variables revealed no significant differences in the diameter of the pancreatic duct guidewire, range of EST incision, biliary maneuver, or procedure time between the Stent and no-stent groups (Table 2).

### Incidence of PEP

The incidence of PEP was 4.2% (1/24) in the stent group and 29.0% (9/31) in the no-stent group, with the no-stent group having a significantly higher incidence ( $P = 0.031$ ) (Table 3). The PEP severity was mild for all the patients in the stent group. In contrast, among the 9 PEP patients in the no-stent group, 8 had mild PEP and 1 had moderate PEP. Intermediate EST incisions were performed in all the patients in the stent group with PEP, whereas among the 9 patients in the no-stent group with PEP, 3 received small incisions, 5 received intermediate incisions, and 1 received a large incision. Conserva-

**Table 2** Comparison of endoscopic procedures between the stent and no-stent groups

	Stent group ( <i>n</i> = 24)	No-stent group ( <i>n</i> = 31)	<i>P</i> -value
Pancreatic guidewire diameter (0.025 inch or 0.035 inch)	12/12	16/15	1.000
Incision range of EST			
Small	3	4	1.000
Medium	21	26	1.000
Large	0	1	1.000
Endoscopic biliary stenting	14	11	0.109
Bile duct stone removal	10	19	0.180
Intraductal ultrasonography	7	10	1.000
Endoscopic nasobiliary drainage	3	6	0.716
Biopsy of the bile duct	2	7	0.271
Cytology of the bile juice	3	6	0.716
Endoscopic naso-gallbladder drainage	3	2	0.643
Peroral cholangioscopy	0	3	0.249
Procedure time (min, mean $\pm$ SD)	59.3 $\pm$ 19.0	66.4 $\pm$ 21.6	0.207

EST: Endoscopic sphincterotomy.

**Table 3** Comparison of complications between the stent and no-stent groups *n* (%)

	Stent group ( <i>n</i> = 24)	No-stent group ( <i>n</i> = 31)	<i>P</i> -value
Overall complications	3 (12.5)	11 (35.5)	0.067
Pancreatitis	1 (4.2)	9 (29.0)	0.031
Bleeding	2 (8.3)	2 (6.5)	1.000
Perforation	0 (0)	0 (0)	
Cholangitis	0 (0)	0 (0)	

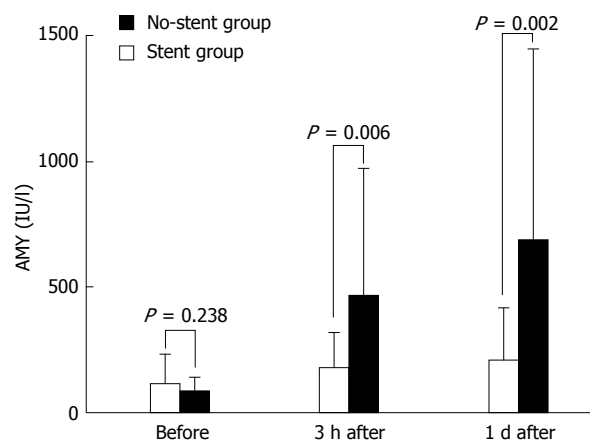
tive therapy without additional endoscopic procedures resulted in improvement in all the patients.

### Overall incidence of complications

With regard to complications other than PEP, bleeding was observed in 2 patients each in the stent group (2/24; 8.3%) and the no-stent group (2/31; 6.5%), with no significant difference in incidence between the two groups ( $P = 1.000$ ). No other complications, such as perforation or cholangitis, were observed in either group. The overall complication rate, including PEP, was 12.5% (3/24) in the stent group and 35.5% (11/31) in the no-stent group. Although the difference was not significant, the rate tended to be higher in the no-stent group ( $P = 0.067$ ) (Table 3).

### Serum amylase levels

The serum amylase levels (means  $\pm$  SD) in the stent group were 118  $\pm$  116.9 IU/L before ERCP, 183.1  $\pm$  136.7 IU/L 3 h after ERCP, and 209.5  $\pm$  208.7 IU/L one day after ERCP; the corresponding values in the no-stent group were 85.5  $\pm$  56.0, 463.6  $\pm$  510.4 and 684.4  $\pm$  759.3 IU/L, respectively. Although no significant dif-

**Figure 2** Comparison of serum amylase levels between the Stent and no-stent groups.

ference in the serum amylase levels before ERCP was observed between the Stent and no-stent groups ( $P = 0.238$ ), the levels 3 h after and one day after ERCP were significantly higher in the no-stent group ( $P = 0.006$  and  $P = 0.002$ , respectively) (Figure 2).

### Risk factors for PEP

The univariate analysis identified the absence of pancreatic duct stenting ( $P = 0.031$ ; OR, 9.4; 95%CI: 1.1-81) and the incidence of endoscopic nasobiliary drainage ( $P = 0.047$ ; OR, 5.3; 95%CI: 1.1-26) as significant risk factors for PEP (Table 4). The multivariate analysis identified the absence of pancreatic stenting ( $P = 0.045$ ; OR, 9.7; 95%CI: 1.1-90) as the only significant risk factor (Table 5).

## DISCUSSION

The precut<sup>[14]</sup> and P-GW techniques<sup>[9-11,15,16]</sup> have been employed for patients with difficult biliary cannulation. The precut technique is difficult to perform and is reported to be associated with a high incidence of complications, such as bleeding, perforation, and pancreatitis<sup>[17]</sup>. Therefore, we perform P-GW as a first choice for patients in whom a guidewire can be placed in the pancreatic duct. Previous studies of the efficacy of P-GW have reported varied results, with the success rate of biliary cannulation ranging from 43.8% to 92.6%<sup>[9-11,15,16]</sup>. However, the studies reporting low success rates (in the 40% range) for biliary cannulation also included patients for whom the placement of a guidewire in the pancreatic duct was unsuccessful; such patients are not considered suitable candidates for P-GW<sup>[15,16]</sup>. When such cases are excluded, the success rate of biliary cannulation using P-GW is high, ranging from 72.6% to 92.6%<sup>[10,11]</sup>.

Another advantage of P-GW, if the procedure can be completed with the guidewire placed in the pancreatic duct, is the ease of placing a pancreatic stent at the end of the procedure. Difficult biliary cannulation is considered a procedure-related risk factor for PEP<sup>[18]</sup>. It is criti-



**Table 4 Risk factors for post-endoscopic retrograde cholangiopancreatography pancreatitis in patients undergoing endoscopic sphincterotomy after biliary cannulation by pancreatic duct guidewire placement**

Univariate analysis	Pancreatitis (+) (n = 10)	Pancreatitis (-) (n = 45)	P-value	OR (95%CI)
Age (< 60 yr)	2	9	1.000	1.0 (0.18-5.5)
Female gender	5	23	1.000	0.96 (0.24-3.8)
Periampullary diverticulum	3	20	0.494	0.54 (0.12-2.3)
Pancreatic guidewire (0.035 inch)	4	23	0.729	0.64 (0.16-2.6)
EST incision range (small)	3	4	0.104	4.4 (0.80-24)
No pancreatic duct stenting	9	22	0.031	9.4 (1.1-81)
Endoscopic biliary stenting	3	22	0.318	0.45 (0.10-2.0)
Bile duct stone removal	5	24	1.000	0.88 (0.22-3.5)
Intraductal ultrasonography	4	13	0.479	1.6 (0.40-6.8)
Endoscopic nasobiliary drainage	4	5	0.047	5.3 (1.1-26)
Biopsy of the bile duct	3	6	0.340	2.8 (0.56-14)
Cytology of the bile juice	3	6	0.340	2.8 (0.56-14)
Endoscopic naso-gallbladder drainage	1	4	0.220	3.5 (0.50-24)
Peroral cholangioscopy	1	2	0.459	2.4 (0.20-29)
Procedure time (> 60 min)	5	19	0.733	1.4 (0.35-5.4)

EST: Endoscopic sphincterotomy.

**Table 5 Risk factors for post-endoscopic retrograde cholangiopancreatography pancreatitis in patients undergoing endoscopic sphincterotomy after biliary cannulation by pancreatic duct guidewire placement**

Multivariate analysis	P-value	OR (95%CI)
Incision range of EST ( $\leq$ small)	0.150	4.7 (0.57-40)
No pancreatic duct stenting	0.045	9.7 (1.1-90)
Endoscopic nasobiliary drainage	0.101	4.6 (0.74-29)

EST: Endoscopic sphincterotomy.

cal to conduct additional research into the prevention of PEP in patients with difficult biliary cannulation who require P-GW.

In recent years, a number of randomized controlled trials have demonstrated the usefulness of pancreatic stenting for the prevention of PEP<sup>[1-5]</sup>. Ito *et al*<sup>[4]</sup> reported the usefulness of pancreatic stenting for preventing PEP in patients with difficult biliary cannulation for whom bile duct cannulation was achieved using P-GW. According to their results, the success rate of pancreatic stenting after biliary cannulation with P-GW was 92.9% (26/28 patients), and the 22.9% incidence of PEP in the group without pancreatic stent placement was significantly higher than the 2.9% incidence in the group that underwent pancreatic stent placement (relative risk, 0.13; 95%CI: 0.016-0.95). Thus, in addition to improving the success rate of biliary cannulation in patients with difficult biliary cannulation, the use of P-GW results in a higher success rate of pancreatic stenting and facilitates the prevention of PEP.

EST is also considered effective for the prevention of PEP because EST reduces the obstruction of the pancreatic juice outflow<sup>[6-8]</sup>. However, it remained unclear whether additional pancreatic stenting might also be necessary for preventing PEP in patients undergoing EST. Because the pancreatic duct remains patent after EST,

the placement of a pancreatic spontaneous dislodgement stent without flaps to prevent PEP often results in the premature dislodgement of the stent. There have also been concerns that the stents may not be sufficiently effective.

However, in our study, the incidence of PEP in the no-stent group was 29.0%, which was significantly higher than the 4.2% incidence in the stent group. The serum amylase levels after ERCP were also significantly higher in the no-stent group compared with the stent group. The multivariate analysis identified the absence of pancreatic duct stenting as the only significant risk factor for PEP. Thus, these findings support that in patients with difficult biliary cannulation for whom P-GW is used to achieve bile duct cannulation, a pancreatic duct stent should be placed to prevent PEP even if EST has been performed.

The need for pancreatic stenting after EST is presumed to be due to the insufficient opening of the pancreatic duct orifice by EST and the potential obstruction of the free outflow of pancreatic juice by the thermo-coagulation degeneration of the pancreatic duct orifice. Furthermore, because pancreatography was performed in all of the patients in this study, the increased internal pressure of the pancreatic duct compared with the opening of the pancreatic duct orifice might have influenced the results. Additionally, this study included patients with difficult cannulation in whom edema of the papilla of Vater may have spread extensively.

Theoretically, creating a large EST incision by applying electric discharges for a brief period of time will open the pancreatic duct without causing electrosurgical current-induced edema, thereby preventing PEP. However, according to the results of this study, PEP occurred in only one patient in the no-stent group, who received a large incision. Moreover, neither the univariate nor the multivariate analysis identified a small EST incision as a risk factor for PEP. Thus, the association between the

range of the incision and the incidence of PEP remains unclear. However, because PEP occurred in 3 of the 4 patients in the no-stent group who received a small EST incision, a small incision cannot be excluded as a risk factor for PEP. Further studies with larger sample sizes would be needed to clarify this issue.

In conclusion, in patients with difficult biliary cannulation who undergo successful biliary cannulation using P-GW, it appears that a pancreatic duct stent should be placed to prevent PEP even if EST is performed. However, because of the limitations of our study, including the small sample size and the retrospective design, further prospective studies using larger sample sizes will be needed to confirm our findings.

## COMMENTS

### Background

The pancreatic duct guidewire placement method is reported to be effective in patients with difficult biliary cannulation. However, difficult biliary cannulation is associated with a high incidence of post-endoscopic retrograde cholangiopancreatography pancreatitis (PEP).

### Research frontiers

The efficacy of pancreatic stenting to prevent PEP in patients with difficult cannulation has been reported. However, endoscopic sphincterotomy (EST) is also considered effective for preventing PEP because it facilitates the outflow of pancreatic juice.

### Innovations and breakthroughs

The authors examined the incidence of PEP in patients with difficult cannulation for whom the bile duct was cannulated using P-GW with or without pancreatic stenting. The incidence of PEP was 4.2% and 29.0% in the stent and no-stent groups, respectively, with the incidence in the no-stent group being significantly higher. A multivariate analysis identified the absence of pancreatic stenting as a significant risk factor for PEP.

### Applications

In patients with difficult cannulation for whom the bile duct is cannulated using P-GW, a pancreatic stent should be placed even if EST has been performed.

### Peer review

The authors report the incidence of post-endoscopic retrograde cholangiopancreatography (ERCP)-pancreatitis in patients with difficult ERCP undergoing the pancreatic duct guidewire placement method of biliary cannulation with or without a PD stent. This is an interesting study.

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