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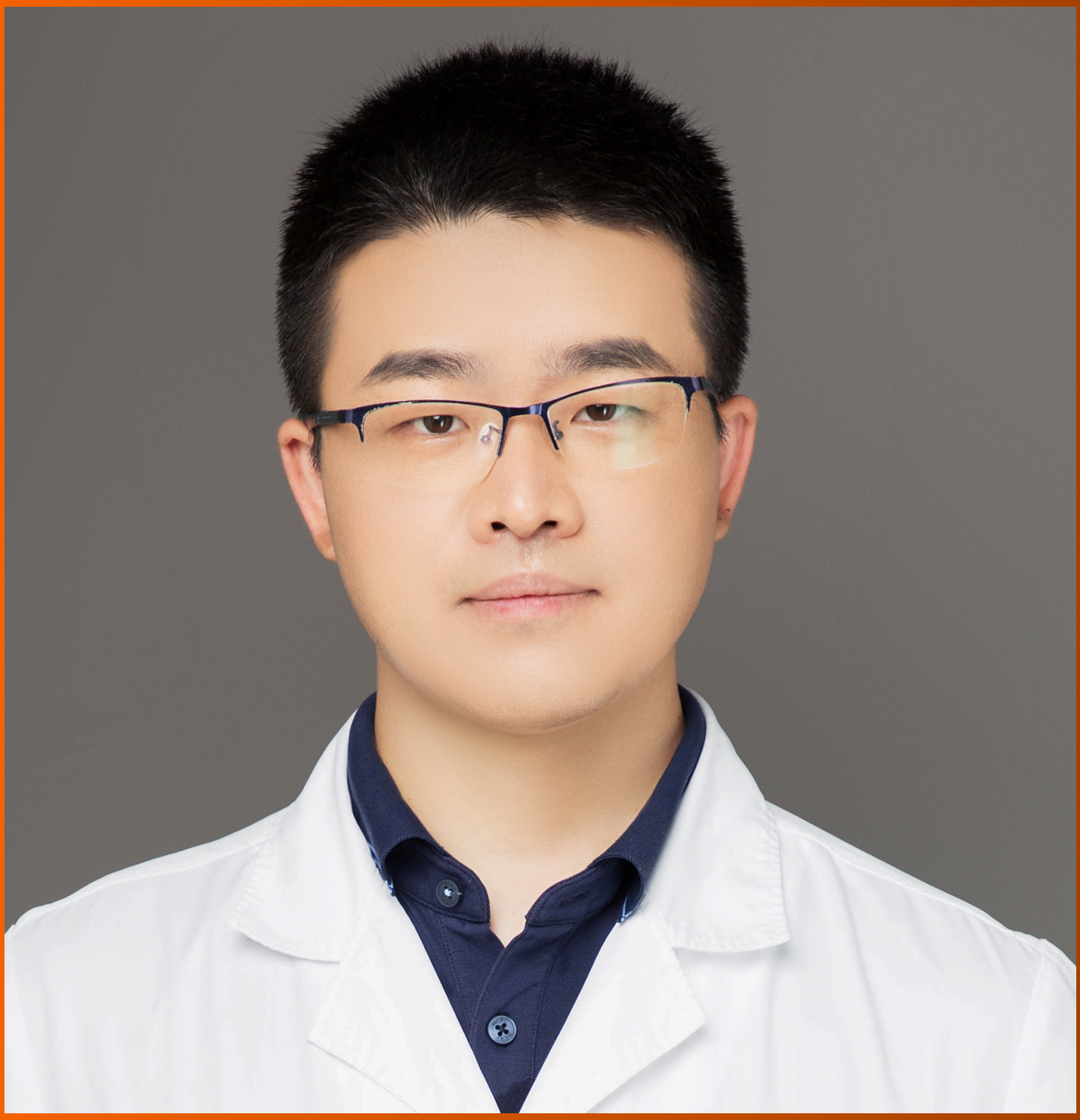

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ABOUT COVER

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AIMS AND SCOPE

The primary aim of *World Journal of Gastrointestinal Endoscopy* (*WJGE*, *World J Gastrointest Endosc*) is to provide scholars and readers from various fields of gastrointestinal endoscopy with a platform to publish high-quality basic and clinical research articles and communicate their research findings online.

WJGE mainly publishes articles reporting research results and findings obtained in the field of gastrointestinal endoscopy and covering a wide range of topics including capsule endoscopy, colonoscopy, double-balloon enteroscopy, duodenoscopy, endoscopic retrograde cholangiopancreatography, endosonography, esophagoscopy, gastrointestinal endoscopy, gastroscopy, laparoscopy, natural orifice endoscopic surgery, proctoscopy, and sigmoidoscopy.

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ORIGINAL ARTICLE

Retrospective Study

Can early precut reduce post-endoscopic retrograde cholangiopancreatography pancreatitis in patients with difficult bile duct cannulation?

Tomohiro Tanikawa, Keisuke Miyake, Mayuko Kawada, Katsunori Ishii, Takashi Fushimi, Noriyo Urata, Nozomu Wada, Ken Nishino, Mitsuhiko Suehiro, Miwa Kawanaka, Hidenori Shiraha, Ken Haruma, Hirofumi Kawamoto

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Abstract

BACKGROUND

Endoscopic retrograde cholangiopancreatography (ERCP) is associated with a variety of adverse events (AEs). One of the most important AEs is post-ERCP pancreatitis (PEP), which is most common in cases of difficult biliary cannulation. Although the precut technique has been reported as a PEP risk factor, recent studies indicate that early precut could reduce PEP, and that precut itself is not a risk factor.

AIM

To evaluate the safety of the precut technique, especially in terms of PEP.

METHODS

We conducted a retrospective study, spanning the period from November 2011 through December 2021. It included 1556 patients, aged ≥ 20 years, who underwent their initial ERCP attempt for biliary disease with a naïve papilla at the Kawasaki University General Medical Center. We compared the PEP risk between the early precut and the delayed precut group.

RESULTS

The PEP incidence rate did not significantly differ between the precut and non-precut groups. However, the PEP incidence was significantly lower in the early precut group than the delayed precut group (3.5% *vs* 10.5%; $P = 0.02$). The PEP incidence in the delayed precut group without pancreatic stent insertion (17.3%)

was significantly higher compared to other cases ($P < 0.01$).

CONCLUSION
Our findings indicate that early precut may reduce PEP incidence. If the precut decision is delayed, a pancreatic stent should be inserted to prevent PEP.

Key Words: Endoscopic retrograde cholangiopancreatography; Post-endoscopic retrograde cholangiopancreatography pancreatitis; Precut; Needle-knife precut papillotomy

Core Tip: Early needle-knife precut papillotomy (NKPP) may significantly reduce the incidence of post-endoscopic retrograde cholangiopancreatography pancreatitis (PEP) in patients with difficult bile duct cannulation. Our single-center retrospective study found that early NKPP (EP) within 10 min of standard cannulation attempts led to a lower PEP rate compared to delayed NKPP (DP). When EP is not feasible, inserting a pancreatic stent after DP effectively prevents PEP, demonstrating a similar protective effect as EP. These findings suggest adopting EP or pancreatic stenting for delayed procedures to improve patient outcomes.

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INTRODUCTION

Biliary cannulation is the first step in therapeutic endoscopic retrograde cholangiopancreatography (ERCP), and is thus crucial for a successful procedure. ERCP has a reported success rate of 67%-99.4%[1,2], and various techniques have been proposed to improve this rate, including wire-guided cannulation, the pancreatic guide-wire technique, and the two-devices-in-one-channel technique[3]. Moreover, the precut technique efficiently increases the biliary cannulation success rate, which is reported as 89.3%-91.5%[4-6]. There are no fixed criteria for selecting a method in cases with challenging biliary cannulation. Each method has advantages and disadvantages, and the endoscopist must choose an appropriate method for each case.

When selecting a procedure to maximize the probability of successful cannulation, the incidence of adverse events (AEs) is an important factor. Post-ERCP pancreatitis (PEP) is one of the most important AEs that is likely to occur in cases with difficult biliary cannulation. Some reports have indicated that the precut technique itself increases the risk of PEP[7,8]. However, recent studies have shown that early precut can reduce PEP, and that precut itself is not a risk factor[9,10]. Cennamo *et al*[5] reported that the timing of the precut procedure did not influence the risk of complications. These contradictory findings leave unanswered questions regarding the safety of the precut technique.

In this study, we evaluated the safety of the precut technique, especially in terms of PEP.

MATERIALS AND METHODS

We performed a retrospective observational analysis. In this study, we adhered to the principles of the 1975 Helsinki Declaration, and received approval from the Institutional Research Ethics Committee (Admission No. 5984-00).

Patients

The patient selection process is illustrated in Figure 1. This retrospective study spanned the period from November 2011 through December 2021 at the Kawasaki University General Medical Center. We enrolled 1556 patients with normal gastrointestinal anatomy and naïve papilla, aged ≥ 20 years, who underwent their first ERCP procedure for biliary disease. Exclusion criteria were indication for a pancreatic procedure, pregnancy, and refusal to give informed consent.

In previous studies, early precut has been defined as initiating precut within 5-12 min of standard attempts, or after fewer than 2-4 unintended cannulation episodes into the pancreatic duct[9-11]. However, no specific definition has been established. In the present study, precut was arbitrarily defined as starting within 10 min of standard cannulation, a factor previously associated with PEP risk.

We prioritized needle-knife precut papillotomy (NKPP) over other precut techniques, because NKPP is suitable for a wide range of cases. Patients were categorized into two groups: early NKPP (EP) group (patients who received precut within 10 min) and delayed NKPP (DP) group (patients who received precut after 10 min). We compared outcomes

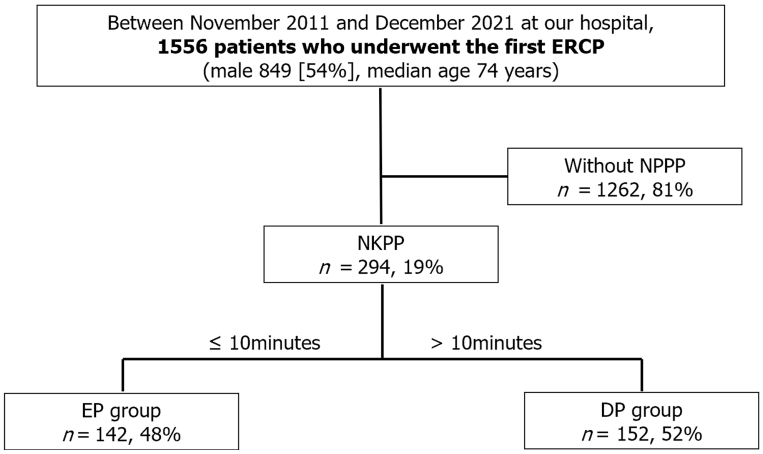

Figure 1 Flow diagram of patient selection. DP: Delayed needle-knife precut papillotomy; EP: Early needle-knife precut papillotomy; ERCP: Endoscopic retrograde cholangiopancreatography; NKPP: Needle-knife precut papillotomy.

between these groups.

Procedure

Procedures were performed using a side-viewing endoscope (JF-260V or TJF-260v; Olympus Co. Ltd., Tokyo, Japan). Conventional contrast cannulation was the standard approach. In difficult cases, trainees opted for wire-guided cannulation or the pancreatic guidewire method. If selective biliary deep cannulation was not achieved within 15 min, the trainers took over, continuing with conventional contrast cannulation. For difficult cases, precut was chosen as the primary option, with no specific time limit. Precut methods typically included NKPP, needle-knife fistulotomy, transpancreatic sphincterotomy, or needle-knife sphincterotomy along with a pancreatic stent. NKPP was most commonly employed and was performed with a KD-10Q-1 instrument (Olympus), due to its adaptability and precision in incising the sphincter.

In cases of difficult cannulation or residual contrast media in the pancreatic duct after the procedure, a temporary pancreatic stent was inserted to mitigate PEP. At the end of the procedure, a guidewire was reintroduced into the pancreatic duct, and a 4Fr or 5Fr temporary plastic pancreatic stent was placed.

Statistical analyses

The primary outcome was the PEP incidence rate, diagnosed according to the Japanese acute pancreatitis guidelines. Secondary outcomes were the biliary cannulation success rate, cannulation time, and effectiveness of pancreatic stents for preventing PEP.

Statistical analyses were conducted using IBM SPSS Statistics version 26 (IBM, Armonk, NY, United States). Continuous variables were compared using the Mann-Whitney *U* test, and are presented as the median and interquartile range. Categorical variables were assessed using Fisher's exact test. For all analyses, a significance level of $P < 0.05$ was applied.

RESULTS

Precut vs non-precut

Table 1 presents the patients' characteristics. Precut procedures were performed in 294 patients (19%). Patients who underwent precut were significantly older than patients without precut (75.5 ± 13.0 years *vs* 73.6 ± 13.4 years; $P = 0.016$). The incidence of malignant disease was significantly higher among patients who received precut compared to those without precut. The PEP incidence rate did not significantly differ between the two groups (7.1% *vs* 5.4%; $P = 0.27$). However, there were significant differences in the cannulation success rate (96.3% *vs* 99.0%; $P < 0.01$), cannulation time (20.3 ± 12.6 min *vs* 5.1 ± 7.2 min; $P < 0.01$), and total procedure time (40.4 ± 16.0 min *vs* 29.7 ± 17.9 min; $P < 0.01$).

EP vs DP

The EP and DP groups did not significantly differ in terms of age, sex, diagnosis, or diverticula. Precut techniques were initiated at 5.7 ± 3.1 min into the procedure in the EP group, and 17.1 ± 5.6 min into the procedure in the DP group. The PEP incidence was significantly lower in the EP group, compared to the DP group (3.5% *vs* 10.5%; $P = 0.02$). The EP and DP group also significantly differed in the cannulation success rate (98.6% *vs* 94.1%; $P = 0.03$), cannulation time (13.2 ± 8.6 min *vs* 27.3 ± 12.0 min; $P < 0.01$), and total procedure time (35.0 ± 15.7 min *vs* 45.8 ± 14.4 min; $P < 0.01$) (Table 2).

Table 1 Baseline characteristics and comparison of post-endoscopic retrograde cholangiopancreatography pancreatitis incidence between needle-knife precut papillotomy cases and non-needle-knife precut papillotomy cases

Characteristic	NKPP, *n* = 294	Non-NKPP, *n* = 1262	*P* value
Age	75.5 ± 13.0	73.6 ± 13.4	0.016
Sex, male	159 (53.7)	690 (54.6)	0.80
Diagnosis			< 0.01
Benign	205 (69.3)	980 (77.6)	
Malignancy	91 (30.7)	283 (22.4)	
Diverticula	77 (26.0)	380 (30.1)	0.18
First endoscopist			0.050
Trainee, *n* = 903	156 (53.0)	747 (59.2)	
Success rate of cannulation	283 (96.3)	1250 (99.0)	< 0.01
Cannulation time in min	20.3 ± 12.6	5.1 ± 7.2	< 0.01
Total procedure time in min	40.4 ± 16.0	29.7 ± 17.9	< 0.01
PEP	21 (7.1)	68 (5.4)	0.27

Data are *n* (%). NKPP: Needle-knife precut papillotomy; PEP: Post-endoscopic retrograde cholangiopancreatography pancreatitis.

Table 2 Baseline characteristics and result of the incident rate of post-endoscopic retrograde cholangiopancreatography pancreatitis between early needle-knife precut papillotomy group and delayed needle-knife precut papillotomy group

Characteristic	EP group, *n* = 142	DP group, *n* = 152	*P* value
Age	74.8 ± 13.6	76.3 ± 12.4	0.39
Sex, male	81 (57)	77 (50.7)	0.29
Diagnosis			
Benign	101 (71.1)	103 (67.8)	0.61
Malignancy	41 (28.9)	49 (32.2)	
Diverticula	30 (21.1)	47 (37.6)	0.064
First endoscopist			< 0.01
Trainee, *n* = 154	43 (30.3)	111 (73.0)	
Trainer, *n* = 141	99 (69.7)	41 (27.0)	
NKPP start time in min	5.7 ± 3.1	17.1 ± 5.6	< 0.01
Success rate of cannulation	140 (98.6)	143 (94.1)	0.027
Cannulation time in min	13.2 ± 8.6	27.3 ± 12.0	< 0.01
Total procedure time in min	35.0 ± 15.7	45.8 ± 14.4	< 0.01
PEP	5 (3.5)	16 (10.5)	0.023

Data are *n* (%). DP: Delayed needle-knife precut papillotomy; EP: Early needle-knife precut papillotomy; PEP: Post-endoscopic retrograde cholangiopancreatography pancreatitis.

Pancreatic stent in precut cases

We inserted an endoscopic pancreatic stent (EPS) in 140 patients (47.6%) who received precut, including 63 patients (44.4%) in the EP group, and 77 patients (50.7%) in the DP group. The findings are presented in Table 3. Notably, patients in the DP group without an EPS had a significantly higher incidence of PEP (17.3%) compared with the incidence rates in other cases ($P < 0.01$). Conversely, among patients in the EP group, the PEP incidence did not differ according to EPS use. Notably, cases with delayed precut and EPS placement exhibited a PEP incidence comparable to cases involving early precut without an EPS.

Table 3 Analysis of efficacy of endoscopic pancreatic stenting for post-endoscopic retrograde cholangiopancreatography pancreatitis prevention

Complication	EP group, *n* = 142		DP group, *n* = 152		*P* value
	Without EPS, *n* = 79	With EPS, *n* = 63	Without EPS, *n* = 75	With EPS, *n* = 77	
PEP	3 (3.8)	2 (3.2)	13 (17.3)	3 (3.9)	< 0.01[a]

[a]*P* < 0.01 without EPS in the DP group *vs* with EPS in the DP group.

Data are *n* (%). DP: Delayed needle-knife precut papillotomy; EP: Early needle-knife precut papillotomy; EPS: Endoscopic pancreatic stenting; PEP: Post-endoscopic retrograde cholangiopancreatography pancreatitis.

DISCUSSION

The present study yielded three key findings. First, the precut technique itself was not a risk factor for PEP. Second, the PEP incidence was lower following early implementation of the precut technique, compared to delayed precut procedures. Third, EPS insertion after delayed precut had a PEP-preventive effect similar to that of early precut.

The precut technique has been considered a PEP risk factor[7,12,13], but it has been unclear whether this association is due to the precut itself or to the prolonged procedure and inadvertent pancreatic duct cannulation. Previous studies have suggested that the reduced PEP incidence with early precut indicated an influence of prolonged procedures[9-11]. Our present findings confirmed that the precut technique itself was not linked to higher PEP risk; however, a delay in precut performance significantly increased the PEP incidence. Bailey *et al*[14] reported that NKPP was not an independent predictor of PEP. Conversely, our findings demonstrated that early precut could prevent PEP. Hence, we infer that PEP may be induced by prolonged stimulation of the papilla and pancreatic duct leading up to the precut, rather than by the precut technique itself, which has been previously reported[14-16]. Notably, our study focused on the technique itself, and further research is needed to investigate the safety of DP independently of the prolonged stimulation. Future studies should endeavor to isolate these variables, to better understand their individual contributions to PEP risk.

There are situations where early implementation of the precut technique is not feasible. Notably, in ERCP training facilities, trainees often initiate the procedure as the operator. Among the cases in the present study, trainees initiated the procedure in 30.3% of cases in the EP group, and 73.0% in the DP group ($P < 0.01$). Many aspects of ERCP training require hands-on experience, and some cases pose difficulties such that precut cannot be performed within 10 min. In this study, such cases exhibited a higher risk of PEP. Moreover, it was evident that EPS could prevent PEP in DP cases. EPS insertion reduced the PEP incidence in cases where precut could not be performed within 10 min, bringing it to a level comparable to that in cases with early precut. In other words, EPS prevented PEP as well as early precut did. Zagalsky *et al*[17] also reported that early precut had a PEP-preventive effect comparable to that of a pancreatic stent. The ESGE guidelines recommend that a pancreatic duct stent should be placed when NKPP is performed, even when pancreatic cannulation is easily obtained[18]. However, we found that EPS placement had no significant PEP-preventative effect in cases where precut was performed within 10 min. We suggest that EPS placement might not be necessary in cases with early precut, but should be performed in cases with delayed precut.

This study had several limitations, including the retrospective study design, and the fact that it was conducted only in our hospital. Additionally, there was no standard definition of early precut, and many other PEP risk factors were included during the procedure. We could not strictly evaluate the risk of precut, because we did not compare precut cases *vs* difficult cannulation cases without precut. Finally, the study included a variety of endoscopists, whose technical skill differences may have affected the PEP incidence. To more thoroughly evaluate the early precut technique, we should plan a multicenter prospective study.

CONCLUSION

In conclusion, our findings indicate that early precut may reduce the incidence of PEP. When encountering cases in which it is difficult to achieve biliary cannulation, it may be preferable to choose the early precut technique rather than repeating conventional cannulation. If the precut decision is delayed, a pancreatic stent should be inserted to prevent PEP.

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FOOTNOTES

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