

Transpancreatic precut papillotomy versus double-guidewire technique in difficult biliary cannulation: prospective randomized study

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ABSTRACT

Background and study aims Difficult biliary cannulation and unintentional pancreatic duct cannulation are thought to be important contributors to pancreatitis occurring after endoscopic retrograde cholangiopancreatography. Our aim was to compare and evaluate the rates of success and complications of transpancreatic precut papillotomy (TPPP) and the double-guidewire technique (DGT), both with prophylactic pancreatic stenting.

Patients and methods From April 2011 to March 2014, patients with difficult biliary cannulation, in whom we planned to first position a guidewire in the pancreatic duct, were enrolled, and 68 patients were prospectively randomly allocated to two groups (TPPP 34, DGT 34). We evaluated the rates of success and complications for each group.

Results TPPP had a significantly higher success rate (94.1%) than DGT (58.8%). The rate of post-ERCP pancreatitis was 2.9% in both groups. There was no significant difference between the two groups in the overall rate of complications related to cannulation.

Conclusion If biliary cannulation cannot be achieved, TPPP should be selected first after unintentional pancreatic duct cannulation.

University Hospital Medical Network Clinical
Trials Registry UMIN 000008200

TRIAL REGISTRATION: Prospective randomized study
UMIN 000008200 at <http://www.umin.ac.jp>

Introduction

In endoscopic retrograde cholangiopancreatography (ERCP), selective biliary cannulation by the standard technique has been reported to fail in 5% to 10% of cases, even in experienced hands [1, 2]. Difficult cannulation is an independent risk factor for post-ERCP pancreatitis (PEP) [2]. Bailey et al. reported that the risk of PEP increased incrementally with each attempt at the papilla, to greater than 10% after four or more attempts [3]. Prolonged and repeated attempts at biliary cannulation can cause more injury to the ampulla and lead to PEP due to obstruction of pancreatic duct outflow. Unintentional cannulation of the pancreatic duct is also a risk factor for PEP [4].

There are two problems associated with difficult cannulations: how to achieve biliary cannulation as soon as possible and how to reduce PEP, especially in unintentional cannulation of the pancreatic duct. The present study was an effort to answer these two questions.

There are two ways to assist bile duct cannulation with pancreatic guidewire placement. One is the double-guidewire technique (DGT), which requires the use of a guidewire to physically occupy the pancreatic duct and another guidewire for bile duct cannulation [5–7]. The other is transpancreatic precut papillotomy (TPPP), which requires a sphincterotomy over the guidewire in the pancreatic duct [8, 9]. The way to reduce PEP is reported to be prophylactic pancreatic stenting, which

initially requires the introduction of a guidewire into the pancreatic duct [10]. The objective of this prospective study was to compare the success rates for bile duct cannulation and the complication rates of TPPP and the DGT, when both were associated with prophylactic pancreatic stenting.

Patients and methods

This was a prospective, randomized study conducted in a tertiary referral hospital in Japan. From April 2011 to March 2014, 2052 ERCPs were performed at Chiba University Hospital, and 64 patients were enrolled in this study. During this period, ERCP was required in all consecutive patients who had clear indications for biliary access, based on physical examination and previously fulfilled objective radiographic criteria. Among these patients, the inclusion criteria were as follows: (i) selective cannulation of the bile duct was not possible within 15 minutes, and selective cannulation of the pancreatic duct was obtained, or (ii) the patient underwent unintentional pancreatic duct cannulation more than three times. The exclusion criteria were age under 20 years, successful deep biliary cannulation within 15 minutes, surgically altered anatomy (Billroth II gastrectomy or Roux-en-Y anastomosis), prior biliary sphincterotomy, uncontrolled coagulopathy, failure of pancreatic duct cannulation, or refusal to participate in the study.

The Chiba University ethical committee approved the study. Written informed consent to participation in the study was obtained from all patients before the first ERCP. The study has been registered in the University Hospital Medical Information Network with the identifier UMIN000008200.

Endoscopic procedures: ERCP, TPPP, DGT, and additional sphincterotomy

Benzodiazepines and antispasmodic agents were administered routinely as premedication before all procedures. Midazolam (3 to 5 mg) and pentazocine (15 mg) were injected for sedation in doses depending on age and tolerance. ERCP was performed using a standard iodinated contrast medium, with a side-viewing therapeutic duodenoscope (JF-240, JF-260V, or TJF-260V; Olympus, Tokyo, Japan). Endoscopic sphincterotomy was performed using a sphincterotome (CleverCut 3; Olympus) with a single electrosurgical current generator (PSD-20; Olympus) at a power of 25W.

Biliary cannulation was initially attempted with a cannula (PR-104Q; Olympus) under the guidance of contrast injected into the bile duct. After the tip of the cannula was inserted into the orifice of the ampulla, contrast medium was gently injected. If the main pancreatic duct was visualized, the cannula was withdrawn and attempts were repeated with the same method or with wire-guided cannulation. Difficult biliary cannulation was defined as failure to achieve biliary access during 15 minutes of cannulation or more than three unintentional accesses to the pancreatic duct. When biliary cannulation failed with the standard technique or with guidewire-assisted cannulation, pancreatic duct cannulation was attempted. A minimal amount of contrast medium (2 or 3 mL) was used to determine the direction of the main pancreatic duct. Randomization was



► **Fig. 1** Transpancreatic precut papillotomy (TPPP). A guidewire was placed in the pancreatic duct, and then a regular sphincterotome was wedged into the pancreatic orifice. The orifice was cut widely enough to expose the lumen of the common bile duct.

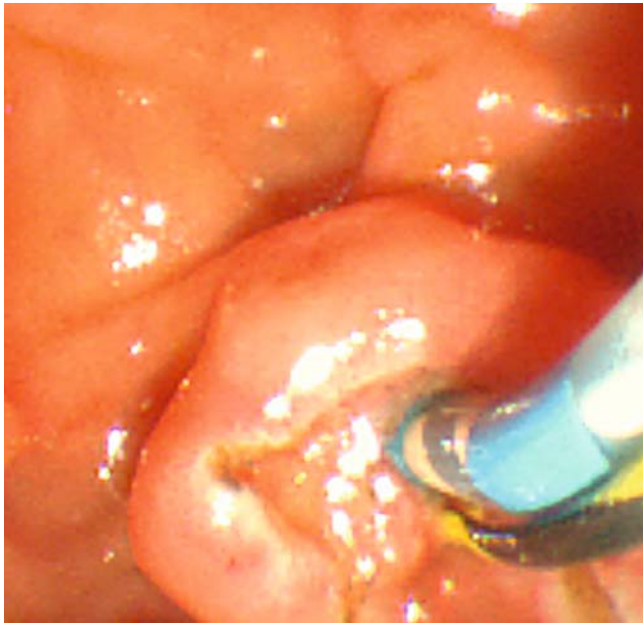
done during the procedure, by the opening of a sealed envelope placed in the operation room: when pancreatic duct cannulation with a guidewire turned out to be successful and the guidewire could be placed in the pancreatic duct, the sealed envelope was opened and the patient was randomly assigned to the TPPP or the DGT group.

Cannulation time was calculated from the moment when the patient was randomly assigned to a group, until the time when the catheter itself or the guidewire was inserted into the bile duct on fluoroscopy.

TPPP was performed as follows. First, a guidewire was placed in the pancreatic duct, and next a regular sphincterotome was wedged into the pancreatic orifice. The length of the cut was nearly the same as that for a regular biliary sphincterotomy, and the direction of the precut was towards the 12-o'clock direction to avoid bleeding. The intention was to cut the orifice widely enough to expose the lumen of the common bile duct. After that step had been done, we aimed in the direction of the bile duct with the same cannula with the second guidewire inside it (► **Figs. 1, 2**).

The DGT was applied as follows. After placement of the guidewire in the pancreatic duct, a second cannula with the second guidewire inside it was passed into the same working channel of the scope alongside the previous guidewire. Biliary cannulation was attempted first in the region towards the upper left of the pancreatic duct guidewire in the orifice of the papilla of Vater (► **Fig. 3**). The second guidewire was manipulated by an assistant.

In total, seven endoscopists carried out TPPP or the DGT. Each endoscopist had at least 3 years' experience in the pancreaticobiliary team at the tertiary referral center, had per-



► **Fig. 2** After transpancreatic precut papillotomy (TPPP), we aimed in the direction of the bile duct with the same cannula with the second guidewire inside, and selective biliary cannulation was achieved.



► **Fig. 3** The double-guidewire technique (DGT) was applied after placement of the guidewire in the pancreatic duct, with a second cannula being placed towards the upper left of the pancreatic duct guidewire.

formed over 300 ERCP-related procedures per year, and was able to achieve selective deep cannulation in more than 90% of cases using standard techniques.

When biliary cannulation with the DGT was not successful after attempts for more than 5–10 minutes by an expert

endoscopist, TPPP was then considered in order to achieve biliary cannulation, according to the judgement of the most highly trained expert among the clinicians confronting the difficult cannulation, and according to the tolerance of the patient for the procedure.

When cannulation of the bile duct was achieved using TPPP or the DGT, additional procedures were performed as necessary. Whether or not selective biliary cannulation was successful, pancreatic duct stenting was accomplished as soon as possible during the procedure to prevent PEP in all patients enrolled in this study. The stent used to prevent PEP was a 5-Fr, 3-cm externally flanged straight prophylactic pancreatic duct stent (Wilson-Cook Medical, Winston-Salem, North Carolina, USA).

We evaluated whether TPPP or the DGT could provide a safe and effective result in difficult cannulations of the bile duct. The outcomes evaluated were the technical success rate for biliary cannulation and the overall rate of complications, especially pancreatitis, related to cannulation. We also investigated the mean cannulation time to achieve biliary access and the overall procedure time.

The patients remained in the hospital for at least 24 hours. All patients received infusion of a protease inhibitor (nafamostat mesylate, 20 mg/day) and antibiotics (cefoperazone-sulbactam or ceftriaxone, 2 g/day) for 2 days, following the conventional standard of care for treating patients who undergo a first ERCP at our center. Serum amylase levels were measured before ERCP and 24 hours after the procedure. Symptoms (abdominal pain, nausea, back pain) and physical findings (abdominal tenderness, percussion tenderness) were evaluated during the hospital stay.

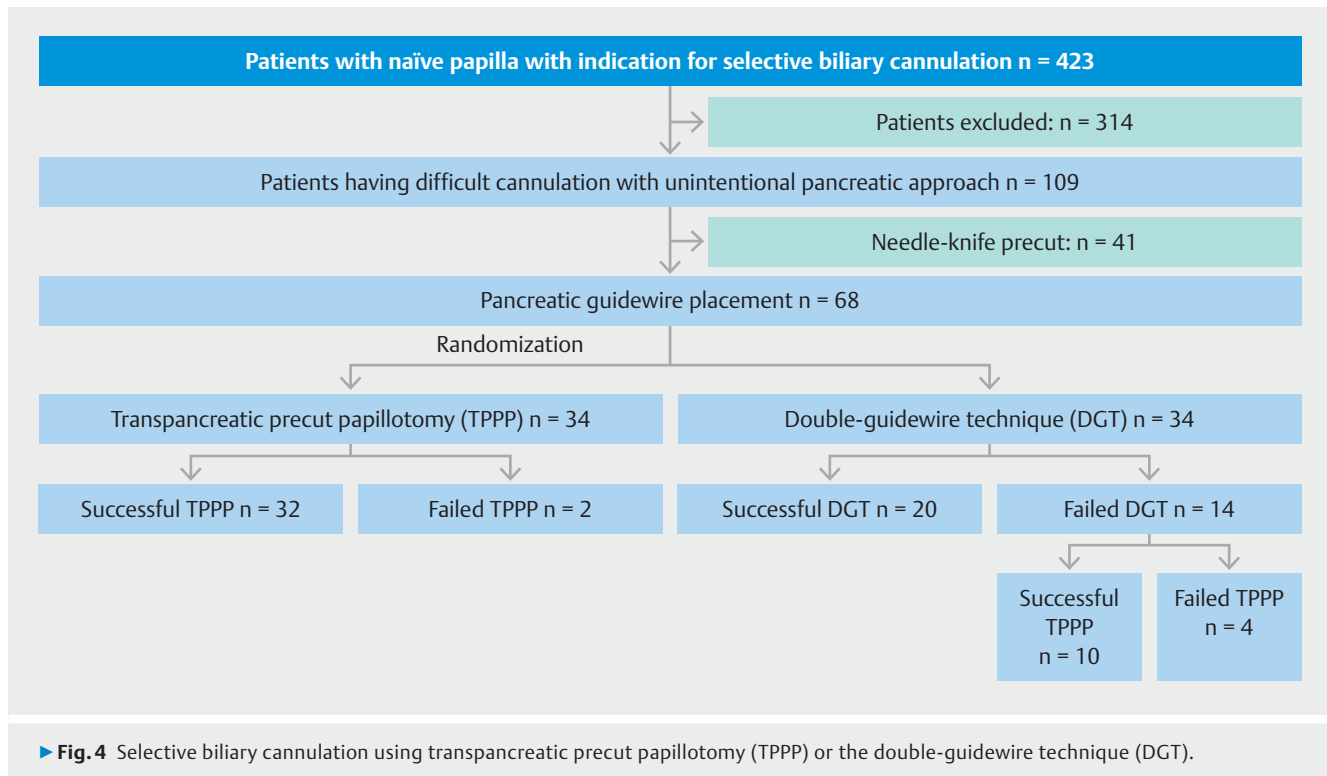
Definitions and classifications

In this study, difficult cannulation was defined as failure to achieve biliary access during 15 minutes of the attempted cannulation or unintentional pancreatic duct cannulation more than three times. Complications of ERCP were classified and graded according to consensus guidelines [4]. The diagnostic criteria for PEP were abdominal pain lasting >24 hours after ERCP and hyperamylasemia (>3 times the upper limit of the normal range).

Statistical analysis

The target sample size for this trial was 68. This number was based on results from a previous trial evaluating the pancreatic duct indwelling-guidewire method for problematic biliary cannulation, where the success rate of biliary cannulation was 89.1% for TPPP and 63.6% for DGT [8]. The estimated probabilities of success were 60% for the DGT group and 90% for the TPPP group. Assuming a group difference of 30%, 32 patients per arm would provide a power of over 80%, enough to detect a difference between the DGT group and the TPPP group, using a two-sided chi-squared test at a 5% level of significance. A dropout rate of 5% was allowed; thus, with 34 patients required per group, a total sample size of 68 patients was required for the trial [11].

Pearson's chi-square test with Yates's correction was used for statistical analysis of categorical variables. Two-sample t-



tests were used to compare continuous variables. The data were analyzed with SPSS software, version 17 (SPSS, Chicago, Illinois, USA). Differences with a P value <0.05 were considered to be statistically significant.

Results

Patient characteristics

During the study period, 2052 ERCP-related procedures were performed at Chiba University Hospital. After exclusion of patients according to the criteria of this study, ERCP with the native papilla of Vater was attempted in 423 patients. In 304 patients, selective biliary cannulation was achieved with a cannulation technique using contrast medium or following a wire-guided cannulation. In 10 patients, the ERCP procedures were not accomplished because of duodenal invasion or bleeding. Thus difficult cannulation occurred in 109 patients. Also pancreatic duct cannulation could not be achieved in 41 patients, who were treated with needle-knife precutting.

Therefore, 68 consecutive patients in whom the indwelling pancreatic duct guidewire technique was successfully applied were enrolled in this study and randomly assigned to the TPPP group (34 patients) or the DGT group (34 patients) (► **Fig. 4**). There were no significant differences between the groups in demographic characteristics or ERCP indication (► **Table 1**).

Rates of successful biliary cannulation and mean cannulation time

Successful initial biliary cannulation was achieved in 32 of the 34 patients (94.1%) in the TPPP group and in 20 of the 34 patients (58.8%) in the DGT group (► **Table 2**). When cannulation

with the DGT was unsuccessful after five attempts or within 10 minutes, transpancreatic papillotomy was performed. As a result, cumulatively, successful biliary cannulation was achieved in 30 of the 34 patients (88.2%) in the DGT group. Pancreatic duct stenting for the purpose of preventing PEP was achieved in all patients.

In patients who underwent successful biliary cannulation without conversion, the mean (standard deviation [SD]) cannulation time was 12.0 (7.2) minutes in the TPPP group ($n=32$) and 3.9 (2.1) minutes in the DGT group ($n=20$). The mean cannulation time was significantly higher in the TPPP group ($P=0.004$). The mean procedure time was 44.2 (10.6) minutes in the TPPP group ($n=32$) and 45.0 (11.8) minutes in the DGT group ($n=20$). There was no significant difference between the groups in the mean time for the overall procedure ($P=0.78$). The mean time to determine unsuccessful cannulation was 9.5 (1.7) minutes in the TPPP group ($n=2$) and 7.7 (0.7) minutes in the DGT group ($n=14$).

Complications of endoscopic biliary cannulation

► **Table 2** shows the complication rates and the characteristics of the complications. The overall incidence of PEP was 2.9% (1/34) in both groups. Severe pancreatitis developed in only one patient, who was in the DGT group, and this patient recovered within 2 weeks after conservative treatment. The incidence of post-ERCP hyperamylasemia was 20.6% (7/34) in both groups. Perforation was not detected in either group.

There were no significant differences between the groups in the rates of complications.

► Table 1 Patient demographic data and indications for endoscopic retrograde cholangiopancreatography (ERCP), according to cannulation technique.

| | Transpancreatic precut papillotomy (TPPP) n = 34 | Double guide-wire technique (DGT) n = 34 |
|---|---|---|
| Sex, n (%) | | |
| ▪ Men | 18 (52.9) | 19 (55.9) |
| ▪ Women | 16 (47.1) | 15 (44.1) |
| Age, mean (SD), years | 69.8 (9.3) | 67.3 (11.3) |
| Indications for ERCP, n (%) | | |
| ▪ Bile duct stone | 9 (26.5) | 9 (26.5) |
| ▪ Biliary cancer | 11 (32.4) | 7 (20.6) |
| ▪ Pancreatic cancer | 8 (23.5) | 7 (20.6) |
| ▪ Benign biliary stricture | 4 (11.8) | 5 (14.7) |
| ▪ Hepatocellular carcinoma | 0 (0.0) | 3 (8.8) |
| ▪ Biliary stricture due to metastatic lymph node | 0 (0.0) | 1 (2.9) |
| ▪ Sphincter of Oddi dysfunction | 0 (0.0) | 1 (2.9) |
| ▪ Gallstone pancreatitis | 2 (5.9) | 0 (0.0) |
| ▪ Suspected anomalous arrangement of the pancreaticobiliary ductal system | 0 (0.0) | 1 (2.9) |
| SD, standard deviation | | |

Discussion

To our knowledge, this is the first prospective randomized study to compare TPPP and the DGT in patients with difficult bile duct cannulation, with prophylactic pancreatic duct stenting in all enrolled patients. Management of difficult biliary cannulation and reduction of PEP remain problematic [12]. A recent large, prospective evaluation of PEP at a referral center found an overall complication rate of 11.4%, with a 7.2% rate of PEP [13]. Complicating factors related to endoscopy include repeated injection of contrast into the pancreatic duct and trauma to the papilla [3, 4, 14]. In the present study, we made two important clinical observations. First, TPPP had a significantly higher cannulation rate than DGT in difficult biliary cannulations. Second, there were no significant differences between the two techniques in complication rates, including pancreatitis; and also the complication rates, including PEP, for both techniques were tolerable compared to those in previous studies evaluating difficult cannulation [12, 13, 15].

A recent guideline [14] defined difficult cannulation as the inability to achieve selective biliary cannulation within 10 minutes or up to five cannulation attempts using standard ERCP techniques. This differed from our study definition of difficult

cannulation, which was planned before the guideline was published. We limited the time for attempting standard techniques, such as contrast-assisted or wire-guided cannulation, to within 15 minutes, which was longer than the time recommended in the guideline. We did not use the number of cannulation attempts as a factor towards changing strategy to TPPP or DGT, because there needed to have been placement already of a guidewire in the pancreatic duct for either technique, regardless of whether more than five attempts were needed.

With regard to the first observation mentioned earlier, TPPP had a significantly higher cannulation rate than the DGT because TPPP allowed clear visualization of the anatomy of the papilla and the lumen of the common bile duct. Although the initial success rate of cannulation with the DGT was lower than those in previous studies [15, 16], we achieved a similar success rate (88.2%) when DGT was followed by TPPP. This was because of the difference in study design. We designed this study as allowing crossover from the DGT to TPPP. In patients with failed selective cannulation, we have previously evaluated the utility of the technique of pancreatic duct guidewire in situ followed by precut papillotomy, and we now believe that it is useful to prepare backup techniques for each method in order to accomplish bile duct cannulation at the initial session [10]. The same idea has been presented in previous studies reporting that precutting was a useful backup technique when the DGT failed [3, 17, 18]. One previous prospective study, by Yoo et al., has evaluated the DGT and transpancreatic sphincterotomy in difficult cannulations [19]. At first glance, the success rates in the present study seem to be lower than the results of the study by Yoo et al. The overall success rate was over 91% for each approach in their study, but that result included successful second attempts on a different day. In the study of Yoo et al., initial successful biliary cannulation was achieved in 27 of the 34 patients (79.4%) in the DGT group and in 29 of the 37 patients (78.4%) in the transpancreatic sphincterotomy group. Their total initial success rate was 78.9% (56/71), which is similar to the 76.4% (52/68) of our study. Furthermore, in the present study, the overall success rate including additional successful biliary cannulation on the same day was 91.2% (62/68), which is almost the same as the result from Yoo et al. [19].

With regard to the second observation, we found that there were no significant differences between the two techniques in complication rates, including pancreatitis, and we found that the complication rates, including PEP, were tolerable with both techniques. Yoo et al. reported a significantly higher post-PEP rate in the DGT group (38.2%) than in the transpancreatic sphincterotomy group (10.8%) [19]. In the present study, we evaluated the safety of TPPP and the DGT using strict difficult biliary cannulation criteria, according to more than three unintentional pancreatic duct cannulations or failure to achieve biliary access during 15 minutes of attempted cannulation. In such cases, we first planned to position a guidewire into the pancreatic duct in order to use a pancreatic stent to reduce the risk of PEP. This appears to be the greatest difference from the report of Yoo et al. [19] and led to the significantly lower rate of PEP.

Several studies and one guideline have already evaluated the utility of prophylactic pancreatic duct stenting for difficult can-

► **Table 2** Rates of successful cannulation and complications according to cannulation technique

| | Transpancreatic precut papillotomy (TPPP) n = 34 | Double guidewire technique (DGT) n = 34 | P value |
|-------------------------------|--|---|---------|
| Successful cannulation, n (%) | 32 (94.1) | 20 (58.8) | 0.001 |
| Complications, n (%) | | | |
| ▪ Pancreatitis | 1 (2.9) | 1 (2.9) | |
| ▪ Mild | 1 (2.9) | 0 (0.0) | |
| ▪ Severe | 0 (0.0) | 1 (2.9) | |
| ▪ Hyperamylasemia | 7 (20.6) | 7 (20.6) | |
| ▪ Hemorrhage | 0 (0.0) | 0 (0.0) | |
| ▪ Cholangitis | 1 (2.9) | 0 (0.0) | |
| ▪ Pneumonia | 0 (0.0) | 1 (2.9) | |
| ▪ Perforation | 0 (0.0) | 0 (0.0) | |

nulation [8, 20–22]. According to these studies, the incidence of PEP in the groups with pancreatic duct stenting was significantly lower than that in the groups without pancreatic duct stenting. Another report found that two patients without a pancreatic stent after pancreatic sphincterotomy died, whereas none of the patients with a pancreatic stent developed PEP [23]. For this reason we believe prophylactic pancreatic duct stenting should be systematically performed in cases where attempts at biliary cannulation lead to inadvertent but repeated cannulation of the pancreatic duct.

In our study, we first used contrast-assisted cannulation. One reason is that this study was planned before recent guidelines were published [14, 24]. Another reason is to avoid injuring the small branch of the pancreatic duct with the guidewire. Although wire-guided cannulation has recently been recommended to reduce the risk of PEP as most ERCPs are planned for therapeutic intent [24, 25], we have consistently first used contrast medium to confirm the direction of the bile duct or the pancreatic duct and changed to wire-guided cannulation if needed. Occasionally, contrast-assisted cannulation may lead to unintentional injection into the pancreatic duct, but we can avoid injecting too much contrast medium intentionally. After confirming the correct direction of the main pancreatic duct with only a minimal amount of contrast medium, we can avoid injuring the thin branch of the pancreatic duct with a guidewire while placing a guidewire gently into the main pancreatic duct. This may be another reason for the lower rate of PEP in the present study.

There was a significant difference in mean cannulation time between the DGT and TPPP groups. The DGT required less time to achieve bile duct cannulation. This was because TPPP required time for precutting in addition to time for preparing a sphincterotome before seeking the bile duct. The difference in cannulation time does not imply inferiority of TPPP, because the overall procedure time was similar in both groups.

The present study does not deny the importance and utility of the DGT. We cannot always select TPPP for patients with dif-

icult bile duct cannulation. Patients who bleed easily should not be treated with TPPP without hesitation, and DGT might be useful in such cases.

A limitation of this study is that the success rate would be influenced by the skills of the endoscopists. As the technical success rate depends on the endoscopists' skills to some extent, it should be recommended that only well-trained endoscopists should perform either method. As there was no guideline for the timing of conversion from the DGT to TPPP when we planned this study, we regarded the length of time for attempts as the most objective criterion, that is, 5 to 10 minutes. Although the timing was always decided by the most highly trained of the clinicians confronting the difficult cannulation, there was potential for investigator bias to affect the primary outcome as the judgment could be somewhat subjective and dependent on physician skill level.

Another limitation of this study is that we did not evaluate the utility of needle-knife precutting itself. We did not select the method first when we managed to place the guidewire into the pancreatic duct [3–5, 26]. Although the utility of early needle-knife precutting has been reported previously, the technique is not recommended for less experienced endoscopists, as it is considered a very high risk procedure [27]. However, current studies also show that precut in expert hands has low complication rates [28, 29]. For this reason, we use needle-knife precutting as the first rescue method only when we cannot achieve pancreatic duct cannulation or when we cannot achieve bile duct cannulation even after TPPP, which happens in only a limited number of cases. However, the safety of needle-knife precutting over a pancreatic duct stent has been recently reported [30]. Further study would be needed to compare TPPP versus needle-knife precut over a pancreatic stent.

In patients with difficult bile duct cannulation, the rate of successful bile duct cannulation after pancreatic duct cannulation had been obtained was higher with TPPP than with the DGT. Among patients undergoing prophylactic pancreatic

stenting, there was no significant difference in the rate of PEP between the TPPP and the DGT groups.

Competing interests

None. The authors report no disclosures relevant to this publication.

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