Hepatobiliary & Pancreatic Diseases International 18 (2019) 73–78

Contents lists available at ScienceDirect

Hepatobiliary & Pancreatic Diseases International

journal homepage: www.elsevier.com/locate/hbpd

Original Article/Pancreas

Comparison of efficacy and safety of transpancreatic septotomy, needle-knife fistulotomy or both based on biliary cannulation unintentional pancreatic access and papillary morphology

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ARTICLE INFO

Article history:
Received 27 April 2018
Accepted 21 November 2018
Available online 24 November 2018

Keywords:
Difficult biliary cannulation
Endoscopic retrograde cholangiopancreatography
Needle-knife fistulotomy
Precut techniques
Transpancreatic septotomy

ABSTRACT

Background: Precut sphincterotomy has been widely performed to facilitate selective biliary access when standard cannulation attempts failed during endoscopic retrograde cholangiopancreatography (ERCP). However, scarce data are available on different precut techniques for difficult biliary cannulation. This study aimed to evaluate the efficacy and safety of transpancreatic septotomy (TPS), needle-knife fistulotomy (NKF) or both based on the presence of unintentional pancreatic access and papillary morphology.

Methods: Between March 2008 and December 2016, 157 consecutive patients undergoing precutting for an inaccessible bile duct during ERCP were identified. Precut techniques were chosen depending on repetitive inadvertent pancreatic cannulation and the papillary morphology. We retrospectively assessed the rates of cannulation success and procedure-related complications among three groups, namely TPS, NKF, and TPS followed by NKF.

Results: The baseline characteristics of the three groups were comparable. The overall success rate of biliary cannulation reached 98.1%, including 111 of 113 (98.2%) with TPS, 35 of 36 (97.2%) with NKF and 8 of 8 (100%) with NKF following TPS, without significant difference among groups. The incidences of total complications and post-ERCP pancreatitis were 9.6% and 7.6%, respectively. There was a trend towards less frequent post-ERCP pancreatitis after NKF (0%) compared with 11 cases (9.7%) after TPS and one case (12.5%) after NKF following TPS, but not significantly different ($P=0.07$). No severe adverse event occurred during this study period.

Conclusions: The choice of precut techniques by the presence of unintended pancreatic access and the papillary morphology brought about a high success rate without increasing risk in difficult biliary cannulation.

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is a valuable diagnostic and therapeutic intervention for various pancreaticobiliary disorders. The access to the desired duct is the crucial step for a success of ERCP, whereas failed biliary cannulation reportedly occurred in 5%–20% of cases [1–4]. Thus precut sphincterotomy is common. However, precutting remains technically challenging. There is still considerable controversy concerning its inherent potential complications, particularly post-ERCP pancreatitis [5–7].

There are several available approaches for precutting that have been developed to gain biliary access when standard cannulation attempts failed [3,8–11], while limited data are available. Although the cannulation success and complication rates of transpancreatic septotomy (TPS), conventional needle-knife precut papillotomy (NKP), and needle-knife fistulotomy (NKF) have been compared previously [12–19], we only found one retrospective study focusing on choosing precut techniques based on the endoscopic morphology of papillae with a sample size of 86 patients [15]. In other relevant studies, the same technique was chosen for precutting over time, depending on personal preference of the endoscopists [10,20].

The present study aimed to evaluate the efficacy and safety of TPS, NKF or both in difficult biliary cannulation, where the selection of precut technique was based on the presence of

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https://doi.org/10.1016/j.hbpd.2018.11.007

unintentional pancreatic access combined with the papillary morphology.

Methods

Patients

Between March 2008 and December 2016, there were 8131 consecutive ERCPs performed by one endoscopist (GB) in the Digestive Endoscopy Center of the Ruijin Hospital, a tertiary referral center. From an established database of patient- and procedure-related detailed information, there were a total of 190 patients who received precut sphincterotomy, namely TPS, NKF or both during ERCP. Patients with previous sphincterotomy, surgically altered anatomy (e.g. Billroth II gastrectomy, Roux-en-Y anastomosis), or inadequate medical data were excluded. A total of 157 patients were reviewed, including demographics, indications for ERCP, previous unsuccessful ERCP, procedure details, procedure-related complications and any potentially associated factors.

All of the patients gave their written informed consent prior to ERCP procedure. This study has been approved by the Institutional Review Board of Ruijin Hospital.

ERCP procedure

Standard biliary cannulation was routinely performed with the guidewire-assisted technique with a double- or triple-lumen pull-type sphincterotome (Smart-tip, ENDO-FLEX GmbH, Voerde, Germany) preloaded with a hydrophilic guidewire (Hydra Jagwire, Boston Scientific, Natick, MA, USA) in all patients. Precut sphincterotomy was resorted when selective biliary access failed after 15-min standard cannulation attempts, or more than 3 unintentional pancreatic cannulation or any opacification. The suitable technique for precutting was prospectively selected at the discretion of the endoscopist, which was principally based on whether repetitive unintended guidewire inserted into the pancreatic duct and the papillary morphology. We classified the morphology of major papillae into two types: (1) a small papilla with no or limited visible intramural segment of the common biliary duct (CBD); (2) a protuberant papilla with visibly bulged or redundant intramural segment of the CBD that protruded from the duodenal wall.

Precut techniques

TPS was primarily chosen if multiple inadvertent pancreatic access occurred, or the papilla was small. With the prior pancreatic guidewire insertion, TPS was performed with a standard sphincterotome, starting from the pancreatic orifice through the septum between the biliary and pancreatic ducts in the direction of the CBD (Fig. 1A, B). The CBD orifice was exposed to the left of the pancreatic orifice, either at the apex or the starting point of the incision, depending on the length of the common channel (long or short, respectively). Once the CBD orifice was visualized, subsequent deep cannulation could generally be achieved and followed by extended sphincterotomy when indicated.

There were three situations considering NKF as the first choice, which were in the absence of pancreatic cannulation, in cases of the biliary calculus impacted at the ampulla or the distal CBD, and in the presence of a protuberant papilla. NKF was performed with a needle-knife sphincterotome (Triple-lumen Microknife XL, Boston Scientific, Natick, MA, USA). The needle tip was anchored over the incarcerated calculus or directly on the summit of the protuberant papilla, and then made a puncture to create an endoscopic choledochoduodenal fistula. Subsequently, the fistulous opening was gently probed via a wire-guided sphincterotome to achieve deep biliary cannulation and if necessary, an upward or downward extension followed for further therapeutic manipulations (Fig. 1C, D).

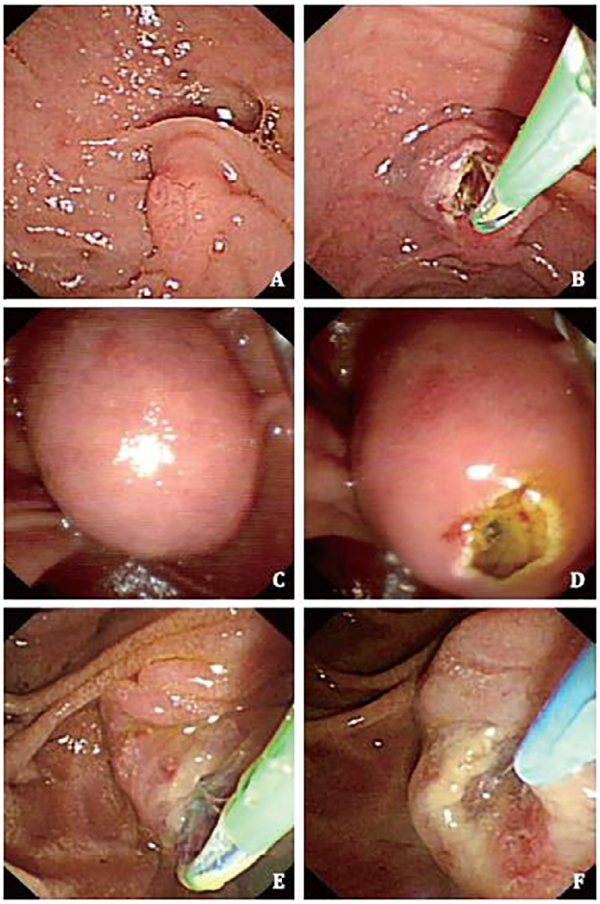

Fig. 1. A and **B**: Transpancreatic septotomy (TPS) for a small papilla; **C** and **D:** Needle-knife fistulotomy (NKF) for a protuberant papilla with an impacted stone; **E** and **F**: A sequential NKF following failed TPS for a protuberant papilla with a recognizable intramural segment of the common bile duct.

In the event of an inaccessible bile duct even after TPS, NKF was subsequently performed in patients with the presence of a recognizable intramural segment of the CBD (Fig. 1E, F).

For the purpose of analysis, patients were divided into three groups based on the precut technique involved during ERCP, namely TPS group, NKF group, and TPS followed by NKF (TPS & NKF) group. All precut techniques were performed by using blended electrosurgical current (VIO 200S, ERBE Electromedizin, Tuebingen, Germany). Prophylactic placement of pancreatic stent was applied in a very tiny size of patients and was also at the discretion of the endoscopist. In addition, rectal nonsteroidal anti-inflammatory drugs were never administered for the prevention of post-ERCP pancreatitis during the entire study period.

There was no further manipulation if attempts at biliary cannulation failed after NKF or TPS followed by NKF. For those patients with initially unsuccessful cannulation, our routine practice was to schedule a second ERCP 5–7 days after the previous one if the failure was due to an edematous papilla. Moreover, the standard process in our institution was that all the patients undergoing ERCP were instructed to be hospitalized overnight for observation and serum amylase examination 3 and 24 h after the procedure. All the discharged patients were informed to remain in contact for the follow-up of any delayed complications.

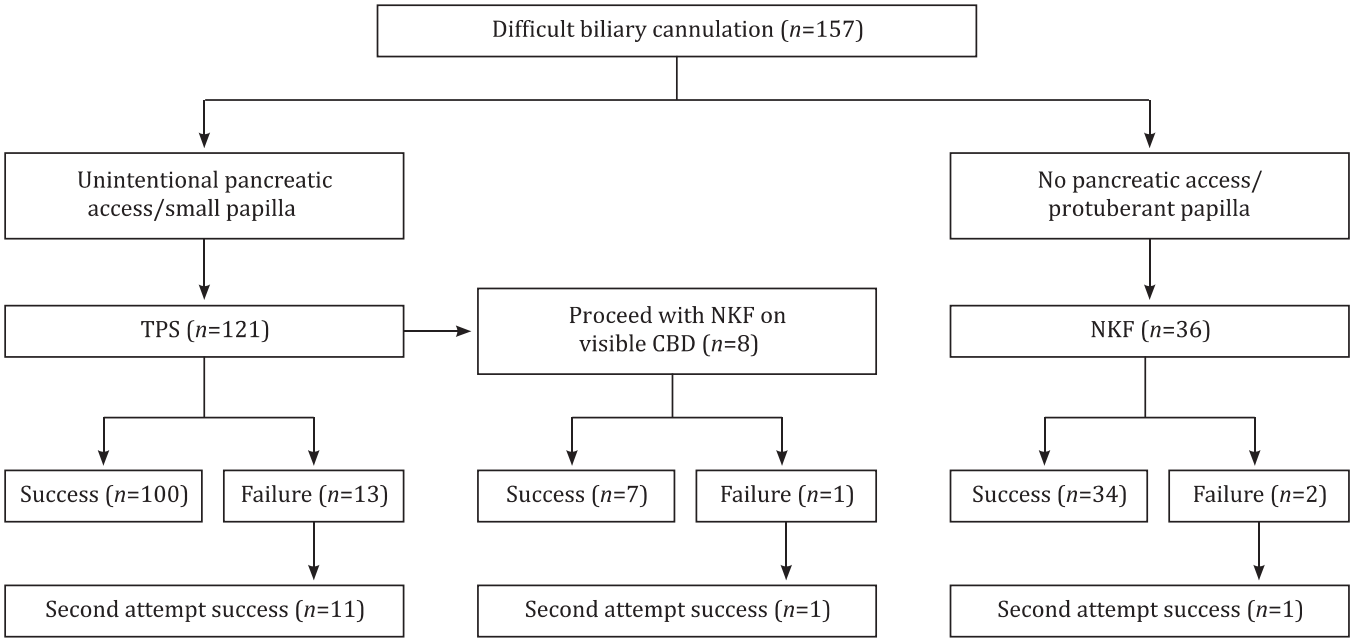

Fig. 2. Flow diagram of patients with different precut strategies for difficult biliary cannulation according to whether unintentional pancreatic access occurred and the papillary morphology. TPS: transpancreatic septotomy; NKF: needle-knife fistulotomy; CBD: common bile duct.

Definitions

Successful biliary cannulation was defined as obtaining deep biliary cannulation with a confirmed cholangiography. The analysis of eventual success rate included the obtainment of biliary access in the second ERCP.

ERCP-associated complications were classified and graded according to established consensus criteria [21]. Post-ERCP pancreatitis was defined as new or worsened abdominal pain with an elevated amylase at least three times the upper limit of the normal level, at more than 24 h after ERCP, requiring admission or prolongation of planned hospitalization. Mild post-ERCP pancreatitis was defined as the presence of post-ERCP pancreatitis requiring hospitalization to 2–3 days. Moderate post-ERCP pancreatitis required hospitalization of 4–10 days. Severe post-ERCP pancreatitis required hospitalization for more than 10 days, or admission to the intensive care unit, or the need for invasive or surgical intervention. Bleeding was defined as clinical evidence of overt gastrointestinal hemorrhage related to ERCP with or without hemoglobin drop. Perforation was diagnosed according to the imaging evidence of intraperitoneal or retroperitoneal leakage of contrast agent observed under radioscopy.

Outcomes

Main outcomes were the initial and eventual success rate of biliary cannulation and the incidence of procedure-related complications.

Statistical analysis

Continuous variables were measured as means (standard deviations) and categorical variables were measured as frequencies (percentages). Statistical analyses for comparing outcomes of the three groups were performed by using the One-way analysis of variance for continuous data and the Pearson Chi-square or the Fisher exact test for categorical data. Differences were considered statistically significant with a two-sided P value < 0.05. All statistical analyses were performed by using STATA 14.0 software (Stata Corp, College Station, Texas, USA).

Results

The final analysis included 157 patients undergoing precut sphincterotomy in difficult biliary cannulation, 113 (72.0%) underwent TPS, 36 (22.9%) underwent NKF and 8 (5.1%) underwent TPS & NKF (Fig. 2). The demographics and indications for ERCP are summarized in Table 1 according to the type of precut technique. The three groups were comparable regarding age, sex, indications, previous failed ERCP and potentially patient- and procedure-related risk factors for post-ERCP complications, except for multiple pancreatic cannulation ($P < 0.001$). Prophylactic pancreatic stenting was only administered in 5 patients (3.2%), of whom 4 (3.5%) in the TPS group and 1 (12.5%) in the TPS & NKF group, without significant difference among groups.

During the initial ERCP, successful biliary access after precutting was achieved in 141 patients (89.8%), including 100 patients (88.5%) with TPS, 34 patients (94.4%) with NKF and 7 patients (87.5%) with TPS & NKF (Table 2). Among the 16 patients with initial failure of biliary cannulation, 13 received a repetitive ERCP using standard cannulation strategy without precutting within 5–7 days, while the remaining 3 (2 of the TPS group and 1 of the NKF group) were not referred to a second ERCP and subsequently resorted to percutaneous or surgical intervention. After the second attempt, the overall success rate of biliary cannulation eventually reached 98.1% (154/157), including 98.2% (111/113) of TPS, 97.2% (35/36) of NKF, and 100.0% (8/8) of TPS & NKF. There was no significant difference in the initial and eventual success rate among groups ($P = 0.546$ and $P = 0.630$, respectively). As technical details outlined in Table 3, there was also no statistically significant difference in additional therapeutic interventions among the three groups.

The procedure-related complication rates were demonstrated in Table 4. The overall complications occurred in 15 of 157 patients (9.6%), including 14 patients (12.4%) in the TPS group, and one patient (12.5%) in the TPS & NKF group. The occurrence of total complications was less frequent after NKF than after TPS or both,

Table 1
Patient characteristics and indications for ERCP.

Variables	Total ($n=157$)	TPS ($n=113$)	NKF ($n=36$)	TPS & NKF ($n=8$)	P value
Age (yr)	65.3 ± 13.7	64.3 ± 13.8	68.1 ± 14.2	67.1 ± 8.3	0.330
Female	71 (45.2%)	52 (46.0%)	17 (47.2%)	2 (25.0%)	0.549
History of pancreatitis[a]	28 (17.8%)	22 (19.5%)	5 (13.9%)	1 (12.5%)	0.861
Previous failed ERCP	7 (4.5%)	6 (5.3%)	1 (2.8%)	0	1.000
Indications					0.421
Choledocholithiasis	32 (20.4%)	22 (19.5%)	8 (22.2%)	2 (25.0%)	
Malignant biliary stricture	63 (40.1%)	44 (38.9%)	17 (47.2%)	2 (25.0%)	
Benign biliary stricture	18 (11.5%)	15 (13.3%)	1 (2.8%)	2 (25.0%)	
Biliary dilation	17 (10.8%)	12 (10.6%)	5 (13.9%)	0	
Suspected SOD	20 (12.7%)	16 (14.2%)	3 (8.3%)	1 (12.5%)	
Acute biliary pancreatitis	7 (4.5%)	4 (3.5%)	2 (5.6%)	1 (12.5%)	
Periampullary diverticulum	35 (22.3%)	26 (23.0%)	8 (22.2%)	1 (12.5%)	0.943
Multiple pancreatic cannulation	115 (73.2%)	107 (94.7%)	0	8 (100.0%)	**<0.001**
Pancreatic contrast injection	29 (18.5%)	26 (23.0%)	3 (8.3%)	0	0.063
Pancreatic stent placement	5 (3.2%)	4 (3.5%)	0	1 (12.5%)	0.212

[a] History of pancreatitis denotes previous pancreatitis either related to ERCP or not. ERCP: endoscopic retrograde cholangiopancreatography; TPS: transpancreatic septotomy; NKF: needle-knife fistulotomy; TPS & NKF: TPS followed by NKF; SOD: sphincter of Oddi dysfunction.

Table 2
Success rate of biliary cannulation.

Variables	Total ($n=157$)	TPS ($n=113$)	NKF ($n=36$)	TPS & NKF ($n=8$)	P value
Initial cannulation success	141 (89.8%)	100 (88.5%)	34 (94.4%)	7 (87.5%)	0.546
Eventual cannulation success	154 (98.1%)	111 (98.2%)	35 (97.2%)	8 (100.0%)	0.630

TPS: transpancreatic septotomy; NKF: needle-knife fistulotomy; TPS & NKF: TPS followed by NKF.

Table 3
Details of procedure after successful biliary cannulation.

Variables	Total ($n=157$)	TPS ($n=113$)	NKF ($n=36$)	TPS & NKF ($n=8$)	P value
EST	60 (38.2%)	45 (39.8%)	11 (30.6%)	4 (50.0%)	0.500
EPBD	19 (12.1%)	14 (12.4%)	4 (11.1%)	1 (12.5%)	1.000
Biliary stent placement	61 (38.9%)	39 (34.5%)	20 (55.6%)	2 (25.0%)	0.063
CBD stone removal	41 (26.1%)	30 (26.5%)	8 (22.2%)	3 (37.5%)	0.610
Stricture dilation	22 (14.0%)	19 (16.8%)	3 (8.3%)	0	0.292
Mechanical lithotripsy	4 (2.5%)	2 (1.8%)	2 (5.6%)	0	0.390

TPS: transpancreatic septotomy; NKF: needle-knife fistulotomy; EST: endoscopic sphincterotomy; EPBD: endoscopic sphincterotomy combined with balloon dilatation; CBD: common bile duct.

Table 4
Procedure-related complications.

Variables	Total ($n=157$)	TPS ($n=113$)	NKF ($n=36$)	TPS & NKF ($n=8$)	P value
Overall complications[a]	15 (9.6%)	14 (12.4%)	0	1 (12.5%)	0.053
PEP	12 (7.6%)	11 (9.7%)	0	1 (12.5%)	0.070
Mild	8 (5.1%)	8 (7.1%)	0	0	0.290
Moderate	4 (2.5%)	3 (2.7%)	0	1 (12.5%)	0.226
Severe	0	0	0	0	NS
Bleeding	2 (1.3%)	2 (1.8%)	0	0	1.000
Perforation	1 (0.6%)	1 (0.9%)	0	0	1.000

TPS: transpancreatic septotomy; NKF: needle-knife fistulotomy; TPS & NKF: TPS followed by NKF; PEP: post-ERCP pancreatitis; NS: not significant.
[a] All recorded complications occurred following precutting after the initial ERCP procedure.

albeit not reaching statistical significance ($P=0.053$). Among the three groups, the most common complication was post-ERCP pancreatitis (12/157, 7.6%). There was a trend towards lower incidence of post-ERCP pancreatitis by NKF (0%) compared with a sole TPS (11/113, 9.7%) and NKF following TPS (1/8, 12.5%, $P=0.070$). Mild post-ERCP pancreatitis was diagnosed in eight cases (5.1%), and moderate post-ERCP pancreatitis in four cases (2.5%), with no severe post-ERCP pancreatitis.

The incidence of procedure-associated bleeding and perforation did not differ significantly among groups (Table 4). Both bleedings were in the TPS group and improved with endoscopic submucosal injection of ice saline-epinephrine and/or placement of hemostatic clips, with no requirement for blood transfusion or surgical intervention. The single perforation (0.6%) occurred in the patient undergoing TPS and was identified immediately at the time of ERCP, who was promptly treated by surgery with retroperitoneal

drainage, requiring a 9-day hospitalization. No procedure-related mortality occurred during this study period.

Discussion

The successful selective cannulation with the minimum risk is the primary step for every ERCP operator. In difficult biliary access, precut sphincterotomy has been the most frequently implemented technique by avoiding repeated procedures and additional costs [3]. Although precutting was conventionally considered as an independent predictor of post-ERCP pancreatitis [5–7], many recent studies suggested that multiple attempts on the papilla, inadvertent pancreatic cannulation, and contrast injection prior to precutting were truly associated with an increased risk of post-ERCP pancreatitis rather than the technique itself [22–26].

For an inaccessible bile duct, precutting was undertaken in 190 of 8131 (2.3%) in our study, which indicated an evidently lower rate of precut implementation compared with previous studies (9.8%–23.1%) [12,25,27]. This difference might result from the high primary cannulation rate performed with the guidewire-assisted technique by the experienced endoscopist. Several experts indicated that the precutting demand tended to decrease with increasing experience of the endoscopist [28]. Moreover, during the early period of our study, the double-guidewire technique was preferred if repetitive unintentional pancreatic cannulation occurred.

In this retrospective analysis, the success rate of biliary access was initially 89.8% after precutting irrespective of the technique used and eventually improved to 98.1% after a second attempt (Table 2). The result indicates that once the edema and inflammation of the papilla have subsided after 5–7 days, a second ERCP attempt is necessary, with emphasis on the efficacy of precut sphincterotomy for achieving biliary access in difficult cases. Furthermore, the recent study suggests that it appears to be effective and safe to perform a second ERCP on patients with initial failure of biliary cannulation more than 4 days after precutting if feasible [1]. The overall success rate of biliary cannulation in our study compares favorably to those reported in other studies with TPS, NKF or both for precutting [12–16,20,29]. The high success rates of biliary cannulation reflect the efficacy of the precut strategy depending on whether inadvertent pancreatic duct cannulation occurred combined with the papillary morphology. It is worth noticing that the selective biliary cannulation was finally achieved in all of the 8 patients (100%) after a sequential NKF following TPS, with an acceptable complication rate (1 of 8, 12.5%). However, due to the relatively small sample included in the TPS & NKF group, further large-scale and prospective studies would be required to validate our experience.

The overall incidence of procedure-related pancreatitis in our study was 7.6%, which was less frequent than other relevant studies (8.8%–16.1%) with the selection of precut technique determined by individual preference [12,14,29]. The post-ERCP pancreatitis rates observed in published studies where NKF was chosen for precutting ranged from 3.9%–5.7% [20,27], either implemented early or late, compared with a rate of 0% after NKF in our study, which might be attributed to our appropriate precut strategy. It could be noted that the outcome of no post-ERCP pancreatitis occurrence after NKF in our study was consistent with a comparative study where NKF was chosen first for a swollen papilla with visible protrusion [15], and was also similar to another previous report concerning the efficacy of NKF in patients with incarcerated biliary stones at the ampulla [30]. Our results showed that NKF could probably be the optimal technique for the patients with a protuberant papilla in which the intramural segment of the CBD was long or the biliary calculus got impacted, meanwhile, unintended pancreatic cannulation rarely occurred. NKF maximally avoided direct trauma and thermal injury to the pancreatic orifice and hence reduced subsequent edema and inflammation of the papillary opening, which preserved the flow of pancreatic juice after the procedure, and theoretically, minimized the chances of associated pancreatitis [12,20].

On the other hand, the inaccessible bile duct might be due to the presence of a septum separated the biliary and pancreatic orifices. Also, repetitive guidewire insertion into the pancreatic duct formed a more accessible tract to follow, causing selective biliary access more challenging. In this situation, TPS might be the technically less demanding approach than other precut techniques [11,18,29,31]. However, a concern remains regarding the higher post-ERCP pancreatitis rate observed after TPS and NKF following TPS compared with NKF (TPS 9.7% vs. TPS & NKF 12.5% vs. NKF 0%, $P=0.070$). One possible explanation for this difference is that patients with TPS had undergone multiple unsuccessful cannulation attempts and repeated inadvertent pancreatic cannulation with or without opacification, which had already resulted in a traumatized papilla and a higher risk of post-ERCP pancreatitis preceding TPS. Besides, prophylactic pancreatic stenting was seldom adopted in our center (only 3.5% in the TPS group), even though the current guideline strongly recommends the placement of pancreatic stent in high-risk patients, particularly receiving TPS [8].

From our perspective, the ideal indication for NKF could be the presence of a protuberant papilla; on the contrary, if there was repeated inadvertent pancreatic access or the presence of a small papilla, it might be safer and preferable to perform TPS first, since the incision depth and direction could be easier to control than NKF. We believe that in cases of continuous inaccessible bile duct even after TPS, it would be reasonable to perform NKF subsequently in patients with a recognizable intraduodenal CBD. Nevertheless, it is crucial to note that precut sphincterotomy should be performed by the skilled endoscopist and restricted to high-volume centers with the capability of prompt multidisciplinary treatment for any potential complications.

The major limitation of our study is its retrospective design. The performance of different precut techniques might be improperly compared owing to the non-randomized fashion and the relatively small number of patients involved in the NKF and TPS & NKF groups. Another obvious limitation is that the proper timing for precutting and the classification of the papillary morphology were based on the judgment of the endoscopist. Hence it would be necessary to add objectivity to the definition criteria on this issue in future studies.

In conclusion, our results suggested that the selection of precut techniques, namely TPS, NKF or both, based on the presence of unintended pancreatic access combined with the papillary morphology would much more likely result in a high degree of successful biliary cannulation and a relative low incidence of procedure-related complications in difficult biliary cannulation. In addition, a sequential NKF following unsuccessful TPS appeared to be effective without increasing associated risk for an otherwise inaccessible bile duct in the presence of a protuberant papilla with a recognizable intraduodenal CBD.

Contributors

GB proposed the research. WJ performed the research and wrote the manuscript. LT collected clinical data and revised the manuscript. LY and BLK performed data analysis. GB is the guarantor.

Funding

None.

Ethical approval

This study has been approved by the Institutional Review Board of Ruijin Hospital.

Competing interest

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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