

# World Journal of *Clinical Cases*

*World J Clin Cases* 2021 June 16; 9(17): 4116-4459



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**ABOUT COVER**

Editorial Board Member of *World Journal of Clinical Cases*, Pietro Scicchitano, MD, Professor, Research Scientist, Department of Emergency and Organ Transplantation, School of Medicine, University of Bari, Bari 70124, Italy. piero.sc@hotmail.it

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**RESPONSIBLE EDITORS FOR THIS ISSUE**

Production Editor: Jia-Hui Li; Production Department Director: Yu-Jie Ma; Editorial Office Director: Jin-Lai Wang.

**NAME OF JOURNAL**

*World Journal of Clinical Cases*

**ISSN**

ISSN 2307-8960 (online)

**LAUNCH DATE**

April 16, 2013

**FREQUENCY**

Thrice Monthly

**EDITORS-IN-CHIEF**

Dennis A Bloomfield, Sandro Vento, Bao-Gan Peng

**EDITORIAL BOARD MEMBERS**

<https://www.wjnet.com/2307-8960/editorialboard.htm>

**PUBLICATION DATE**

June 16, 2021

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**ARTICLE PROCESSING CHARGE**

<https://www.wjnet.com/bpg/gerinfo/242>

**STEPS FOR SUBMITTING MANUSCRIPTS**

<https://www.wjnet.com/bpg/GerInfo/239>

**ONLINE SUBMISSION**

<https://www.f6publishing.com>

## Retrospective Study

# Primary needle-knife fistulotomy for preventing post-endoscopic retrograde cholangiopancreatography pancreatitis: Importance of the endoscopist's expertise level

Sung Yong Han, Dong Hoon Baek, Dong Uk Kim, Chang Joon Park, Young Joo Park, Moon Won Lee, Geun Am Song

**ORCID number:** Sung Yong Han 0000-0002-0256-9781; Dong Hoon Baek 0000-0003-1512-9745; Dong Uk Kim 0000-0002-7208-7753; Chang Joon Park 0000-0002-2438-1499; Young Joo Park 0000-0001-8416-0615; Moon Won Lee 0000-0002-8411-6398; Geun Am Song 0000-0003-2100-8522.

**Author contributions:** Kim DU and Song GA contributed study concept and design; Park CJ and Park YJ contributed data acquisition; Han SY and Lee MW contributed data analysis and interpretation; Han SY and Baek DH contributed drafting of the manuscript; Kim DU and Song GA contributed critical revision of the manuscript.

**Supported by** Korea Medical Device Development Fund Grant Funded by the Korea Government the Ministry of Trade, Industry and Energy (Project Number: 9991007196), No. KMDF\_PR\_20200901\_0066.

**Institutional review board**

**statement:** The study protocol was approved by the Institutional Review Board of the Pusan National University (approval No. H-1805-023-067).

**Sung Yong Han, Dong Hoon Baek, Dong Uk Kim, Chang Joon Park, Young Joo Park, Moon Won Lee, Geun Am Song**, Division of Gastroenterology and Hepatology, Internal Medicine and Biomedical Research Institute, Pusan National University Hospital, Busan 49241, South Korea

**Corresponding author:** Dong Uk Kim, MD, PhD, Associate Professor, Division of Gastroenterology and Hepatology, Internal Medicine and Biomedical Research Institute, Pusan National University Hospital, 179 Gudeok-ro, Seo-gu, Busan 49241, South Korea. [amlm3@hanmail.net](mailto:amlm3@hanmail.net)

## Abstract

### BACKGROUND

Needle-knife fistulotomy (NKF) is used as a rescue technique for difficult cannulation. However, the data are limited regarding the use of NKF for primary biliary cannulation, especially when performed by beginners.

### AIM

To assess the effectiveness and safety of primary NKF for biliary cannulation, and the role of the endoscopist's expertise level (beginner *vs* expert).

### METHODS

We retrospectively evaluated the records of 542 patients with naïve prominent bulging papilla and no history of pancreatitis, who underwent bile duct cannulation at a tertiary referral center. The patients were categorized according to the endoscopist's expertise level and the technique used for bile duct cannulation. We assessed the rates of successful cannulation and adverse events.

### RESULTS

The baseline characteristics did not differ between the experienced and less-experienced endoscopists. The incidence rate of post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis (PEP) was significantly affected by the endoscopist's expertise level in patients who received conventional cannulation with sphincterotomy (8.9% *vs* 3.4% for beginner *vs* expert,  $P = 0.039$ ), but not in those who received NKF. In the multivariable analysis, a lower expertise level of the biliary endoscopist ( $P = 0.037$ ) and longer total procedure

**Informed consent statement:**

Signed informed consent forms were waived by the Institutional Review Board of the Pusan National University.

**Conflict-of-interest statement:**

Authors declare no conflict of interests for this article.

**Data sharing statement:** No additional data are available.

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**Manuscript source:** Unsolicited manuscript

**Specialty type:** Medicine, research and experimental

**Country/Territory of origin:** South Korea

**Peer-review report's scientific quality classification**

Grade A (Excellent): 0  
Grade B (Very good): 0  
Grade C (Good): C, C  
Grade D (Fair): 0  
Grade E (Poor): 0

**Received:** March 8, 2021

**Peer-review started:** March 8, 2021

**First decision:** March 27, 2021

**Revised:** April 5, 2021

**Accepted:** April 20, 2021

**Article in press:** April 20, 2021

**Published online:** June 16, 2021

**P-Reviewer:** Matsubara S

**S-Editor:** Gao CC

**L-Editor:** A

**P-Editor:** Li JH

time ( $P = 0.026$ ) were significant risk factor of PEP in patients who received conventional cannulation with sphincterotomy but only total procedure time ( $P = 0.004$ ) was significant risk factor of PEP in those who received NKF.

**CONCLUSION**

Primary NKF was effective and safe in patients with prominent and bulging ampulla, even when performed by less-experienced endoscopist. We need to confirm which level of endoscopist's experience is needed for primary NKF through prospective randomized study.

**Key Words:** Needle-knife fistulotomy; Primary biliary cannulation; Endoscopic retrograde cholangiopancreatography; Expertise levels; Pancreatitis

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**Core Tip:** Needle-knife fistulotomy (NKF) is used as a rescue technique for difficult cannulation. However, the data are limited regarding the use of NKF for primary biliary cannulation, especially when performed by beginners. Our retrospective study aims to assess the effectiveness and safety of primary NKF for biliary cannulation, and the role of the endoscopist's expertise. The incidence rate of post-endoscopic retrograde cholangiopancreatography pancreatitis was significantly affected by the endoscopist's expertise level in patients who received conventional cannulation with sphincterotomy, but not in those who received NKF. Primary NKF may be effective and safe in achieving ductal access in patients with naïve papilla, regardless of experience.

**Citation:** Han SY, Baek DH, Kim DU, Park CJ, Park YJ, Lee MW, Song GA. Primary needle-knife fistulotomy for preventing post-endoscopic retrograde cholangiopancreatography pancreatitis: Importance of the endoscopist's expertise level. *World J Clin Cases* 2021; 9(17): 4166-4177

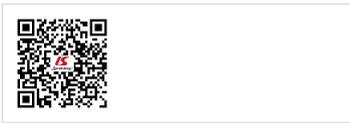
**URL:** <https://www.wjgnet.com/2307-8960/full/v9/i17/4166.htm>

**DOI:** <https://dx.doi.org/10.12998/wjcc.v9.i17.4166>

**INTRODUCTION**

Needle-knife fistulotomy (NKF) is used as a rescue technique when cannulation is difficult[1]. Many studies have reported the effectiveness and safety of early precut NKF for preventing post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis (PEP). In particular, precut NKF was reported to be associated with a higher rate of successful cannulation and lower incidence of PEP than conventional cannulation techniques[2-6]. Recently, randomized controlled trial study on NKF has been published, proved the safety and efficacy of primary NKF in high-risk cohort of PEP[7]. Despite these encouraging reports, NKF has not been adopted as a primary cannulation technique because most endoscopists believe that a high level of experience is required in order to achieve a sufficiently high rate of successful cannulation and an acceptable rate of adverse events with a use of primary NKF in patients with naïve papilla. Several previous studies on the effectiveness and safety of early NKF reported that NKF procedures performed by less experienced or experienced endoscopists provided comparable rates of adverse events[8,9]. However, there are no published data regarding the level of expertise that is needed for achieving the effectiveness and safety of NKF for primary biliary cannulation.

It is of utmost importance to minimize the risk of PEP, which is difficult to control and potentially lethal even in cases handled by expert biliary endoscopists. Other life-threatening adverse events related to NKF, such as perforation and bleeding, have become relatively manageable due to the continuous developments in instrumentation (especially covered metallic stent, endoclips and absorbable hemostatic powder) and radiologic interventions (*e.g.*, angiographic embolization). However, there are only few study about that the safety of primary NKF for achieving bile duct access in patients with naïve papilla[10]. Furthermore, it is necessary to compare how many manageable adverse events occur between beginners and experts when performed NKF *vs* conven-



tional cannulation for primary biliary cannulation in patients with naïve papilla.

We aimed to assess the effectiveness and safety of primary NKF according to expertise level of endoscopists in patients with naïve papilla undergoing bile duct cannulation.

## MATERIALS AND METHODS

### *Patient selection and stratification*

Among the patients who received ERCP at our hospital, we identified 568 patients who were managed by an expert (over 3000 ERCP procedures) as well as 693 patients managed by a beginner (over 500 ERCP observations with an assistance and then over 300 ERCP procedures with supervision of an expert) between April 2014 and March 2016. The beginner was trained by the expert for a year prior to dispatch. We retrospectively reviewed the medical records of candidates and excluded patients who underwent previous ERCP or presented with biliary pancreatitis at admission. Patients who did not change to altered method even in difficult cannulation were also excluded. And we also excluded patients with non-prominent ampulla, because, they were not suitable for NKF. Finally, 542 patients with naïve papilla (expert, 237; beginner, 305) were enrolled in this study to analyze the effectiveness and safety of primary biliary cannulation, as well as to clarify the role of the endoscopist's expertise level (Figure 1). This study was conducted in accordance with the ethical guidelines of the Declaration of Helsinki (revised in 2013) and the study protocol was approved by the institutional review board of our Hospital (H-1805-023-067).

The patients were stratified according to the endoscopist's expertise level (beginner *vs* expert) and according to the primary cannulation technique employed (conventional cannulation *vs* NKF). Among the 237 patients managed by the expert, 147 underwent conventional cannulation using a guidewire-assisted technique, while 90 underwent NKF. Among the 305 patients managed by the beginner, 228 received conventional cannulation and 77 received NKF.

### *Procedures*

Conventional cannulation was conducted by using a guidewire-assisted technique with various guidewires (Jagwire from Boston scientific, MA, United States; Terumo from Olympus Co., Tokyo, Japan; and Visiglide from Olympus Co.). The catheter impacts in the papilla before attempting to advance the guidewire for cannulation. If the ampullary orifice was probed > 5 times or > 5 min had passed without achieving biliary access; more than one unintended pancreatic duct cannulation or opacification, we switched to another technique such as pancreatic guidewire-assisted biliary cannulation, pancreatic duct stent placement followed by precut sphincterotomy, or NKF. However, as the study was retrospective in design, the time taken to change to the rescue method was not exactly equal in all cases but was constant. Prophylactic pancreatic stenting was attempted when there was pancreatic duct contrast injection or over twice of pancreatic duct cannulations. Sphincterotomy was performed in all patients. Patients who were performed ERCP without sphincterotomy were not enrolled. In precut sphincterotomy, the needle-knife (Boston scientific, MA, United States) was initially placed at the orifice of the ampulla and the incision was made in an upward direction between the 11 and 12 o'clock positions. In precut NKF, the orifice of the ampulla of Vater remained without contact. The needle-knife as used to initially make a mucosal incision at the maximal bulging point of the papillary roof of the ampulla and then cut the oral side of papillary muscle at the 11-12 o'clock position[12] (Figure 2). In order to reduce the risk of perforation, the needle was kept short with minimal incision of whitish papillary muscles until the red mucosa of bile duct or bile was visualized. After biliary cannulations, additional sphincterotomy was not required for biliary stenting after biopsy or small stone removal, but additional sphincterotomy or endoscopic balloon dilatation was required to remove large stones.

### *Outcome measures*

We evaluated the initial and final cannulation success rates, cannulation time, total procedure time, and ERCP-related adverse events in each group (expert *vs* beginner; conventional cannulation with sphincterotomy *vs* NKF). The effectiveness and safety of NKF for primary biliary cannulation were established based on the outcomes noted in patients managed by the expert.



Procedural success was defined as selective cannulation in a single ERCP session. Cannulation time was calculated from the first probing of the ampullary orifice until selective bile duct cannulation. Total procedure time was calculated from the first probing of the ampullary orifice until the end of the procedure. Our institution has some rules that during the ERCP procedure, we must capture the photo (confirmation of ampulla, after succeeding of cannulation, end of procedure). These pictures can be used to estimate cannulation time and total procedure time.

We monitored for PEP by measuring serum amylase and lipase levels before and at 24 h after the procedure. Abdominal radiography was performed to check for perforation 4 h after the procedure in patients with abdominal pain after procedure. ERCP-related adverse events were defined as bleeding, PEP, and perforation, the severity of which was classified according to the Cotton criteria[11]. Hyperamylasemia was defined as high amylase levels without abdominal pain or signs of pancreatitis.

Non-prominent ampulla was defined as a small papilla without marked oral protrusion. And bulging of the ampulla was defined as a marked swelling from the bulge in the papillary roof to the oral ridge of the duodenal wall[12]. The information that was including procedure method, outcome parameter were retrospectively reviewed by a third biliary endoscopist.

### Statistical analysis

Statistical analysis was performed using IBM SPSS statistical software, version 21.0 (IBM Corp, Armonk, NY, United States). Baseline characteristics, procedural characteristics, and outcomes were compared between the groups that were defined based on the endoscopist's expertise level (expert *vs* beginner) and cannulation technique (conventional cannulation *vs* NKF). Univariate and multivariate analyses were conducted to identify the predictors of PEP. In multivariable analysis, logistic regression analysis was used to identify factors predicting PEP. Factors with *P* values < 0.2 on univariate analysis were included in multivariate analysis, along with clinically meaningful variables. Descriptive statistics are presented as frequencies and percentages for categorical variables and as means  $\pm$  SD for continuous variables. Two-sample comparisons were performed using the  $\chi^2$  test or Fisher's exact test. For proportions, Student's *t*-tests were used for normally distributed variables. A two-sided *P* value of < 0.05 was used to indicate statistical significance in all analyses.

## RESULTS

### Baseline characteristics

The demographic and clinical characteristics of the 542 patients included in the study are summarized in Table 1 (ampulla configurations[12] were shown in Figure 3). The two groups defined based on the endoscopist's expertise level did not differ significantly in terms of age, sex, ampullary morphology (*e.g.*, periampullary diverticulum, ampulla configurations), or disease entity. The mean age of the patients was  $67.8 \pm 13.4$  years, with a male predominance (56.6%). With respect to the ampullary morphology, 163 patients (30.1%) had a periampullary diverticulum. In total, 200 patients underwent ERCP due to malignant biliary obstruction (36.9%), of them underwent biliary drainage. Among the patients managed by the expert, those who underwent NKF were younger and frequently with periampullary diverticulum. ( $66.6 \pm 14.2$  years *vs*  $68.7 \pm 12.6$  years, *P* = 0.070; 34.2% *vs* 26.9%, *P* = 0.067; respectively). And Table 2 shows baseline characteristics in patient according to expertise level and cannulations methods. There were no significantly difference each group, except ratio of patients with periampullary diverticulum between expertized levels in primary NKF group (32.2% *vs* 18.2%, *P* = 0.039).

### Relationship between expertise level and outcomes of different techniques

The results of the comparison between the groups defined according to the endoscopist's expertise level are summarized in Table 3. Among the patients who underwent NKF, the expertise level was not associated with any significant differences in outcomes, including PEP incidence rate, procedural success rate, except cannulation time (4.2 min *vs* 5.5 min, *P*=0.010). However, among patients who underwent conventional cannulation with sphincterotomy, the PEP rate was significantly lower in patients managed by the expert than in those managed by the beginner (3.4% *vs* 8.9%, *P* = 0.039). Generally, the incidence rate of adverse events (PEP, hyperamylasemia, bleeding and perforation) was lower among patients managed by the expert.

**Table 1** Baseline characteristics between the experienced and less experienced endoscopists

	Total, n = 542, (%)	Experienced, n = 237, (%)	Less-experienced, n = 305, (%)	P value
Age (yr)	67.8 ± 13.4	66.6 ± 14.2	68.7 ± 12.6	0.070
Male (%)	307 (56.6)	129 (54.4)	178 (58.4)	0.361
Periampullary diverticulum	163 (30.1)	81 (34.2)	82 (26.9)	0.067
Ampulla configurations				0.224
Non-prominent	0 (0)	0 (0)	0 (0)	
Prominent	455 (83.9)	205 (86.5)	250 (82.0)	
Bulging	65 (12.0)	25 (10.5)	0 (13.1)	
Distorted	15 (2.8)	3 (1.3)	12 (3.9)	
Hook-nose shape	7 (1.3)	4 (1.7)	3 (1.0)	
Malignancy	200 (36.9)	91 (38.4)	109 (35.7)	0.525
Benign diseases	342 (63.1)	146 (61.6)	196 (64.3)	

**Table 2** Baseline characteristics between the conventional technique with sphincterotomy and needle-knife fistulotomy groups

	Conventional technique with sphincterotomy, n = 375, (%)			Primary NKF less-experienced, n = 167, (%)		
	Experienced, n = 147, (%)	Less-experienced, n = 228, (%)	P value	Experienced, n = 90, (%)	Less-experienced, n = 77, (%)	P value
Age (yr)	68.8 ± 12.9	68.7 ± 12.1	0.964	63.1 ± 15.6	68.7 ± 14.3	
Male	75 (51.0)	130 (57.0)	0.256	54 (60.0)	48 (62.3)	0.759
Periampullary diverticulum	52 (35.4)	68 (29.8)	0.262	29 (32.2)	14 (18.2)	0.039 <sup>a</sup>
Ampulla configurations			0.625			0.265
Non-prominent	0 (0)	0 (0)		0 (0)	0 (0)	
Prominent	136 (92.5)	205 (89.9)		69 (76.7)	54 (70.1)	
Bulging	8 (5.4)	19 (8.3)		17 (18.9)	16 (20.8)	
Distorted	2 (1.4)	3 (1.3)		1 (1.1)	5 (6.50)	
Hook-nose shape	1 (0.7)	1 (0.4)		3 (3.3)	2 (2.6)	
Malignancy	58 (39.5)	80 (35.1)	0.393	33 (36.7)	29 (37.7)	0.895
Benign diseases	89 (60.5)	148 (64.9)		57 (63.3)	48 (62.3)	

<sup>a</sup>P < 0.05.

NKF: Needle-knife fistulotomy.

**Clinical factors associated with PEP incidence**

Among the 542 patients with naïve papilla who underwent ERCP and presented with no pancreatitis at admission, a total of 29 developed PEP. In the univariate analysis, the endoscopist's expertise level and total procedure time were significantly associated with PEP incidence in patients who underwent conventional cannulation, whereas the cannulation time and total procedure time were significantly associated with PEP incidence in patients who underwent NKF. In the multivariate analysis, the endoscopist's expertise level ( $P = 0.037$ ) and total procedure time ( $P = 0.026$ ) were the independent predictor significantly associated with PEP incidence in patients who underwent conventional cannulation, whereas a longer total procedure time ( $P = 0.004$ ) was associated with PEP occurrence in patients who underwent NKF (Table 4).

**Table 3** Compared results between the experienced and less-experienced endoscopists in each primary cannulation technique

	Conventional technique with sphincterotomy			NKF		
	Experienced ( <i>n</i> = 147) (%)	Less-experienced ( <i>n</i> = 228) (%)	<i>P</i> value	Experienced ( <i>n</i> = 90) (%)	Less-experienced ( <i>n</i> = 77) (%)	<i>P</i> value
Success rate	361/375 (96.3)			161/167 (96.4)		0.936
	144/147 (98.0)	217/228 (95.2)	0.166	88/90 (97.8)	73/77 (94.8)	0.306
Cannulation time (min)	4.8 ± 3.5			4.8 ± 3.2		0.951
	5.1 ± 3.5	4.6 ± 3.6	0.200	4.2 ± 3.1	5.5 ± 3.1	0.010 <sup>a</sup>
Total procedure time (min)	17.2 ± 9.2			15.2 ± 8.2		0.019 <sup>a</sup>
	17.6 ± 9.6	16.9 ± 8.9	0.490	14.9 ± 8.4	15.6 ± 8.0	0.598
Post-ERCP pancreatitis	25 (6.7)			4 (2.4)		0.040 <sup>a</sup>
	5 (3.4)	20 (8.9)	0.039 <sup>a</sup>	1 (1.1)	3 (3.9)	0.243
Hyperamylasemia	52 (14.0)			13 (7.8)		0.041 <sup>a</sup>
	15 (10.2)	37 (16.4)	0.090	5 (5.6)	9 (11.7)	0.156
Bleeding	10 (2.7)			6 (3.6)		0.568
	2 (1.4)	8 (3.6)	0.202	2 (2.2)	4 (5.2)	0.306
Perforation	1 (0.3)			0 (0)		0.505
	0 (0)	1 (0.4)	0.423	0 (0)	0 (0)	NA

<sup>a</sup>*P* < 0.05.

NKF: Needle-knife fistulotomy; ERCP: Endoscopic retrograde cholangiopancreatography; NA: Not available.

## DISCUSSION

Early NKF has been confirmed as a highly successful rescue procedure in cases with difficult bile duct access, being associated with low PEP incidence[9,13-15]. Furthermore, it has been observed that the incidence rates of severe bleeding and perforation are similar between NKF and conventional cannulation with sphincterotomy. However, primary NKF continues to be considered a high-risk procedure in patients with naïve papilla.

In our study, the incidence rate of PEP was significantly higher in patients managed by the beginner than in those managed by the expert endoscopist, although there was no significant difference in the final rate of successful cannulation (Supplementary Table 1). However, the endoscopist's expertise level did not influence the PEP rate in patients who received NKF. Few studies have been published regarding the impact of the endoscopist's experience level on NKF outcomes. Lee *et al*[9] reported that an endoscopist with experience of > 100 ERCPs, including > 10 precut procedures, can perform NKF efficiently and safely. In our study, the beginner had observed and assisted > 500 ERCP procedures, and then performed > 300 ERCP procedures with the supervision of an expert. Based on the European guidelines regarding papillary cannulation[16], NKF should be performed only by endoscopists who achieve successful biliary cannulation in > 80% of cases. A single-operator learning curve analysis for biliary cannulation suggested that procedural success rates of > 80% can be obtained after > 350 supervised ERCP procedures[17]. Taken together, these previous findings and our present results suggest that it is acceptable to perform NKF after > 500 ERCP observations with an assistance and then > 300 ERCP procedures with the supervision of an expert.

In our study, the incidence rates of PEP (8.3% *vs* 2.4%, *P* = 0.010) and hyperamylasemia (15.6% *vs* 8.4%, *P* = 0.023) was significantly lower in patients who received NKF than in those who received conventional cannulation, even though the rates of other serious adverse events did not differ. A recent study reported that in comparison to delayed NKF, early NKF was associated with a significantly lower PEP incidence[1]. When cannulation is difficult, PEP probably occurs due to injury to the ductal orifice rather than due to the delayed NKF itself[18], thus suggesting that early NKF helps minimize interaction with the pancreatic duct. However, the same recent study[1] concluded that primary precut NKF is not recommended in ERCP practice

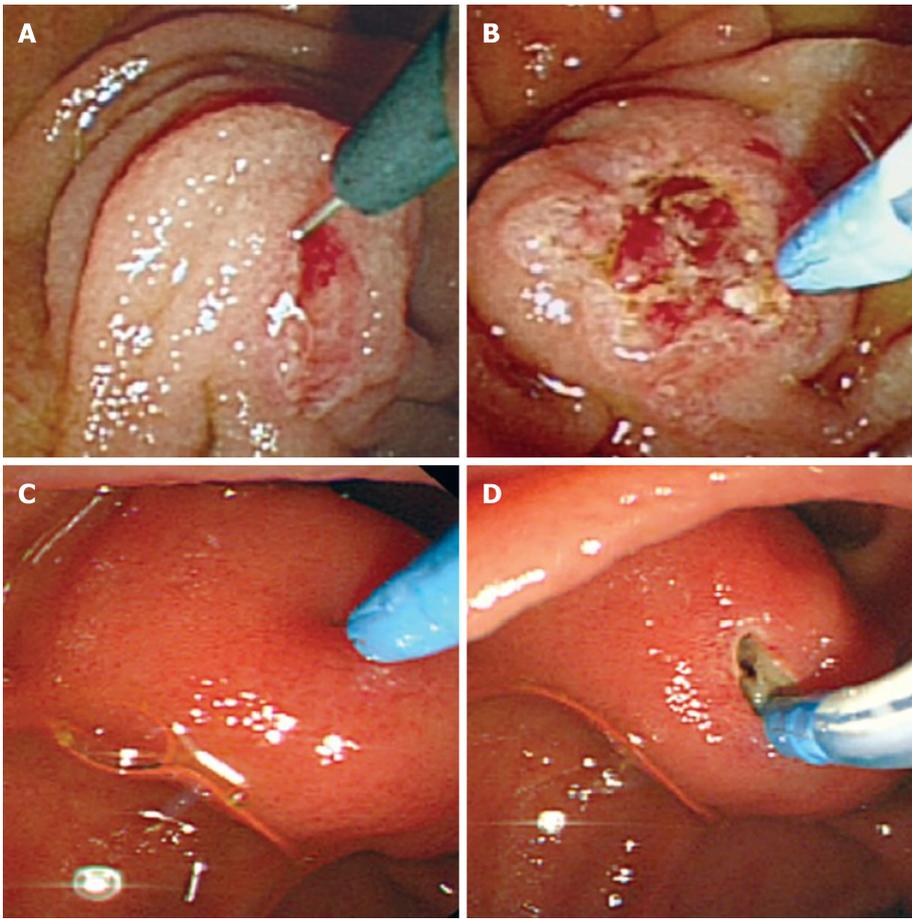
**Table 4 Clinical factors associated with post endoscopic retrograde cholangiopancreatography pancreatitis in conventional technique with sphincterotomy and needle-knife fistulotomy group**

	Conventional technique with sphincterotomy						NKF					
	Total	With PEP	Without PEP	P value		Odd ratio (95%CI)	Total	With PEP	Without PEP	P value		Odd ratio (95%CI)
	n = 375, (%)	n = 25, (%)	n = 350, (%)	Uni-	Multi-		n = 167, (%)	n = 4, (%)	n = 163, (%)	Uni-	Multi-	
Age (yr)	68.7 ± 12.4	65.6 ± 12.5	69.0 ± 12.4	0.194	0.126	0.98(0.94-1.01)	65.7 ± 15.3	69.8 ± 11.9	65.6 ± 15.3	0.593	-	
Male (%)	205 (54.7)	12 (48.0)	193 (55.1)	0.490			102 (61.1)	2 (50.0)	100 (61.3)	0.648	-	
Periampullary diverticulum	120 (32.0)	8 (32.0)	112 (32.0)	0.999			43 (25.7)	1 (25.0)	42 (25.8)	0.973	-	
Malignancy	138 (36.8)	9 (36.0)	129 (36.9)	0.932			62 (37.1)	3 (75.0)	59 (36.2)	0.114	0.165	4.74(0.41-54.8)
Benign diseases	237 (63.2)	16 (64.0)	221 (63.1)	-			105 (62.9)	1 (25.0)	104 (63.8)	-	-	
Less-experienced endoscopist	228 (60.8)	20 (80.0)	208 (59.4)	0.044 <sup>a</sup>	0.037 <sup>a</sup>	2.94(1.07-8.10)	77 (46.1)	3 (75.0)	74 (45.4)	0.243	0.110	6.40 (0.45-90.6)
Pancreatic duct stent	72 (19.2)	4 (16.0)	68 (19.4)	0.675			0 (0.0)	0 (0.0)	0 (0.0)	-	-	
Cannulation time (min)	4.8 ± 3.5	5.3 ± 3.5	4.7 ± 3.5	0.431			4.8 ± 3.2	8.8 ± 1.7	4.7 ± 3.1	0.010 <sup>a</sup>	0.945	0.99 (0.75-1.31)
Total procedure time (min)	17.2 ± 9.2	21.0 ± 8.8	16.9 ± 9.2	0.031 <sup>a</sup>	0.026 <sup>a</sup>	1.04 (1.01-1.08)	15.2 ± 8.2	30.0 ± 9.3	14.8 ± 7.9	0.000 <sup>a</sup>	0.004 <sup>a</sup>	1.14 (1.04-1.25)

<sup>a</sup>P < 0.05.

NKF: Needle-knife fistulotomy; PEP: Post-endoscopic retrograde cholangiopancreatography pancreatitis; CI: Confidence interval.

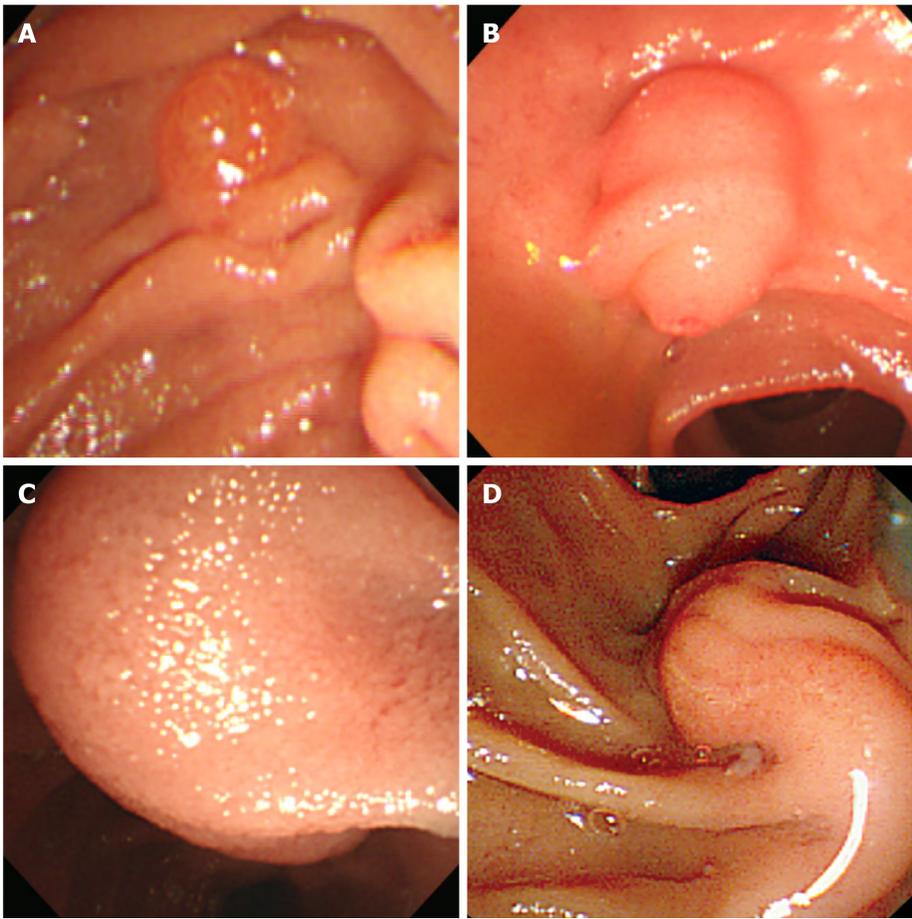
because conventional cannulation is highly successful in accessing the common bile duct. NKF has been criticized as potentially unsafe to be used as a primary cannulation technique. Nevertheless, we could not determine any specific situation in which PEP might occur. Many studies have confirmed that NKF is as safe as conventional cannulation techniques[9,13-15]. Moreover, NKF helps minimize interaction with the pancreatic duct, whereas conventional techniques may cause PEP due to pancreatic duct irritation. A previous study reported that primary NKF was not associated with PEP[8]. However, when a deep incision is made through the needle, the pancreatic duct may be damaged. Moreover, some patients have long common channel of pancreatico-biliary junction that are covered with ampullary muscle. In such cases, the pancreatic duct may be damaged by primary NKF. Therefore, PEP may occur in some patients despite undergoing primary NKF. In case of pancreatic duct cannulation *via* primary NKF, a pancreatic duct stent was not used, which may be a potential cause of PEP in primary NKF. However, the PEP rate was significantly lower in NKF despite the level of the endoscopist's expertise. Finally, we did not find any other serious adverse events in patients who received NKF. Therefore, we recommend primary NKF as a good alternative technique for preventing PEP occurrence.



**Figure 2 Comparison of precut sphincterotomy and needle-knife fistulotomy.** A: Precut sphincterotomy. The needle is placed at the orifice of the ampulla; B: Precut sphincterotomy. Precutting was performed with slight upward tension; C: Needle knife fistulotomy. Mucosal incision at the maximal bulging point of the papillary roof of the ampulla; D: Needle knife fistulotomy. Incision at the oral side of the bile duct at the 11-12 o'clock position relative to the ampulla of Vater.

We had no standard criteria for the selection of the cannulation technique. However, the morphology of the infundibulum was an important factor in the decision to try primary NKF. Specifically, if the infundibulum is large and covers the papilla, it is difficult to approach the ampullary orifice, and thus, NKF is expected to provide better results because it facilitates access to the bile duct at a site distinct from the ampullary orifice. The expert frequently performed primary NKF procedures in patients who had large infundibula. If the patients had a small ampulla without an infundibulum, primary NKF was not performed. If the infundibulum extended beyond the field of view, a catheter was used to remove the air from the duodenum and probe the duodenal wall in order to evaluate the extent of the infundibulum. If a retracted ampulla or small ampulla was identified, conventional methods were used instead of NKF. In such ampulla, NKF is not considered suitable due to complications such as perforation. Primary NKF was preferred in patients with PEP risk factors such as non-dilated bile duct (< 9 mm)[18], low serum levels of total bilirubin, and young age, which is why the age was lower in patients who received NKF than in those who received conventional cannulation.

Our study has several limitations. First, this was a retrospective study, and the effect of selection bias could not be excluded. Second, the number of NKF procedures performed by the beginner was not uniformly distributed along the study period. Moreover, the PEP incidence was higher in the first half of the study period, when the beginner performed mostly conventional cannulation with sphincterotomy. Third, there was no definitive criteria for primary NKF. On the other hand, the present study enrolled a relatively large cohort of patients who received primary NKF. Furthermore, to the best of our knowledge, this is the first study to analyze the outcomes of primary NKF according to the endoscopist's expertise level.



**Figure 3 Ampulla configurations.** A: Non-prominent; B: Bulging; C: Hook-shape, ampulla of Vater orifice was not shown due to huge bulging; D: Distorted.

## CONCLUSION

Our findings suggest that PEP risk is not associated with the endoscopist's expertise level in cases of primary NKF. Therefore, we recommend primary NKF as an effective and safe method for achieving ductal access in patients with prominent and bulging infundibulum, and may be especially useful for beginners because, compared to conventional cannulation with sphincterotomy, NKF is less likely to induce PEP due to insufficient expertise of the endoscopist. Further prospective studies are warranted to validate our present results.

## ARTICLE HIGHLIGHTS

### **Research background**

Needle-knife fistulotomy (NKF) is used as a rescue technique for difficult cannulation.

### **Research motivation**

However, the data are limited regarding the use of NKF for primary biliary cannulation, especially when performed by beginners.

### **Research objectives**

To assess the effectiveness and safety of primary NKF for biliary cannulation, and the role of the endoscopist's expertise.

### **Research methods**

To evaluate the records of 542 patients with naïve prominent bulging papilla and no history of pancreatitis, who underwent bile duct cannulation at a tertiary referral center.

**Research results**

The incidence rate of post-endoscopic retrograde cholangiopancreatography pancreatitis was significantly affected by the endoscopist's expertise level in patients who received conventional cannulation with sphincterotomy, but not in those who received NKF.

**Research conclusions**

Primary NKF may be effective and safe in achieving ductal access in patients with naïve papilla, regardless of experience.

**Research perspectives**

Primary NKF as an effective and safe method for achieving ductal access in patients with prominent and bulging infundibulum, and may be especially useful for beginners.

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