



Primary needle-knife fistulotomy versus rescue precut: a systematic review and meta-analysis of outcomes

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Background and Aims: Post-ERCP pancreatitis (PEP) is encountered especially after difficult and prolonged standard biliary cannulation (SBC). Access sphincterotomy techniques such as needle-knife fistulotomy (NKF) aid in biliary cannulation but carry risks of PEP, bleeding, and perforation. We conducted a systematic review and meta-analysis to assess the safety and success of primary NKF (p-NKF; before attempted cannulation) compared with rescue precut (precut techniques used if SBC failed).

Methods: We searched multiple databases through December 2021 for studies comparing outcomes of p-NKF versus rescue precut. The primary outcome was risk of PEP in both groups, and secondary outcomes were rates of adverse events, rates of successful biliary cannulation, and time required for biliary cannulation.

Results: Five studies, including 2 randomized controlled trials, with 1375 patients were included in the final analysis, with 541 patients in the p-NKF group and 834 in the control group. Patients undergoing NKF had an overall lower risk of PEP (odds ratio [OR], .33; 95% confidence interval [CI], .17-.66; $I^2 = 0\%$) and asymptomatic hyperamylasemia (OR, .58; 95% CI, .36-.96; $I^2 = 0\%$) compared with control subjects. The pooled rate of PEP with NKF was 1.85% (95% CI, .71-2.98), and the pooled rate of successful initial cannulation was 94.7% (95% CI, 92.7-96.7; $I^2 = 72\%$) in the p-NKF group. The time required for biliary cannulation was comparable between the 2 groups (difference in means, -2.48 minutes; 95% CI, -7.70 to 2.74; $I^2 = 99\%$). In terms of adverse events, there was no difference between the 2 groups for bleeding (OR, 1.19; 95% CI, .53-2.69; $I^2 = 0\%$), cholangitis (OR, .79; 95% CI, .23-2.79; $I^2 = 0\%$), or perforation (OR, .90; 95% CI, .17-4.75; $I^2 = 0\%$).

Conclusions: Although our study was limited to data from expert advanced endoscopists, our analysis showed that performing p-NKF compared with rescue access sphincterotomy was associated with a lower risk of PEP, with similar successful biliary cannulation rates, cannulation times, and overall safety profile. (iGIE 2023;2:44-51.)

(footnotes appear on last page of article)

ERCP is an invaluable procedure performed for a wide range of endoscopic pancreatobiliary interventions since 1968.¹ Deep cannulation of the common bile duct is a crucial step essential for successful biliary interventions, which make up most ERCP procedures. Standard biliary cannulation (SBC) can be challenging; even in the hands of expert endoscopists, it may fail in as many as 5% to 20% of cases.^{2,3} Additionally, repeated cannulation attempts can lead to periampullary trauma, thereby increasing risk of post-ERCP pancreatitis (PEP).⁴ Historically, several studies have also identified repeated failed biliary cannulation attempts as a risk factor for PEP.^{5,6} To allow for early successful biliary access and thereby reduce the risk of PEP, rescue precut sphincterotomy techniques such as needle-knife sphincterotomy (NKS) or needle-

knife fistulotomy (NKF) can be performed to facilitate bile duct cannulation.⁷

Precut sphincterotomy is a technique used when attempts at gaining biliary access with the aid of standard catheters, cannulotomes, and guidewires have failed.⁸ Traditionally, the use of this technique was restricted as a salvage procedure because it has been identified as a risk factor for PEP.⁹ Prior studies have concluded that in experienced hands, early implementation of precut and persistent cannulation attempts have similar overall cannulation rates. Although early precut implementation reduces PEP risk, the overall adverse event rate is no different when compared with standard cannulation techniques.¹⁰ A meta-analysis of 7 randomized controlled trials (RCTs) also concluded that when compared with persistent cannulation

attempts, early precut sphincterotomy itself does not increase the risk of PEP in patients with difficult biliary access. Furthermore, performing NKF can significantly decrease the risk of PEP when performed by experienced endoscopists.¹¹

The potential benefits of obtaining biliary access with early precut has prompted investigators to evaluate outcomes of NKF or NKS even before attempting biliary cannulation. We conducted a systematic review and meta-analysis to investigate outcomes after primary NKF (p-NKF) as compared with precut techniques performed if SBC failed (control).

METHODS

Search strategy

The published English literature was searched by an experienced librarian and 2 other authors (J.B. and S.C.) for studies that reported outcomes after a primary precut and/or access sphincterotomy was performed during an ERCP. A comprehensive search of several databases from inception to November 2021 was performed. The databases included PubMed, Ovid Medline, CINAHL, Cochrane, Google Scholar, and [ClinicalTrials.gov](https://www.clinicaltrials.gov) (including epub ahead of print, in-process & other non-indexed citations). A manual search for studies of interest was performed by 2 authors (J.B. and S.C.).

Search strategies were created using a combination of key words and standardized index terms. Key words included “precut,” “primary precut,” “needle knife fistulotomy,” “ERCP,” and “endoscopic retrograde cholangiopancreatography.” Results were limited to English language studies. Reference lists of evaluated studies were examined to identify other studies of interest.

Details of study selection are provided [Supplementary Figures 1 and 2](#) (available online at www.igiejournal.org). The full search strategy is available in Appendix 1 (available online at www.igiejournal.org). The Meta-analysis Of Observational Studies in Epidemiology checklist was followed and is provided in Appendix 2 (available online at www.igiejournal.org).¹²

Study selection

In this meta-analysis, we included all published RCTs and retrospective/prospective cohort studies that included ERCPs performed with p-NKF and compared them with those in which precut/access sphincterotomy was performed if SBC failed (control). Studies were included irrespective of inpatient or outpatient setting, follow-up time, geography, and whether they were published as full manuscripts or abstracts, as long as they provided the clinical outcomes data needed for the analysis. Unpublished data were not obtained. Exclusion criteria were studies in which primary NKS (as opposed to NKF) was performed, studies in the pediatric population (age <18 years), studies

without a control group, studies of prisoners, and studies not published in English.

Data abstraction and quality assessment

Data on study-related outcomes from individual studies were abstracted independently onto a standardized form by 2 authors (J.B. and S.C.). One author (S.C.) cross-verified the collected data for possible errors, and 3 authors (V.B., A.S., and L.Y.N.) did the quality scoring independently. The Newcastle-Ottawa scale was used to assess the quality of observational studies.¹³ This quality score consisted of 8 questions, the details of which are provided in Supplementary Table 1 (available online at www.igiejournal.org). The quality of evidence presented in the RCTs and risk of bias in all included studies was assessed using the Grading of Recommendations Assessment, Development and Evaluation methodology (Supplementary Table 2, available online at www.igiejournal.org).¹⁴

Outcomes assessed

All outcomes were assessed for the p-NKF group and control group (where rescue access sphincterotomy was performed if SBC failed). We calculated overall pooled rates for both groups separately and odds ratio (OR) to compare outcomes. The following outcomes were assessed. Primary outcomes were pooled ORs for PEP with p-NKF versus control and pooled rates and ORs for successful biliary cannulation with p-NKF versus control.

Secondary outcomes were pooled rates and ORs for adverse events (bleeding, perforation, asymptomatic hyperamylasemia, and cholangitis) with p-NKF versus control and pooled mean difference in time required for successful biliary cannulation with p-NKF versus control.

ERCP-related adverse events including PEP, bleeding, perforation, and cholangitis were defined according to the American Society for Gastrointestinal Endoscopy consensus criteria.^{15,16} The time required for cannulation was calculated as the time between initial contact with the ampulla until selective deep bile duct cannulation was achieved.

Statistical analysis

We used meta-analysis techniques to calculate the pooled estimates and 95% confidence intervals (CIs) for each outcome following the methods suggested by DerSimonian and Laird¹⁷ using the random-effects model.¹⁷ When the number of incidences of an outcome was zero in a study, a continuity correction of .5 was added to the number of incident cases before statistical analysis.¹⁸ The inverse variance method was used to estimate pooled ORs for all outcomes.¹⁹ Heterogeneity between studies was assessed by means of a χ^2 test and quantified with the I^2 statistic. Values of <40%, 30% to 60%, 50% to 90%, and >75% were suggestive of low, moderate, substantial, and considerable heterogeneity, respectively. A $P < .05$ was used a priori to define significance between the

TABLE 1. Study details and patient characteristics

Study	Year	Design and location	Indication for ERCP	Sample size		Mean age (standard deviation) or [range] (y)		Sex (M/F)	
				p-NKF	Control	p-NKF	Control	p-NKF	Control
Khatibian et al ²³	2008	RCT, Iran	Choledocholithiasis, SOD, cholangiocarcinoma, common bile duct parasites, periampullary tumors, primary sclerosing cholangitis	106	112	56.6 (17.9)	55.9 (17.2)	49/57	37/75
Furuya et al ²⁴	2018	RCT, Brazil	Choledocholithiasis	51	51	60.9 (18.1)	57.4 (19.3)	18/33	18/33
Jang et al ²²	2020	RCT, South Korea	Choledocholithiasis, SOD, benign and malignant biliary strictures	96	87	57.8 (14.8)	54.6 (17)	39/57	30/87
Canena et al ²⁵	2021	Retrospective, cohort, Portugal	Choledocholithiasis, malignant biliary strictures, leaks	121	209	71.3 [18-97]	75.2 [18-96]	59/62	88/121
Han et al ²⁶	2021	Retrospective, cohort, South Korea	Benign and malignant biliary obstruction	167	376	65.7 (15.3)	68.7 (12.4)	102/65	205/170

p-NKF, Primary needle-knife fistulotomy; RCT, randomized controlled trial; SOD, sphincter of Oddi dysfunction.

TABLE 2. Study outcomes

Study	Total no. of patients		Post-ERCP pancreatitis		Bleeding		Perforation		Cholangitis		Asymptomatic hyperamylasemia		Rates of successful cannulation	
	p-NKF	Control	p-NKF	Control	p-NKF	Control	p-NKF	Control	p-NKF	Control	p-NKF	Control	p-NKF	Control
Khatibian et al, ²³ 2008	106	112	2	3	0	0	1	0	0	0	—	—	88	100
Furuya et al, ²⁴ 2018	51	51	1	5	0	0	1	2	2	4	0	2	51	39
Jang et al, ²² 2020	96	87	0	8	3	1	0	0	3	2	13	15	96	87
Han et al, ²⁶ 2021	167	375	4	25	6	10	0	1	—	—	13	52	161	361
Canena et al, ²⁵ 2021	121	209	3	13	2	6	0	0	0	0	—	—	121	202

p-NKF, Primary needle-knife fistulotomy.

groups compared. All analyses were performed using Rev-Man version 5 software from the Cochrane collaboration (the Cochrane Collaboration, Copenhagen, Denmark).

RESULTS

Search results and population characteristics

From an initial pool of 104 studies, 59 obvious duplicates were removed, and 45 titles and 19 relevant abstracts were screened for eligibility. Full texts selected by manual search were added to this pool. Subsequently, 7 full-length articles were assessed out of which 2 were excluded because they reported on outcomes of NKS.^{20,21} Ulti-

mately, 5 studies with 1375 patients were included in the final analysis.²²⁻²⁶

All studies compared patients undergoing ERCP with p-NKF (p-NKF group, n = 541) and those in whom access sphincterotomy was performed if SBC failed (control group, n = 834). There were 645 men and 730 women in our analysis with a mean age range from 54.6 to 75.2 years. Further details on patient characteristics, etiology, and study outcomes are presented in [Tables 1 and 2](#).

Characteristics and quality of included studies

Three studies included were RCTs²²⁻²⁴ and 2 were retrospective cohort studies.^{25,26} Two studies originated from South Korea, 1 from Brazil, 1 from Iran, and 1 from

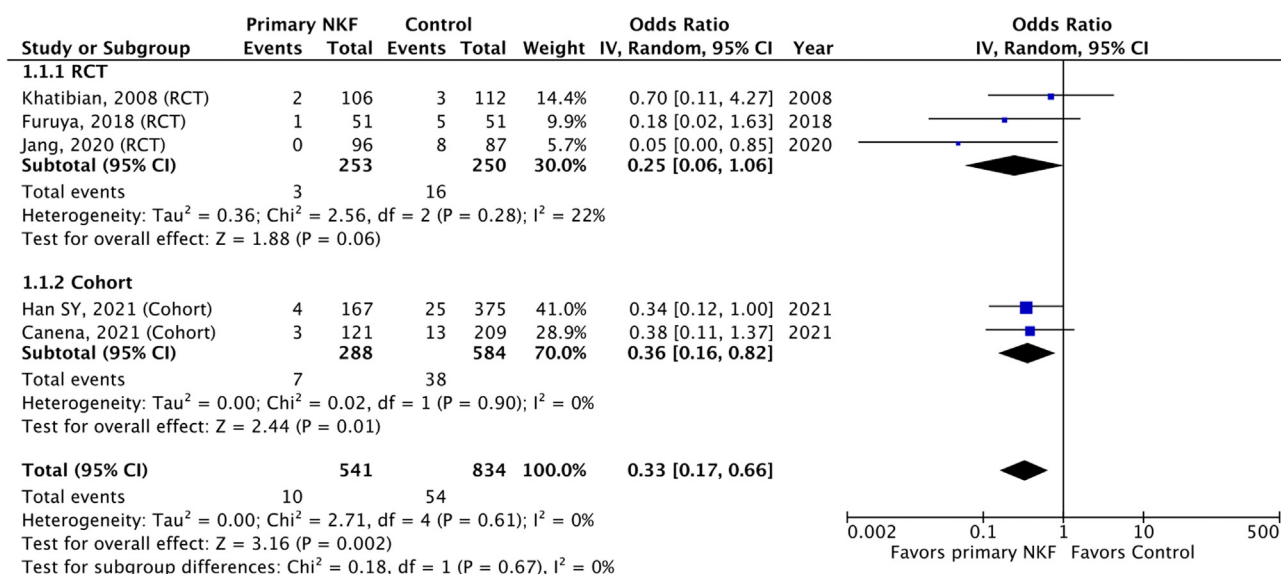


Figure 1. Preferred Reporting for Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram. NKF, needle-knife fistulotomy.

Portugal. All patients in the p-NKF group did not undergo attempts at biliary cannulation before performing NKF.

The definition of attempted biliary cannulation varied across the studies based on the number of cannulation attempts, number of pancreatic duct cannulations/injections, and duration of attempted cannulation. Four studies performed a precut after a maximum of 10 minutes of failed cannulation attempts,^{22,24,26} whereas 1 study allowed up to 15 minutes of attempted cannulation before performing a precut.²³ Three studies allowed for pancreatic duct stent placement along with a precut sphincterotomy in the control group.^{22,24,26} Only 1 study used prophylactic nonsteroidal anti-inflammatory agents as PEP prophylaxis in both the p-NKF and control groups alike.²⁵ Patients in the control groups of all studies underwent NKF if they had failed SBC.

Based on the Newcastle-Ottawa scale for study quality assessment, all included cohort studies were considered of high quality. Based on the Grading of Recommendations Assessment, Development and Evaluation quality assessment for RCTs, risk of bias was estimated as low with a high quality of evidence (grade A).

Meta-analysis outcomes

Primary outcomes were pooled rates, ORs, and the number needed to treat for and pooled rates for successful biliary cannulation. For pooled rates, ORs, and the number needed to treat for PEP, the pooled OR of developing PEP with p-NKF as compared with control was .33 (95% CI, .17-.66; $I^2 = 0\%$; $P = .002$ (Fig. 1). The pooled rates of PEP in the p-NKF and control groups were 1.85% (95% CI, .71-2.98) and 6.47% (95% CI, 4.80-8.14), respectively. The number needed to treat for p-NKF to prevent 1 event of PEP was 21.6. The pooled rate of successful initial

cannulation with p-NKF was 95.2% (95% CI, 93.4-97.01). The pooled ORs for successful biliary cannulation were comparable between the p-NKF group and control group (OR, 2.43; 95% CI, .71-8.27; $P = .16$; $I^2 = 72\%$) (Fig. 2).

Secondary outcomes were pooled rates and ORs for adverse events and mean difference in time required for initial biliary cannulation. The pooled incidence of bleeding was comparable between the 2 groups (OR, 1.19; 95% CI, .53-2.69; $I^2 = 0\%$; $P = .67$ (Fig. 3). Pooled rates of bleeding in the p-NKF and control groups were 2.03% (95% CI, .84-3.22) and 2.04% (95% CI, 1.08-2.99), respectively. There were 2 perforation events in the p-NKF group and 3 in the control group. Overall pooled incidence of perforation was comparable between the 2 groups (OR, .90; 95% CI, .17-4.75; $P = .91$; $I^2 = 0\%$) (Supplementary Fig. 3, available online at www.igiejournal.org).

The incidence of cholangitis was reported in 3 studies and occurred in 5 of 374 patients in the p-NKF group and 6 of 459 in the control group. The overall incidence of cholangitis was comparable in the 2 groups (OR, .79; 95% CI, .23-2.79; $P = .72$) (Supplementary Fig. 4, available online at www.igiejournal.org). Asymptomatic hyperamylasemia was reported in 3 studies. The overall incidence of asymptomatic hyperamylasemia was lower in the p-NKF group. The pooled OR of asymptomatic hyperamylasemia with p-NKF as compared with control was .58 (95% CI, .36-.96; $I^2 = 0\%$; $P = .03$) (Supplementary Fig. 5, available online at www.igiejournal.org).

The mean difference in the time required for biliary cannulation was 2.48 minutes less in the p-NKF group as compared with the control group. However, the difference was not statistically significant ($P = .35$, $I^2 = 99\%$).

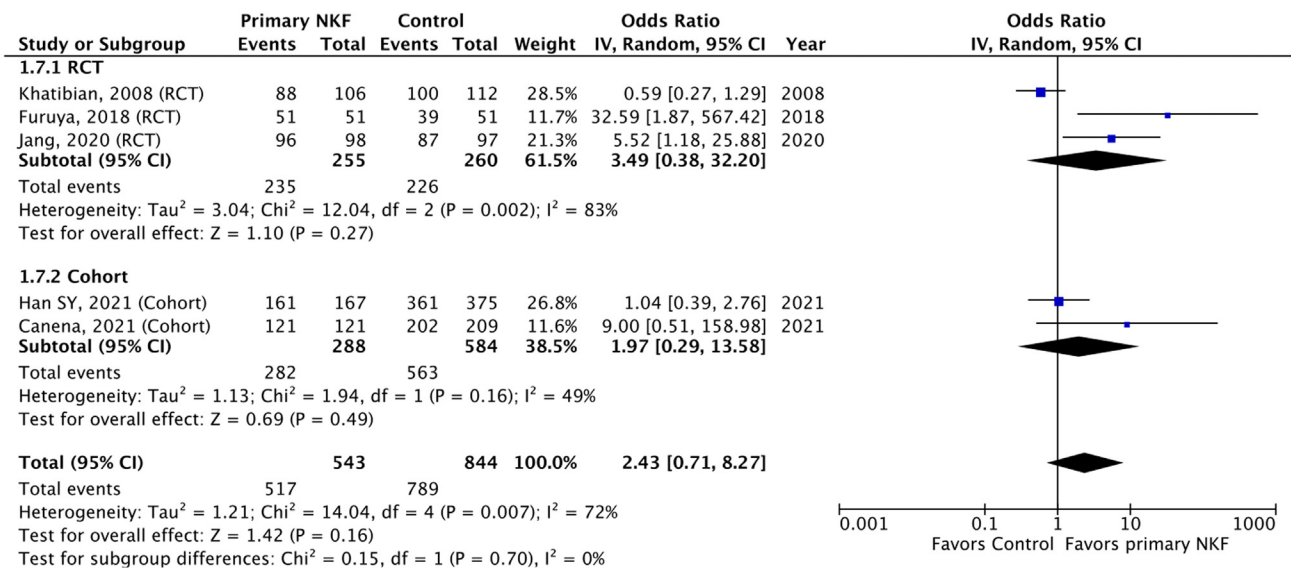


Figure 2. Forest plot, pooled odds ratio of successful initial biliary cannulation. *CI*, confidence intervals; *NKF*, needle-knife fistulotomy; *RCT*, randomized controlled trials.

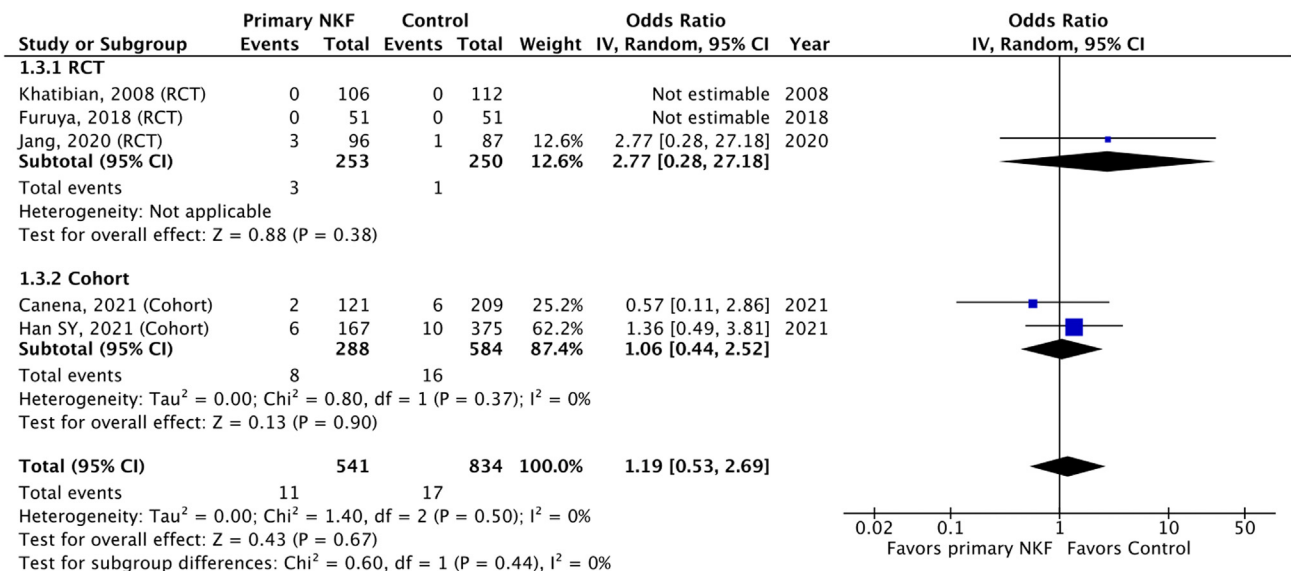


Figure 3. Forest plot, pooled odds ratio of bleeding. *CI*, confidence intervals; *NKF*, needle-knife fistulotomy; *RCT*, randomized controlled trials.

Validation of meta-analysis results

Sensitivity analysis. To assess whether any 1 study had a dominant effect on the meta-analysis, we excluded 1 study at a time and analyzed its effect on the main summary estimate. The pooled OR for asymptomatic hyperamylasemia lost statistical significance when the study by Han et al²⁶ was excluded (OR, .69; 95% CI, .32-1.50; $P = .35$). This finding could be explained by the fact that this outcome was reported only by 3 studies and was likely underpowered while running the sensitivity analysis. No significant difference was noted on the pooled-effects estimate for any other outcome with the exclusion of any 1 study.

Heterogeneity. We assessed dispersion of the calculated rates using CI and I^2 percentage values. The CI depicts the extent of dispersion, and I^2 denotes what proportion of the dispersion is true versus due to chance.²⁷ Overall low heterogeneity was noted among pooled ORs of PEP, bleeding, and perforation. Moderate to substantial heterogeneity was noted for pooled ORs of successful biliary cannulation and high heterogeneity was noted for mean difference in time taken for biliary cannulation.

Publication bias. Publication bias was not assessed with funnel plots because the number of studies included in the analysis was <10 .²⁸

DISCUSSION

This analysis shows that performing p-NKF was associated with a significantly lower incidence of PEP when compared with rescue access sphincterotomy performed if SBC techniques had failed (OR, .33; $P = .002$). We found that the pooled rate of PEP with p-NKF was 1.85%, which is significantly lower than previously reported in the literature.¹¹ In terms of safety outcomes, p-NKF had similar rates of bleeding, perforation, and cholangitis as compared with the control group. We found no significant difference in the ORs of successful cannulation or the time required for successful biliary cannulation between the 2 groups. It is possible that the lower incidence of PEP seen among patients undergoing p-NKF is the result of a lesser degree of manipulation of the periampullary region with less resultant trauma as compared with repeated biliary cannulation attempts followed by rescue access sphincterotomy.

Rescue access sphincterotomy techniques are useful interventions to gain access to the biliary tree, especially in cases of difficult biliary cannulation. However, their popularity has been limited because they have been associated with an increased risk of PEP.^{5,9,29-36} Across multiple studies, rescue access sphincterotomy was used after several failed biliary cannulation attempts, which in itself is an independent risk factor for PEP. Data suggest that performing an early precut sphincterotomy, referred to as an “early precut,” further reduces the risk of PEP.^{4,37,38}

Precut biliary sphincterotomy can be performed using multiple different techniques, such as NKF, NKS, and transpancreatic precut sphincterotomy.^{31,39} All these techniques can be performed either as a primary access or secondary (rescue) technique.⁴⁰ NKF involves identifying the intraduodenal portion of the common bile duct and using a needle-knife to incise directly into the bile duct, with the initial incision beginning superior to the papillary orifice, thus minimizing thermal damage to the native orifice. The fistula is further away from the pancreatic duct compared with the native orifice of the papilla. NKS, on the other hand, involves using a needle-knife to cut starting at the native papillary orifice and using electrocautery while moving the cutting wire superiorly to create an incision toward the 11 o'clock position (the expected position of the intraduodenal portion of the distal common bile duct).⁴¹⁻⁴³

A recent meta-analysis reported no significant difference in PEP rates with NKF and SBC.⁴⁴ The analysis was limited by the number of studies included and by presence of certain degree of heterogeneity.⁴⁴ To overcome these limitations, we included all RCTs and prospective and retrospective cohort studies in our study. Our analysis has several other strengths, including a systematic literature search with well-defined inclusion criteria, careful exclusion of redundant studies, inclusion of good-quality studies with detailed extraction of data, rigorous evaluation of

study quality, and statistics to establish or refute the validity of the results of our meta-analysis. We included only those studies in which p-NKF was performed and compared with SBC with or without rescue precut. The adverse events assessed in our study had homogenous definitions based on consensus guidelines.^{15,16} Finally, all studies included had comparison groups and were full-text articles with complete information on patient characteristics and outcomes.

There are also several limitations to this study, most of which are inherent to any meta-analysis. First, we had only 5 studies included in our analysis, which was because of our strict selection criteria that could have underpowered some of our outcomes. Data were insufficient to assess outcomes of cohort studies and RCTs separately. Second, there was some variability about the definition of failure of standard cannulation and adopting a rescue precut technique in the control group. Third, because of the strict failure criteria defined by 1 study, patients requiring longer cannulation times were excluded from the cannulation time calculation, which could have influenced the calculation in the control group.²² Fourth, publication bias cannot be ruled out because unpublished data were not obtained and assessment of publication bias with funnel plots was not performed because the number of studies was <10. Finally, heterogeneity was present in some of our secondary outcomes, which is likely because of inclusion of observational studies in addition to RCTs in our analysis, resulting in selection bias.

Nevertheless, our analysis shows that in expert hands performing p-NKF compared with rescue access sphincterotomy after SBC techniques have failed is associated with a lower risk of PEP, without compromising successful biliary cannulation rates, cannulation times, and overall safety profile. Further RCTs comparing p-NKF with other cannulation techniques are needed to validate our findings.

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DISCLOSURE

The following author disclosed financial relationships: D. G. Adler: Consultant for Boston Scientific. All other authors disclosed no financial relationships.

Abbreviations: CI, confidence interval; NKF, needle-knife fistulotomy; NKS, needle-knife sphincterotomy; OR, odds ratio; PEP, post-ERCP pancreatitis; p-NKF, primary needle-knife fistulotomy; RCT, randomized controlled trial; SBC, standard biliary cannulation.

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