

Standard Cannulation versus Fistulotomy for Biliary Access in Endoscopic Retrograde Cholangiopancreatography: Should We Expect the Same Success when Treating Choledocholithiasis?

Marta Moreira^a Isabel Tarrio^a Alda João Andrade^a Tarcísio Araújo^a
João Sousa Silva Fernandes^b Jorge Canena^{c, d, e} Luís Lopes^{a, f, g}

^aDepartment of Gastroenterology Hospital de Santa Luzia, Viana do Castelo, Portugal; ^bDepartment of Gastroenterology Hospital CUF, Viseu/Coimbra, Portugal; ^cDepartment of Gastroenterology, Professor Doutor Fernando Fonseca Hospital, Amadora, Portugal; ^dCintesis – Center for Health Technology and Services Research, Porto, Portugal; ^eDepartment of Gastroenterology, Nova Medical School-Faculty of Medical Sciences, Lisbon, Portugal; ^fLife and Health Sciences Research Institute (ICVS), School of Medicine, University of Minho, Braga, Portugal; ^gICVS/3B's - PT Government Associate Laboratory, Braga/Guimarães, Portugal

Keywords

Choledocholithiasis · Endoscopic retrograde cholangiopancreatography · Catheterization · Needle-knife fistulotomy · Precut techniques

Abstract

Introduction: To access the common bile duct in endoscopic retrograde cholangiopancreatography (ERCP), needle-knife fistulotomy (NKF) can be associated with a shorter sphincterotomy compared to standard cannulation. We aimed to compare the success and safety of NKF versus standard cannulation in the treatment of choledocholithiasis. **Methods:** A cohort of 379 naïve patients with choledocholithiasis who underwent ERCP between 2005 and 2022 was retrospectively analyzed. The patients were divided into two groups: group A (179 consecutive patients) underwent NKF, while group B (180 patients) received standard biliary access and were matched for stone characteristics and ERCP year. **Results:** Stone removal success

rate for group A was significantly lower than that for group B in the initial ERCP (82.0% vs. 92.1%, $p = 0.003$). In group A, success rates for stone removal were 90.2%, 80%, and 29.4% for stone sizes <10 mm, 10 mm–15 mm, and >15 mm, respectively ($p < 0.001$). In contrast, group B showed success rates of 99.2%, 81.5%, and 71.4% for the same stone size categories ($p < 0.001$). Pancreatitis occurred in 3.7% of group A and 5.8% of group B patients ($p = 0.340$). Regression analysis revealed that NKF cannulation, stone size (>10 mm), and having 4 or more stones were associated with lower stone removal success compared to standard cannulation in the initial ERCP (OR 0.34, $p = 0.015$; stone size 10–15 mm: OR 0.20, $p < 0.001$; stone size >15 mm: OR 0.05, $p < 0.001$; 4 or more stones: OR 0.4, $p = 0.040$). **Conclusions:** The removal of common bile duct stones after NKF access, although safe and effective, is less successful than after a standard cannulation, especially at the baseline ERCP.

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Canulação convencional versus fistulotomia para acesso à via biliar em CPRE: devemos esperar o mesmo sucesso no tratamento da coledocolitíase?

Palavras Chave

Coledocolitíase · Colangiopancreatografia retrógrada endoscópica · Cateterização · Fistulotomia com *needle-knife* · Técnicas de pré-corte

Resumo

Introdução: Para aceder à via biliar na CPRE, a fistulotomia com *needle-knife* (NKF) pode estar associada a uma esfínterectomia mais curta em comparação com a canulação convencional. O nosso objetivo é comparar o sucesso e a segurança da NKF versus a canulação convencional no tratamento da coledocolitíase. **Métodos:** Foi analisada retrospectivamente uma coorte de 379 pacientes *naïve* com coledocolitíase confirmada submetidos a CPRE entre 2005 e 2022. Os pacientes foram divididos em dois grupos: Grupo A (179 pacientes consecutivos) submetidos a NKF, enquanto no Grupo B (180 pacientes) o acesso biliar foi realizado por técnicas convencionais, sendo emparelhados quanto ao número e tamanho dos cálculos e quanto ao ano em que a CPRE foi realizada. **Resultados:** A taxa de sucesso na remoção de cálculos para o Grupo A foi significativamente inferior à do Grupo B na CPRE inicial (82.0% vs. 92.1%, $p = 0.003$). No Grupo A, as taxas de sucesso na remoção de cálculos foram de 90.2%, 80% e 29.4% para tamanhos de pedra <10 mm, 10 mm–15 mm e > 15 mm, respetivamente ($p < 0.001$). Por outro lado, o Grupo B apresentou taxas de sucesso de 99.2%, 81.5% e 71.4% para as mesmas categorias de tamanho dos cálculos ($p < 0.001$). A pancreatite ocorreu em 3.7% dos pacientes do Grupo A e 5.8% dos pacientes do Grupo B ($p = 0.340$). A análise de regressão revelou que no grupo A, o tamanho dos cálculos (>10 mm) e ter 4 ou mais cálculos estavam associados a uma menor taxa de sucesso em comparação com a canulação convencional na CPRE inicial (OR 0.34, $p = 0.015$; cálculo com 10–15 mm: OR 0.20, $p < 0.001$; cálculo com >15 mm: OR 0.05, $p < 0.001$; 4 ou mais cálculos: OR 0.4, $p = 0.040$). **Conclusões:** O tratamento da coledocolitíase por CPRE após acesso por NKF, embora segura e eficaz, é menos bem-sucedida do que após canulação convencional, especialmente na CPRE inicial.

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Introduction

Choledocholithiasis accounts for 8–20% of gallstone disease, and endoscopic retrograde cholangiopancreatography (ERCP) is the gold standard for its treatment. The key step for successful therapeutic ERCP is selective deep biliary cannulation [1, 2]. However, standard techniques for biliary cannulation fail in 5–35% of cases, even with experienced endoscopists [1, 3]. Precut techniques have emerged as rescue procedures for accessing bile ducts. The European Society of Gastrointestinal Endoscopy (ESGE) recommends needle-knife fistulotomy (NKF) as the preferred technique for pre-cutting [4, 5]. Since NKF incision is made above and to the left of the papillary orifice, it avoids the contact with the pancreatic duct, being associated with a lower incidence of post-ERCP pancreatitis (PEP) [6–8].

Theoretically, NKF can be associated with a shorter sphincterotomy length, therefore creating the possibility of a lower success rate in the treatment of choledocholithiasis, when compared with larger sphincterotomies after standard cannulation. In the literature, to our knowledge, there is not a study designed to evaluate this specific topic. We aimed to compare the success and safety of NKF versus standard cannulation in the treatment of choledocholithiasis.

Materials and Methods

This was a retrospective cohort study of *naïve* patients with confirmed choledocholithiasis submitted to ERCP between 2005 and 2022. Patients were selected from a prospective database maintained at our department and allocated into two groups (sample size assuming an effect size of 10%). Exclusion criteria were partial or total gastrectomy, evidence of duodenal or gastric outlet obstruction, or history of coagulopathy.

First, 179 consecutive *naïve* patients with confirmed choledocholithiasis submitted to NKF (as shown in Fig. 1) followed by sphincterotomy after failed standard cannulation (defined as more than 5 contacts with the papilla, more than 5 min spent while attempting to cannulate, or more than one unintended pancreatic duct cannulation or opacification) were selected (group A). The classic precut technique was not used in these patients. Subsequently, a control group (group B) with 180 *naïve* patients in whom standard biliary access followed by sphincterotomy was feasible was randomly selected by the investigators to match group A for stone size, number of stones, and year of the ERCP. These variables were considered important to minimize the differences in the perceived difficulty of the ERCP, potentially caused by the number or size of the stones, as well as the ability of the endoscopist.

All patients were submitted to sphincterotomy after NKF or standard cannulation. Large balloon dilatation and mechanical

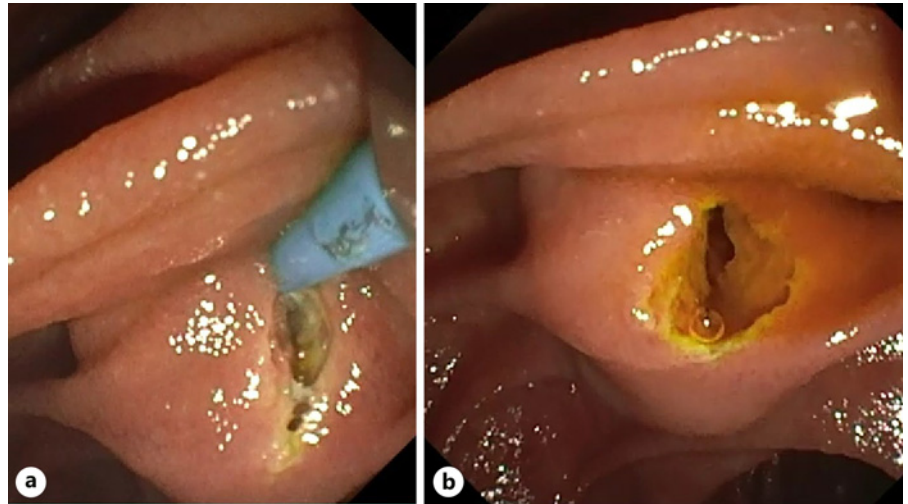


Fig. 1. **a** Needle-knife is used to perform an incision 3–5 mm from the papillary orifice. **b** Fistula between the duodenal and common bile duct luminae.

lithotripsy were allowed when necessary. In all patients, a stone extraction was attempted in the index ERCP in both groups. A plastic stent was placed in those patients who needed a repeat ERCP. Regarding the prophylaxis of PEP, patients received rectal indomethacin or hyperhydration with Ringer's lactate. Pancreatic stents were placed after multiple pancreatic cannulations.

The study variables included the following parameters: age (expressed in years), gender distribution, rates of pancreatic cannulation and stent placement, occurrence of adverse events (such as bleeding, pancreatitis, bowel perforation, and cholangitis), size and quantity of stones (in millimeters), initial success rate of stone removal during the first ERCP, overall success rate considering the need for additional ERCPs, techniques employed for stone extraction, and utilization of advanced ERCP techniques (if applicable), which encompassed mechanical lithotripsy, balloon dilation, and laser lithotripsy. Additionally, the rate of repeat ERCP procedures was also assessed.

The main outcomes were the rate of stone removal at baseline ERCP and adverse events. As this study was based on a prospective database, the follow-up of complications was performed in a systematic manner by the investigation team 30 days after ERCP.

Qualitative variables are summarized using absolute and relative frequencies, and quantitative variables are summarized using the mean and standard deviation or the median and range, depending on their distribution profiles. The normality of the quantitative variables was assessed using the histogram distribution and the Shapiro-Wilk test.

Differences between categorical variables were tested using a χ^2 test and Fisher's exact test. For quantitative variables, student's *t* test and Mann-Whitney test were used for comparisons, depending on initial normality assessment.

A logistic regression was performed to evaluate predictors of success and adverse events. The model contained 5 independent variables (age, sex, number of stones, largest stone size, and cannulation type) that were selected based on the clinical probability of interfering with the success of the ERCP treatment.

The null hypothesis was rejected when the test statistics *p* values were less than <0.05. Statistical analysis and graphics

Table 1. Demographic and stone characteristics (*N* = 379)

	<i>N</i> (%)
Age, years	
Median, min, max	79.57 (26–97)
Sex	
Female	224 (59.10)
Male	155 (40.90)
Largest stone in <i>mm</i>	
Mean, SD	8.39, 5.28
Number of stones	
1 stone	156 (41.16)
2 stones	83 (21.90)
3 stones	45 (11.87)
≥4 stones	95 (25.07)

SD, standard deviation; IQR, interquartile range.

were performed using Stata software (StataCorp. 2015; Stata Statistical Software: Release 14; College Station, TX, USA: StataCorp LP).

Results

As shown in Table 1, a total of 379 patients were included (*n* = 224, 59.1% females, mean age 75.10 years [26–97 years]). The stone removal success rate was, globally, 87.1% in the index ERCP. In 56 (14.8%) patients, a repeated ERCP was deemed necessary, and the global success rate for complete stone extraction was 97.9%. Balloon catheters (81%) and wire baskets (45.1%) were used to extract stones. There was a need for advanced stone extraction techniques in 21 patients (5.5%) in the index ERCP and 10.8% in the repeated ERCP.

Table 2. ERCP techniques, success, and adverse events

	N (%)
Stone removal success (ERCP index)	330 (87.07)
Stone removal success (global)	371 (97.89)
Stone extraction techniques	
Balloon catheters	307 (81.00)
Wire baskets	171 (45.12)
Advanced stone extraction techniques (ERCP index)	21 (5.54)
Mechanical lithotripsy	15 (3.96)
EPBD	6 (1.58)
Advanced stone extraction techniques (global)	41 (10.82)
Mechanical lithotripsy	18 (4.79)
EPBD	8 (2.11)
Laser lithotripsy	15 (3.96)
ERCP repeat	56 (14.78)
Adverse events	25 (6.60)
Pancreatitis	18 (4.75)
Bleeding	4 (1.06)
Cholangitis	3 (0.80)
Perforation	3 (0.80)
Pancreatic cannulation	60 (15.83)
Pancreatic stent placement	5 (1.32)
EPBD, endoscopic papillary balloon dilation.	

Table 3. Demographic and stone characteristics per type of cannulation

	NKF, n (%)	Standard, n (%)	p value
Age			0.076
Median, min, max	79 (30, 97)	80 (26.96)	
Sex			0.268
Female	117 (61.91)	107 (56.36)	
Male	72 (38.13)	83 (43.74)	
Largest stone in mm (mean±SD)	8.46±6.00	8.33±4.78	0.068
<10	122 (64.55)	122 (64.21)	
≥10 or ≤15	50 (26.46)	54 (28.42)	
>15	17 (8.99)	14 (7.37)	
Number of stones (mean±SD)	2.67±1.79	2.24±1.45	0.957
EPBD, endoscopic papillary balloon dilation.			

As shown in Table 2, overall, 25 procedures had complications: the rates of pancreatitis, bleeding, cholangitis, and bowel perforation were 4.8%, 1.1%, 0.8%, and 0.8%, respectively. Pancreatic cannulation was performed in 60 patients (15.8%), with 5 (1.3%) receiving a pancreatic stent.

As shown in Table 3, both groups were similar regarding age, sex, and stone characteristics. The success in the index ERCP group A was significantly lower than that of the control group (82% vs. 92.1%, $p = 0.003$), as demonstrated in Table 4.

As revealed in Table 5, the stone removal success in the NKF group at the initial ERCP, for stones <10 mm,

10 mm–15 mm, and >15 mm, was 90.2%, 80%, and 29.4%, respectively ($p < 0.001$); in group B, it was 99.2%, 81.5%, and 71.4%, respectively ($p < 0.001$). Pancreatitis occurred in 3.7% of patients in group A and in 5.8% in group B ($p = 0.340$).

In the regression analysis (Table 6), NKF cannulation was associated with a lower stone removal success rate compared with standard cannulation in the initial ERCP (odds ratio [OR] 0.34; 95% CI: 0.14–0.81; $p = 0.015$). Stone size (10–15 mm and >15 mm) and having 4 or more stones were also predictors for a lower rate of stone removal in the initial ERCP (stone size 10–15 mm: OR 0.20, $p = 0.000$; stone size >15 mm: OR 0.05, $p = 0.000$; 4 or more stones: OR 0.4, $p = 0.040$, respectively).

Table 4. ERCP techniques, success, and adverse events by type of cannulation

	NKF (n = 189), n (%)	Standard (n = 190), n (%)	p value
Stone removal success (ERCP index)	155 (82.01)	175 (92.11)	0.003
Stone removal success (global)	182 (96.30)	189 (99.47)	0.031
Stone extraction techniques			
Balloon catheters	153 (80.96)	154 (81.05)	0.980
Wire baskets	76 (40.21)	95 (50.00)	0.056
Advanced stone extraction techniques (ERCP index)	10 (5.29)	11 (5.79)	0.832
Mechanical lithotripsy	5 (2.65)	10 (5.26)	–
EPBD	5 (2.65)	1 (0.53)	–
Advanced stone extraction techniques (global)	21 (11.11)	20 (10.53)	0.217
Mechanical lithotripsy	7 (3.70)	11 (5.79)	–
EPBD	6 (3.14)	3 (1.58)	–
Laser lithotripsy	5 (2.65)	10 (5.26)	0.217
ERCP repeat	35 (18.52)	21 (11.05)	0.191
Adverse events	13 (6.88)	14 (7.37)	0.307
Pancreatitis	7 (3.70)	11 (5.80)	0.340
Bleeding	2 (1.06)	2 (1.05)	1.000
Cholangitis	3 (1.59)	0 (0.00)	–
Perforation	1 (0.53)	2 (1.05)	0.123
Pancreatic cannulation	37 (19.58)	23 (12.11)	0.461
Pancreatic stent placement	5 (2.65)	0 (0.00)	0.024

EPBD, endoscopic papillary balloon dilation.

Table 5. ERCP techniques, success, and adverse events by stone size (mm)

	<10 mm, n (%)	10 mm – ≤ 15 mm, n (%)	>15 mm, n (%)	p value
Cannulation technique				–
NKF	122 (50.00)	50 (48.07)	17	
Standard	122 (50.00)	54	14	
Stone removal success (ERCP index)	231 (94.67)	84 (80.77)	15 (48.39)	0.000
NKF	110 (90.16)	40 (80.00)	5 (29.41)	0.000
Standard	121 (99.18)	44 (81.48)	10 (71.43)	0.000
Stone removal success (global)	240 (98.36)	101 (97.12)	30 (96.77)	0.687
NKF	119 (97.54)	47 (94.00)	16 (94.12)	0.531
Standard	121 (99.18)	54 (100.00)	14 (100.00)	0.756
Advanced extraction techniques (ERCP index)	3 (1.23)	11 (10.58)	7 (22.58)	0.000
Mechanical lithotripsy	2 (0.08)	9 (8.65)	4 (12.90)	0.000
EPBD	1 (0.40)	2 (1.92)	3 (9.68)	
Laser lithotripsy	0 (0.00)	0 (0.00)	0 (0.00)	–
Advanced extraction techniques (global)	3 (1.23)	19 (18.27)	19 (61.30)	0.000
Mechanical lithotripsy	2 (0.08)	11 (10.57)	5 (16.13)	–
EPBD	1 (0.40)	4 (3.85)	4 (12.90)	–
Laser lithotripsy	0 (0.00)	5 (4.81)	10 (32.26)	0.000
ERCP repeat	16 (6.56)	26 (25.00)	14 (45.16)	0.000

EPBD, endoscopic papillary balloon dilation.

Table 6. Logistic regression model for ERCP stone extraction success

	Success ERCP index				Success ERCP global			
	OR	<i>p</i> value	95% CI		OR	<i>p</i> value	95% CI	
Age	1.01	0.597	0.98	1.03	0.97	0.419	0.90	1.04
Sex								
Female	Base case				Base case			
Male	0.57	0.123	0.28	1.17	2.20	0.387	0.37	13.09
Number of stones								
1	Base case				Base case			
2	1.06	0.909	0.40	2.77	0.58	0.614	0.71	4.78
3	0.80	0.749	0.21	3.10	0.26	0.312	0.02	3.57
≥4	0.40	0.040	0.35	1.65	0.84	0.869	0.10	6.91
Largest stone size, mm								
<10	Base case				Base case			
10–≤ 15	0.20	0.000	0.09	0.46	1.25	0.754	0.30	5.17
>15	0.05	0.000	0.02	0.15	1.29	0.884	0.04	41.36
Cannulation type								
NFK	Base case		1.24		Base case			
Standard	2.93	0.015	1.24	6.92	6.60	0.143	0.53	82.67

Discussion

In our study, the ERCP success rate for complete stone extraction was over 87% at the index procedure and nearly 98% overall. These findings are consistent with a meta-analysis evaluating ERCP quality indicators, which found that stone extraction is successful in 88% of procedures [9].

When comparing the two groups, standard cannulation proved to have a higher success rate in stone removal at the index ERCP when compared to NKF, although both techniques demonstrated a high success rate, particularly for stones under 10 mm (>90% success rate). The difference between groups was more pronounced in stones with more than 15 mm, with 29% success rate in the index NKF ERCP and 71% in the standard cannulation group. These data could support our hypothesis that the lower success rate is probably related to a smaller biliary orifice in NKF. However, when including the repeat ERCP (global ERCP success rate), the stone size did not convey a difference. This finding could be attributed to the use of plastic stents after a failed index ERCP and an increased utilization of alternative advanced stone extraction techniques in the repeat ERCP, which might have contributed to overcoming the challenges posed by larger stone sizes, such as the length of sphincterotomy. Our findings suggest that, in patients undergoing NKF, the use of large balloon dilation or a careful extension of sphincterotomy during the first ERCP could potentially enhance its therapeutic effec-

tiveness and decrease the requirement for repeat ERCP. These observations align with Archibugi et al. [10], who reported that the reintervention rate for choledocholithiasis was significantly higher in a short term after ERCP by NKF, particularly because of incomplete common bile duct clearing.

As expected, the largest stone size and number of stones were predicting factors that influence index ERCP stone removal success, though it is important to note that the number of stones only had a significant impact on the overall success rate if there were 4 or more. Recently, there has been a growing interest in the scientific community regarding the utilization of primary NKF as a first-line approach, rather than a rescue method, for cannulating the common bile duct and gaining access to the biliary tree without any contact with the papilla orifice [11]. Canena et al.'s recent meta-analysis demonstrated that primary NKF was associated with high rates of cannulation success, low rates of complications, and shorter procedural duration [12]. However, according to our findings, NKF is not as effective as the standard cannulation when it comes to treatment of choledocholithiasis, the most common indication for ERCP.

The observed complication rate in our study was 6.6%, like those reported in the literature (5.0–15.9%) [4, 5]. Notably, the incidence of PEP was 4.8%, which was lower than the anticipated range of 5–7% [5, 13]. In our analysis, the type of cannulation did not demonstrate a statistically significant impact on the occurrence of PEP. However, there

was a notable trend toward a lower PEP rate in the NKF group (3.7%) compared to standard cannulation (5.8%).

Mavrogiannis et al. [14] published a prospective study aimed to compare the success and safeness of NKF (74 patients) with classic precuts (79 patients) that showed similar results as ours, meaning more repeat ERCP and lithotripsy are needed more often. Also, NKF proved to be safer than needle-knife precut papillotomy with respect to pancreatic complications.

As NKF is a rescue and expertise-demanding technique, it is impractical to develop randomized controlled trials comparing both techniques, so this study of 379 patients matched for demographic and stone characteristics can provide important data regarding the impact on the success rate of NKF in the treatment of choledocholithiasis. The retrospective design and 17-year timeframe are important limitations that precluded the inclusion of variables such as duration of the procedure or the morphology of the papilla. In the future, it would be interesting to study this matter in a prospective manner.

Statement of Ethics

The study was approved by the Ethical Committees from “Comissão de Ética para a Investigação em Ciências da Vida e da Saúde (CEIVCS)” – 089/2022 and “Comissão de Ética em Saúde (CES)” of Hospital de Santa Luzia – 57/2022. All the study

procedures were carried out in accordance with the Declaration of Helsinki, and all patients provided written informed consent before their procedures.

Conflict of Interest Statement

The authors declare no conflicts of interest for this article.

Funding Sources

This study did not require any funding.

Author Contributions

Marta Moreira wrote the manuscript. Isabel Tarrio and Alda João Andrade helped with the data collection. Tarcísio Araújo, João Sousa Silva Fernandes, Jorge Canena, and Luís Lopes were responsible for the revision of the methodology and manuscript edition.

Data Availability Statement

The data that support the findings of this study are not publicly available due to containing information that could compromise the privacy of research participants but are available from M.M. upon reasonable request.

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