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Safety and Efficacy of Primary Needle-knife Precut during ERCP Procedure

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ABSTRACT

Background: Difficult biliary cannulation during endoscopic retrograde cholangiopancreatography (ERCP) is a major risk factor for post-ERCP pancreatitis (PEP). Needle-knife sphincterotomy (NKS) is commonly used as a rescue technique after failed standard cannulation; however, increasing evidence suggests that early or primary use of NKS may reduce pancreatic duct trauma and procedural complications. This study aimed to evaluate the safety and efficacy of primary needle-knife precut (PNKP) compared with secondary precut in patients with swollen ("pregnant") papillae.

Patients and Methods: This randomized controlled trial was conducted at Sayed Galal and Damietta Al-Azhar University Hospitals between December 2023 and November 2025. Sixty patients with swollen papillae undergoing ERCP were enrolled and randomized into two groups: Group A (secondary precut after failed standard cannulation; n=40) and Group B (primary precut as the initial cannulation strategy; n=20). Baseline characteristics, procedural outcomes, complication rates, and hospitalization parameters were compared.

Results: Baseline demographic, clinical, and laboratory parameters were comparable between groups. Procedure time was significantly shorter in the primary precut group (18.3 ± 4.8 minutes) compared with the secondary precut group (25.4 ± 6.2 minutes; $p < 0.01$). Successful biliary-cannulation rates were similar (95% vs. 97.5%; $p = 0.51$). Post-ERCP pancreatitis occurred more frequently in the secondary precut group (10% vs. 5%; $p = 0.03$), accompanied by higher unintended pancreatic duct cannulation rates (17.5% vs. 0%; $p = 0.01$). Post-procedural serum amylase levels were significantly higher in Group A ($p = 0.01$). Repeat ERCP was required more often in the secondary precut group (5% vs. 0%; $p = 0.04$), and hospital stay was significantly longer (2.5 ± 1.0 vs. 1.8 ± 0.7 days; $p = 0.03$). Major complications, including bleeding, perforation, and cholangitis, were low and comparable between groups.

Conclusion: Early use of needle-knife in patients with swollen papilla was associated with shorter time of procedure, less incidence of post-ERCP pancreatitis and hospital admissions.

Keywords: ERCP; Needle-Knife Precut; Difficult Cannulation; Pancreatitis; Swollen Papilla; Sphincterotomy.

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INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) has become a standard procedure for the diagnosis and treatment of pancreaticobiliary diseases. Common bile duct (CBD) cannulation is mandatory for successful endoscopic biliary treatment, and usually, transpapillary cannulation is the preferred method [(1)]

Selective deep cannulation is a critical step for the performance of endoscopic retrograde cholangiopancreatography (ERCP). The incidence of difficult biliary cannulation has been reported in many studies**,** ranging from 10% to 40% in patients with native papilla [(2)]

Difficult cannulation is an independent risk factor for post-ERCP pancreatitis (PEP), PEP incidence has been reported to be 8%–12% in patients with difficult cannulation whereas it is 3%–5% in patients without difficult cannulation [(3)]

The European Society of Gastrointestinal Endoscopy has proposed the 5–5–1 criteria for the definition of difficult cannulation: > 5 minutes spent attempting to cannulate, > 5 contacts with the papilla to cannulate, > 1 unintended PD cannulation or opacification ,The clear definition of difficult cannulation is important for making decisions during or after ERCP, including determining the appropriate time to transfer to advanced cannulation techniques and whether prophylactic methods should be administered to reduce the risk of PEP [(4)]

Available options to improve the success rate When the cannulation proves difficult, advanced cannulation techniques are often necessary, including the double guidewire technique, trans-pancreatic sphincterotomy, or needle-knife precut [(5)]**.**

Physician controlled guidewires or endoscopic ultrasound-guided interventions like the rendezvous procedure or hepato-gastrostomy [(6-8)]**.**

Although NKS has long been considered an independent procedure-related risk factor of PEP, confounders like a prolonged procedure time, repetitive unintentional pancreatic cannulation, and excessive manipulation causing ampullary edema might have exaggerated the incidence of PEP because almost all studies on NKS were conducted in the setting of difficult cannulation [(7)]**.**

Post-ERCP pancreatitis is the most common and serious complication of ERCP**.** Since the consensus definitions and revisions in 2010, PEP has been defined as the development of typical abdominal pain with amylase ≥3X the upper limit of normal, and requiring unplanned hospital admission, or prolongation of admission by at least 1 day [(3, 9)]**.** The development of PEP results in a significant increase in the global cost of care. Based on Medicare cost estimates in 2005, the cost of ERCP with PD stenting was $1952 compared to $5687 for the care of patients with PEP [(10)]

Needle-knife sphincterotomy (NKS) involves making an incision at the suprapapillary region extending to the ampulla of Vater orifice and was first introduced by Siegel in 1980. Several studies have shown that this technique significantly improves the success rates of cannulation in difficult cases [(11, 12)]**.**

In this study we aimed to assess the safety and efficacy of primary needle-knife precut in cases of pregnant and or swollen papilla during ERCP procedure.

PATIENTS AND METHODS

Study Design: This study was a randomized controlled trial designed to evaluate the safety and efficacy of primary needle-knife precut (PNKP) during endoscopic retrograde cholangio-pancreato-graphy (ERCP) in patients with swollen papillae. The study was conducted at Sayed Galal and Damietta Al-Azhar University Hospitals, from December 2023 to November 2025. The study compared the outcomes of primary needle-knife precut as an initial cannulation strategy versus secondary precut after failed standard cannulation attempts.

Population: During the study period, a total of 500 patients underwent endoscopic retrograde cholangiopancreatography (ERCP) for various biliary indications, patients were carefully evaluated for eligibility based on predefined inclusion and exclusion criteria. Patients were enrolled after providing informed verbal and written consent. The diagnosis of a swollen papilla was established based on its endoscopic appearance, characterized by a prominent, bulging papilla with an edematous mound obscuring the papillary orifice.

Exclusion criteria: Patients were excluded if standard biliary cannulation was successful or if they had a history of pancreatitis. Those with previous upper gastrointestinal (GIT) surgery (e.g., Billroth II or Roux-en-Y reconstruction), coagulopathy (INR >1.5 or platelets <50,000/mm^3), or anatomical alterations affecting ERCP (e.g., periampullary diverticula) were also excluded. Pregnant patients, confirmed by a positive pregnancy test, were not eligible.

Randomization and Group Allocation: From the total of all patients subjected to ERCP, 60 eligible patients were selected and enrolled in the study, patients were randomly allocated into two groups using an odd and even number-based selection system: Group A (Secondary Precut Group): This group consisted of 40 patients whom underwent needle-knife sphincterotomy (NKS) after failed attempts at standard cannulation and Group B (Primary

Precut Group): This group consisted of 20 patients whom underwent early needle-knife sphincterotomy as the first attempt at cannulation in cases of swollen papillae.

Pre-Procedure Evaluation: All patients underwent a comprehensive pre-procedure assessment. A detailed medical history was obtained, including presenting symptoms, prior surgical interventions, and associated comorbidities. A thorough physical examination was performed to evaluate the general condition and to exclude contraindications to endoscopic retrograde cholangiopancreatography (ERCP). Baseline laboratory investigations included complete blood count, liver function tests (alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase, and total bilirubin), serum amylase and lipase, renal function tests (serum creatinine), and coagulation profile (prothrombin time, international normalized ratio, and platelet count), RBS, FBS ,HBA1C and Viral hepatitis markers (HBsAg, HCV antibodies and HIV ab) were assessed in all patients. Female patients of reproductive age underwent pregnancy testing prior to the procedure.

All patients underwent abdominopelvic ultrasonography to evaluate the biliary tree, gallbladder, liver parenchyma, and pancreatic duct. Magnetic resonance cholangiopancreatography (MRCP) was performed when additional anatomical delineation or clarification of biliary pathology was required.

ERCP Procedure: All ERCP procedures were conducted in the Endoscopy Unit of Al-Azhar University Hospitals. Procedures were performed using either the Fujifilm ELUXEO™ 7000 video endoscopy system with a Fujifilm therapeutic duodenoscope (ED-580T) or the Pentax EPK-i7010 processor coupled with a Pentax therapeutic duodenoscope (ED-3490TK). Both systems provided high-definition imaging and a 4.2-mm working channel suitable for advanced biliary interventions. All procedures were carried out in a dedicated fluoroscopy suite equipped with a Toshiba Infinix C-arm system to enable real-time radiographic monitoring and documentation.

Patient Preparation and Sedation: Patients fasted for at least 6–8 hours before the procedure. Pre-procedure evaluation included assessment of vital signs, cardiopulmonary status, and coagulation parameters. Intravenous access was established using an 18- or 20-gauge cannula, and lactated Ringer's solution was initiated at 3 mL/kg/h starting 30 minutes before ERCP. All patients received rectal indomethacin (100 mg) 30 minutes prior to scope insertion for prophylaxis against post-ERCP pancreatitis (PEP). Prophylactic antibiotics (e.g., ceftriaxone 1 g intravenously) were administered in patients with biliary obstruction or anticipated incomplete biliary drainage. Patients were positioned in either the left lateral or prone position according to anesthesiologist preference. Continuous monitoring included electrocardiography, pulse oximetry, and non-invasive blood pressure measurement. Supplemental oxygen (2–4 L/min) was delivered via nasal cannula. Sedation was achieved using either conscious sedation with intravenous midazolam (2–5 mg) and fentanyl (50–100 µg) titrated to effect, or deep sedation with propofol infusion (0.5–1 mg/kg bolus followed by 25–75 µg/kg/min) under anesthesiologist supervision.

Duodenoscope Intubation and Papillary Assessment: The duodenoscope advanced through the oropharynx, esophagus, and stomach into the second portion of the duodenum. Carbon dioxide insufflation was used throughout the procedure to reduce post-procedural abdominal distention. The major duodenal papilla was carefully inspected. Eligible cases included patients with a swollen, bulging, or edematous papilla ("pregnant papilla") in which the papillary mound obscured the orifice, rendering standard cannulation technically challenging.

Cannulation Techniques: Patients were allocated into two groups according to the initial cannulation strategy.

Standard Cannulation (Group A: Secondary Precut Group): Selective biliary cannulation was initially attempted using a sphincterotome (Clever Cut 3V, Olympus) preloaded with a 0.035-inch hydrophilic guidewire (Jagwire™, Boston Scientific). The sphincterotome was oriented toward the 11–12 o'clock position of the papillary orifice, and the guidewire was gently advanced under fluoroscopic guidance. Successful biliary access was confirmed by bile aspiration and contrast injection demonstrating opacification of the common bile duct. If selective cannulation was not achieved after 5 minutes, five papillary contacts, or one unintended pancreatic duct cannulation, standard attempts were discontinued and needle-knife sphincterotomy (secondary precut) was performed.

Primary Needle-Knife Precut (Group B – Primary Precut Group): In Group B, needle-knife papillotomy was used as the primary access technique. A needle-knife papillotome (MicroKnife XL, Boston Scientific) was positioned at the 11–12 o'clock orientation on the papillary roof. Electrosurgical current was delivered using an ERBE VIO 200 D generator in EndoCut Q mode (Effect 2, Cut Duration 1, Cut Interval 6). A controlled 3–5 mm incision was made along the presumed bile duct axis until the submucosal whitish sphincter fibers were exposed. The incision was extended until bile efflux was observed or the ampullary orifice was clearly visualized. A guidewire was then advanced through the incision into the bile duct under fluoroscopic guidance. Once selective cannulation was achieved, contrast cholangiography was performed to evaluate biliary anatomy and identify stones, strictures, or ductal dilatation.

Therapeutic Interventions: Therapeutic interventions were performed according to the underlying pathology. These included completion sphincterotomy, balloon sphincteroplasty (8–12 mm) for large stone extraction, stone retrieval using extraction balloons or Dormia baskets, and plastic stent placement (7–10 Fr) in cases of biliary obstruction or cholangitis. Fluoroscopy was used to confirm complete stone clearance and proper stent positioning. Minor bleeding during precut incision was managed with epinephrine (1:10,000) irrigation and mechanical tamponade using the sphincterotome tip. In cases of persistent oozing, brief applications of soft coagulation were applied. Perforation was excluded by maintaining adequate duodenal distention and monitoring for extraluminal contrast leakage under fluoroscopy.

Prophylaxis Against Post-ERCP Pancreatitis: Standardized measures were implemented to minimize the risk of PEP. All patients received rectal indomethacin (100 mg). Aggressive hydration with lactated Ringer's solution (20 mL/kg) was administered immediately post-procedure. Prophylactic pancreatic duct stenting (5-Fr single-pigtail, 3 cm) was performed in patients with repeated inadvertent pancreatic duct cannulation or suspected papillary edema.

Operator Experience: All procedures were performed by consultant endoscopists with experience exceeding 300 ERCP procedures and more than five years of advanced biliary endoscopy practice. This ensured procedural uniformity and minimized inter-operator variability.

Post-Procedure Follow-Up: Patients were monitored for at least 48 hours after ERCP. Serum amylase levels were measured 6 hours post-procedure to detect early pancreatitis. Clinical assessment included evaluation for abdominal pain, nausea, vomiting, fever, bleeding, or signs of perforation. A follow-up visit was conducted two weeks after the procedure to assess delayed complications, including cholangitis, bleeding, or perforation, and to evaluate overall clinical recovery.

Ethical Considerations: The study protocol was reviewed and approved by the Committee of Hepatology, Gastroenterology, and Infectious Diseases Department, the Faculty of Medicine Committee, and the Ethical Committee of Al-Azhar University. Written informed consent was obtained from all participants prior to enrollment. The consent form outlined the study objectives, procedures, potential risks, and anticipated benefits.

Statistical analysis: Data analysis was conducted with SPSS (Statistical Package for the Social Sciences) version 28. Categorical variables were characterized by their absolute frequencies and compared using the chi-square test and Fisher's exact test when applicable. The Kolmogorov–Smirnov test was employed to validate assumptions for parametric test application. Quantitative variables were characterized by their means and standard deviations or by their medians and interquartile ranges, depending on the data type. Independent sample t-tests were employed for regularly distributed data, while Mann-Whitney tests were utilized for non-normally distributed data to compare quantitative data between two groups. Binary logistic regression was employed to discover independent risk factors linked to specific health issues. The threshold for statistical significance was established at $P<0.05$. A highly significant difference was seen when $p\leq0.001$.

RESULTS

The baseline demographic and clinical characteristics were comparable between the two groups. The mean age did not differ significantly between Group A (52.3 ± 10.5 years) and Group B (50.8 ± 11.2 years) ($p = 0.56$). Similarly, gender distribution was balanced (male: female ratio 22:18 vs. 11:9; $p = 0.89$), and mean BMI showed no significant difference (26.4 ± 3.2 vs. 25.8 ± 3.5 kg/m²; $p = 0.45$) (Table 1).

The prevalence of comorbidities was also similar across groups. The proportion of patients without comorbid conditions was slightly higher in Group B (60%) compared to Group A (52.5%), though this difference was not statistically significant. Rates of hypertension (30% in both groups) and diabetes mellitus (20% in both groups) were identical, while cardiovascular disease and chronic liver disease were infrequent and evenly distributed. Pre-procedural laboratory parameters, including hemoglobin, platelet count, bilirubin, liver enzymes (ALT, AST, ALP), serum creatinine, and INR, demonstrated no statistically significant differences (all $p > 0.05$). Overall, these findings confirm that both groups were well matched at baseline, supporting the validity of subsequent comparisons in procedural and clinical outcomes (Table 1).

The indications for ERCP were similarly distributed between the two groups. Management of choledocholithiasis was the most common indication in both Group A and Group B (80% each; $p = 1$). Cholangitis secondary to choledocholithiasis occurred in 12.5% of patients in Group A and 10% in Group B ($p = 0.78$), while relief of biliary obstruction due to malignancy or stricture accounted for 7.5% and 10% of cases, respectively ($p = 0.74$). These findings indicate no statistically significant difference in procedural indications between the groups (Table 2).

Regarding endoscopic and radiologic findings, choledocholithiasis was detected in most patients (92.5% in Group A vs. 90% in Group B; $p = 0.74$). All patients in both groups had a dilated common bile duct (>8 mm), and intrahepatic biliary dilation was present in 95% of cases in each group. Gallstones were observed in 75% of patients in both cohorts. Biliary strictures, pancreatic head

masses, and pancreatic duct dilation were infrequent and comparably distributed. Overall, the two groups demonstrated similar clinical indications and biliary findings, supporting their comparability prior to intervention (Table 2).

Procedure time was significantly shorter in the primary precut group compared with the secondary precut group. The mean procedure time in Group A was 25.4 ± 6.2 minutes, whereas in Group B it was 18.3 ± 4.8 minutes ($p < 0.01$). Median values similarly favored Group B (17 minutes; range 12–25) over Group A (24 minutes; range 18–35), indicating a consistently shorter procedural duration when primary needle-knife precut was used.

The need for prophylactic pancreatic duct stenting was significantly higher in Group A (7.5%; 3/40) compared with none in Group B ($p = 0.02$). Despite this, overall successful biliary cannulation rates were comparable between groups (97.5% in Group A vs. 95% in Group B; $p = 0.51$), demonstrating no significant difference in technical success. Post-ERCP pancreatitis (PEP) occurred more frequently in Group A (10%) than in Group B (5%), with a statistically significant difference ($p = 0.03$). Most cases were mild, with only one moderate case in Group A. Additionally, unintended pancreatic duct cannulation was significantly more common in Group A (17.5%) compared to none in Group B ($p = 0.01$). These findings suggest that primary precut may reduce procedural time and pancreatic duct manipulation without compromising cannulation success (Table 3).

Overall complication rates were low in both groups. Post-procedural bleeding occurred in one patient (2.5%) in Group A and in none of the patients in Group B, with no statistically significant difference ($p = 0.2$). Similarly, perforation was reported in one patient (2.5%) in Group A and was not observed in Group B ($p = 0.5$). The incidence of cholangitis was comparable between groups (5% in each; $p = 1$), indicating no significant difference in infectious complications. However, post-procedural serum amylase levels were significantly higher in Group A (450 ± 120 U/L) compared with Group B (320 ± 90 U/L) ($p = 0.01$), suggesting greater pancreatic irritation in the secondary precut group. Repeat ERCP was required in 5% of patients in Group A, whereas no cases required repeat intervention in Group B ($p = 0.04$). Additionally, hospital stay was significantly longer in Group A (2.5 ± 1.0 days) compared with Group B (1.8 ± 0.7 days; $p = 0.03$). These findings suggest that primary precut may be associated with reduced pancreatic enzyme elevation, fewer repeat procedures, and shorter hospitalization without increasing major complications (Table 4).

Table (1): Baseline demographic, clinical, and laboratory characteristics of patients undergoing ERCP in the secondary precut (Group A) and primary precut (Group B) groups (n=60)

Characteristic		Group A (Secondary Precut) (n=40)	Group B (Primary Precut) (n=20)	p-value
Age (years), mean ± SD		52.3 ± 10.5	50.8 ± 11.2	0.56
Gender (Male: Female)		22:18	11:09	0.89
BMI (kg/m²) (mean ± SD)		26.4 ± 3.2	25.8 ± 3.5	0.45
Associated Comorbidity	Hypertension	12 (30%)	6 (30%)	1.0
	Diabetes Mellitus	8 (20%)	4 (20%)	1.0
	Cardiovascular Disease	5 (12.5%)	2 (10%)	0.78
	Chronic Liver Disease	3 (7.5%)	1 (5%)	0.7
Pre-Procedural Laboratory Parameters	Hemoglobin (g/dL)	12.5 ± 1.8	12.8 ± 1.6	0.5
	Platelet Count (×10³/mm³)	220 ± 60	230 ± 55	0.45
	Bilirubin (mg/dL)	3.5 ± 1.2	3.2 ± 1.1	0.3
	ALT (U/L)	85 ± 30	80 ± 25	0.4
	AST (U/L)	90 ± 35	85 ± 30	0.45
	ALP (U/L)	150 ± 50	140 ± 45	0.35
	Serum Creatinine (mg/dL)	0.9 ± 0.2	0.8 ± 0.2	0.25
	INR	1.1 ± 0.2	1.0 ± 0.1	0.15

Table (2): Indications and endoscopic/radiologic findings among patients undergoing ERCP in the secondary precut (Group A) and primary precut (Group B) groups (n=60)

		Group A (Secondary Precut) (n=40)	Group B (Primary Precut) (n=20)	p-value
Indication	Management of choledocholithiasis	32 [80%]	16 [80%]	1
	Cholangitis (due to choledocholithiasis)	5 [12.5%]	2 [10%]	0.78
	Relief of biliary obstruction (due to cancer or stricture)	3 [7.5%]	2 [10%]	0.74
Finding	Choledocholithiasis	37 [92.5%]	18 [90%]	0.74
	Dilated Common Bile Duct (>8 mm)	40 [100%]	20 [100%]	1
	Intrahepatic Biliary Dilation	38 [95%]	19 [95%]	1
	Gallstones (in Gallbladder)	30 [75%]	15 [75%]	1
	Biliary Stricture	2 [5%]	1 [5%]	1
	Pancreatic Head Mass	1 [2.5%]	1 [5%]	0.63
	Pancreatic Duct Dilation	4 [10%]	2 [10%]	1

Table (3): Procedural characteristics and clinical outcomes in patients undergoing ERCP using secondary precut (Group A) versus primary precut (Group B).

		Group A (Secondary Precut) n=40	Group B (Primary Precut) n=20	p-value
Procedure Time (Minutes)	Mean ± SD	25.4 ± 6.2	18.3 ± 4.8	**<0.01**
	Median (Range)	24 (18–35)	17 (12–25)	
Need for Pancreatic Stenting (%)		7.5% (3/40)	Zero	0.02
Successful Biliary Cannulation Rates (%)		97.5% (39/40)	95% (19/20)	0.51
Post-ERCP Pancreatitis	PEP Cases (%)	10% (4/40)	5% (1/20)	0.03
	Severity (Mild/Moderate/Severe)	3/1/**0**	1/0/0	-
Unintended Pancreatic Duct Cannulation (%)		17.5% (7/40)	Zero	0.01

Table (4): post-procedural complications, biochemical outcomes, need for repeat ERCP, and duration of hospital stay among patients undergoing ERCP using secondary precut (Group A) versus primary precut (Group B).

		Group A (Secondary Precut) (n=40)	Group B (Primary Precut) (n=20)	p-value
Complications	Bleeding	1 (2.5%)	0 (0%)	0.2
	Perforation	1 (2.5%)	0 (0%)	0.5
	Cholangitis	2 (5%)	1 (5%)	1
Serum Amylase Levels (Post-Procedure, U/L)		450 ± 120	320 ± 90	**0.01**
Numbers of cases	(Repeat ERCP Cases (%)	5% (2/40)	0% (0/20)	**0.04**
Hospital Stay (day)	Mean ± SD	2.5 ± 1.0	1.8 ± 0.7	**0.03**
	Median (Range)	2 (1–5)	2 (1–3)	-

DISCUSSION

The present study was designed to evaluate the safety and efficacy of primary needle-knife precut sphincterotomy as an initial cannulation strategy during ERCP in patients with swollen papillae, compared with the conventional approach of performing needle-knife precut only after failure of standard biliary cannulation. The optimal timing of precut sphincterotomy remains a subject of debate, particularly in anatomically difficult papillae where repeated cannulation attempts may increase the risk of adverse events.

In this study, procedural outcomes, complication rates and recovery parameters were compared between two well-matched groups. The baseline characteristics were comparable between both groups regarding patient age, gender and body mass index. These findings are consistent with previous studies evaluating early versus delayed precut techniques, which reported balanced baseline characteristics between study groups [13,14].

In contrast, some broader ERCP studies have reported that demographic factors such as older age or higher BMI may be associated with increased procedural difficulty or higher complication rates. These findings disagree with our study, and the reported associations often vary depending on patient selection and definitions of difficult cannulation [15].

In the present study, comorbidities were not recorded for more than half of the patients (52.5% vs. 60%). Hypertension and diabetes mellitus were equally distributed in both groups (30% vs. 30% and 20% vs. 20%, respectively). Cardiovascular disease (12.5% vs. 10%) and chronic liver disease (7.5% vs. 5%, p = 0.7) also showed no significant differences, confirming baseline similarity between groups. These findings are consistent with several ERCP studies in which common comorbidities, such as hypertension and diabetes, were evenly distributed between procedural groups. In addition, ERCP literature commonly emphasizes the importance of documenting comorbidities as part of baseline patient assessment in studies evaluating procedural techniques and complications [16].

In our study, pre-procedural laboratory parameters showed no significant differences between both groups. These findings are consistent with previous studies, where baseline laboratory parameters are routinely assessed and often found to be similar between comparison groups, particularly in studies evaluating different cannulation strategies, including primary precut techniques. Comparable hemoglobin and platelet counts suggest similar bleeding risk at baseline, while similar bilirubin and INR values reflect comparable degrees of biliary obstruction and liver synthetic function [17].

In contrast Some studies focusing on high-risk populations, such as patients with cirrhosis or severe cholangitis, have reported significant variations in bilirubin and coagulation profiles associated with worse outcomes [18]. Therefore, the comparable distribution of ERCP indications further supports the conclusion that differences in outcomes are mainly attributable to the timing of the precut technique rather than underlying pathology [13].

In our study, the procedure time was significantly longer in Group A (Secondary Precut) compared to Group B (Primary Precut) (25.4 ± 6.2 minutes versus 18.3 ± 4.8 minutes). These findings indicate that primary precut was associated with a significantly shorter procedure duration. This result agrees with recent studies and meta-analyses demonstrating that early or primary advanced cannulation techniques reduce overall procedure duration by shortening the time spent on unsuccessful standard cannulation attempts [19]. However, some studies have reported no significant difference in procedure time between early and rescue precut approaches; such discrepancies may be explained by variations in operator experience, procedural protocols, and definitions of cannulation time [20].

In the present study, successful biliary cannulation rates were high in both groups. Cannulation was achieved in 97.5% (39/40) of patients in Group A (Secondary Precut) and 95% (19/20) in Group B (Primary Precut) (p = 0.51). These results demonstrate comparable efficacy between the two techniques in achieving successful biliary access, indicating that both approaches are similarly effective in terms of cannulation success. These findings agree with previous studies reporting comparable success rates between early and delayed precut approaches, particularly when procedures are performed by experienced endoscopists. Other studies demonstrating high cannulation success rates with primary or early needle-knife precut, often exceeding 90% when performed by experienced endoscopists [13].

In contrast older studies reported lower success rates with precut techniques, particularly when performed late or by less experienced operators. Meta-analyses have suggested improved success rates with early precut compared with repeated standard cannulation attempts [21].

In our study, the incidence of complications was low and comparable between both groups, with no statistically significant differences, indicating similar safety profiles for both techniques. These results are aligned with published literature showing that needle-knife precut does not significantly increase bleeding, perforation, or infection rates when performed by skilled endoscopists [22].

In the current study, the incidence of post-ERCP pancreatitis (PEP) was significantly higher in Secondary than Primary Precut. PEP occurred in 10% (4/40) of patients in Group A versus 5% (1/20) in Group B (p = 0.03). Regarding severity, Group A showed 3 mild and 1 moderate cases, whereas Group B had only 1 mild case with no moderate or severe presentations. These findings suggest a lower incidence and milder severity of PEP with primary precut.

This result is consistent with the conclusions of the ESGE guideline**,** which emphasizes that early precut performed by experienced endoscopists may reduce the risk of PEP by limiting pancreatic duct instrumentation. These results are in line with recent literature showing that early primary needle-knife precut reduces PEP by minimizing repeated papillary trauma and pancreatic duct manipulation**.** reported reduced pancreatic duct cannulation and lower PEP incidence with early precut, while**.** observed high success rates and no increase in pancreatitis [(15)]**.**

In our study, post-procedure serum amylase levels were significantly higher in Group A (Secondary Precut) compared to Group B (Primary Precut). The mean serum amylase level was 450±120 U/L in Group A versus 320 ± 90 U/L in Group B. This observation is consistent with literature showing that prolonged or difficult cannulation is associated with higher post-ERCP amylase levels and increased risk of post-ERCP pancreatitis**.** Early use of advanced cannulation techniques has been associated with reduced pancreatic duct trauma and lower enzyme elevation [(23)]**.**

Although elevated amylase alone does not confirm pancreatitis, the lower post-procedure amylase levels observed in the primary precut group support a protective effect of early biliary access.

In the present study, the need for repeat ERCP was higher in Group A (Secondary Precut) compared to Group B (Primary Precut). Repeat ERCP was required in 5% (2/40) of patients in Group A, whereas no cases were reported in Group B (0/20), with a statistically significant difference. This result is consistent with ERCP literature demonstrating that failed initial cannulation often necessitates repeat procedures, whereas higher first-pass success reduces the need for reintervention [(24)]**.**

On the other side, some earlier reports and studies with less experienced endoscopists found no significant difference in repeat ERCP rates between primary and secondary precut techniques, highlighting the influence of operator experience, patient selection, and procedural protocols [(25)]**.**

In our study, post-procedure hospital stay was significantly longer in Secondary than primary Precut. These findings are consistent with broader ERCP data linking shorter hospital stay to fewer complications, reduced pancreatic irritation, and more efficient procedures**.** Techniques that minimize procedural trauma and cannulation time are generally associated with earlier discharge [(26)]**.** However, others have reported no significant difference in hospital stay between primary and secondary precut groups, particularly in cohorts with high-risk patients or where operator experience varied, indicating that patient characteristics and procedural expertise may influence the impact of precut timing on hospitalization [(22)]**.**

Conclusion: Early use of needle-knife in patients with pregnant papilla was associated with shorter time of procedure, less incidence of post-ERCP pancreatitis and hospital admissions.

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