

ORIGINAL ARTICLE

Medicine Science 2026;35(2):582-6

Why not direct precut in anatomically challenging papillae: A single-center retrospective analysis

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Received 10 October 2025; Accepted 26 November 2025

Available online 09 April 2026 with doi: 10.5455/medscience.2025.10.263

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Abstract

Precut sphincterotomy is traditionally reserved as a rescue technique following failed biliary cannulation during endoscopic retrograde cholangiopancreatography (ERCP). However, repeated unsuccessful attempts increase the risk of post-ERCP pancreatitis (PEP). This study evaluated whether initiating ERCP with primary precut in anatomically challenging papillae reduces the incidence of PEP compared with rescue precut and conventional cannulation. We retrospectively analyzed 147 patients who underwent ERCP between January 2018 and February 2025 at a tertiary surgical endoscopy center. Patients were stratified into three groups: Group 1 (Primary Precutting, n=51), patients with difficult papillae (edematous, long/mobile, or tumor-infiltrated) in whom ERCP was initiated with direct precut; Group 2 (Standard Cannulation, n=49), patients with normal papillae successfully cannulated using a wire-guided technique; and Group 3 (Rescue Precutting, n=47), patients with difficult papillae who underwent precut after failed standard attempts. Demographic features, procedural outcomes, and complications were compared. The incidence of PEP was significantly higher in Group 3 (25.53%) than in Group 1 (7.85%) and Group 2 (8.16%) ($p=0.015$). No difference was observed between Groups 1 and 2. Post-ERCP serum amylase levels were also highest in Group 3 (388 ± 81.26 U/L) compared with Groups 1 (149.04 ± 43.61 U/L) and 2 (135 ± 22.84 U/L) ($p=0.001$). Cannulation success was comparable among groups (92.15%, 93.87%, and 89.36%, respectively; $p=0.718$). Bleeding rates were low and similar across groups ($p=0.608$), and no perforations occurred. In anatomically difficult papillae, direct precut should be considered the preferred initial strategy in experienced centers, as it achieves comparable safety to standard cannulation while markedly lowering the risk of PEP relative to delayed (rescue) precut.

Keywords: Precut sphincterotomy, difficult cannulation, endoscopic retrograde cholangiopancreatography, post-ERCP pancreatitis, biliary access

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP), first described in 1968, has become an indispensable tool in the diagnosis and treatment of pancreatobiliary disorders, particularly choledocholithiasis and extrahepatic cholestasis. The most technically demanding step of ERCP is selective biliary cannulation, and failure rates of up to 18% have been reported even in expert centers [1-3].

Traditionally, when standard wire-guided cannulation fails, alternative access techniques are considered. Among these, precut sphincterotomy (needle-knife papillotomy or

fistulotomy) is the most widely used rescue method. The precut is generally performed after repeated unsuccessful cannulation attempts or in cases where pancreatic duct cannulation predominates, both of which are well-established risk factors for post-ERCP pancreatitis (PEP). Reported success rates with precut exceed 89-91%, but the timing of its application remains debated. Some earlier studies associated precut with higher PEP risk, whereas more recent data suggest that early or primary precut, when performed by experienced endoscopists, does not increase PEP and may reduce the risks associated with prolonged manipulations [4-6].

The decision to apply precut is also influenced by papillary

CITATION

Ballı E, Bilgi Kirmacı M, Akici M, et al. Why not direct precut in anatomically challenging papillae: A single-center retrospective analysis. Med Science. 2026;35(2):582-6.



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anatomy. Morphological features such as marked edema, long or mobile papillae, or tumor infiltration at the papilla are strong predictors of difficult cannulation. In such anatomically challenging situations, repeated standard attempts may exacerbate trauma and increase complication rates [1,3,7,8].

Based on these considerations, our study aimed to evaluate the outcomes of primary precut as the initial cannulation strategy in patients with papillae anticipated to be difficult. We compared this approach with both rescue precut after failed attempts and successful standard wire-guided cannulation, focusing particularly on the incidence of PEP and procedure-related complications.

Material and Methods

Study Design and Setting

This retrospective cohort study was conducted at the General Surgery Department of Afyonkarahisar Health Sciences University, a tertiary referral and educational center for ERCP.

Ethics approval was obtained from the Institutional Ethics Committee of Afyonkarahisar Health Sciences University (Approval Date: 07 February 2025; Protocol No: 2025/2). All procedures were carried out in accordance with the ethical standards of the 1964 Declaration of Helsinki and its later amendments. Written informed consent was obtained from all participants prior to the procedure.

Our institution performs over 500 ERCP procedures each year. All procedures included in this study were performed by five experienced general surgeons specializing in endoscopic interventions. There is no gastroenterology department involved in ERCP at our center; all procedures are managed by the general surgery team.

Patient Selection and Group Classification

This study included patients who underwent ERCP between January 2018 and February 2025. Patients were categorized into three groups based on their initial cannulation technique.

Group 1 (primary precutting): Patients in whom selective biliary cannulation was presumed to be difficult and in whom the procedure was initiated directly using the precutting technique (n=54).

Group 2 (standard cannulation): Patients with normal papillary anatomy in whom wire-guided cannulation with a round-tip sphincterotome was successfully performed without precutting (n=50).

Group 3 (rescue precutting): Patients who initially underwent wire-guided cannulation, but after five times failed attempts, precutting was performed to achieve successful cannulation (n=50).

Patients in Group 3 had papillae that met the same morphological criteria for difficult cannulation as those in Group 1 (i.e.,

edema, mobility, and tumor infiltration); however, ERCP was initially attempted using standard cannulation, and precutting was applied only after five times failed attempts. In contrast, Group 2 comprised patients with normal papillary anatomy in whom cannulation was achieved without a precut intervention.

Three patients from Group 1, one patient from Group 2, and three patients from Group 3 were excluded from the study because their data could not be accessed through the system. A total of 147 patients were included in the study.

Demographic characteristics, procedural details, and PEP rates were compared between the groups.

ERCP Procedure and Techniques

All ERCPs were performed by experienced endoscopists using a side-viewing duodenoscope (Fujinon XL-Series, Japan). The procedures were performed under general anesthesia with the patients in the left lateral decubitus position.

Cannulation Techniques

Standard Cannulation: A 4.4F-tip sphincterotome and 0.035-inch straight guidewire were used for wire-guided biliary access.

Precutting Technique: A 5-mm needle-knife sphincterotome was used to perform an incision starting at the 11 o'clock position of the papilla and extending toward the biliary duct. Cannulation was attempted using a sphincterotome and guidewire.

Criteria for Direct Precutting Approach

In 2021, we published an article in the LESS journal describing the first precut approach. In this article, we have defined a number of criteria that indicate that cannulation will be difficult or unsuccessful [9]. Since 2021, our center has adopted a direct precutting strategy for patients with papillae exhibiting features associated with difficult cannulation, based on previously published criteria. These features include:

- Severely edematous papilla,
- Long, mobile papilla,
- Tumor infiltration at the papilla.

Patients who met at least one of these criteria underwent immediate precutting without prior wire-guided attempts.

Data Collection and Outcome Measures

Patient demographic characteristics, procedural outcomes, and post-ERCP complications were retrospectively extracted from the hospital electronic medical records. The primary outcome was the incidence of PEP, defined as

Serum amylase levels >3 times the upper limit of normal within 24 hours post-procedure,

New or worsening abdominal pain, consistent with pancreatitis.

The secondary outcomes included cannulation success rates, bleeding incidence, and other ERCP-related complications.

Exclusion Criteria

Patients were excluded if they had any of the following:

- Prior gastric or duodenal surgery affecting papillary access,
- Severe duodenal obstruction preventing scope passage,
- Previously failed ERCP referred from another center,
- Pre-existing acute or chronic pancreatitis,
- Biliary or pancreatic duct stenting,
- Age <18 years.

Statistical Analysis

Continuous variables were tested for normality using the Kolmogorov-Smirnov test. Normally distributed variables were analyzed using Analysis of variance (ANOVA), with post-hoc Tukey tests for group comparisons. Non-normally distributed variables (post-ERCP amylase levels) were analyzed using the Kruskal-Wallis test. Categorical variables (PEP incidence, gender distribution) were compared using Chi-square or Fisher’s

exact test A p-value<0.05 was considered statistically significant. Statistical analyses were performed using IBM Statistical Package for the Social Sciences (SPSS) Statistics v25.

Result

A total of 147 patients were included in this study. Of the 147 patients who participated in the study, 51 (34.69%) were in group Group 1, 49 (33.33%) were in Ggroup 2, and 47 (31.97%) were in group 3. The most common indication for ERCP was choledocholithiasis, which was observed in 88.23% of patients in Group 1, 93.87% in Group 2, and 85.10% in Group 3. No significant difference was observed in the prevalence of choledocholithiasis between the groups. Tumors were a less frequent indication, accounting for 9.80% of cases in group 1, 2.05% in group 2, and 8.51% in group Group 3. The lower incidence of tumors in Group 2 may be attributed to the patient selection criteria favoring cases with anatomical feasibility for standard cannulation attempts. Benign biliary strictures were the least common indication across all groups, with a prevalence of 1.97% in Group 1, 4.08% in Group 2, and 6.39% in Group 3. The highest proportion was observed in Group 3, but the difference was not statistically significant. The detailed distribution of ERCP indications across the groups is presented in Table 1.

Table 1. Distribution of ERCP indications across the study groups

ERCP indication	Group 1 (n=51)	Group 2 (n=49)	Group 3 (n=47)
Choledocholithiasis, n (%)	45 (88.23)	46 (93.87)	40 (85.10)
Tumor, n (%)	5 (9.80)	1 (2.05)	4 (8.51)
Benign stricture, n (%)	1 (1.97)	2 (4.08)	3 (6.38)

ERCP: Endoscopic retrograde cholangiopancreatography

The incidence of PEP varied significantly among the groups, with the highest rate observed in the rescue precutting group (Group 3: 25.53%) and the lowest rates recorded in the primary precutting (Group 1: 7.85%) and standard cannulation groups (Group 2: 8.16%) (p=0.015). The overall success rate of biliary cannulation was high across all groups, with rates of 92.15% in Group 1, 93.87% in Group 2, and 89.36% in Group 3, showing no statistically significant difference (p=0.718). Among the patients in whom cannulation failed, alternative approaches, such as percutaneous transhepatic biliary drainage (PTBD) or surgery, were required in 2.85% of Group 1, 10.64% of Group 3, and the procedure was repeated 2 days later for three patients in Group 2, and successful cannulation was achieved using the standard method. The incidence of post-ERCP bleeding was low, with one case each in Groups 1 (1.96%) and 3 (2.12%), and no cases in Group 2, with no significant intergroup difference (p=0.608). The sex distribution was similar across the groups, with no significant differences between female and male patient proportions (p=0.910). The cannulation failure rates were 2.85% in Group 1, 6.13% in Group 2, and 10.64% in Group 3 (Table 2), Figure 1.

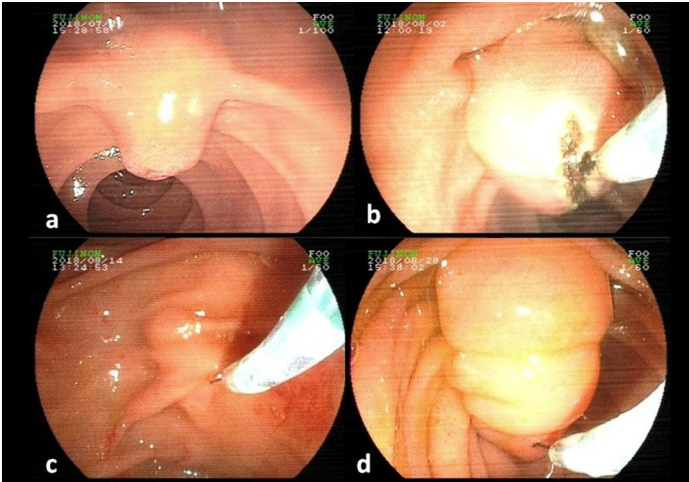


Figure 1. Stepwise precutting technique. (a) Endoscopic view of a difficult papilla before the intervention. (b) Initial incision using a needle-knife sphincterotome. (c) Further dissection to expose the biliary orifice. (d) Successful biliary access achieved after precutting

Table 2. Post-ERCP pancreatitis, cannulation success, and complication rates

Clinical outcomes	Category	Group 1		Group 2		Group 3		p value
		n	%	n	%	n	%	
Pancreatitis	Yes	4	7.85	4	8.16	12	25.53	0.015*
	No	47	92.15	45	91.84	35	74.47	
Cannulation	Successful	47	92.15	46	93.87	42	89.36	0.718
	Unsuccessful	4	7.85	3	6.13	5	10.64	
Bleeding	Yes	1	1.96	0	0	1	2.12	0.608
	No	50	98.04	49	100	46	97.88	
Gender	Female	28	54.90	29	59.18	27	57.44	0.910
	Male	23	45.10	20	40.82	20	42.56	

Chi-Square Test, Fisher’s Exact Test, ERCP: Endoscopic retrograde cholangiopancreatography

The mean age of patients was comparable across the three groups, with Group 1 (Primary Precutting) at 63.39 ± 2.03 years, Group 2 (Standard Cannulation) at 62.55 ± 2.20 years, and Group 3 (Rescue Precutting) at 60.98 ± 2.05 years. There was no statistically significant difference in the age distribution among the groups ($p=0.713$). Post-ERCP serum amylase levels varied significantly between the groups. The highest levels were observed in Group 3 (388 ± 81.26 U/L), which was significantly higher than those in Groups 1 (149.04 ± 43.61 U/L) and 2 (135 ± 22.84 U/L) ($p=0.001$). Detailed comparisons of age and post-ERCP amylase levels across groups are presented in Table 3.

Table 3. Comparison of age and post-ERCP amylase levels among study groups

Groups	Group 1	Group 2	Group 3	p
Age	63.39 ± 2.03	62.55 ± 2.20	60.98 ± 2.05	0.713
Post - ERCP amylase level	149.04 ± 43.605^a	135 ± 22.836^a	388 ± 81.256^b	0.001

Analysis of Variance (ANOVA), Kruskal-Wallis Test, Post-hoc Tukey Test, ERCP: Endoscopic retrograde cholangiopancreatography

Discussion

PEP remains the most frequent and clinically relevant complication of ERCP, with incidences ranging from 3% to 15% in high-risk populations and mortality up to 0.7% in severe cases (1,6). Several patient- and procedure-related factors, including female sex, pancreatic duct injections, sphincter of Oddi dysfunction, and difficult cannulation, have been established as major contributors to PEP development [1,7]. Among these, repeated unsuccessful cannulation attempts and papillary trauma are particularly important, as they prolong the procedure and directly increase the risk of PEP [1,6,7].

Traditionally, precut sphincterotomy has been applied as a rescue technique after standard wire-guided cannulation has failed. Early studies suggested that precut itself was a risk factor for PEP, reinforcing its role as a last resort [10,11]. However, subsequent evidence challenged this assumption, demonstrating that the increased risk was largely attributable to repeated failed attempts prior to precut rather than the technique itself [5]. Recent randomized trials and meta-analyses further indicated that early

or primary precut performed by experienced endoscopists may reduce the incidence of PEP compared with delayed precut [5,12].

Our study supports these findings by demonstrating that primary precut in anatomically challenging papillae resulted in PEP rates (7.85%) comparable to standard cannulation in normal papillae (8.16%), and significantly lower than rescue precut after failed attempts (25.53%). Moreover, post-procedural amylase levels, an objective surrogate marker of pancreatic irritation, were also significantly lower in the primary precut group than in the rescue group. These observations reinforce the concept that prolonged manipulations and repeated cannulation failures—not the precut technique itself—constitute the main drivers of PEP.

The anatomical predictors of difficult cannulation are well established, including severe papillary edema, long or hypermobile papillae, and papillary tumor infiltration [2,6,13]. In our cohort, these features guided the decision for primary precut, thereby reducing the need for multiple standard attempts and minimizing papillary trauma. This strategy was associated with high cannulation success (92.15%), comparable to both standard

cannulation (93.87%) and rescue precut (89.36%). Thus, primary precut in anatomically challenging papillae achieved effective biliary access without increasing the risk of failure.

With regard to safety, post-ERCP bleeding occurred in only one case each in the primary and rescue precut groups and in none of the standard group, with no significant differences. Importantly, no perforations were observed across the entire cohort. These findings are consistent with previous large-scale studies reporting bleeding incidences between 0.3% and 2% and perforation rates below 1% [1,7]. Collectively, our data confirm that primary precut, when performed by trained endoscopists in high-volume centers, does not increase adverse events [14,15]

The clinical implications of these results are significant. In patients with papillae showing morphological features predictive of difficult cannulation, direct precut should be considered the preferred initial approach in experienced centers. This strategy reduces the risk of PEP, avoids prolonged manipulations, and maintains high cannulation success without adding safety concerns. These findings align with the growing body of literature advocating for early precut in selected patients [9,16,17].

Nevertheless, this study has inherent limitations. Its retrospective design precludes detailed assessment of procedural time metrics, such as duration of cannulation attempts before precut in the rescue group. In addition, the sample size, although sufficient to demonstrate significant differences in PEP incidence, remains relatively modest compared with multicenter datasets. Finally, as all procedures were performed in a single surgical endoscopy unit, the generalizability of our findings may be limited to similarly high-volume, experienced centers.

Clinical Implications

The findings of this study highlight that in anatomically challenging papillae, where difficult cannulation is anticipated, direct precut should no longer be regarded solely as a rescue technique. When applied by experienced endoscopists in high-volume centers, primary precut offers a safer alternative to prolonged standard attempts, effectively lowering the incidence of PEP while maintaining comparable success and complication rates. This approach may refine current clinical practice by promoting earlier intervention in selected patients.

Conclusion

In anatomically difficult papillae, direct precut as the initial strategy is both safe and effective, achieving high cannulation success while significantly reducing the risk of PEP compared with delayed rescue precut. This technique should be considered the preferred approach in experienced centers.

Ethical Approval

Approved by the Institutional Ethics Committee of Afyonkarahisar Health Sciences University (No: 2025/2; Date: 07 February 2025).

Patient Consent

Informed consent was waived due to the retrospective design.

Conflict of Interest

The authors declare no conflict of interest.

Funding

No financial support was received.

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