ORIGINAL ARTICLE

# Early precut fistulotomy for biliary access: time to change the paradigm of "the later, the better?"

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**Background:** The precut timing during the biliary cannulation algorithm is a subject of controversy. Some studies suggest that early institution of precut is a safe and effective strategy even though the extent to which this approach may affect the duration of the ERCP is seldom addressed.

**Objective:** To assess the success, safety, and procedure duration of an early precut fistulotomy (group A) versus a classic precut strategy after a difficult biliary cannulation (group B).

**Design:** Single-center, prospective cohort study.

**Setting:** University-affiliated hospital.

**Patients:** A total of 350 patients with a naïve papilla.

**Interventions:** Standard biliary cannulation followed by needle-knife fistulotomy (NKF).

**Main Outcome Measurements:** Biliary cannulation rate, NKF success, adverse events, and ERCP duration.

**Results:** The overall cannulation rate was similar, at 96% and 94% for groups A and B, respectively. The adverse event rate was 6.2% and 6.4%, respectively, with pancreatitis as the most frequent adverse event (group A, 3.9%; group B, 5.2%). The mean ERCP duration was, however, significantly shorter in group A, both when biliary cannulation was achieved without precutting (14 minutes vs 25 minutes, $P < .001$) as well as when biliary cannulation was attempted after NKF (18 minutes vs 31 minutes, $P < .0001$).

**Limitations:** Single-center study design, referral center.

**Conclusions:** If the endoscopist is experienced in ERCP and precut techniques, an early precut strategy should be the preferred cannulation strategy because this approach is as safe and effective as the late fistulotomy approach and substantially reduces ERCP duration. (Gastrointest Endosc 2014;■:1-8.)

ERCP is an endoscopic interventional procedure commonly used in the management of biliary and pancreatic disorders.[1] Deep cannulation of the common bile duct (CBD) is one of the most demanding maneuvers performed during ERCP and is a prerequisite for a successful endoscopic biliary intervention. However, even among experienced endoscopists, biliary cannulation may fail in as many as 15% to 35% of the attempts when relying on standard methods alone.[2,3] If the decision is to continue with the ERCP in these patients, then other cannulation techniques are required to gain access to the bile duct.[4,5] Precut, a papilla incisional technique, is one of the available

*Abbreviations: ASA, American Society of Anesthesiologists; CBD, common bile duct; NKF, needle-knife fistulotomy.*

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options after a difficult biliary cannulation. The 2 most common precut techniques include the classic needle-knife and the needle-knife fistulotomy (NKF).

Although precut is known to increase the biliary cannulation rate, several prospective studies classify precut as an independent risk factor for post-ERCP adverse events.[4,6] Nonetheless, many endoscopists who favor precut argue that the reported high adverse events rates result from the conventional approach of merely resorting to precut after prolonged efforts at biliary cannulation (which is, per se, a risk factor for post-ERCP adverse events) and thus propose its early institution in the cannulation approach.[5,7]

There are studies suggesting that early institution of the precut is a safe and effective strategy even though conflicting results concerning post-ERCP adverse events have been reported when compared with conventional techniques.[8] However, these studies have seldomly addressed the impact of the precut timing in the global ERCP duration.

The aim of this study was to compare 2 alternative biliary cannulation strategies: early precut fistulotomy and late precut fistulotomy.

**Take-home Message**

- An early precut cannulation strategy is at least as successful and safe as the classic cannulation strategy of using precut only after a difficult cannulation and presents 1 main advantage: there is a substantial reduction in the duration of the ERCP. If the endoscopist is experienced with these techniques, why not consider an early precut strategy the preferred approach?

## METHODS

### Type of study, setting, and selection of participants

This was a prospective cohort, single-center study that was conducted at a university-affiliated hospital. Between January 2011 and February 2012, all consecutive patients with naïve papillae referred for biliary ERCP, with the ability to give informed consent, were eligible for recruitment. Exclusion criteria were (1) a periampullary diverticulum (defined as a papilla on the edge of or within the diverticulum), (2) Billroth II gastrectomy, (3) abnormal coagulation test results (international normalized ratio $>1.5$, prothrombin time $>3$ seconds of the upper limit of normal), and (4) tumors of the papilla (diagnosed during ERCP). These criteria either precluded the use of the precut technique (criterion 3) or potentially decreased its technical safety because of anatomic features (criteria 1, 2, and 4).[9]

The hospital's ethics committee approved this study, and informed consent was obtained from all patients for the procedure.

### Study design and definitions

The 2 endoscopists in this study had similar experience in ERCP, performing more than 200 ERCPs per year with a mean of more than 10% of NKFs per year. Before December 2010, the 2 endoscopists regularly used precut fistulotomy as a rescue technique after a difficult biliary cannulation according to the policy of the unit and had comparable results in terms of success, adverse events, and duration of the ERCP. Endoscopist A started using an early precut NKF approximately 2 months before the beginning of the study and completed 20 procedures. After January 2011, endoscopist A started using fistulotomy at an earlier phase, whereas the other endoscopist (endoscopist B) continued with the standard unit cannulation policy. Patients were assigned to each endoscopist according to their available schedules (each endoscopist performed ERCP on a different day of the week) by an administrative assistant blinded to the study, per the standard protocol of the unit. On average, each endoscopist usually was assigned the same number of patients per week.

**Group A (early precut fistulotomy strategy).** CBD cannulation of patients assigned to endoscopist A was initially attempted by using a standard biliary approach. If biliary access was unsuccessful after 5 minutes or after as many as 5 biliary attempts (by using wire-guided direction as a roadmap for CBD identification before injection) or if there was any pancreatic duct cannulation, an NKF was performed. The NKF time limit was 15 minutes, after which ERCP was discontinued. For the purpose of analysis, this group was subdivided into 2 subgroups: A1 (successful expeditious standard cannulation subgroup) and A2 (early NKF subgroup).

**Group B (late precut fistulotomy strategy).** CBD cannulation of patients assigned to endoscopist B was initially attempted by using standard biliary cannulation. If the biliary access was unsuccessful after 15 minutes or after as many as 10 biliary attempts (by using wire-guided direction as a roadmap for CBD identification before injection), an NKF was subsequently attempted. The NKF time limit was 15 minutes, after which ERCP was discontinued. For the purpose of analysis, these patients were also divided into 2 subgroups: B1 (successful classic standard cannulation subgroup) and B2 (late NKF subgroup).

Biliary cannulation was confirmed after obtaining a cholangiogram with the catheter inserted selectively in the CBD. After ERCP, all patients were hospitalized for at least 24 hours before discharge. Serum amylase or lipase levels were only obtained if adverse events were suspected. The durations of both ERCP and CBD cannulation were measured from the moment the papillotome was advanced out of the tip of the endoscope in front of the papilla. Data on the procedure (eg, duration, number of biliary attempts, pancreatic duct cannulation) and adverse events were collected by a research nurse present in the ERCP

suite, but not directly involved in the ERCP. Postprocedure adverse events were collected by the research nurse by using the electronic clinical records and, if necessary, contacting the patient or the patient's primary care provider, as necessary. Follow-up data (from 30 days after ERCP) were obtained from all patients.

Adverse events were defined according to guidelines established by a consensus conference on ERCP (Table 1).[10]

## ERCP and cannulation techniques

All patients were prepared and sedated by an anesthesiologist as standard medical practice. A therapeutic videoduodenoscope (TJF 160 VR; Olympus Corporation, Melville, NY) was used in all procedures, and diathermy was applied by using electrosurgical current in the 120-W endocut mode, effect 3 (Olympus-PSD 60; Olympus Corporation).

Pharmacological prophylaxis of post-ERCP pancreatitis was not performed during the period of the study, and prophylactic pancreatic stents were not used.

**Standard biliary cannulation.** Standard cannulation of the bile duct was regularly attempted with a triple-lumen sphincterotome (Ultratome XL; Boston Scientific, Natick, Mass) preloaded with contrast and a guidewire (Jagwire; Boston Scientific). We attempted to cannulate with the tip of the sphincterotome, and, once inside the duct, a wire was advanced. If this was unsuccessful, the endoscopist could opt for another biliary catheter (tapered tip or ball tip) or use different guidewires.

**Needle-knife fistulotomy.** NKF was performed by using a needle-knife (Olympus KD-11Q; Olympus Corporation). After making a puncture in the papilla above the orifice, the incision was made upward or downward (depending on the position of the initial puncture), along the axis of the bile duct, while maintaining at least a 3-mm distance from the papillary orifice. The cut was slowly extended until the CBD was exposed, followed by a small incision in the muscle. The CBD was then cannulated directly with the closed needle-knife or with a papillotome (wire guided) if the needle-knife did not slide.

Once deep cannulation was achieved, a cholangiogram was obtained by using low-osmolality, nonionic contrast (Ultravist [iopromide]; Bayer Schering Pharma, Berlin, Germany), and the necessary therapeutic maneuvers were performed.

A second ERCP was proposed 7 to 14 days later in case of a failed first ERCP approach; the procedure was performed by the same endoscopist.

## Outcome measures

The main outcome measures were successful biliary cannulation, post-ERCP adverse events, and total duration of the ERCP.

## Statistical analysis

Statistical analysis was performed by using the SPSS software, version 20.0.0 (IBM, Armonk, NY).

**TABLE 1. Consensus definition of ERCP adverse events**

| Adverse event | Severity | Grading criteria |
|---|---|---|
| Pancreatitis | Mild | Clinical pancreatitis, amylase >3 times normal at least 24 h after ERCP, requiring admission (or prolongation of) up to 3 days |
| | Moderate | Hospitalization of 4-10 days |
| | Severe | Hospitalization for >10 days or hemorrhagic pancreatitis, pancreatic necrosis, pseudocyst, or percutaneous or surgical intervention |
| Bleeding | Mild | Clinical evidence of bleeding, decrease in hemoglobin to <3 g/L and no need for transfusion |
| | Moderate | Transfusion (≤4 units); no angiographic intervention or surgery |
| | Severe | Transfusion (≥5 units) or intervention (angiographic or surgical) |
| Perforation | Mild | Possible or only very slight leak of fluid or contrast, treatable by fluids and suction for ≤3 days |
| | Moderate | Any definite perforation treated for 4-10 days |
| | Severe | Medical treatment for >10 days or intervention (percutaneous or surgical) |

Variables were summarized by using the mean, standard deviation, range (if continuous and normal distribution), and proportions (if categorical). Differences between groups were measured using a $\chi^2$ test for categorical variables, whereas continuous variables were analyzed by using a 2-sample $t$ test. $P < .05$ was considered statistically significant.

## RESULTS

A total of 390 patients with naive papilla underwent ERCP from January 2011 to February 2012. After applying the exclusion criteria, 350 patients were included in this study (Fig. 1). The mean age for the entire group was 68.2 years (range 18-102 years), 28% of whom were American Society of Anesthesiologists (ASA) grade III or IV, and 55% of the population were female (n = 193).

Patients were assigned to an early precut fistulotomy strategy (expeditious standard cannulation followed by an early precut fistulotomy in case of failure) (group A,

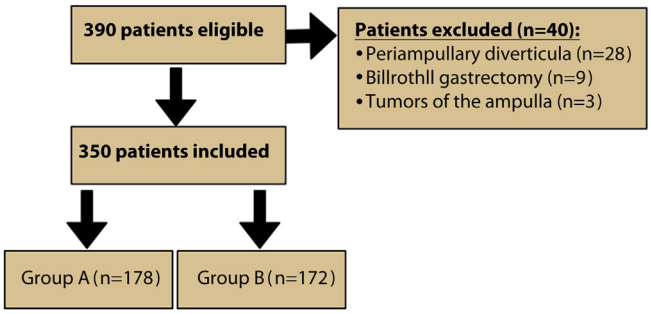


**Figure 1.** Flowchart of the study design.

n = 178) or a late precut fistulotomy strategy (classic standard biliary cannulation followed by a late fistulotomy in case of failure) (group B, n = 172). Analysis of both groups demonstrated that patients were matched for age, sex, ASA grade, distal CBD diameter, indications, interventions, main pancreatic duct cannulation, and final diagnosis (Table 2). The 2 groups were also comparable according to the grade of ERCP difficulty: grade 1 (group A, 78% vs group B, 80%; $P = .658$), grade 2 (group A, 22% vs group B, 20%; $P = .534$).[11]

## Biliary cannulation rate

The biliary cannulation rates are summarized in Table 3. In the early precut fistulotomy strategy, CBD cannulation was successful by using the standard cannulation technique in 130 patients of a total of 178 (73%). An early NKF was performed on the remaining patients, and deep biliary cannulation was achieved in 41 of the 48 patients (85.4%), resulting in a 96% success rate for the first ERCP. In group B, CBD cannulation by the standard technique was successful in 137 patients of a total of 172 patients (79.7%). A late NKF was performed on the remaining patients, and deep biliary cannulation was achieved in 24 of the 35 patients (68.6%), resulting in a 93.6% cannulation rate for the first ERCP in this group.

In group A, a second ERCP was scheduled for 4 of the 7 failures (the other 3 patients were not referred for a second ERCP). The CBD was cannulated during the second ERCP in 4 patients, increasing the NKF success rate to 93.8% (45/48) and overall biliary cannulation success rate to 98.3% after 2 ERCPs (175/178).

In group B, a second ERCP was scheduled for 7 of the 11 patients (the remaining 4 patients were not referred for a second ERCP). The CBD was cannulated during the second ERCP in 5 patients, increasing the NKF success rate to 82.9% (29/35) and overall biliary cannulation success rate to 95.9% after both ERCPs (165/172).

## Post-ERCP adverse events

The overall adverse event rate was 6.2% in group A and 6.4% in group B. Pancreatitis was the most common adverse event, with a 3.9% rate in group A and 5.2% rate in group B. Only 1 severe adverse event was reported and managed successfully with conservative measures in the successful expeditious standard cannulation subgroup (Table 4).

**Successful standard cannulation subgroups (subgroups A1 and B1).** The post-ERCP adverse events rate for patients in whom the biliary duct was successfully accessed by standard techniques was 5.3% in group A1 and 5.8% in group B1. There were 6 patients with pancreatitis in the classic standard cannulation subgroup (4.4%) and 5 patients (3.8%) in the successful expeditious standard cannulation subgroup. The only case of severe pancreatitis occurred in 1 patient in the early precut fistulotomy strategy.

**NKF after unsuccessful standard cannulation subgroups (subgroups A2 and B2).** The adverse event rate for patients undergoing NKF was 8.3% in subgroup A2 and 8.6% in subgroup B2. The post-ERCP pancreatitis rate was higher in the late precut fistulotomy strategy (subgroup B2) compared with the early precut fistulotomy strategy (subgroup A2) (8.6% vs 4.2%). There were 2 patients (4.2%) with mild bleeding in group A and no bleeding in group B.

## Duration of the ERCP procedure

The mean duration of the complete ERCP procedure with the early precut fistulotomy strategy was significantly shorter than with the late precut fistulotomy strategy, both when biliary cannulation was achieved without the precut (14 minutes vs 25 minutes, $P < .001$) as well as when biliary cannulation was attempted with an NKF (18 minutes vs 31 minutes, $P < .001$) (Table 5).

# DISCUSSION

The precut timing in the biliary cannulation algorithm is a subject of controversy, even in centers with precut expertise.[7,12,13] This study compared the standard cannulation policy of our unit (late precut fistulotomy) with an alternative cannulation protocol (early precut fistulotomy) adopted by one of the endoscopists. The criteria for switching from a standard cannulation to precut during an ERCP were arbitrarily defined by the judgment of the endoscopists involved, based on their experience as reported in previous studies.[4-6] For comparative purposes, these arbitrary definitions are an obvious limitation, and it would be important to define objective criteria on this topic in the future.

There are several described precut techniques that mainly use 2 accessories: a needle-knife (free-hand technique) and a traction papillotome, although other devices such as the Iso-Tome (MTW Endoskopie, Wesel, Germany) or endoscopic scissors were reported.[14,15] Moreover, there are no definite data demonstrating the superiority of an

**TABLE 2. Patient's characteristics, indications, and diagnosis**

| | Group A (n = 178), no. (%) | Group B (n = 172), no. (%) | *P* value |
|---|---|---|---|
| Age (mean, SD) | 69 (15.9) | 66.9 (18.8) | .249 |
| Male sex | 79 (44) | 78 (45) | .470 |
| ASA grade III-IV | 44 (25) | 47 (27) | .467 |
| History of pancreatitis, no. (%) | 14 (8) | 11 (6) | .356 |
| Previous failed ERCP, no. (%) | 9 (5) | 11 (6) | .451 |
| Indications, no. (%) | | | |
| Choledocholithiasis | 103 (58) | 102 (59) | .782 |
| Malignant jaundice | 27 (15) | 24 (14) | .473 |
| Dilated CBD | 18 (10) | 18 (10) | .564 |
| Bile leaks | 8 (4) | 7 (4) | .462 |
| Acute gallstone pancreatitis | 8 (4) | 9 (5) | .403 |
| Other | 14 (8) | 12 (7) | .516 |
| Final diagnosis | | | |
| Choledocholithiasis | 81 (46) | 79 (46) | .563 |
| Normal cholangiogram findings | 42 (24) | 38 (22) | .491 |
| Malignant biliary stricture | 33 (18) | 31 (18) | .533 |
| Bile leaks | 5 (3) | 5 (3) | .651 |
| Benign biliary stricture | 5 (3) | 5 (3) | .597 |
| Other | 12 (7) | 14 (8) | .552 |
| Pancreatogram | 16 (9) | 22 (13) | .148 |
| Sphincterotomy | 173 (97) | 171 (99) | .123 |

*SD*, Standard deviation; *ASA*, American Society of Anesthesiologists; *CBD*, common bile duct.

individual precut technique in terms of safety or success.[16] However, theoretically, NKF may have a lower rate of pancreatitis compared with the classic precut technique because the pancreatic orifice is avoided; nonetheless, further studies are required to clarify this issue.[16]

As expected, the biliary cannulation success rate after standard cannulation attempts was higher with the late precut (80%) than the early precut (73%) strategy, although not achieving statistical significance ($P = .092$). The registered CBD cannulation rates following a standard approach are comparable to those of existing studies, such as the 67% cannulation rate reported by Lim et al[17] in less than 5 minutes and the 83% reported by Bruins Slot et al[2] within a time limit of 30 minutes. The overall biliary cannulation rate higher than 90% obtained in this study was also comparable to other reports from tertiary centers.[3,6,9] When a second ERCP was performed in the primary failures, the overall CBD cannulation improved to more than 96% in both groups. The strategy of performing a second ERCP when an NKF is unsuccessful in the first ERCP was highly effective and safe, as previously reported.[17,18] The results suggest that the success rates for these 2 cannulation strategies are similar.

Despite the higher success rate of the standard cannulation in the late precut strategy, the reported 7% difference entailed spending an extra time (11 minutes) on the complete procedure (14 minutes vs 25 minutes). The difference in the ERCP duration when NKF was performed (18.5 minutes vs 31.3 minutes) was based on the initial duration of the standard attempts and not the NKF itself because the average difference in duration of the NKF (albeit statistically significant) between the 2 strategies (5.3 minutes vs 6.5 minutes) was only 1.2 minutes. The shorter duration of the ERCP may be clinically beneficial if one considers the relatively high percentage of elderly and advanced grade ASA patients (>25% grades III/IV). It is important to emphasize that the complexity of the ERCP procedures was comparable, and both endoscopists had previous similar indicators. The impact of lowering the threshold of the precut timing in the total duration of the

**TABLE 3. ERCP and NKF success rate**

| | Group A (n = 178), no. (%) | Group B (n = 172), no. (%) | *P* value |
|---|---|---|---|
| Successful standard cannulation | 130 (73) | 137 (80) | .092 |
| Fistulotomy attempt | 48 (27) | 35 (20) | .092 |
| Cannulation success after NKF (first ERCP) | 41 (85) | 24 (69) | .059 |
| Cannulation success in the first ERCP | 171 (96) | 161 (94) | .221 |
| Overall fistulotomy success | 45 (94) | 29 (83) | .509 |
| Overall biliary cannulation rate | 175 (98) | 165 (96) | .532 |

*NKF*, Needle-knife fistulotomy.

**TABLE 4. ERCP adverse events**

| | Group A (n = 178), no. (%) | Group B (n = 172), no. (%) | *P* value |
|---|---|---|---|
| Adverse events (<30 days) | 11 (6) | 11 (6) | .478 |
| Pancreatitis | 7 (4) | 9 (5) | – |
| Bleeding | 4 (2) | 2 (1) | – |
| Successful standard cannulation | 7 (5) | 8 (6) | .921 |
| Pancreatitis | 5 (4) | 6 (4) | – |
| Mild | 3 (2) | 4 (3) | – |
| Moderate | 1 (1) | 2 (2) | – |
| Severe | 1 (1) | 0 (0) | – |
| Bleeding (mild) | 2 (2) | 2 (2) | – |
| NKF after unsuccessful standard cannulation | 4 (8) | 3 (9) | .644 |
| Pancreatitis (mild) | 2 (4) | 3 (9) | – |
| Bleeding (mild) | 2 (4) | 0 (0) | – |

*NKF*, Needle-knife fistulotomy.

ERCP has seldomly been addressed in previous studies, and as far as it is known, this is the first study to report this variable in detail when comparing 2 cannulation strategies with different precut timings.

Although precut strategy may increase the rate of a successful cannulation to more than 95%,[2,6,17] several prospective studies have indicated the precut strategy to be an independent risk factor for post-ERCP adverse events, particularly pancreatitis.[4,6,19] The adverse event rate for the precut strategy reported in the medical literature varies from 2% to 30%, depending on several factors, including the expertise of the center, the selection of patients, and the design of the study.[4,20,21] As the use of the precut strategy generally follows a difficult cannulation, it remains a matter of debate whether the increased risk is related to the precut itself or is linked to the manipulation of the papilla that precedes it. A difficult cannulation is characterized by repeated biliary attempts and/or manipulation (wires and injection of contrast) of the main pancreatic duct, which is in likely to induce trauma, edema, and inflammation to the papillary bed, thus obstructing main pancreatic duct drainage.[22] Furthermore, the NKF is technically challenging because of the need to master the control of the needle-knife (especially the depth) as well as the need to be proficient in recognizing the CBD.[23]

Although the overall post-ERCP adverse events were similar with both cannulation strategies (6.2% vs 6.4%), when the NKF subgroups were analyzed, a tendency for a higher pancreatitis risk became apparent, albeit not statistically significant, in the late NKF (8.6% vs 4.2%). The pancreatitis rate for the early precut strategy is comparable between the 2 subgroups (A1, 3.8% and A2, 4.2%),

**TABLE 5. ERCP procedure and CBD cannulation duration**

| | Group A (min) | Group B (min) | *P* value |
|---|---|---|---|
| Duration of CBD cannulation attempts | | | |
| Successful standard cannulation, mean (SD) | 4.4 (0,5) | 12.3 (2,4) | <.001 |
| Successful NKF cannulation, mean (SD) | 5.3 (3.9) | 6.5 (3.3) | <.001 |
| Failed NKF cannulation, mean (range) | 12.2 (2.1-14.1) | 11.8 (3.1-13.8) | .187 |
| Total duration of ERCP procedure | | | |
| Successful standard cannulation, mean (SD) | 14 (10,9) | 25 (15,4) | <.001 |
| NKF after unsuccessful standard cannulation, mean (SD) | 18,5 (12,8) | 31,3 (15,3) | <.001 |

*CBD*, Common bile duct; *SD*, standard deviation; *NKF*, needle-knife fistulotomy.

suggesting that the actual procedure of NKF is not the risk factor for pancreatitis. Lim et al[17] also reported a comparable post-ERCP pancreatitis rate between the early NKF patients and the standard cannulation group (4.2% vs 3.4%). The probable culprit is the longer duration of standard attempts, as suggested by the late precut strategy. Another interesting point is the fact that the only severe adverse event occurred in the least probable group: successful expeditious standard cannulation subgroup. An easy biliary cannulation does not preclude a pancreatitis. This supports the notion that the mechanism of post-ERCP pancreatitis is complex and further studies are required to unveil it. We should emphasize that in our unit, we do not perform sphincter of Oddi manometry, nor do we offer or perform ERCP for suspected sphincter of Oddi dysfunction type III patients. All cases of bleeding were mild, with no need for transfusions.

As the historical overall adverse event rate was low, including pancreatitis, prophylactic pancreatic stenting is seldomly performed at our center. In this cohort of patients, no pancreatic stents were used, although currently there is strong evidence recommending periprocedural rectal administration of nonsteroidal anti-inflammatory drugs in all ERCPs and/or pancreatic stents in high-risk patients.[24]

These results suggest that an early precut strategy is at least as successful and safe as the classic cannulation strategy, but with 1 main advantage: there is a substantial reduction in the duration of the ERCP. Additionally, if the endoscopist is experienced in these techniques, why is an early precut strategy not the preferred approach? Because the results were obtained in a unit with expertise in ERCP and NKF, this suggestion cannot be applicable to the average endoscopist, as recommended by other authors.[16]

The main drawback of this study could be considered our study design. The rationale behind this study was that a simple strategy (early NKF strategy) would result in an equal or higher success rate of cannulation, with a similar or lower proportion of adverse events and possibly saving time. Because previous studies reported a diversity of outcomes estimates, the number of patients needed to perform a randomized, controlled trial would be difficult to calculate, and a very large number of patients would be needed if we anticipate differences of 5% in terms of adverse event rates and/or cannulation rates and/or time spent on the fistulotomy that was seldom described before.[9] Thus, we decided to simply describe our experience using (as much as possible) standardized procedures prospectively and for the first time address all 3 outcomes combined. Our data could now give more support for a multicenter trial design to increase the evidence of our recommendations, even though it would be an extremely difficult project to implement.

In conclusion, the early use of a precut fistulotomy is as safe and effective as the classic approach of performing the precut only after a difficult biliary cannulation. Moreover, the results suggest that the risk of post-ERCP pancreatitis may originate from the difficult biliary cannulation and not the fistulotomy itself. In addition, this strategy substantially decreases the time to perform the ERCP, an issue that should be addressed in future studies, taking into consideration other factors such as costs, scheduling, and anesthesia.

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