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;80:634-41.)

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