Needle Knife Sphincterotomy Does Not Increase the Risk of Pancreatitis in Patients With Difficult Biliary Cannulation

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BACKGROUND & AIMS: **Biliary cannulation is unsuccessful during 5%–10% of endoscopic retrograde cholangiopancreatography (ERCP) procedures. Needle knife sphincterotomy (NKS) can improve success of cannulation but is often used as a last resort and is associated with post-ERCP pancreatitis (PEP). We evaluated the safety and efficacy of performing NKS during early stages of difficult cannulation and the relationship between difficult cannulation and the risk of PEP.**

METHODS: **We performed a prospective trial of consecutive patients with an intact papilla who were undergoing ERCP at tertiary referral center; 73 patients were defined as having difficult biliary cannulation according to predefined cannulation parameters. These patients were randomly assigned to groups that received either NKS or continued standard cannulation. Main outcome measures were PEP and successful biliary cannulation.**

RESULTS: **Of 464 patients with an intact papilla undergoing ERCP, 73 met the criteria for difficult cannulation. Cannulation success in difficult cannulation cases was 86%, with a PEP rate of 19%. There was no difference in eventual cannulation success between the groups. However, 65% of the patients assigned to the standard cannulation group required crossover to NKS. There was no significant difference in development of PEP among patients in the early NKS group (20.5%) vs standard cannulation (17.6%). Pancreatic duct stents were inserted in 23 of the patients in the early NKS arm and in 15 in the standard cannulation arm. The number of cannulation attempts (more than 7) increased the risk of PEP ($P < .01$). On the basis of multivariate analysis, independent risk factors for PEP were failure of early cannulation and failure of biliary cannulation.**

CONCLUSIONS: **Early application of NKS during difficult cannulation does not increase the risk of PEP. The risk of PEP increases greatly after 7–8 attempts at or failure of cannulation. Further studies are required to assess whether early implementation of NKS during difficult cannulation reduces the development of PEP. Australia and New Zealand Clinical Trials registry: ANZTRN 12,612,000,060,842.**

Keywords: Precut Sphincterotomy; Liver; Pancreas; Surgery.

Endoscopic retrograde cholangiopancreatography (ERCP) is a pivotal component of the established therapies for pancreaticobiliary disease.[1] Since first reported more than 40 years ago,[2] cannulation of the desired duct remains one of the integral elements to a successful procedure; however, conventional techniques even in high-volume centers fail in 5%–10% cases.[3,4] Needle knife sphincterotomy (NKS), also referred to as precut sphincterotomy or access papillotomy,[5] may allow cannulation success rates to approach 100%. However, it has long been considered technically challenging and potentially hazardous.[6] NKS is often performed at the end of a difficult and prolonged cannulation effort that is associated with repeated attempts and multiple prior pancreatic duct (PD) cannulations. These 2 factors are both independently linked with a higher incidence of post-ERCP pancreatitis (PEP).[7,8] Prospective evaluation of the quantitative relationship between difficult cannulation and PEP is not established; however, as time and failed attempts accumulate, there is a watershed period where the likelihood of selective biliary cannulation declines and the risk of PEP swiftly escalates.[9] The challenge is to identify the seminal events immediately before this point and apply an intervention to reduce the risk and deliver success. The application of an early NKS strategy for difficult cannulation in response to these triggers may reduce the occurrence of PEP; this formed the basis for our study.

Abbreviations used in this paper: CS, continued standard; ERCP, endoscopic retrograde cholangiopancreatography; ES, early success; NKS, needle knife sphincterotomy; OR, odds ratio; PD, pancreatic duct; PEP, post-ERCP pancreatitis.

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Methods

The study was designed as a randomized, prospective single-center study. The Sydney West Area Health Service human ethics and research committee approved the study. All patients gave their informed consent.

Patients

From July 2007–December 2009, all patients with an intact papilla and without exclusion criteria were invited to participate in the study. Exclusion criteria included the following: age younger than 18 years, acute illness (hypoxia, systolic blood pressure less than 90 mm Hg, hemodynamic instability), inability or refusal to give informed consent, and recent (<2 weeks) diagnosis of acute pancreatitis. Patients with a preprocedure diagnosis of pancreatic or ampullary malignancy were excluded, because in our experience, PEP is very uncommon in these subgroups, and tumor-related anatomic variation may alter the cannulation technique. Patients with surgically altered anatomy (Billroth-II, Roux-en-Y anastomosis) were also excluded, because cannulation technique is fundamentally different compared with normal anatomy. As a tertiary referral center, referrals are received from other centers/endoscopists for difficult cannulation cases including previously failed biliary cannulation. Patients with a previously failed cannulation were enrolled in the study unless an NKS had been previously attempted or the patient had developed PEP as a result of the previous attempt.

Study Design

The study was performed in a tertiary referral university hospital endoscopy unit, which has a dedicated ERCP training fellow. Each procedure was supervised by 1 of 4 senior endoscopists (M.J.B., S.J.W., R.H., and D.R.), each with a career experience of more than 3000 ERCPs and an individual annual caseload of between 100 and 600 procedures per year. Procedures were performed in a dedicated endoscopic fluoroscopy room, with the patient in the prone position with monitored anesthesia care by using propofol-based sedation. An Olympus Exera TJF-160R duodenoscope (Olympus Optical, Japan, Tokyo) was used in all cases. All procedures were commenced with a wire-guided cannulation technique that has been previously described in detail,[4] which uses a triple-lumen sphincterotome (CleverCut3; Olympus Optical Co, Ltd) and a 400-mm length hydrophilic wire (Jagwire; Boston Scientific, Natick, MA). If required, an NKS was performed by using a 3-mm-long Olympus needle knife (Olympus Optical Co). The dedicated ERCP fellow commenced the majority of procedures. A strictly defined cannulation protocol was implemented throughout the study: 5 minutes allocated for successful biliary cannulation from the first touch of the papilla, a total of 5 cannulation attempts, and no more than 2 inadvertent PD cannulations. If the fellow exceeded any of the parameters, the consultant took over the case. The consultant also followed the same cannulation protocol. Successful cannulation was defined as free and deep instrumentation of the biliary tree. A cannulation attempt was defined as sustained contact between the sphincterotome and the papilla for at least 5 seconds. Early success (ES) was defined as successful cannulation within the parameters of the cannulation protocol. If the consultant was unsuccessful according to the prescribed parameters, the patient was then randomized to continued standard (CS) cannulation techniques or to early NKS. Randomization was revealed at the time by the opening of a sealed envelope by a member of the endoscopy team. After randomization, 10 minutes was allotted for cannulation with unlimited attempts. At the conclusion of the additional 10 minutes, patients in the standard cannulation arm were classified as conventional cannulation failures. Crossover to the NKS arm was then allowed if clinically appropriate. Time intervals were based on previous prospective correlation trials at our center.[4,9]

The NKS technique was standardized and followed the conventional (freehand papillotomy/deroofing) NKS (Figure 1) method.[4,10] The cut was commenced from the superior aspect of the papillary orifice and extended upward in 2-mm increments by using Endocut I from an ERBE Vio 300 generator (Tübingen, Germany). The goal was to completely divide the majority of the papillary mound in a controlled stepwise fashion with a single pass, thus unroofing the biliary orifice, which once identified was then selectively cannulated with a guidewire passed through a sphincterotome. All operators used the same technique. The sphincterotomy was then completed in the conventional manner after successful cannulation.

Endoscopists placed a pancreatic stent (Zimmon; Cook Medical, Bloomington, IN; single pigtail, 2–5 cm 5F, single proximal flange with the proximal end not beyond the pancreatic genu) before NKS if the PD had been cannulated at least twice. If the

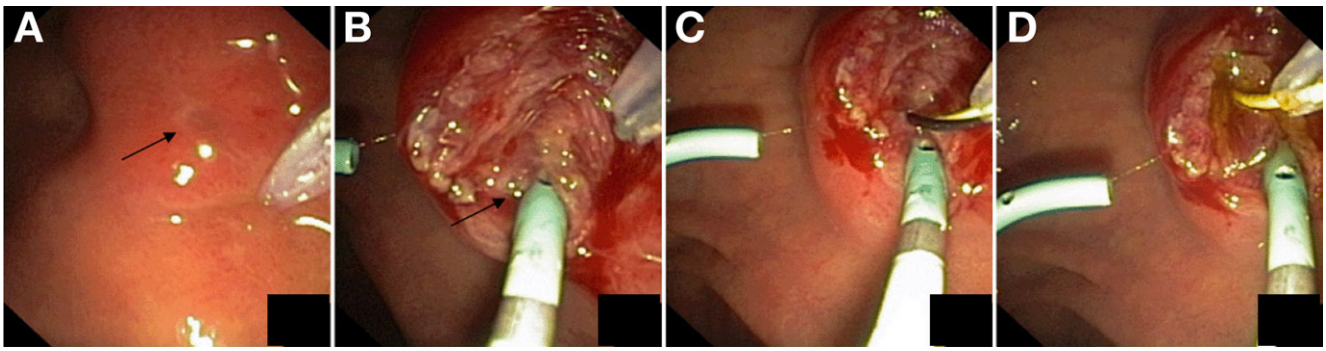

Figure 1. Technique of NKS over PD stent. (*A*) Sphincterotome tip at PD orifice. *Arrowhead* at biliary orifice. (*B*) A 5F pancreatic stent in situ. Papillotomy NKS performed through the fibromuscular sphincter and exposing the biliary orifice (*arrowhead*) between the 10 and 11 o'clock positions in relation to the pancreatic stent. (*C*) Soft-tipped 0.035-mm biliary wire inserted through biliary orifice and into bile duct (confirmed on x-ray not shown). (*D*) After complete sphincterotomy with biliary wire and pancreatic stent still in situ and evidence of spontaneous bile drainage.