Needle-Knife Fistulotomy versus Standard Method for Cannulation of Common Bile Duct: A Randomized Controlled Trial

Morteza Khatibian MD*, Rasoul Sotoudehmanesh MD*, Ali Ali-Asgari MD*, Zohreh Movahedi MD*, Shadi Kolahdoozan MD*

Background: Endoscopic retrograde cholangiopancreatography with endoscopic sphincterotomy has become widely available for the treatment of pancreatobiliary diseases; however, it has mortality and complications. The aim of this study was to compare the success rates and complications of two different methods of common bile duct cannulation.

Methods: From June 2003 through February 2004, patients who were candidates for endoscopic retrograde cholangiopancreatography and/or endoscopic sphincterotomy were randomly divided into two groups: standard cannulation (group A) and suprapapillary needle-knife fistulotomy (group B). Postendoscopic retrograde cholangiopancreatography pancreatitis, cholangitis, bleeding, and perforation were evaluated.

Results: Two hundred and eighteen cases (86 males and 132 females with a mean±SD age of 56.2±17.5 years) were enrolled in this study. Group A, contained 112 patients and group B included 106 patients. In group A, the final cannulation success was achieved in 100 patients (89.3%). Cannulation was successful in 88 patients (83.0%) in group B. Difficulty in cannulation occurred more frequently in group A (25.5% vs. 2.6%, \( P = 0.002 \)).

There were two patients in group B and three patients in group A who developed pancreatitis after endoscopic retrograde cholangiopancreatography. Perforation occurred in one patient in group B, which was improved with medical support. Bleeding and cholangitis were not occurred in any of the groups. The overall complication rate was 3/112 in group A and 3/106 in group B.

Conclusion: Needle-knife fistulotomy is safe and can be applied as an effective alternative to standard technique for common bile duct cannulation in expert hands.

Keywords: Common bile duct • complications • endoscopic retrograde cholangiopancreatography • methods

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is the most complex endoscopic procedure, because it requires specialized equipment and has a long learning curve to develop proficiency. The success rate of ERCP ranges from 80 to 95%, even among experienced endoscopists.\(^1,2\) When standard methods of biliary cannulation are failed, precut techniques are used as the last resort for selective biliary cannulation.

Among precut techniques the most popular methods are standard precutting (papillotomy through the orifice) and suprapapillary needle-knife fistulotomy (NKF).\(^3,4\) In NKF method, pancreatitis as the most common serious complication is minimized, because incision is started a few millimeters above the papillary orifice.\(^2,4\)

Most experts feel that precut techniques are risky, and they should be performed by expert endoscopists and followed by failure in standard cannulation methods. Our experience has shown that NKF has few complications.

The aim of this study was to evaluate and
compare the efficacy and safety of initial NKF and standard ERCP, for cannulation of the common bile duct (CBD).

**Materials and Methods**

Patients undergoing ERCP by two experienced gastroenterologists in Department of Gastrointestinal Endoscopy, Shariati Hospital, Tehran, Iran (a referral center in Tehran affiliated to Tehran University of Medical Sciences) were eligible for inclusion in the study. They were not enrolled in the study if any of the following criteria were present: 1) a history of gastrojejunostomy surgery, 2) pregnancy, 3) a known hypersensitivity to contrast agents, 4) age less than 12 years, 5) history of previous sphincterotomy, and 6) refusal of giving informed written consent.

The final diagnosis was documented by radiologic, endoscopic findings during ERCP, endoscopic ultrasound, or surgery. The patients were randomly assigned to the following groups:

- **Group A (standard method):** selective cannulation of the CBD in standard method was attempted with standard wire-guided sphincterotome. Cannulation was attempted for no more than 15 minutes. If standard transpapillary cannulation was unsuccessful, NKF was performed for CBD cannulation.

- **Group B (NKF):** NKF technique was performed with a papillotome (MicroKnife XL, Boston Scientific, Natrick, USA) and pure cutting current. Near the transverse duodenal fold, at least five millimeter above the orifice, perpendicular to the papilla at 11 – 12 o'clock position, and three millimeters deep to surface, precut piercing was made on the bulged intraduodenal segment of the CBD. After piercing, the bulging area cannulation was tried by covered papillotome. If cannulation was not achieved, one or two additional small incisions were made and the angle was changed slightly in the direction of the presumed course of the CBD. By pressing with unloaded needle-knife in the made hole, bulging of the muscle was visible and then precut was extended one to two millimeter to this direction (Figure 1). If the attempt was successful, the opening was extended cephalad with the sphincterotome and blended current.

Difficulty of cannulation was graded as previously described, according to total number of attempts on the major papilla (in group A) or the created fistula (in group B) with all devices, before final cannulation of the CBD. Difficulty of cannulation was described as easy (one to five attempts), moderate (six to 15 attempts), and difficult (more than 15 attempts).

For the patients with choledocholithiasis, stone extraction after successful papillotomy was performed by using either a balloon catheter or a basket. Mechanical lithotripter was not available and was not used for extraction of large stones in our study. Surgery was recommended for stones that could not be extracted. In these patients, second attempt was performed within two weeks. Sphincter of Oddi dysfunction (SOD) was defined by the Milwaukee Biliary Group Classification.

Postprocedural serum amylase level would be checked, if the patient had abdominal pain. Post-ERCP pancreatitis was defined as abdominal pain and serum amylase levels higher than three times of the upper normal limit. Complications were defined and graded according to the scheme proposed by Cotton et al. Patients without complications were discharged from the hospital after four to six hours. If the patient developed pancreatitis, he or she would be admitted to the hospital for longer periods.

The study was approved by the institutional review board of the Digestive Disease Research
Comparison between NKF and conventional method for cannulation of CBD

Center of Tehran University of Medical Sciences, according to the declaration of Helsinki. Written informed consent was obtained according to the guidelines of the institute.

Patients were assigned into two treatment groups by simple random allocation. Participants and those administering the interventions were not blinded, but pancreatitis and other complications were assessed by an investigator, who was blinded to the patients’ allocation.

Successful cannulation was the primary outcome of this study. Secondary outcomes were difficult cannulation and post-ERCP complications including pancreatitis, bleeding, cholangitis, and perforation.

We assumed that the frequency of difficult cannulation would be 20% in group A and 5% in group B. Based on 0.9 power to detect a significant difference (P=0.05, two-sided), 100 patients were required for each study group. Quantitative variables were presented with mean±standard deviation, if not otherwise specified. Qualitative variables were presented with their number, percent, and 95% confidence intervals. Mann-Whitney U-test was used to compare the number of attempts for cannulation in the treatment groups. The Chi-square test was used to compare the complications and cannulation success of the treatment groups. A P value<0.05 was considered significant for all tests.

Results

From June 2003 through February 2004, a total of 242 patients were referred for ERCP. Twenty-four cases were excluded because of a history of gastrojejunostomy surgery, refusal of giving informed written consent, and history of previous sphincterotomy. Thus, 218 cases (86 males and 132 females with a mean±SD age of 56.2±17.5 years) were enrolled in the study. Baseline characteristics of the patients in the two groups are shown in Table 1.

Cannulation was successful in 100 (89.3%, 95% CI: 82.0 – 94.3) patients in group A and 88 (83%, 95% CI: 74.4 – 89.7) patients in group B (P=0.18). Biliary access was achieved in repeated ERCP of 11/12 patients in group A and 17/18 patients in group B.

Moderate difficulty in cannulation occurred more frequently in group A (25.5% vs. 2.6%, P=0.002). In cases with choledocholithiasis, stone extraction was successful in 48 (69.9 %) patients in group A and 34 (64.2 %) cases in group B (P=0.53).

A statistically significant relationship was not found between successful cannulation and final diagnosis, sex, or age.

There were two patients (1.9%, 95% CI: 0.2 – 6.6) with post-ERCP pancreatitis in the NKF group and three cases (2.6%, 95% CI: 0.6 – 7.6) in the standard cannulation group. Perforation occurred in one patient in the NKF group, which improved by medical support. Bleeding and cholangitis were not seen in any of the groups. The overall complication rate was 3/112 in group A and 3/106 in group B.

Discussion

This study shows that the success rate of cannulation and complications of NKF are similar to standard cannulation by sphincterotome, but cannulation was easier in the NKF group.

The percentage of patients with failed biliary sphincterotomy in our study was less than previous

Table 1. Baseline demographic and clinical characteristics of the patients undergoing initial needle-knife fistulotomy or standard cannulation to access the common bile duct in a randomized controlled trial.

<table>
<thead>
<tr>
<th></th>
<th>Needle-knife fistulotomy</th>
<th>Standard cannulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants, n (%)</td>
<td>106 (48.6)</td>
<td>112 (51.4)</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>49 (46.2)</td>
<td>37 (33.0)</td>
</tr>
<tr>
<td>Female</td>
<td>57 (53.8)</td>
<td>75 (67.0)</td>
</tr>
<tr>
<td>Age (mean ± SD)</td>
<td>56.6 ± 17.9</td>
<td>55.9 ± 17.2</td>
</tr>
<tr>
<td>CBD* diameter (mean ± SD)</td>
<td>13.0 ± 6.1</td>
<td>13.5 ± 6.2</td>
</tr>
<tr>
<td>Stone size (mean ± SD)</td>
<td>11.9 ± 5.8</td>
<td>10.8 ± 5.9</td>
</tr>
<tr>
<td>Final diagnosis, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cholecodocholithiasis</td>
<td>54 (51.9)</td>
<td>75 (68.8)</td>
</tr>
<tr>
<td>SOD**</td>
<td>22 (21.2)</td>
<td>14 (12.8)</td>
</tr>
<tr>
<td>Others***</td>
<td>28 (26.9)</td>
<td>20 (18.3)</td>
</tr>
</tbody>
</table>

*CBD=common bile duct; **SOD=sphincter of Oddi dysfunction; ***Others: parasites in CBD, cholangiocarcinoma, periampullary tumors, primary sclerosing cholangitis, normal.
reports (16 to 44%).

Needle knife papillotomy (NKP) has been shown to be highly effective for cannulating the CBD in these patients. Most experienced endoscopists are familiar with the use of a needle knife, and success rates range between 85% and 99%. Although effective, NKP is still considered a potentially dangerous technique, especially when performed by less-experienced endoscopists. Complication rates have been reported variable and can be high. Use of this technique is recommended only for therapeutic reasons by most experts. Modifications of classic NKP have been proposed to reduce the risks. Among those modifications the most distinctive are NKF and NKP over a stent.

To the best of our knowledge, there are few articles that assessed the efficacy and safety of NKF (first attempted) for the cannulation of CBD in patients who need interventional ERCP for the treatment of biliary diseases. In these studies, NKF has been found as an effective procedure in gaining access to the biliary tree at the first or the second attempt after a few days. In addition, the overall success rate for this type of precutting technique is comparable with those previously reported. Our success rate of 83.0% for NKF was satisfactory, while the cannulation in this procedure was easier than standard method. Thus, NKF method is an effective technique for primary or secondary (after failure of transpapillary approach) attempt in cannulation of CBD. Recchia et al reported a success rate of 96%, whereas O’Connor et al reported a success rate of 89% with the use of the same technique. Like our results, these success rates have been achieved in the second attempts.

In our study, none of the studied factors were significantly related to successful cannulation except for stone size in patients with choledocholithiasis. CBD diameter was not an important factor for CBD cannulation. We did not find similar finding in the published literature.

In patients with choledocholithiasis, the success rate of stone extraction with standard accessories (balloon or basket) was similar in groups A and B (P=0.6). Theoretically, large stones cannot be easily extracted through the necessarily smaller opening made in NKF. Mavrogiannis et al showed that larger stones were extracted in the NKF group with more difficulty. The weakness of both techniques in extracting larger stones was more apparent in our study.

The complication rate for both techniques was similar (2.8% for NKF and 2.6% for standard cannulation). This concept remains controversial. de Weerth et al and O’Connor et al reported low rates of pancreatitis (4% and 2.4%, respectively) after the use of a similar technique by NKF. Most investigators including Katsinelos et al (1.5%), Bruins et al (0.5%), and Huibregtse et al (1%) have reported a lower rate of post-ERCP pancreatitis. However, there are reports of less satisfactory results, including those of Freeman et al (3.6%, severe pancreatitis) and Boender et al (6%).

We used all measures to minimize the risk of post-ERCP pancreatitis, and attempted to cannulate the CBD in a programmed, step-by-step manner. Similar criteria have been used by others. These preventive strategies may describe the equally low rate of pancreatitis in both groups. Other reason for this result may be explained by the lower number of patients enrolled in each group. The use of prophylactic pancreatic stent placement also remains an important issue. In our experience the rate of pancreatitis was low, thus prophylactic pancreatic stent placement was not performed. There is now a good body of literature for the use of pancreatic stent placement in high-risk groups, e.g., the difficult CBD cannulation. It should be used in such cases in centers with higher pancreatitis rates.

A mild perforation occurred in one patient in the NKF group who was managed by medical support without surgical intervention. The incidence of perforation has been reported less than 0.5% in recent series, which is similar to our results.

There was no post-ERCP bleeding in our patients. Low rates of bleeding have been reported by several investigators, such as de Weerth et al (4%), O’Connor et al (1.2%), and Huibregtse et al (1.5%). However, higher rates have been reported by others, including Bruins et al (5.5%), Mavrogiannis et al (5.9%), and Boender et al (10%). The relatively high rate of bleeding in these studies might be related to the use of pure cutting current for both precutting techniques.

In addition, cholangitis and death did not occur in our study, which were comparable to the low rates of these complications reported in most studies.

Moreover, most complications in our study were mild, and all patients got well with
conservative treatment.

Our results show that NKF is safer than it was thought previously. We found a similar rate of successful cannulation and complications, but less difficulty in cannulation. We suggest this method as an alternative to the standard technique, at least in difficult patients.

**Acknowledgment**

*This research has been supported by Tehran University of Medical Sciences’ Grant Number 81.4.*

**References**


