Managing Difficult Cannulations in Endoscopic Retrograde Cholangiopancreatography: A Prospective Randomized Control Trial Study of Precut Needle Knife Sphincterotomy versus Transpancreatic Sphincterotomy Technique

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ABSTRACT

Objective: To evaluate the success rate of cannulations and rate of procedure-related complications between needle knife sphincterotomy (NKS) and transpancreatic sphincterotomy (TPS) techniques, and to evaluate the most effective cannulation time to proceed with NKS or TPS.

Methods: This study recruited 52 patients with inaccessible bile ducts by the standard cannulation at Khon Kaen Hospital from May 2012 to May 2015. Patients were randomly allocated to the NKS group (N=21) or the TPS group (N=21). Successful cannulations, and complications between NKS and TPS were collected and assessed.

Results: Successful cannulations by TPS and NKS were achieved in 14 cases (53.8%) and 13 cases (50%) respectively (p value = 0.781). Post ERCP pancreatitis was found in 2 cases using TPS, and in 3 cases using NKS. There were 3 cholangitis cases in TPS group, and 2 cholangitis cases in NKS group. Perforations were found in 3 cases and 1 case in TPS and NKS group, respectively. There were 4 deaths in this study, one case in TPS group and 3 cases in NKS group. Complications and mortality between TPS and NKS were not statistically significant (P>0.05). After 40 minutes of the ERCPs, there was less chance for a successful cannulation. Unsuccessful cannulations between TPS and NKS was not statistically different according to the Kaplan-Meier analysis.

Conclusion: TPS and NKS are able to increase successful cannulations. There are no significant differences in the cannulation success rate and rate of complications between the TPS and NKS. The appropriate time to terminate a cannulation in difficult cases is found to be 40 minutes.

Keywords: ERCP; Transpancreatic precut sphicterotomy; needle knife sphicterotomy; difficult cannulation; time for successful cannulation (Siriraj Med J 2019;71: 175-180)

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is challenging endoscopic procedure which has a long learning curve. ERCP operators need to perform 180 ERCPs under supervision to achieve a 70-80% successful cannulation.[1] A successful cannulation is defined as the passing guide wire from the duodenal papilla to the common bile duct which is the key to success in the ERCP procedure.[2,3] According to a study of the outcomes of ERCP at Khon Kaen Hospital, the success rate for

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cannulations using the standard cannulation technique at Khon Kaen Hospital was 78%.[4] This success rate was low in comparison with expert ERCP centers which have a successful cannulation rate of 90-95%.[5] Therefore, Khon Kaen Hospital has to increase its successful cannulation rate in ERCP by using a special technique to overcome difficult cannulations. There are many cannulation techniques to deal with difficult cannulations such as precut needle knife sphicterotomy, transpancreatic sphicterotomy technique, needle knife fistulotomy, and endoscopic ultrasound-guide cholangiography.[3,6]

At Khon Kaen Hospital, we are familiar with the needle knife sphicterotomy (NKS) technique and the transpancreatic sphicterotomy (TPS) technique. NKS has been used to overcome difficult cannulations by many institutions for a long time with evidence of an increasing successful cannulation rate to 92-96.9%[7-9], and TPS, a newer technique, described by Goff in 1995[10], has also been used by ERCP operators with 72.5-97.3% cannulation success rate.[11-15] According to previous studies, the procedural related complications in NKS and TPS were 10-24.2%[7-9] and 11.1-5.8%[11,15] respectively. There were several studies that evaluated successful cannulation rates and complication rates between NKS and TPS techniques. The randomized controlled trial from Catalano et al.[16] demonstrated higher a successful cannulation rate in TPS than with NKS while the complication rate was the same; a study from Lee et al.[15] showed a similar successful cannulation rate and complication rate between TPS and NKS. Therefore, the use of NKS or TPS to achieve a successful cannulation rate is still being debated.

There are several studies stating that prolonged a cannulation time was associated with an increased rate of post-ERCP pancreatitis (PEP).[17-20] Therefore, the appropriate cannulation time should be balanced between successful cannulation rates and complications, so the most effective cannulation time to increase the chances of a successful cannulation should be investigated.

The objectives of this study are to evaluate successful cannulation rates and procedures related to complications between the NKS and TPS techniques; to evaluate the most effective required time for proceeding with either NKS or TPS in an attempt to increase the chances of a successful cannulation.

MATERIALS AND METHODS

This study was approved by Khon Kaen Hospital Ethics Committee (issue number 56/01/2555) and registered in the Thai Clinical Trials Registry (TCTR number 20150224003). Patients who had been treated with ERCP procedure at the Endoscopic Unit, Department of Surgery, Khon Kaen Hospital during May 2012 to May 2015 were recruited into the study. All of the patients were treated with ERCP by the first author (S. Siripornadulsilp). Patients with unstable vital sign, post-sphincterotomy patients, patients with gastric outlet obstructions, and patients with surgically altered anatomy were excluded. There were 286 patients who did not meet the exclusion criteria and participated in the study. All the participants gave informed consent before undergoing ERCP. Of the 286 participants, 52 had difficult cannulations which were defined as lasting more than 10 minutes in attempting to cannulate after visualization of ampulla of Vater, or there were more than three unintended pancreatic duct cannulations.[21] The patients with difficult cannulation conditions were randomly allocated to either the NKS or the TPS group by sealed envelopes. There were 26 patients in each group. NKS was defined as using a needle-knife, specifically a MicroKnife XL 5.5F, Boston Scientific, El Coyol, Alajuela, Costa Rica, to perform an incision at the upper margin of the papilla orifice toward the direction of bile duct until the underlying biliary sphincter was visualized. TPS was defined as cutting the septum between the pancreatic duct and bile duct by sphicterotome toward the direction of the bile duct after selective cannulation of the pancreatic duct.

In our institution, ERCP patients were given intravenous prophylactic antibiotic 15 minutes before the ERCP procedure. The videoduodenoscopes were Olympus TJF 140, Olympus TJF 140R, Fujinon EO-250XT5, Olympus TJF130, and Olympus TJF150. The patients were given 2% lidocaine viscus as a local anesthetic agent. During ERCP, the patient's vital signs and oxygen saturation were monitored with a pulse oximetry by endoscopic nurses. After ERCP, the patients were sent to the surgical ward for observation for at least 24 hours. In this study, a successful cannulation was defined as the insertion of a sphincterotome to the common bile duct.[21] The ERCP-related complications were defined as the "consensus criteria" described by Cotton et al[23]; PEP was abdominal pain with an increase in serum amylase of more than three times the normal upper limit 24 hours after ERCP. Post-ERCP cholangitis was defined as abdominal pain with fever of more than 38 degree Celsius that lasted more than 24 hours after ERCP and a demonstration of obstructive jaundice in a liver function test. Hemorrhage was clinical evidence of bleeding with a hemoglobin drop of more than 2 g/dL. Perforation was the presence of fluid leakage or contrast media in the abdominal cavity or retroperitoneal cavity during ERCP procedures or from imaging studies.

The characteristics of the participants was demonstrated with descriptive statistic. The Chi-square test and the Fisher exact test were used in comparing categorial data between NKS and TPS. The effective required time for a successful cannulation was estimated by the Kaplan-Meier method.

RESULTS

Baseline characteristics of the patients are shown in Table 1.

There was no difference in the baseline characteristics between the TPS patients and NKS patients. (Table 2)

There was no difference in successful cannulations and procedural related complications between the TPS and NKS patients. In this study, there were 4 procedural related mortality cases. The indications for ERCP in these patients were 2 CBD stone cases and 2 malignancy cases. There were 3 death cases in the NKS group and 1 death case in TPS group. The causes of death are described in Table 3.

There were 51 patients of 52 patients that had complete cannulation time data. The cannulation time was not recorded in one patient. The patients were allocated and treated with TPS or NKS according to the study protocol. The median survival time (the median cannulation time) was 30 minutes, and the 95% confidence interval was 6.8-53.2 minutes. The majority of successful cannulations were in the first 30 minutes. There were only a few successful cannulations after 40 minutes as only one successful cannulation occurred in the 40th to 60th minute of the cannulation.

Fig 2 shows a comparison of non-successful cannulations between TPS and NKS by using the Kaplan-Meier method. After the 20th minute, there were 15 cases in TPS group and there were 13 cases in the NKS group who did not have successful cannulations. After the 40th minute, there were 6 cases in the TPS group and 8 cases in NKS group that did not have successful cannulations. The unsuccessful cannulations between TPS and NKS showed no statistical significance.

TABLE 1. Baseline characteristics of the patients between the TPS and NKS group.

Characteristics	TPS (N=26)	NKS (N=26)	P-value
Gender			
Female N (%)	11 (42.3)	18 (69.2)	0.05*
Male N (%)	15 (57.7)	8 (30.8)	
Age			
Mean (SD)	61 (11.3)	59.6 (15.5)	
Median (Min-Max)	61.5 (36-82)	61 (21-85)	
Diabetes mellitus N (%)	5 (19.2)	6 (23.1)	1.00**
Hypertension N (%)	4 (15.4)	3 (11.5)	1.00**
IH N (%)	1 (3.8)	0 (0)	1.00**
CBD stone N (%)	6 (23.1)	9 (34.6)	0.36*
Biliary stricture N (%)	4 (15.4)	2 (7.7)	0.67**
Malignancy N (%)	16 (61.5)	14 (53.8)	0.58*
Bile Leakage N (%)	0 (0)	1 (3.8)	1.00**

*P-value from Chi-square test, **P-value from fisher exact test

Abbreviations: IH = Ischemic heart disease, CBD = Common bile duct, TPS = transpancreatic sphicterotomy, NKS = needle knife sphicterotomy

TABLE 2. Successful cannulation and complications between TPS and NKS group.

Techniques	TPS (N =26)	NKS (N =26)	P-value
Successful cannulation N (%)	14 (53.8)	13 (50)	0.78*
Complications			
Pancreatitis N (%)	2 (7.7)	3 (11.5)	1.00**
Cholangitis N (%)	3 (11.5)	2 (7.7)	1.00**
Perforation N (%)	3 (11.5)	1 (3.8)	0.61*
Bleeding N (%)	0 (0)	0 (0)	NA
Hypoxia N (%)	0 (0)	1 (3.8)	1.00**
Subcutaneous emphysema N (%)	1 (3.8)	0 (0)	1.00**
Death N (%)	1 (3.8)	3 (11.5)	0.61*

*P-value from Chi-square test, **P-value from fisher exact test
Abbreviations: NA = Not applicable, TPS = transpancreatic sphicterotomy, NKS = needle knife sphicterotomy

TABLE 3. Causes of death.

Case	Age	Indication	Technique	Complication
1	41	CBD stone	TPS	Pancreatitis
2	57	CBD stone	NKS	Cholangitis
3	47	Malignancy	NKS	Pancreatitis and perforation
4	74	Malignancy	NKS	Pancreatitis and cholangitis

Abbreviations: CBD = Common bile duct, TPS = transpancreatic sphicterotomy, NKS = needle knife sphicterotomy

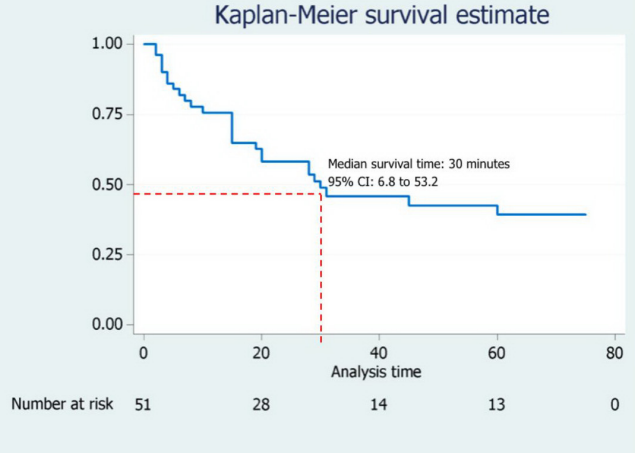

Fig 1. Kaplan-Meier Curve of All Patients.

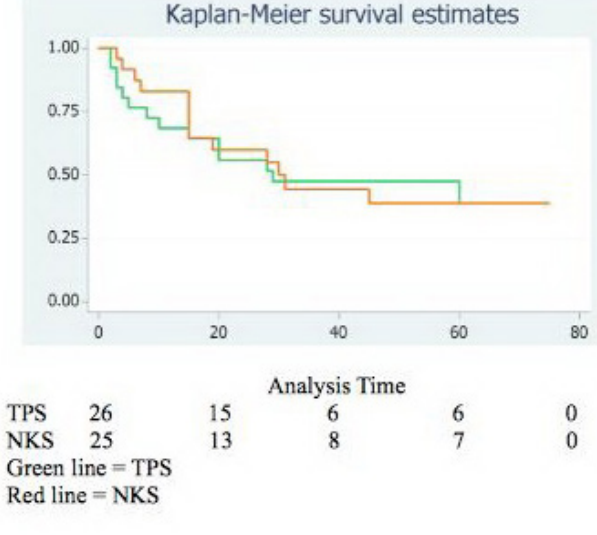

Fig 2. Kaplan-Meier Curve of TPS and NKS.

DISCUSSION

In this study, successful cannulations in difficult cannulation cases between TPS and NKS were the same as the result of the previous study from Lee et al.[15] The procedural related complications between TPS and NKS were similar as the previous studies from Lee et al.[15], Catalano et al.[16], and Zang et al.[24] Although TPS was not shown to be better than NKS in increasing the rate of successful cannulations, both cannulation techniques could increase the rate of successful cannulations in difficult cannulation cases. In this study, there were 286 participants who met the inclusion criteria and 52 (18.2%) of them were difficult cannulation cases. According to the results of this study, for TPS and NKS, each technique could increase the cannulation rate by at least 50%; therefore, these techniques could raise successful cannulation rates in ERCP patients in our institution to over 90%. The crossover of TPS and NKS techniques was reported to improve the final successful cannulation rates to 95.3%[15]; however, this study did not decide to evaluate TPS and NKS in a crossover regime.

Although the successful cannulations and complications between TPS and NKS were not statistically different, there were more procedural related deaths in the NKS group; moreover, technically, it is relatively easy to perform pancreatic duct cannulations[16,25] and there is no special instrument and additional time for placing special instruments for TPS while NKS needs special instruments such as a needle-knife (MicroKnife XL) and additional time to place the needle-knife to the ampulla. As a result, TPS is a more attractive method to overcome difficult cannulation in comparison with NKS. However, according to the European Society of Gastrointestinal Endoscopy (ESGE), clinical guideline for papillary cannulation and sphincterotomy techniques at ERCP, in difficult cannulation cases that had no unintentional pancreatic guide wire insertion, the initial technique that should be used to overcome difficult cannulation is NKS.[26]

The most common complications in this study were PEP and cholangitis. In this study, PEP occurred in 7.7% and 11.5% in the TPS and NKS groups respectively, the rate of PEP was comparable with the rate of PEP in the previous study from Lee et al.[15] which reported a 10.7% PEP occurrence in the TPS group and 5.3% in the NKS group, while Zang et al.[24] reported 9.6% and 10.5% of PEP in the TPS and NKS group respectively. In this study, the rate of cholangitis was 11.5% and 7.7% in TPS and NKS respectively. The cholangitis rate was high in comparison with the study from Lee et al.[15], which reported a cholangitis rates of 3% in TPS and no cholangitis in NKS. In the study from Catalano et al., there was no reported cholangitis as a procedural related complication.[16] The high rate of cholangitis in this study might be due to the high incidence of hilar cholangiocarcinoma in northeastern Thailand.[27] Therefore, the rate of palliative biliary drainage for malignant cases was also high. According to previous studies, palliative endoscopic biliary drainage for hilar cholangiocarcinoma was responsible for a high rate of cholangitis, ranging from 8.8-40.7%.[28-31]

The second objective of this study is to define the most effective required time for proceeding with either NKS or TPS to increase the rate of successful cannulations. In this study, the majority of successful cannulations were in the first 30 minutes. There was only one successful cannulation occurred in the 40th to 60th minute of the cannulation. However, we did not evaluate the correlation between increasing cannulation time and ERCP-related complications.

CONCLUSION

In this study, both TPS and NKS increased successful ERCP cannulations, but there was no difference in successful cannulations and procedural-related complications between TPS and NKS. There was little chance to make a successful cannulation after the 40th minute before a cannulation.

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