

Prospective Controlled Trial for Difficult Bile Duct Cannulation Using Needle-Knife Precut Technique and Double-Guidewire Technique

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ABSTRACT

Background: Difficult bile duct cannulation is one of the main problems in endoscopic retrograde cholangiopancreatography (ERCP). Double-guidewire (DG) cannulation technique is a promising approach for this problem, an alternative to the well-known technique of needle-knife (NK) precut access cannulation.

Objective: To compare the outcome of NK precut technique and DG technique in patients whom bile duct cannulation is difficult to perform.

Patients and Methods: During a 20-months study period, 50 patients with difficult bile duct cannulation defined by unsuccessful attempts to get into the common bile duct after 15 minutes from initial cannulation. Twenty-five patients were assigned to each group using NK precut technique (NK group) and DG technique (DG group). Success rate and complication rate were compared between the two groups.

Results: Successful bile duct cannulation was achieved in 18 of 25 patients (72%) in the NK group and in 19 of 25 patients (76%) in the DG group ($p = 0.747$). The incidence of post-ERCP pancreatitis was 2 of 25 patients (8%) in the former group and 6 of 25 patients (24%) in the latter ($p = 0.247$). The incidence of bleeding complication was 11 of 25 patients (44%) in the NK group, and zero in the DG group ($p = 0.0002$).

Conclusion: DG technique was not superior to NK precut technique in achieving bile duct cannulation in patients with difficult bile duct cannulation. DG technique was associated with a higher risk of post-ERCP pancreatitis, but significantly safer than NK precut technique with regard to bleeding complication.

Key words : endoscopic retrograde cholangiopancreatography, ERCP, bile duct cannulation.

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INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) has remained an effective procedure in the treatment of pancreatobiliary diseases the procedure, however, can be associated with serious complications such as post-ERCP pancreatitis, bleeding, perforation

and even death⁽¹⁾. Various methods of solving the problem of difficult cannulation by conventional technique, have been created. The precut technique using needle-knife (NK) has been successfully reported⁽²⁾. Another technique, the double-guidewire technique (DG), involves the use of guide wire pre-insertion into the pan-

creatic duct and leaving the guideline to occupy the common channel to stabilize the papilla, straighten the common channel and lift it toward the working channel. Such approach may facilitate a deep bile duct cannulation by utilizing another cannulation device alongside the pancreatic guidewire through the same working channel (Figures 1 and 2)⁽³⁾. DG technique has been shown promising in cases of difficult bile duct cannulation, especially in avoiding use of using NK precut technique, an established risk for post-ERCP pancreatitis (Figures 3 and 4)⁽⁴⁾.

Post-ERCP pancreatitis is the most common serious complication occurring between 1.3% to 24.4%

in non-selected series⁽⁵⁾. The NK precut technique is usually chosen as a rescue technique whenever deep bile duct cannulation with standard conventional technique is unsuccessful. Increasing use of DG technique has raised concerns regarding an increased possibility of triggering post-ERCP pancreatitis due to greater disturbance to the pancreatic duct⁽⁶⁾. To date there are only a small number of reported studies on DG technique, with only two prospective studies comparing DG technique to standard conventional cannulation technique in difficult bile duct cannulation⁽⁷⁻⁹⁾. There are also no studies comparing NK precut and DG technique. The present study was a pilot prospective con-

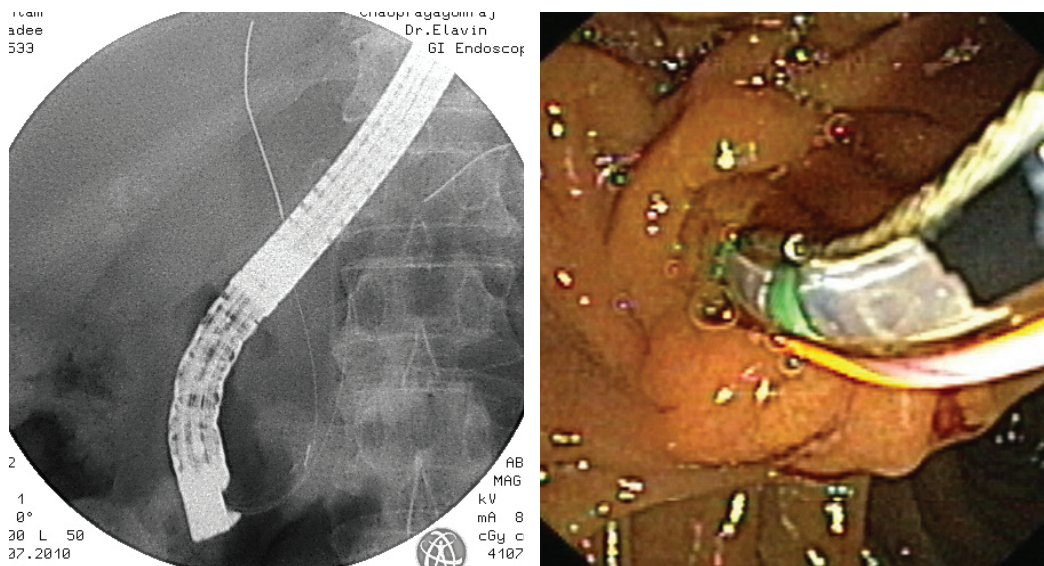


Figure 1-2. Double-guidewire technique for bile duct cannulation

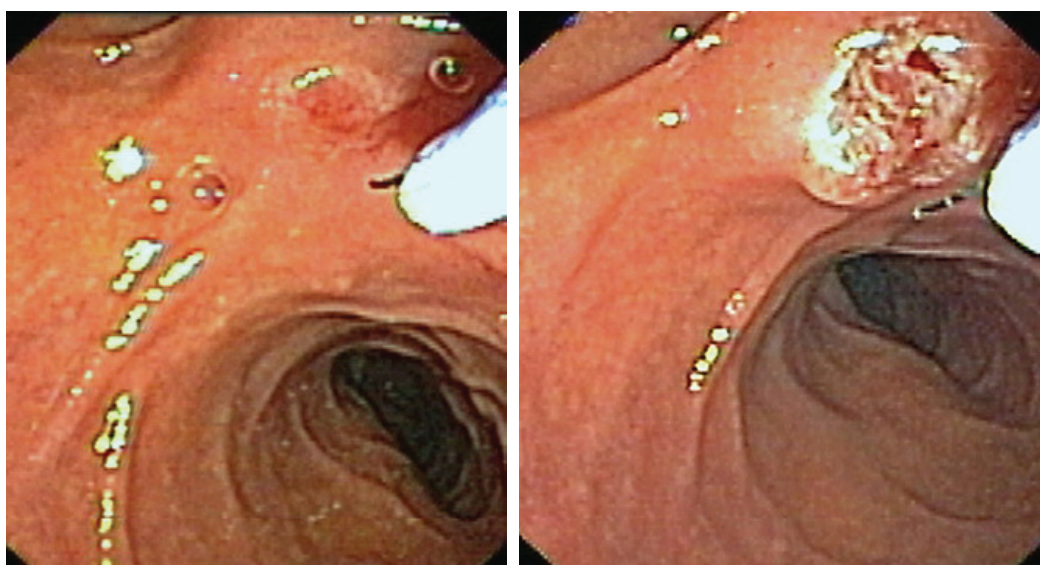


Figure 3-4. Needle-knife precut access for bile duct cannulation

trolled study to compare successful cannulation rate and complication rate between these two techniques.

PATIENTS AND METHODS

This prospective controlled study was conducted at the gastrointestinal endoscopy unit of a referral hospital in Central Thailand. Patients undergoing ERCP at Chaoprayayommaraj Hospital between 1 December 2008 and 31 July 2010 were considered eligible for enrollment.

Inclusion criteria were (1) age 15 or older, (2) inpatient admission for at least 24 hour to monitor post ERCP pancreatitis, and (3) difficult cannulation after attempted cannulation by standard conventional technique. Exclusion criteria were (1) previous ERCP with or without sphincterotomy, (2) previous ERCP with papillary dilatation, (3) pre-procedure diagnosis of acute pancreatitis, (4) prior pancreatic or biliary stenting, (5) previous performed surgical biliary-intestinal anastomosis, (6) use of any prophylaxis drug for post-ERCP pancreatitis, and (7) pregnancy or breastfeeding. Attending endoscopist in this study had clinical experience in ERCP over four years as well as previous experience in both the NK precut and the DG cannulation technique. The initial cannulation was made using pull-type standard sphincterotome preloaded with a guidewire, regardless of the length of the sphincterotome nose, the size of the guidewire (normally 0.035 and 0.025-inch) and various brands of the devices. No prophylaxis medication for post ERCP induced pancreatitis. Difficult bile duct cannulation was defined as failure to achieve deep bile duct cannulation using standard conventional ERCP cannulation technique with guidewire after than 15 minutes from the initial cannulation, with or without repeated cannulation of the pancreatic duct at least 3 times, regardless of the number of attempts and the number of transient pancreatic duct cannulation during the first 15 minutes.

Once the guidewire as seen from fluoroscopy, entered the second half of the pancreatic duct, the DG technique would be selected. But in those cases in which the guidewire could not be inserted deep enough for the DG technique, the NK precut technique would be chosen instead.

Successful bile duct cannulation was defined as sufficiently deep cannulation into the common bile duct. In the NK group, free hand cutting would start

from the ampullary orifice upward, layer by layer, until bile duct cannulation was achieved. DG technique cannulation was performed as described in previous studies^(7,8). In cases with repeated failure to cannulate the bile duct after an additional 30 minutes, the endoscopist would either terminate the ERCP examination right away or carry on using any preferred alternative technique for an appropriate length of time. ERCP related complications were defined and graded according to international consensus criteria⁽¹⁰⁾.

Statistical analysis

The study hypothesis was that by using DG technique, the success rate for deep bile duct cannulation could be increased for at least 30% compared to NK precut access technique. The number of patients needed for the study was based on results from previous studies using NK precut access technique for difficult bile duct cannulation, with reported immediate success rate at about 70%^(11,12). The chi-square test was used for α value of 5% and statistical power of 80% (β value of 20%). All analyses were performed by Mann-Whitney U test to compare continuous variables, and Pearson's chi square or Fisher's exact test for categorical variables with significance set at $p < 0.05$.

RESULTS

A total of 214 ERCP procedures were performed between 1 December 2008 and 31 July 2010. Of these, 171 were first-time procedures and successful bile duct cannulation was achieved in 161 cases (94.2%). A total of 50 patients fulfilled the study criteria, 25 for the NK group and 25 patients for the DG group. One-hundred and twenty-one patients were excluded, 118 after successful straight forward cannulation with standard conventional technique, and 3 cases due to unmet criteria or successful cannulation by other techniques (diagnosis of acute gall stone pancreatitis 1 case, pancreatic stent placement during the procedure 1 case and previous biliary-enteric anastomosis surgery 1 case) (Figure 5). Baseline characteristics of the two groups including age, sex and indication for ERCP were shown in Table 1.

Deep bile duct cannulation was successful in 18 of the 25 patients (72%) in the NK group and in 19 of the 25 patients (76%) for DG group. The difference was not statistically significant (Table 2).

The incidence of post-ERCP pancreatitis was 8%

(2/25) in the NK group and 24% (6/25) in the DG group, which was not statistically significant. The severity of pancreatitis was mild to moderate in nearly all cases (7 of 8 cases or 87.5% in each group) (Table 3).

Bleeding at sphincterotomy site was observed in

11 of 25 patients (44%) in the NK group, and non in the DG group (Table 2). Bleeding was significantly higher in the NK group compared to the DG group (11% vs 0%, $p=0.0002$). All bleeding incidences were mild and readily controlled with using either adrena-

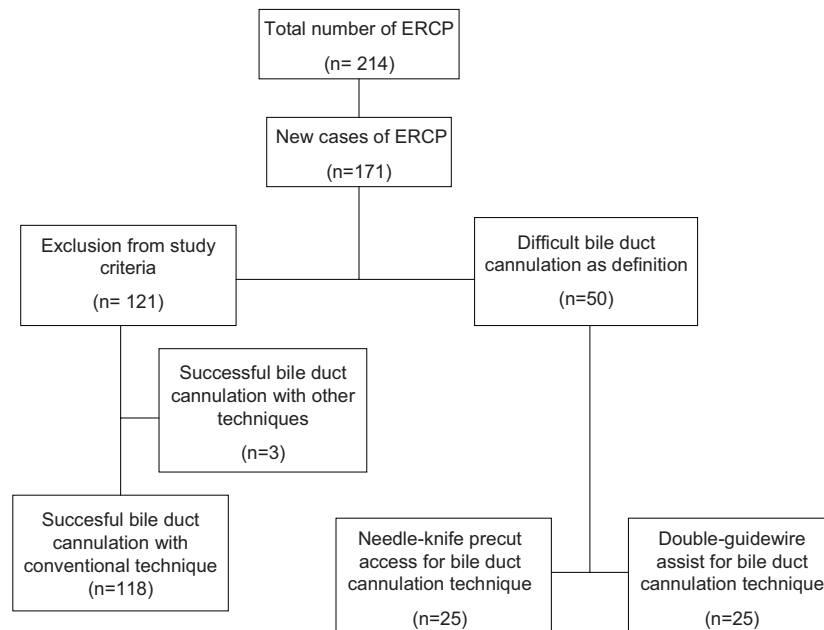


Figure 5. Diagram of procedures.

Table 1. Baseline characteristics of study groups.

	NK group (n = 25)	DG group (n = 25)
Age, years, mean (range)	63.4 (31-90)	62.3 (33-92)
Sex, male : female	14:11	12:13
Indication for ERCP		
Diagnosis	0	1
Cholelithiasis	7	3
Cholangitis	6	7
Post operative CBD leakage	0	2
Biliary obstruction from neoplasm	9	9
Other	3	3
ERCP finding		
Cholelithiasis	9	5
Dilated CBD without stone or obstruction	2	8
CBD stenosis from neoplasm	6	8
CBD stenosis of unknown etiology	1	0
Other	7	4
ERCP maneuvers		
Biliary sphincterotomy with/without balloon swept	2	8
Sphincterotomy with stones removal	8	3
Sphincterotomy with biliary stenting	8	11
Other	7	3

Table 2. Comparison of outcomes in NK and DG groups.

	NK group (n = 25), %	DG group (n=25), %	p-value
Successful cannulation	18 (72)	19 (76)	0.747
Complication			
Post ERCP pancreatitis	2 (8)	6 (24)	0.247
Bleeding at sphincterotomy site	11 (44)	0 (0)	0.0002

Table 3. Post ERCP pancreatitis.

Pancreatitis complication	NK group (n = 25), %	DG group (n = 25), %
Mild	1 (4)	4 (16)
Moderate	0 (0)	2 (8)
Severe	1 (4)	0 (0)
Total	2 (8%)	6 (24%)

line 1:10,000 irrigation to the bleeding point via the sphincterotome catheter or adrenaline 1:10,000 sub-mucosal injection. Blood transfusion was not needed in any cases. Other complications such as cholangitis and perforation were not noted in this study.

Failure of cannulation in the DG group occurred in 6 cases, 3 of which was reverted after changing to NK precut access. Termination of ERCP procedure after more than 60 minutes was necessitated in all the remaining failure cases in both groups. A repeat ERCP one week thereafter was performed (data not shown).

DISCUSSION

Selective deep bile duct cannulation in difficult cases requires high skill and experience. Various techniques have been proposed to solve the problem, most commonly the NK precut access to open the ampulla thereby exposing the deep portion of the distal common bile duct followed by conventional sphincterotomy after successful bile duct cannulation.

Another technique of bile duct cannulation involves placing a guidewire deep into the pancreatic duct. This often facilitates cannulation of the bile duct with a second catheter placed alongside the guidewire in the same endoscopic channel. Although the reported success rates appear promising, there are concerns for higher incidence of post-ERCP pancreatitis compared to standard conventional technique⁽⁷⁻⁹⁾.

To date, there are no studies directly comparing the NK precut and the DG technique for difficult bile duct cannulation. These techniques are useful when cannulation becomes difficult. Both are associated with an increased risk of post-ERCP pancreatitis. There are two well known prospective studies and one retrospective study comparing DG technique and conventional cannulation method⁽⁷⁻⁹⁾. In both studies from Japan by Maeda *et al*⁽⁷⁾ and Ito *et al*⁽⁹⁾ prophylaxis protease inhibitor infusion was given for prevention of post-ERCP pancreatitis and wire-guided cannulation was not used. In contrast to another study from Spain by Tejada *et al*⁽⁸⁾ in which preloaded guidewire in the cannulation catheter was employed and no prophylaxis medication for post-ERCP pancreatitis was used. An important issue concerning DG groups from these three studies was the diverse the definitions of difficult bile duct cannulation. Maeda *et al* and Ito *et al* specified a time limit (10 minutes), as with the present study. Tajeda *et al* commented on potential uncontrolled bias by the endoscopists, as the number of cannulation attempts is considered a risk factor for post-ERCP adverse events⁽¹³⁾. Tejada *et al* set a limit on the number of cannulation attempts in their definition of difficult cannulation (failure of 5 attempts initially using standard conventional technique).

In practice, it is hard to gauge the difficulty at each cannulation as successful bile duct cannulation depends much on the endoscopist's experience. The prerequisite for DG technique was the ability to achieve deep guidewire cannulation into the pancreatic duct, which is not easy in certain patients with unfavorable pancreatic duct anatomy. Such patients may be suitable candidates for NK precut or other cannulation techniques rather than the usual DG technique.

The loose definition of difficult bile duct cannulation was especially framed in this study, hence the inclusion in the definition of the time limit (15 minutes for failure from standard cannulation technique)

and the outcome of cannulation attempt (at least 3 cannulation attempts over the 15-minute time limit) with or without repeated pancreatic duct cannulation. Patients were accordingly assigned to either study group based on the outcome of cannulation attempt during the first 15 minutes. We considered such definition to be more practical and realistic. Our study also differs from previous studies in term of comparison between NK precut and DG technique in patients with difficult bile duct cannulation. We noted similar cannulation success rates in both groups.

It is interesting that the incidence of post-ERCP pancreatitis was higher in the DG group, though not statistically significant, while bleeding at sphincterotomy site was noted more frequently in the NK precut access group. Although post-ERCP pancreatitis in most cases was mild to moderate in severity grading, it nevertheless caused prolongation of hospital stay and increased patients suffering from pain. Bleeding at sphincterotomy site which absence in DG group but significant higher in the NK precut group, on the other hand, was mild and readily controlled by local endoscopic treatment without serious consequence. It is, therefore, very difficult to determine which technique, NK precut or DG technique, is better in term of success rate or complications, as DG technique was associated with higher rate of post-ERCP pancreatitis. Future study using a temporary pancreatic duct stent for prophylaxis of post-ERCP pancreatitis in DG technique (as recommended by the European Society of Gastrointestinal Endoscopy (ESGE) guideline for prophylaxis of post-ERCP pancreatitis)⁽¹⁴⁾ should assess whether or not an improved complication rate can be achieved using the NK precut technique.

There were limitations in this study. Firstly, the number of enrolled patients in this first pilot study comparing NK precut and DG technique was too small to achieve statistical significance. Secondly, the study was not randomized or blinded as the ERCP procedure could not be conducted in a blinded manner. Thirdly, the effect of the guidewire entering the pancreatic duct during the first 15 minutes and the volume of contrast injection into the pancreatic duct which may contribute to post-ERCP pancreatitis were not evaluation.

In conclusion, our study suggested that DG technique was not more advantageous than compare to NK precut technique in achieving bile duct cannulation. The possibility of an increased risk of post-ERCP pan-

creatitis in DG technique should be further investigated. Endoscopists should carefully choose between NK precut and DG technique in difficult situation, keeping in mind the risk of post-ERCP pancreatitis with the DG technique versus bleeding at sphincterotomy site with the NK precut access technique.

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