The THAI Journal of SURGERY 2014;35:64-68.
Official Publication of the Royal College of Surgeons of Thailand

Original Article

Outcomes of Therapeutic Endoscopic Retrograde Cholangiopancreatography

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Abstract

Objective: **To study the outcomes of therapeutic endoscopic retrograde cholangiopancreatography (ERCP) performed by one endoscopist focusing on results and complications of first biliary cannulation.**

Methods: **Two hundred and fifty nine consecutive therapeutic ERCP procedures were included in the study. Patients were classified into three groups according to sphincterotomy techniques: (1) standard endoscopic sphincterotomy (EST); (2) precut EST; (3) endoscopic balloon dilation (EPBD)/endoscopic large balloon dilation (EPLBD). Characteristics of patients, indications for ERCP, number of instruments used, results and complications were analyzed.**

Results: ERCP for malignant biliary strictures and unintentional pancreatic duct injection were significantly more frequent in the precut EST group compared with the standard EST group. The majority of patients in the EPBD/EPLBD group had cholelithiasis, and required more instrumentation. Of the 259 cases, first biliary cannulation was achieved by using standard sphincterotomy in 204 cases (79%). Immediate precut EST after failed standard cannulation was successful in 46 of 50 cases (92%). The cumulative cannulation success rate was 97% (250 of 259). The precut EST group had the highest complication rate (14%), which was not significantly higher than that in the standard EST group (5%). The EPBD/EPLBD group had the lowest complication rate of 2%.

Conclusion: **Malignant biliary obstruction may cause difficulty in biliary cannulation and may require the use of the precut technique to achieve successful cannulation. Precut EST using both septotomy and needle knife techniques could increase the rate of successful biliary cannulation in difficult cases without significantly increasing the risk of complications. Early precut should be considered when facing with difficult cases to avoid over manipulation of the papilla. EPBD/EPLBD was safe and effective for biliary cannulation and treatment of large CBD stones.**

Keywords: **Cholelithiasis, common bile duct stone, endoscopic balloon dilation, endoscopic retrograde cholangiopancreatography, endoscopic sphincterotomy**

INTRODUCTION

Therapeutic endoscopic retrograde cholangiopancreatography (ERCP) is a very useful procedure for the treatment of biliary tract diseases. The key to success is to achieve deep biliary cannulation which would provide a means for applying other instruments to perform therapeutic procedures. The techniques used for biliary cannulation usually start with the standard endoscopic sphincterotomy (EST) catheter preloaded with guidewire and contrast media. Precutting techniques are normally used after standard

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techniques have failed. Early precut using a needle knife followed by transpancreatic duct precutting called septotomy can also be done. There are many studies showing that both techniques are safe and effective for biliary cannulation. Endoscopic balloon dilation (balloon diameter less than 1 cm: EPBD) or large balloon dilation (balloon diameter greater than 1 cm: EPLBD) are alternative techniques used to replace traditional sphincterotomy in certain situations. EPBD and EPLBD can also be used to dilate the papilla after EST for the treatment of large common bile duct (CBD) stones, and have been shown to be safe and effective.

The present study reviews the outcomes of ERCP performed within the past five years by one endoscopist (K.L.), focusing on patient's characteristics, clinical indications, number of instruments used, results and complications of first biliary cannulation.

Materials and Methods

Between November 2008 and November 2013, 354 ERCPs performed by one endoscopist (K.L.) at the Surgical Department of Nopparat Rajathanee Hospital, Bangkok, Thailand, were reviewed. Ninety five cases were excluded. Among those excluded were pure pancreatic cases, cases where the papilla was not identified, papillary carcinoma, and cases in whom EST was previously done. Two hundred and fifty nine consecutive therapeutic biliary ERCP procedures were included in the study. Patients were classified into three groups according to EST technique.

In all procedures, we began with the use of a standard triple-lumen sphincterotome (Ultratome XL; Boston Scientific, Natrick, USA or Clever Cut; Olympus Medical systems Corp., Tokyo, Japan), preloaded with contrast and a guidewire (0.035" or 0.025" Jackwire; Boston Scientific, Miami, USA or 0.35 angled tip Radifocus guide wire M; Terumo corporation, Shibuya-Ku, Japan) to aid biliary cannulation. When biliary cannulation was achieved, EST was done using the Endocut mode in the ERBE system (120W cut, 15W coagulation, ERBE USA, Atlanta, GA). If this cannulation and EST was successful in a patient, he or she was classified as Group 1, i.e., standard ESTgroup. If the attempted biliary access failed, or if three or more pancreatic duct injections occurred during the attempt, then the pre-cutting technique was performed. If the pancreatic duct was cannulated unintentionally, wire assisted transpancreaticseptotomy technique was used. If the pancreatic duct was not cannulated, pre-cut using triple lumen needle knife (Wilson-Cook Medical, USA) was performed. In very difficult cases, both precutting techniques were used. Patients who underwent these procedures were classified as Group 2, i.e., the precut EST group.

Patients in whom the standard EST technique may increase the risk of post-ERCP bleeding or perforation, or those with large common bile duct stones, after biliary cannulation was achieved using standard techniques, a limited EST was done, followed by EPBD/EPLBD using a balloon catheter (CRE Esophageal/Pyloric maximum diameter 12 mm or 15 mm, length 5 cm, Boston Scientific, USA). The balloon was selected based on the diameter of bile duct and the size of the stones. The balloon would be gradually inflated until the recommended size was reached, and would remain inflated for 30 seconds. In patients with common bile duct stone, the stones would be removed using balloon extraction, baskets, or mechanical lithotripter as needed. Patients requiring these procedures would be classified as Group 3, i.e., the EPBD/EPLBD group.

Sedation for the ERCP procedures consisted of a combination of propofol or fentanyl and midazolam with buscopan as needed for duodenal relaxation. General anesthesia was given depending on patient's conditions and the anesthesiologist's decision. All patients underwent continuous cardiopulmonary monitoring throughout the procedure. The procedures were done in left lateral position, using an Olympus Video Duodenoscope (TJF160R, Olympus Corporation, Tokyo, Japan). After completion of the ERCP, patients were closely observed for post-ERCP complications.

Data for the study was obtained by a review of the medical records. Complications were defined using criteria described by Cotton et al[10]. Differences in categorical variables were tested for statistical significance using Fisher's exact test. *T*-test or rank test was used for quantitative variables. The statistical software package SPSS for Windows version 19 (SPSS Inc, Chicago, IL) was used for statistical analysis. A significance level of 5% was used throughout.

Results

Two hundred and fifty nine consecutive therapeutic procedures were included in the study. There were 105 men and 154 women, with a mean age of 59.1 years. The indications for ERCP were cholelithiasis in 54% of patients, suspected or proven biliary tract malignancy in 22%, and other benign conditions in 24%. Procedures classified as standard EST was performed on 147 patients, those classified as precut procedures was performed on 50 patients, and EPBD/EPLBD was done on 62 patients.

There was no statistically significant difference between the three groups in terms of age, gender, the setting of procedures, the choice of anesthesia, and mean operative time; see Table 1. The precut EST group had a significantly higher frequency of malignant biliary strictures. Also, the frequency of unintentional pancreatic duct injection was significantly higher. The EPBD/EPLBD group had a much higher frequency of cholelithiasis, and a higher mean number of instruments used.

Because the cannulation techniques of both the standard EST and EPBD/EPLBD groups were identical, successful biliary cannulation in either group was considered a success of the standard cannulation technique. Of the 259 cases, first biliary cannulation was successfully performed by the standard technique in 204 cases (142 cases in the standard EST group and 62 cases in the EPBD/EPLBD group) - a success rate of 79%. Immediate precut after failed standard cannulation was successful in 46/50 cases - a success rate of 92%. Total cannulation success rate was thus 250/259 or 97%. Because precut techniques were used after failure of standard techniques, and hence the former was performed on more difficult cases (such as malignant biliary tract stricture), comparing the success rates among the three groups would not be valid.

Overall, complications occurred in 16 of 259 patients, thus the total complication rate was 6%; see Table 2. No major bleeding complications occurred in

Table 1 Contrasting the clinical characteristics among three groups of patients

	All	Standard EST	Precut EST	EPBD/ EPLBD	*p*-value
Total number	259	147	50	62	
Age (mean)	59.1	58.4	56.3	63.1	
Gender					
- Male	105 (41%)	63 (43%)	23 (46%)	19 (31%)	0.179
- Female	154 (59%)	84 (57%)	27 (54%)	43 (69%)	
Setting					
- Elective	249 (96%)	138 (94%)	50 (100%)	61 (98%)	0.110
- Emergency	10 (4%)	9 (6%)	0	1 (2%)	
Anesthesia					
- Intravenous sedation	23 (9%)	11 (7%)	3 (6%)	9 (14%)	0.221
- General anesthesia	236 (91%)	136 (93%)	47 (94%)	53 (86%)	
Unintentional pancreatic duct injection	22 (8%)	9 (6%)	11 (22%)	2 (3%)	< 0.001
Number of instruments used (mean)	1.8	1.7	1.62	2.4	
Operating time (mean)	41.4	30.5	61.8	50.9	
Diagnosis					
- Cholelithiasis	141 (54%)	64 (44%)	20 (40%)	57 (92%)	< 0.001
- Gallstone pancreatitis	15 (6%)	12 (8%)	1 (2%)	2 (3%)	
- Benign stricture of bile duct	8 (3%)	6 (4%)	1 (2%)	1 (2%)	
- Malignant stricture of bile duct	56 (22%)	36 (25%)	19 (38%)	1 (2%)	
- CBD injury (leakage/stricture)	14 (5%)	10 (7%)	4 (8%)	0	
- Normal cholangiogram/passing stone	25 (10%)	19 (13%)	5 (10%)	1 (2%)	
Condition					
- Benign	203 (78%)	111 (76%)	31 (62%)	61 (98%)	< 0.001
- Malignant	56 (22%)	36 (24%)	19 (38%)	1 (2%)	

Table 2 Comparison of complications among the three ERCP groups

	All	Standard EST	Precut EST	EPBD/EPLBD	*p*-value
Major bleeding	0	0	0	0	
Pancreatitis	8 (3%)	4 (3%)	4 (8%)	0	
Perforation	2 (1%)	1 (1%)	1 (2%)	0	
Cholangitis	5 (2%)	3 (2%)	1 (2%)	1 (2%)	
Minor bleeding	1 (1%)	0	1 (2%)	0	
Overall	16 (6%)	8 (5%)	7 (14%)	1 (2%)	0.029*

*Fisher's exact test p-value for the comparison of overall complications

any group. In the standard EST group, the complication rate was 5% (8/147). In this group, there were four cases of pancreatitis, one case of guide wire perforation and three cases of cholangitis. In the precut group, the septotomy technique was used in 36 cases, the needle knife technique was used in 7 cases, and combined techniques used in 7. Of the 36 septotomy cases, 5 had complications (2 with pancreatitis, one cholangitis, one guide wire perforation and one minor bleeding). There were no complications with the needle knife technique, and two cases of pancreatitis occurred in the combined group. The complication rate in the precut EST group was higher than those in both the standard EST and EPBD/EPLBD groups, but was only significantly so when compared with the EPBD/EPLBD technique (7/50 vs 1/62; Fisher's exact test p-value, 0.021). The complication rate in the EPBD/EPLBD group was only 2% (1/62: one case of cholangitis). This group had the lowest complication rate among the three groups (Table 2), but was significant statistically only when compared with the precut group.

DISCUSSION

Precut is an access sphincterotomy that is usually performed when standard cannulation has failed. Many studies support early application of the needle knife during difficult cannulation, which does not seem to increase the risk of pancreatitis, suggesting that pancreatitis develops as a consequence of the attempt to cannulate the papilla, and pancreatic duct injection, and not from precutting[1,2].

Wire assisted transpancreaticseptotomy (ortrans-pancreatic precut sphincterotomy) is a safe and effective alternative to traditional needle knife precutting[6,8]. In expert hands, transpancreatic precut sphincterotomy has a similar rate of pancreatitis compared with conventional biliary sphincterotomy[3]. Other studies reported higher success and lower overall complication rates compared with needle knife precutting[7].

In the present study, the success rate of biliary cannulation using the standard technique was 78% (204 of 259 cases) and the rate using the precut technique was 92% (46 of 50 cases). Thus the overall cannulation success rate was 97% (250 of 259), which was within the range reported in other studies. The lower success rate in the precutting group was likely due the underlying causes of biliary obstruction.

The overall complication rates reported in previous studies were in the range 12% to 18%. In the present study the complication rate was slightly lower, at only 6 %. The incidence of pancreatitis was lower in both the standard EST and EPBD/EPLBD groups compared with the precut group. Both higher overall complication rate and pancreatitis rate in the precut group might be the result of over manipulation of the papilla, leading to an increased risk of complications. The incidence of pancreatitis in the present study was similar to those reported in a previous study, which revealed a late-access pancreatitis rate of 14.9%, as compared with the rate of 2.6% after early precut[1].

EPLBD is an effective and safe maneuver for the removal of large or difficult CBD stones and EPBD should be considered as an alternative to EST for patients in whom EST could not be routinely performed. Prior studies reported that EPLBD was associated with fewer overall complications than EST, and limited EST followed by large balloon dilation is well accepted as an effective method for retrieving large CBD stones, with a low incidence of perforation or bleeding compared with extensive EST. In the present study EPLBD did not increase the risk of adverse events, and had a very low complication rate of 2%.

Conclusions

Malignant biliary obstruction could complicate biliary tract cannulation and more frequently needed precut techniques to achieve success. Both septotomy and needle knife techniques are safe and effective, and could provide additional means of biliary tract cannulation in difficult cases, without significantly increasing the risk of complications. Early precut should be considered when facing difficult cases to avoid over manipulation of the papilla that might increase the risk of complications. EPBD/EPLBD is safe and effective for the treatment of large CBD stones.

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