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BRIEF ARTICLE

Limited endoscopic sphincterotomy plus large balloon dilation for choledocholithiasis with periampullary diverticula

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Abstract

AIM: To investigate the effectiveness and safety of limited endoscopic sphincterotomy (EST) plus large balloon dilation (LBD) for removing choledocholithiasis in patients with periampullary diverticula (PAD).

METHODS: A total of 139 patients with common bile duct (CBD) stones were treated with LBD (10-20 mm balloon diameter) after limited EST. Of this total, 73 patients had PAD and 66 patients did not have PAD (controls). The results of stone removal and complications were retrospectively evaluated.

RESULTS: There were no significant differences between the PAD and the control groups in overall successful stone removal (94.5% *vs* 93.9%), stone removal in first session (69.9% *vs* 81.8%), mechanical lithotripsy (12.3% *vs* 13.6%), and complications (11.0% *vs* 7.6%). Clinical outcomes were also similar between the types of PAD, but the rate of stone removal in first session and the number of sessions were significantly lower and more frequent, respectively, in type B PAD (papilla located near the diverticulum) than controls [23/38 (60.5%) *vs* 54/66 (81.8%), $P = 0.021$; and 1 (1-2) *vs* 1 (1-3), $P = 0.037$, respectively] and the frequency of pancreatitis was significantly higher in type A PAD (papilla located inside or in the margin of the diverticulum) than in controls (16.1% *vs* 3.0%, $P = 0.047$).

CONCLUSION: Limited EST plus LBD was an effective and safe procedure for removing choledocholithiasis in patients with PAD. However, some types of PAD should be managed with caution.

Key words: Endoscopic sphincterotomy; Large balloon dilation; Choledocholithiasis; Periampullary diverticula

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INTRODUCTION

Although endoscopic sphincterotomy (EST) is the standard treatment for removing common bile duct (CBD) stones, it is associated with complications, including pancreatitis, bleeding, and perforation. Complications are primarily related to the indications for the procedure and applied endoscopic techniques, rather than age or general medical condition of the patients[1].

Staritz *et al*[2] introduced endoscopic papillary balloon dilation (EPBD) as an alternative method of removing bile duct stones. However, since Disario *et al*[3] reported a high frequency of pancreatitis and two deaths in an EPBD group, EPBD has seldom been used in removing bile duct stones. Recently, EPBD is primarily being used in patients with bleeding tendencies.

Since Ersoz *et al*[4] introduced large balloon dilation (LBD) after EST as an alternative technique in patients with bile duct stones that were difficult to remove with conventional methods, such as basket or balloon catheter extraction after EST, several studies have reported the safety and effectiveness of LBD after EST for removing bile duct stones[5-7].

Periampullary diverticula (PAD) are extraluminal mucosal outpouchings of the duodenum that arise within a radius of 2-3 cm from the ampulla of Vater[8]. PAD are found in 9% to 32.8% of patients who have undergone an endoscopic retrograde cholangiopancreatography (ERCP). The prevalence of PAD has a tendency to increase with age[8-15] and PAD occurred in up to 65% of elderly patients in some studies[16]. PAD are associated with an increased number of complications, which can be explained by a difficult technical approach during an ERCP; but many studies have reported conflicting results regarding the true impact of PAD on clinical outcomes[9-15].

Limited EST plus LBD can be a useful method for removing CBD stones in patients with PAD that are difficult to remove with conventional methods. However, the effectiveness and safety of limited EST plus LBD in these patients has not been evaluated. Therefore, we evaluated the clinical efficacy of limited EST plus LBD for removing CBD stones in patients with PAD.

MATERIALS AND METHODS

Patients

From August 2007 to August 2008, we enrolled consecutively 139 patients who had CBD stones ≥ 10 mm in diameter and who underwent limited EST followed by large-diameter (≥ 10 mm) balloon dilation for removal of bile duct stones. All patients were admitted to the hospital. Exclusion criteria included coagulopathy (international normalized ratio > 1.5), low platelet count (< 50000/mL), anticoagulation or antiplatelet therapy, acute pancreatitis, septic shock, prior EST, Billroth Ⅱ anatomy or Roux-en-Y gastrojejunostomy, and combined intrahepatic bile-duct stones. Informed consent from all patients was obtained and the study was approved by the ethics committee of the internal review board of Pusan National University.

Methods

ERCPs were performed by experienced endoscopists who performed over 300 biliary interventions per year. Patients were placed under conscious sedation with midazolam and meperidine. After the side-viewing endoscope (JF-240 or TJF-240; Olympus Optical Co., Ltd., Tokyo, Japan) was advanced into the descending duodenum, 10 mg of cimetropium bromide was administered intravenously to reduce duodenal peristalsis. Selective cannulation of the bile duct was achieved by using a conventional catheter and a pull-type sphincterotome with or without a guidewire. If those attempts failed to yield deep bile duct cannulation after more than 10 min, and/or the pancreatic duct had been cannulated more than 3 times, a needle-knife fistulotomy (NKF) was used to gain access. The subsequent procedures were performed by Kang's methods[5]. Follow-up endoscopy was performed on the first or second day after the procedure to determine whether bleeding was present, if immediate bleeding after EST or balloon dilation was noted, and bleeding control therapy was administered. The results of stone removal and complications were retrospectively evaluated.

Definitions

Stone size, number, and diameter of CBD were documented on ultrasound, computed tomography, and ERCP. Stone size was estimated based on the relative diameters of the stone and the shaft of the endoscope, as measured on the cholangiogram.

Limited EST was defined as sphincterotomy performed until the upper margin of the cut portion was located at one third of major EST.

Two different types of PAD were classified according to the location of the major papilla with respect to the diverticulum: type A: papilla located inside or in the margin of the diverticulum; type B: papilla located near the diverticulum.

Serum amylase (reference range, 36-128 IU/L) and lipase (22-51 IU/L) concentrations were measured before and after (4 and 24 h, respectively) the procedure. A complete blood cell count and a liver function test were checked the next morning after the procedure.

Post-ERCP pancreatitis was defined as sustained abdominal pain for 24 h after the procedure and a serum amylase level increased by three-fold or more[1,17,18]. Hemorrhage was considered to be clinically significant only when there was clinical evidence of bleeding, such as me-

Table 1 Baseline characteristics of patients with common bile duct stones who also had periampullary diverticula (periampullary diverticula group) or did not have periampullary diverticula (control group), median (range)

Characteristics	PAD group	PAD subtypes			Control group	P^2 value
		Type A	Type B	P^1 value		
No. of patients	73	35 (47.9)	38 (52.1)		66	
M:F	36:37	19:16	17:21	NS	39:27	NS
Age (yr)	70 (40-89)	74 (54-88)	66.5 (40-89)	NS	64 (23-89)	< 0.001
CBD diameter (mm)	15 (10-30)	16 (10-26)	15 (10-30)	NS	15 (11-38)	NS
Size of stones (mm)	14 (10-33)	14 (10-30)	14 (10-33)	NS	12 (10-35)	NS
No. of stones	2 (1-20)	2 (1-9)	2 (1-20)	NS	2 (1-7)	NS
Distal CBD stricture	4	3	1	NS	1	NS
Needle-knife fistulotomy	7	3	4	NS	11	NS

[1]Comparing between subgroups of periampullary diverticula (PAD); [2]Comparing PAD group with control group. CBD: Common bile duct; NS: Not significant.

Table 2 Outcome of limited endoscopic sphincterotomy plus large balloon dilation in patients with common bile duct stones who also had periampullary diverticula (periampullary diverticula group) or did not have periampullary diverticula (control group)

Characteristics	PAD group	Control group	P^2 value
Overall stone removal, *n* (%)	69/73 (94.5)	62/66 (93.9)	NS
Type A	33/35 (94.3)		NS
Type B	36/38 (94.7)		NS
P^1 value	NS		
Stone removal in first session, *n* (%)	51/73 (69.9)	54/66 (81.8)	NS
Type A	28/35 (80)		NS
Type B	23/38 (60.5)		0.021
P^1 value	NS		
No. of sessions, median (range)	1 (1-3)	1 (1-2)	NS
Type A	1 (1-3)		NS
Type B	1 (1-3)		0.037
P^1 value	NS		
Diameter of balloon dilation (mm), median (range)	13.5 (10-20)	12.5 (10-20)	NS
Type A	13.5 (10-20)		NS
Type B	13.8 (10-20)		NS
P^1 value	NS		
Mechanical lithotripsy required, *n* (%)	9/73 (12.3)	9/66 (13.6)	NS
Type A	5/35 (14.3)		NS
Type B	4/38 (10.5)		NS
P^1 value	NS		

[1]Comparing between subgroups of periampullary diverticula (PAD); [2]Comparing PAD group with control group. NS: Not significant.

lena or hematemesis, together with a decrease of at least 2 g/dL in the hemoglobin level, or the need for blood transfusion for stabilization of vital signs[1,17,18].

Statistical analysis

For the statistical analysis, the χ^2 test and Fisher's exact test was used for categorical variables and the Student *t* test or ANOVA test for continuous variables. Analyses were performed with SPSS 12.0 (SPSS Inc., Chicago, IL). A *P* value < 0.05 was considered statistically significant. Continuous variables are expressed as the median (range).

RESULTS

A total of 139 patients (median age, 68 years old; 76 men, 63 women) with CBD stones underwent limited EST plus LBD. Seventy-three patients (median age, 70 years old; 36 men, 37 women) had PAD (PAD group) and 66 patients (median age, 64 years old; 39 male, 27 female) did not have PAD (control group). There were no differences between the two groups regarding baseline characteristics, except age (70 years *vs* 64 years, $P < 0.001$) (Table 1).

In the PAD group, type A PAD comprised 35 patients (47.9%) and type B PAD comprised 38 patients (52.1%). There were no differences between the two types regarding baseline characteristics (Table 1).

The rate of overall stone removal and stone removal in first session did not differ significantly between the PAD and the control groups [overall, 69/73 (94.5%) *vs* 62/66 (93.9%); and first session, 51/73 (69.9%) *vs* 54/66 (81.8%), respectively] (Table 2). Failure of complete stone clearance occurred in 8 patients, 4 from each group. The major causes in 7 patients were capture failure with mechanical basket due to multiple, impacted, or large stones (3 patients in the PAD group, 4 patients in the control group) and one patient (PAD group) had large stones above

Table 3 Complications of limited endoscopic sphincterotomy plus large balloon dilation in patients with common bile duct stones who also had periampullary diverticula (periampullary diverticula group) or did not have periampullary diverticula (control group) *n* (%)

Complications	PAD group	Control group	P^2 value
Pancreatitis	7/73 (9.6)	2/66 (3.0)	NS
Type A	5/35 (14.3)		0.047
Type B	2/38 (5.3)		NS
P^1 value	NS		
Hemorrhage	0/73 (0)	1/66 (1.5)	NS
All complications	7/73 (9.6)	3/66 (4.5)	NS
Type A	5/35 (14.3)		NS
Type B	2/38 (5.3)		NS
P^1 value	NS		

[1]Comparing between subgroups of periampullary diverticula (PAD); [2]Comparing PAD group with control group. NS: Not significant.

the stricture. These patients had a biliary stent placed to ensure biliary drainage and were treated by percutaneous transhepatic cholangioscopy with electrohydraulic lithotripsy (7 patients) or open surgery (1 patient).

The groups had a similar frequency of mechanical lithotripsy [9/73 (12.3%) *vs* 9/66 (13.6%)]. Large-sized stones (> 15 mm) were the main indication for mechanical lithotripsy.

Between the types of PAD, there were no significant differences in the overall stone clearance, the stone removal in the first session, or the use of mechanical lithotripsy. However, when comparing each type of PAD with the controls, the rate of stone removal in first session and the number of sessions in type B PAD were significantly lower and more frequent, respectively, than controls [23/38 (60.5%) *vs* 54/66 (81.8%), $P = 0.021$ and 1 (1-2) *vs* 1 (1-3), $P = 0.037$, respectively] (Table 2).

The overall frequency of short-term complications was similar between the PAD and control groups [7/73 (9.6%) *vs* 3/66 (4.5%)] (Table 3). The frequency of pancreatitis did not differ significantly between the PAD and control groups [7/73 (9.6%) *vs* 2/66 (3.0%)]. Pancreatitis occurred in 5 and 2 patients with type A and B PAD, respectively. Pancreatitis related to NKF only occurred in one control patient. In comparing each type of PAD with controls, pancreatitis was significantly higher in type A PAD than controls [5/31 (14.3%) *vs* 2/66 (3.0%), $P = 0.047$]. All pancreatitis cases were clinically mild and they were treated conservatively. Clinically significant hemorrhage occurred in one patient in the control group. Immediate bleeding occurred after 10 mm balloon dilation and was controlled by endoscopic treatment. The next day, melena occurred and a blood transfusion was performed. Active bleeding was not found in a follow-up endoscopy, but blood clots appeared in the major papilla. Hemorrhage did not occur in any patient in the PAD group. Perforation and cholangitis did not occur in any patient.

DISCUSSION

The majority of CBD stones are removed by EST and conventional methods, but 10%-15% may be difficult to remove by conventional methods. The main reasons for failure are a difficult approach to the bile duct (PAD, Billroth Ⅱ anatomy, Roux-en-Y gastrojejunostomy), large (> 15 mm) stones, and impacted stones[19,20].

Conflicting results have been reported regarding the true impact of PAD on the technical success and complications of ERCP[9-15]. Many studies have reported recently that PAD does not make a difference to the success and complication rates of ERCP[14,15,21]. However, clinical outcomes associated with the technical success of selective cannulation of the bile duct or EST may be influenced by PAD. Boix *et al*[15] classified PAD into three types, according to the position of the major papilla. That study concluded that the presence or type of PAD did not significantly influence the difficulty of deep cannulation, but they did not evaluate the association between the types of PAD and the technical difficulties in removing CBD stones.

After the first study from Ersoz *et al*[4] demonstrating the technique of EST plus LBD, several studies established this procedure as an effective and safe treatment for removing CBD stones[5-7]. However, there have been few studies about the effectiveness and safety of EST plus LBD in patients with PAD. Three recent studies reported clinical outcomes of EST plus LBD in patients with PAD[22-24]. Two studies reported similar results for stone removal (84% *vs* 87.5%, 93.8% *vs* 89.2%) and complications (8.3% *vs* 18.8%, 3.1% *vs* 10.8%) between the PAD and control groups[22,23]. These studies suggested that minor EST with LBD in patients with PAD was a safe treatment modality for removing CBD stones. Another study compared minor EST plus EPBD with EST alone in patients with PAD and found similar outcomes in terms of overall stone clearance (100% *vs* 100%), stone clearance at first attempt (78% *vs* 72%), and the use of mechanical lithotripter (12% *vs* 21%)[24]. However, complications were rare in the EST plus EPBD group compared to EST alone (4% *vs* 21%, $P < 0.005$). The authors suggested that minor EST plus EPBD was safer than EST alone for removing bile duct stones in patients with PAD. However, these studies had limitations due to being published in abstract form and having a small number of patients.

In the current study, the rates of overall stone removal and the stone removal in first session did not differ significantly between the PAD and control groups (94.5% *vs* 93.9% and 69.9% *vs* 81.8%, respectively). The overall success rate of stone removal was similar to those of previous studies (84%-100%)[5,23,24]. The stone removal in first session rate in the PAD group was lower than that of the control group and of previous studies (81.8%-95%)[5,7,22], although this was not statistically different. This finding might be attributed to an older age group (median ages, 70 years old *vs* 62 years old, $P < 0.001$); elderly patients tend to have cardiopulmonary instability or poor general condition, thus they are less able to tolerate the procedure for long. The high prevalence of multiple stones in the PAD group might also have influenced the poor result, though this was not significantly different from controls.

Finally, the PAD condition might reduce the potential aggressiveness of the procedure by the endoscopist due to the consideration of possible complications.

The outcomes of stone removal were not different between the types of PAD. However, the rate of stone removal in the first session in type B PAD was lower compared to type A PAD, although the difference was not statistically significant. In comparing each type of PAD with controls, the rate of stone removal in first session and the number of sessions in type B PAD was significantly lower and more frequent, respectively, than controls, [23/38 (60.5%) *vs* 54/66 (81.8%), $P = 0.021$; and 1 (1-2) *vs* 1 (1-3), $P = 0.037$, respectively]. This finding might be attributed to a higher prevalence of multiple stones in type B PAD compared to controls and type A PAD, although this difference was not statistically significant.

The frequency of mechanical lithotripsy was similar between the PAD and control groups (12.3% *vs* 13.6%) and was similar to results with other studies (8.0%-12%)[5,6,24]. Again, no differences were found between the types of PAD in the frequency of mechanical lithotripsy.

These results suggest that the success rate for the clearance of bile duct stones and the use of mechanical lithotripsy were influenced by the number and size of the stones rather than the presence or type of PAD.

Generally, the length of EST is shorter in patients with PAD than in those without PAD due to the weakness of the sphincter of choledochus and risk of perforation in patients with PAD. For similar reasons, the diameter of the balloon may be influenced by the position of the major papilla in PAD; there was a tendency to use a smaller sized balloon in PAD compared to controls. However, in the current study, there was no difference in balloon diameters between the PAD and control groups or between the types of PAD. Although the precise reasons are not clear, PAD itself had no influence on the diameter of balloon.

In the current study, the overall rates of complication were not significantly different between the PAD and control groups (9.6% *vs* 4.5%). However, pancreatitis in the PAD group occurred more frequently than in other studies (4%-8.3%)[5-7,23,24]. Nevertheless, all pancreatitis cases were clinically mild and they were treated conservatively. The rate of pancreatitis was not statistically different between the types of PAD. However, the frequency of pancreatitis in type A PAD was significantly higher than in controls (14.3% *vs* 3.0%, $P = 0.047$). In the current study, the cause of more frequent pancreatitis in type A PAD is not clear, but it may be related to the presence of type A PAD. Firstly, the cannulation of the bile duct in type A PAD is generally more difficult than in type B PAD or in controls due to more frequent cases of poorly detectable papilla or more difficult prediction of the direction of bile duct in type A PAD. These features may lead to induction of pancreatitis because of the unnecessary injection of contrast medium or manipulation of the pancreatic duct, but the frequency of NKF due to difficult cannulation was not significantly different among the groups in our study. Secondly, because EST before LBD was performed to prevent post-ERCP pancreatitis by induction of separation between the pancreatic and biliary orifices, the more frequent pancreatitis in type A PAD may be related to injury of the pancreatic duct during balloon dilation due to less separation between the pancreatic and biliary orifices after EST compared to the control group and type B PAD group. Clinically significant hemorrhage did not occur in any patient in the PAD group.

In conclusion, limited EST plus LBD was equally successful and had similar complication rates in the PAD and control groups for the clearance of CBD stones. Therefore, this procedure is effective and safe for removing CBD stones in patients with PAD. Nevertheless, this procedure requires caution in some types of PAD for successful stone removal and prevention of complications. Larger and prospective studies are needed to evaluate clinical outcome in the presence of different types of PAD due to the retrospective nature and relatively small sample sizes in this study.

COMMENTS

Background

Endoscopic sphincterotomy (EST) plus large balloon dilation (LBD) is a useful method to remove common bile duct (CBD) stones, but the effectiveness and safety of this procedure is not well known in patients with periampullary diverticula (PAD) which are reportedly associated with difficulties and complications during associated procedures. We conducted this trial to evaluate the effectiveness and safety of limited EST plus LBD for removing CBD stones in patients with PAD.

Research frontiers

The majority of CBD stones are removed by EST and conventional methods, but 10%-15% may be difficult to remove by conventional methods. The main reasons for failure are a difficult approach to the bile duct (PAD, Billroth II anatomy, Roux-en-Y gastrojejunostomy), large (> 15 mm) stones, and impacted stones. In addition, PAD are associated with an increased number of complications, which can be explained by a difficult technical approach during an ERCP. However, conflicting results have been reported regarding the true impact of PAD on the technical success and complications of ERCP. Therefore, LBD after EST in some patients with PAD may be ineffective and complicated.

Innovations and breakthroughs

After the first study by Ersoz *et al* demonstrating the technique of EST plus LBD, several studies established this procedure as an effective and safe treatment for the removal of bile duct stones; but there have been few studies about the effectiveness and safety of EST plus LBD in patients with PAD. Three recent studies reported clinical outcomes of EST plus LBD in patients with PAD, but these studies had limitations due to being published in abstract form and having a small number of patients.

Applications

Limited EST plus LBD was equally successful and had similar complication rates in the PAD and control groups for the clearance of CBD stones. Therefore, this procedure is effective and safe for removing CBD stones in patients with PAD.

Terminology

Limited EST was defined as sphincterotomy performed until the upper margin of the cut portion was located at one third of major EST. Two different types of PAD were classified according to the location of the major papilla with respect to the diverticulum: type A: papilla located inside or in the margin of the diverticulum; type B: papilla located near the diverticulum. LBD was defined as the diameter of the balloon used for dilation being 10 to 20 mm.

Peer review

Kim *et al* have performed a retrospective study in order to evaluate the effectiveness and safety of limited EST plus LBD for removing CBD stones in patients with PAD. This paper is interesting and it could be valuable for other researchers.

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