



Comparison of the usefulness of endoscopic sphincterotomy, endoscopic papillary large-balloon dilation with combined approaches for common bile duct stones.

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Abstract

Objective: To investigate endoscopic treatment of common bile duct stones (CDS) in patients by sphincter small incision combined with balloon dilatation of the the efficacy and safety.

Method: 296 patients with common bile duct stones treated in our department between July 2009 and July 2013, randomized comparison of SES +ELBD (group A, n = 104) and EPBD alone (group B, n = 96), traditional EST (group C, n = 96) for the treatment of CDS. A group underwent small incision endoscopic sphincterotomy (< 0.5cm), Wilson-cook, the balloon according to the size of stone and dilatation of common bile duct dilatation teat sphincter (diameter of 12, 15, 18mm), the position of the balloon adjustment under X-ray monitoring, balloon injection pressure 5atm, maintain 1min, intermittent 1min, expanding again 1 times, to fully expanded papillae group B, expansion method of operation with the above A group; C group adopts the push-pull papillotome, according to the size of stone, EST usually 10 ~ 15mm. After the stone basket stone, part of patients with stone to stone basket after mechanical lithotripsy(ML).

Results: ERCP total success rate was 96.3% (285/296). Remove the complete stone rate once: 94.23% in A group and B group 91.67%, C group 83.75% patients, not a clear stones placed nasobiliary drainage tube. Mechanical lithotripsy group A: 10/99 cases (10.10%), group B: 12/92 cases (13.04%), group C: 8/94, 8.51%. A group of 8/99 cases occurred complications (8.08%), group B: 10/92 cases (10.87%), C group 17/94 cases (18.09%). 6 cases of acute pancreatitis after operation in A group, 2 cases of acute cholangitis, 4 cases of hemorrhage after operation in B group, 6 cases of acute pancreatitis after operation; 7 cases of hemorrhage after operation in C group, including 1 cases of endoscopic hemostasis, 10 cases of acute pancreatitis; were cured conservatively, no perforation occurred in three groups. A group and C group is a complete stone clearance rate were statistically significant (P <0.05), the complication rate of A group and C group had significant difference (P <0.05).

Conclusion: SES +ELBD than the traditional EST on rates of successful stone removal in the first session is high, the low rate of complications of ERCP.

Keyword: small endoscopic sphincterotomy; endoscopic papillary balloon dilatation; common duct stone; complication

I. Introduction

Endoscopic sphincterotomy (EST) is currently recognized as the primary endoscopic treatment for common bile duct stones. However, it is difficult to remove multiple (≥ 3) or large (≥ 15 mm) common bile duct stones with EST alone. but the complication rate is still high. Within a simple endoscopic papillary balloon dilation (EPBD) to treat choledocholithiasis compared with EST, EPBD reduced the incidence of bleeding, perforation and other complications, and effective protection of the duodenal sphincter function, but the relative incidence of postoperative pancreatitis high^{1,2}. Recently, EST plus endoscopic papillary large-balloon dilation (EPLBD) was reported to be an effective treatment for such bile duct stones³. In this study, the endoscopic small papilla incision combined large papillary

balloon dilatation (SES + ELBD) treatment of common bile duct stones, explore the efficacy and safety of the method.

II. Materials and Methods

Between July 2009 to July 2013, 296 cases of common bile duct stones in our hospital with Endoscopic treatment of bile duct stones application. All patients with B-Ultrasound or CT and MRCP examination to confirm the diagnosis of common bile duct stones. Randomized comparison SES + ELBD (A group, n = 104) with *alone* of EPBD (group B, n = 96), conventional EST (group C, n = 96) treatment of bile duct stones. There were no significant differences between the three groups with respect to gender, age and general condition ($P > 0.05$), Table 1.

Table 1. three groups of patients general Materials

groups	N (Cases)	Age (Year old)	Stone size (mm)	Choledocholithiasis (Number)	Sex	
					Male(%)	Female(%)
SES +ELBD	104	62.18±12.16	13.73 ±2.95	1.63 ±0.68	47.2	50.8
EPBD	96	64.53±11.82	12.56± 3.78	1.71 ±0.78	51.5	48.5
EST	96	63.52±13.53	11.47±3.67	1.61 ±0.59	52.7	47.5

Equipment

Olympus TJF-240 electronic duodenoscopy, ERBE-ICC200, Olympus- KD210Q -0725, Duodenal papilla knife, Olympus BML-4Q mechanical lithotripsy, stone basket (FG-22Q-1), stone balloon catheter (Wilson-cook 18 mm.6.8 Fr), endoscopic papillary dilation balloon (Wilson-cook 12.15.18mm) and so on.

Treatment

SES + ELBD group underwent a small incision of papillary sphincterotomy, cut length less than 0.5cm, and using the endoscopic papillary dilatation balloon (Wilson-Cook) to expand in diameter(12.15.18mm) according to the degree of stone size and common bile duct dilatation. In the X-ray monitoring, and dilation balloon located in the center of the papillary, the balloon maximum pressure 5atm, Time of balloon dilation 1min, intermittent 1min, once again expand to full expansion of the Sphincterotomy; EPBD group, Balloon dilation method of operation is the same group SES + ELBD; EST group, general sphincterotomy diameter of 10 ~ 15mm According stone size,. Three groups were based on stone size with stone basket, when the stones can not be removed with a basket for mechanical lithotripsy. After Postoperative routine endoscopic nasobiliary drainage.

Postoperative care

The Patients were kept fasting for at least 24h after endoscopy, and maintained on liquid to semi-liquid diet for one week after the Postoperative. Post-operative vital signs were monitored to detect any complications., with or without abdominal pain, Haematemesis, Blood in the stool, Laboratory Routine blood. CRP. liver function test, blood and urine amylase, observe whether acute pancreatitis, cholangitis and perforation of the symptoms and signs. Eesomeprazole and antibiotics were used for 3 days.

Statistical analysis

The statistical analysis was performed using SPSS 11.0 software. Comparisons of quantitative data between groups were evaluated using t test. Comparisons of categorical data between groups were evaluated using Fisher's exact test. p value of <0.05 was considered statistically significant.

III. Results

The ERCP total success rate (285/296) 96.3%. The mean operation time (A Group: 25 minutes, Group B: 27 minutes, C Group: 30 minutes) There was no significant difference; among the three groups a complete stone clearance rate, A group was 94.23% and group B 91.67%, group C 83.75 %. A group of mechanical lithotripsy: 10/99 patients (10.10%), Group B: 12/92 patients (13.04%), Group C: 8/94 patients (8.51%). The rate of complications ,A group, 8/99 cases (10.10%), group B, 10/92 cases (10.87%), group C, 17/94 cases (18.09%). A group, after six cases of acute pancreatitis, acute cholangitis in 2 cases were cured by conservative; group B, 4 cases of postoperative with hemobilia, postoperative acute pancreatitis, 6 cases were cured by conservative; group C, 7 cases of postoperative with hemobilia, including within endoscopic hemostasis one case, postoperative acute pancreatitis 10 cases were cured by conservative; three groups were not severe pancreatitis and perforation complications. (Table 2), the three groups a complete stone clearance rate of group A and group C was statistically significant ($P < 0.05$), the incidence of complications in group A and group C was statistically significant ($P < 0.05$). The incidence of acute pancreatitis in each group was not significantly different.

Table 2 Comparison of three groups of patient outcomes and the recent occurrence of complications

groups	ERCP Success rate (n)	Disposable stone clearance (%)	complications (%)	hemobilia (n)	pancreatitis (n)	cholangitis (n)
SES +ELBD	99	94.23	08.08	0	6	2
EPBD	92	91.67	10.87	4	6	0
EST	94	83.75	18.09	7	10	0

Perforation group A and group C first stone success rate χ^2 value 6.06, $P < 0.05$. with a significant difference. A group and B group first stone success rate χ^2 value 0.50. $P > 0.05$. no significant difference; group B Compare χ^2 values in the group C first stone success rate 3.05, $P > 0.05$, no significant difference. A group A and group C complication rate between χ^2 value 4.58. $P < 0.05$. significant difference, A concurrent group A and group B disease incidence χ^2 value 0.45. $P > 0.05$. no significant difference between group B and group C complication rate between the χ^2 value 2.11. $P > 0.05$. no significant difference.

IV. Discussion

With digestive endoscopy technology continues to progress and improve, endoscopic retrograde cholangiopancreatography (ERCP) and its related technologies has effective treatment methods with the liver, gallbladder, pancreas disease. Currently choledocholithiasis had endoscopic methods: (1), endoscopic sphincterotomy (EST) ; (2), endoscopic papillary balloon dilatation (EPBD) alone ; (3) within underwent endoscopic a small papilla incision combined papillary balloon dilatation (SES + EPBD) ⁴ ; Mu H et al⁵ . Three hundred patients who were hospitalized between June 2007 and June 2008 with common bile duct stones >10 mm in diameter were randomly assigned to the EST or EST-EPBD group. We compared the short-term (≤ 3 years) and long-term (> 3 years) recurrence of ductal stones in the two groups over a 72-month follow-up period. CONCLUSIONS: Small-incision EST-EPBD has a similar overall success rate and a significantly lower rate of the recurrence of ductal stones, compared with those of EST alone. Minimal size of the duodenal papilla incision protects against the recurrence of ductal stones. Fu BQ et al. reported ⁶The ERCP in 560 cases from 2011 to 2012., common bile duct stones in 206 patients included in the study were randomly divided into EPBD, 10-12 mm balloon dilatation or EST (n = 103 cases). Two group conventional basket or balloon stone, the successful stone

removal in the first session in the EPBD group success rate 94 cases (91.3%), 75 cases (72.8%) EST group, EPBD group was significantly higher than the success rate of stone removal EST group. The group of a complete stone clearance rate, A group was 94.23% and group B was 91.67%, group C 80.75%, SES + ELBD group and EST group than in $P < 0.05$, there are significant differences, results are in agreement with the literature report, but, the present study data show EPBD group than in the group with EST $P > 0.05$, no statistically significant difference, Lastly, due to the relatively small sample size. prospective randomized controlled studies are needed to provide more robust evidence of the efficacy of SES + EPBD.

Since 1983 endoscopic papillary balloon dilation (EPBD) have been proposed, and gradually used clinically. compared with EST, which maintains the duodenal papillary and mucosal integrity, and has the low complications of bile duct bleeding and perforation. But complicated by pancreatitis after EPBD, the rate was 4.8% ~ 19.5%⁷. The study total incidence of complications in group A, group B, C group were 8.08%, 10.87%, 18.09%, complication of SES + EPBD group was significantly lower than EST, with significant difference. But the incidence of acute pancreatitis in each group was analyzed statistically, no significant difference between the groups. To study the risk factors and prevention and treatment of EPBD complicated with pancreatitis, and it is helpful for the EPBD to exert the advantages and reduce or avoid the complications of pancreatitis. Some scholars have pointed out that^{8,9}, EPBD causes pancreatitis, the main mechanism is the expansion of the balloon to the duodenal papilla sphincter and pancreatic duct opening caused by oppression and repeated mechanical stimulation, so that the papilla occur edema, increased pressure within the pancreatic duct, Poor drainage of pancreatic juice caused the pancreatitis. Takeshi et al¹⁰. The use of reduced to pneumatic compression method to reduce the stimulation of the duodenal papilla. Choledocholithiasis in 324 patients were improved treatment by EPBD, the balloon pressure from the usual 8 atm, the balloon is reduced to filling pressure, and the balloon tamponade time to be reduced from the usual 2min to 1.5min, the results showed that 13 cases of pancreatitis (4.0%), with no severe cases that improved EPBD can significantly reduce the incidence of postoperative pancreatitis. Our experience is: ① SES + EPBD is the preferred method of Endoscopic treatment of common bile duct stones, especially for papillary diverticulum, flat like nipples, cirrhosis, coagulation disorders, bleeding tendency, elderly and frail patients with common bile duct stones; ② EPBD treatment, papillary sphincter balloon dilation time of 1min, avoid long time of oppression expansion; ③ SES + EPBD, be sure to control the length of the Sphincterotomy, generally less than 0.5cm; ④ balloon dilatation should be intermittent expansion method, to alleviate the suffering of patients, so that the expansion effect is obvious; ⑤ ENBD routine method after ERCP. SES + EPBD or EPBD, to prevent complications caused by residual biliary stones obstruction and papilledema. In short, SES + EPBD can be achieved with simple EST equal or superior treatment of stone effect, postoperative complications was significantly lower than EST, Reduce the incidence of hemobilia and perforation; It Added the lack of pure EPBD, That is a low incidence of hyperamylasemia and pancreatitis; and the remaining portion of duodenal sphincter function, preventing retrograde biliary tract infections and other long-term postoperative complications. The method takes advantage of EST and EPBD; it has little effect on the structure of the duodenal sphincter functions, safe, simple, effective and so on.

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