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Small endoscopic sphincterotomy combined with endoscopic papillary large-balloon dilation in the treatment of patients with large bile duct stones

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Summary
Background To compare the effectiveness and safety of the combination of endoscopic papillary large-balloon dilation (EPLBD) and small endoscopic sphincterotomy (SEST) with either EST or EPLBD alone in the treatment of large bile duct stones.

Methods A total of 127 patients with large bile duct stones were enrolled and randomly divided into four treatment groups (the SEST + EPLBD group, the EPLBD + SEST group, the EST group, and the EPLBD group) in a 1:1:1:1 ratio. Evaluation variables included the success rates of complete stone removal, complete stone removal without the use of endoscopic mechanical lithotripsy (EML), and complete stone removal in one session, as well as the occurrence of short- and long-term postoperative complications.

Results The overall rate of stone clearance was quite similar among the four treatment groups. There was no significant difference in the rate of complete stone removal without the use of EML among these groups. However, the combination treatment groups required relatively fewer sessions than did the EPLBD group. The incidence rates of short- and long-term complications were relatively lower in the two combination groups than in the EST and EPLBD groups.

Conclusions A combination of SEST and EPLBD appears to be safe and effective for patients with large bile duct stones. This combination may have potential safety advantages in comparison with EST or EPLBD alone.

Keywords Small endoscopic sphincterotomy · Endoscopic papillary balloon dilatation · Choledocholithiasis · Common bile duct stones

Introduction

Since 1974, when endoscopic sphincterotomy (EST) during endoscopic retrograde cholangiopancreatography (ERCP) was first reported [1, 2], this technique has been frequently used in clinics and considered the standard therapy for the treatment of choledocholithiasis. However, because EST requires an adequate incision of the major ampulla (usually 10–15 mm) and achieves biliary cannulation, it can cause irreversible damage to the biliary sphincter during the surgical procedure, consequently increasing the risk of several complications such as perforation, hemorrhage, biliary reflux, and acute pancreatitis [3–5].

Endoscopic papillary balloon dilation (EPBD) has been advocated as an alternative to EST because it is widely believed that this approach can preserve the function of the biliary sphincter, thus decreasing the incidence of hemorrhage and perforation as compared with EST [6–9]. Nevertheless, EPBD is only effective for removal

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of small to moderate bile duct stones (less than 8 mm in diameter) due to the biliary opening being smaller than that with EST [10, 11]. In addition, the incidence rates of hyperamylasemia and acute pancreatitis appear to be significantly higher for EPBD than for EST [11, 12].

To overcome the above-mentioned limitations of EST and EPBD, surgeons and gastroenterologists have been seeking new approaches that allow for effective removal of large or difficult common bile duct (CBD) stones with low incidence of postoperative complications. Recently, many studies have suggested a combination of endoscopic papillary large-balloon dilation (EPLBD) and small EST (SEST) as a promising alternative to conventional EST or EPBD [13–16]. Bang et al. [17] evaluated the efficacy and complications of EPLBD after limited EST for the treatment of choledocholithiasis in 22 patients and showed that EPLBD combined with limited EST had comparable efficacy and safety to those reported for conventional EST. Kim et al. [18] retrospectively compared the therapeutic benefits and complication rates of the combination of EPLBD plus SEST with those of EST alone. Their results suggested that when compared with EST, the combination technique reduced the use of endoscopic mechanical lithotripsy (EML). In a recently published meta-analysis, accumulated data showed that EPLBD combined with SEST is a safe and effective procedure for the clearance of large or difficult CBD stones without any additional risk of severe complications [19]. In spite of these findings, there is still a lack of evidence from prospective randomized clinical trials. Therefore, in the current study, we designed a single-center, randomized, parallel-group clinical trial, with the aim being to compare the effectiveness and safety of the combination of EPLBD and SEST with either EST or EPLBD alone in the treatment of patients with large bile duct stones.

Patients and methods

Study design

A single-center, randomized, parallel-group clinical trial was conducted in the current study. A total of 168 consecutive patients with choledocholithiasis were assessed for eligibility by the Department of Gastroenterology of the corresponding author's institute from March 2009 to December 2011. The study protocol was approved by the institutional ethics committee and all participants provided informed written consent.

Inclusion and exclusion criteria

Inclusion criteria were as follows: (1) age ≥18 years old; (2) having choledocholithiasis with stones detected by ultrasonography; (3) the shortest diameter of the largest stone ≥10 mm, as demonstrated by endoscopic retrograde cholangiopancreatography (ERCP); (4) American Society of Anesthesiologists (ASA) physical status I–III; (5) body mass index (BMI) <35 kg/m^2; (6) intention to undergo the assigned interventions.

Exclusion criteria were (1) age <18 years old; (2) having clinical, radiologic, or biochemical evidence of cholangitis and pancreatitis; (3) the shortest diameter of the largest stone <10 mm; (4) ASA physical status IV or more; (5) BMI ≥35 kg/m^2; (6) presence of chronic devastating diseases such as neoplasm, cirrhosis, liver abscess, suppurative or necrotizing cholecystitis, gallbladder empyema, or perforation; (7) pregnancy; (8) recurrent choledocholithiasis.

Interventions

Patients who met the inclusion criteria were randomly assigned to the four treatment groups [SEST followed by EPLBD (SEST + EPLBD), EPLBD followed by SEST (EPLBD + SEST), EST, and EPLBD groups] in a 1:1:1:1 ratio using a computer-generated stochastic system. Before ERCP, routine laboratory tests including complete cell blood counts, hepatic functions, coagulation profile, and serum amylase (reference range: 25–125 IU/L) and lipase levels (reference range: 5.6–56 IU/L) were carried out for all patients. All ERCPs were performed using a side-viewing duodenoscope (ED-3430, Pentax, Tokyo, Japan) to document the size of CBD stones, the number of stones, and the presence of periampullary diverticulum on the cholangiogram. Stone size was measured with reference to the diameter of the endoscope shaft. A periampullary diverticulum was defined endoscopically as a depressed lesion of >5 mm in size with intact mucosa within a radius of 2.5 cm of the papilla [18].

All endoscopic procedures in the four treatment groups were performed by two surgeons who had extensive experience in biliary interventions based on their clinical performance (more than 200 biliary endoscopic interventions per year during 10 years). The four treatment groups had the same protocol of general anesthesia. In the EST group, the endoscopic procedure was conducted with a pull-type sphincterotome (Cook Medical, Bloomington, USA) according to a standard method reported in the literature [20]. For patients in the EPLBD group, a balloon catheter (Fusion®, 12–20 mm, Cook Medical) was inserted over a guide wire. The diameter of the balloon was matched to the maximal diameter of the CBD and the size of the stones. The balloon was positioned across the main duodenal papilla so that two thirds of it was inside the distal CBD and one third was outside the papillary orifice. Then, the balloon was gradually inflated with diluted contrast medium. The disappearance of the waist of the balloon should be paid attention to while the balloon is expanded. Once the waist disappeared, inflation was maintained for 60 s, and then the balloon was deflated and removed. Afterwards, the bile duct stones were removed with a Dormia basket (Olympus, Tokyo, Japan) or retrieval balloon (Olympus). A mechanical lithotripter (Olympus) was used to crush the stones when needed.

In the SEST + EPLBD group, SEST was performed based on the protocols described by Minami et al. [21]. Compared with conventional EST, the length of the incision in this group was limited to one third because the purpose of this incision was to direct the insertion of the balloon catheter and control the direction of sphincter dilation. After SEST, a guide wire was inserted into the bile duct and a balloon catheter (Fusion®, 12–20 mm, Cook Medical) was passed over the guide wire and positioned across the papilla. Then, the dilation of the balloon and removal of stones were performed the same as in EPLBD sessions.

In the EPLBD + SEST group, the first procedure of EPLBD was carried out in the same way as described above. After the balloon catheter was removed, a pull-type sphincterotome (Cook Medical) was used to make an incision from the orifice of papilla proximally. But the length of incision was also limited to one third of that in conventional EST. The sphincterotome was then removed and the bile duct stones were removed using a Dormia basket (Olympus, Tokyo, Japan) or retrieval balloon (Olympus). Mechanical lithotripsy was used when necessary. After clearance of bile duct stones, laparoscopic cholecystectomy was performed in patients who had residual gallbladder stones.

Immediately following the endoscopic intervention, all patients received prophylactic antibiotics and nonsteroidal anti-inflammatory drugs (NSAIDs). Prophylactic pancreatic stents were used based on the judgments of the treating physicians. Routine laboratory tests were performed 3 and 8 h post operation to monitor changes in the level of serum amylase and other blood biochemical parameters. Then, all patients stayed in hospital for at least 3 days to observe possible complications.

Evaluation of clinical outcomes

For all four treatment groups, ductal clearance was verified by either a final cholangiogram during the endoscopic procedure or a follow-up cholangiogram obtained 3 days after the initial procedure through an endoscopic nasobiliary catheter after the stones were removed from the bile duct. Complete stone removal was defined as overall complete bile duct stone clearance by the assigned interventions regardless of whether EML was used as an adjunctive procedure or not. Complete stone removal without use of EML was defined as complete stone clearance by the assigned interventions without the assistance of EML, irrespective of the session number of the assigned interventions. Complete stone removal in one session was defined as complete stone clearance when only one session of the assigned interventions was carried out without considering the use of EML as an adjunctive procedure.

Procedure-related complications were closely monitored during hospital stays and periodically reviewed at outpatient follow-up examinations. Briefly, during the first 3 months postoperatively, patients received follow-up every month. Afterwards, follow-up was every 3 months until the first postoperative year. At each follow-up examination, routine laboratory tests, upper gastrointestinal series (barium swallow), and magnetic resonance cholangiopancreatography (MRCP) were conducted to identify complications or the recurrence of cholelithiasis. All complications were classified according to the established criteria proposed by Freeman et al. [22]. Short-term complications were defined as complications that occurred within 4 weeks postoperatively, such as bleeding, perforation, biliary infection, and pancreatitis. Long-term complications were defined as complications that occurred after 4 weeks until the first year postoperatively, such as pancreatitis, cholangitis, recurrence of cholelithiasis, biliary stricture, and biliary malignancy.

Statistical analysis

Sample size was calculated based on the success rate of complete stone removal in one session. We hypothesized that the combination of SEST and EPLBD would be associated with an increase of 30 % in the success rate of complete stone removal in one session as compared with EPLBD alone. A sample size of 25 patients from each group was considered necessary to document a significant effect with a statistical power (1–β) of 85 % (2-sided $\alpha = 0.10$). To avoid underpowering due to an incorrect estimate of (1–β) and α, we decided to enroll 30 subjects per group in this study.

All statistical analyses were performed using SPSS 17.0 software (SPSS Inc., Chicago, IL). All quantitative variables were tested for normality distribution using the Kolmogorov–Smirnov test. Data with normal distribution are presented as mean ± standard deviation (SD). Data with skewed distribution are presented as median and range (minimum–maximum). For categorical variables, data are presented as counts and percentages. Statistical significance of quantitative variables among groups was assessed by one-way analysis of variance (ANOVA) or nonparametric Kruskal–Wallis test. Statistical significance for categorical variables was assessed using the chi-squared test or Fisher's exact test. A value of $p < 0.05$ was considered statistically significant.

Results

Demographics of patients

As shown in Fig. 1, a total of 168 patients who were diagnosed with choledocholithiasis were accessed for eligibility for this study. After successful screening, 127 patients were randomly assigned to four treatment groups ($n = 33$ for the SEST + EPLBD group, $n = 32$ for the EPLBD + SEST group, $n = 32$ for the EST group, and $n = 30$ for the EPLBD group). All patients in these groups received the allocated intervention and completed 1-year follow-up visits,

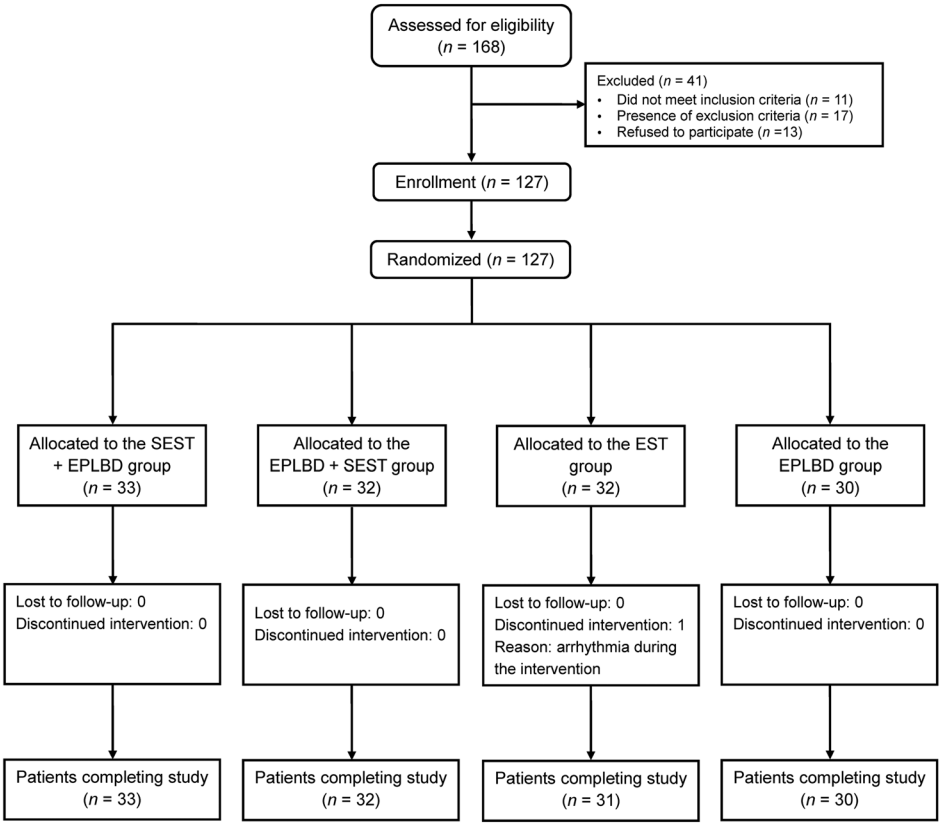

Fig. 1 Consolidated Standards of Reporting Trials (CONSORT) flowchart of the current study

SEST: small endoscopic sphincterotomy; EPLBD: endoscopic papillary large-balloon dilation; EST: endoscopic sphincterotomy

except for one patient in the EST group who discontinued the study due to severe cardiac arrhythmia during the intervention. Demographics of patients are shown in Table 1. There were no significant differences in terms of age, gender, physical status, and clinical characteristics among the four treatment groups. All patients had an intact gallbladder at the time of surgical procedure.

Outcomes of stone removal

The outcomes of stone removal in all treatment groups are summarized in Table 2. Of 126 patients who completed the assigned interventions, 120 (95.2%) ultimately achieved complete stone removal and 116 (92.1%) did so without use of EML. Among these patients, 19 (3 in the SEST + EPLBD group, 6 in the EPLBD + SEST group, 4 in the EST group, and 6 in the EPLBD group) had residual gallbladder stones and therefore received laparoscopic cholecystectomy.

Six patients from the four groups (two in the SEST + EPLBD group, two in the EPLBD + SEST group, one in the EST group, and one in the EPLBD group) failed to achieve complete stone clearance with the allocated interventions due to the presence of large periampullary diverticulum or large gallstones. These patients finally converted to open surgery.

The overall stone clearance rate was quite similar among the four treatment groups (Table 2). There was also no significant difference in the rate of complete stone removal without the use of EML among these groups ($p = 0.316$). In the first session, however, the EPLBD group showed a considerably lower stone clearance rate (20 of 30 patients, 66.7%) when compared with the other three groups. But there was no statistically significant difference in the rate of stone clearance between either of the two combination treatment groups and the EST group or the EPLBD group. Additionally, all the treatment groups differed significantly with regard to the percentage of patients who received further sessions for complete clearance of the stones ($p = 0.004$); and the combination treatment groups required relatively fewer sessions than did the EPLBD group. Furthermore, only four patients in the EPLBD group underwent EML for stone removal.

Short-term complications

Within the first 4 weeks of follow-up, no postoperative death occurred in the four treatment groups of the current study. The short-term complications for each group are shown in Table 3. All complications were mild or moderate and self-limiting. There was no statistically significant difference in the incidence of overall com-

Table 1 Demographics of patients in the four treatment groups

Variables[a]	SEST + EPLBD (*N* = 33)	EPLBD + SEST (*N* = 32)	EST (*N* = 32)	EPLBD (*N* = 30)	*p* value
Age, years	64.8 ± 5.5	65.1 ± 4.8	65.6 ± 7.4	64.7 ± 6.5	0.937
Gender, M/F	15/18	14/18	18/14	13/17	0.700
BMI, kg/m^2	26.4 ± 4.1	25.9 ± 3.9	26.6 ± 4.3	26.2 ± 5.2	0.931
ASA physical status I/II/III	17/11/5	17/12/3	16/13/3	14/12/4	0.981
Number of bile duct stones, *n* (%)					0.728
< 3	13 (39.4)	16 (50.0)	14 (43.8)	11 (36.7)	
≥ 3	20 (60.6)	16 (50.0)	18 (56.2)	19 (63.3)	
Diameter of stones, *n* (%)					0.494
< 15 mm	19 (57.6)	21 (65.6)	24 (75.0)	21 (63.6)	
≥ 15 mm	14 (42.4)	11 (34.4)	8 (25.0)	9 (36.4)	
Caliber of CBD, mm	18.1 ± 4.2	17.2 ± 3.3	17.9 ± 5.5	18.4 ± 5.8	0.784
Periampullary diverticulum, *n* (%)	12 (36.4)	15 (46.9)	11 (34.4)	14 (46.7)	0.631
Serum amylase before ERPC, IU/L[b]	67.3 (19.2–271.4)	62.5 (18.5–171.2)	70.3 (21.0–201.0)	71.0 (24.8–184.0)	0.885

SEST small endoscopic sphincterotomy, *EPLBD* endoscopic papillary large-balloon dilation, *EST* endoscopic sphincterotomy, *M* male, *F* female, *BMI* body mass index, *ASA* American Society of Anesthesiologists, *CBD* common bile duct, *ERPC* endoscopic retrograde cholangiopancreatography, *IU* international unit

[a]Continuous variables with normal distribution are presented as mean ± SD unless otherwise noted

[b]Data are presented as median and range (minimum–maximum) due to skewed distribution

plications among all groups ($p = 0.572$). Nevertheless, it should be noticed that both the EST and the EPLBD group showed a relatively higher incidence of postoperative complications. Three patients in the EPLBD group experienced mild acute pancreatitis, and three in the EST group experienced biliary reflux. But no perforation was observed in any of the treatment groups.

Long-term complications

During the first postoperative year, no deaths occurred in the four treatment groups. The long-term complications observed are presented in Table 4. No long-term complications occurred in the SEST + EPLBD and EPLBD + SEST groups. However, three patients in the EST group and one patient in the EPLBD group experienced complications, including biliary infection, biliary reflux, and biliary stricture. Additionally, recurrence of cholelithiasis was observed in two cases in the EST group. These two patients consequently underwent surgical treatment and then recovered.

Discussion

In the current study, we performed a randomized, parallel-group clinical trial to investigate the effect of SEST combined with EPLBD in the treatment of patients with large bile duct stones. The results showed that the combination of SEST and EPLBD was similarly effective in complete stone removal as compared with conventional EST or EPLBD alone but might be comparatively safer than these two techniques. These findings demonstrate the safety and efficacy of this combination therapy for the treatment of large bile duct stones.

Although EST is widely used for removal of CBD stones, it has been reported to result in many early complications including bleeding, acute pancreatitis, and perforation [23]. Conventional EPBD appears to have advantages over EST in preventing postoperative complications and preserving papillary sphincter function [24, 25]. However, this technique is difficult in removing large and multiple stones with a diameter greater than 10 mm [25]. In 2003, Ersoz et al. [26] first reported the effectiveness of the combination of biliary sphincterotomy plus dilation with a large balloon for bile duct stones. Recently, accumulated evidence has suggested that SEST in conjunction with EPLBD, when compared with conventional EST, has the same effectiveness in the clearance of large bile duct stones and a lower risk of severe postoperative complications [19, 27, 28]. Furthermore, Kim et al. [18] showed that SEST plus EPLBD required less use of mechanical lithotripsy than did EST alone. Consistent with these published findings, our results indicate that the combination of SEST and EPLBD has effectiveness comparable to EST alone in complete endoscopic clearance of stones in one session. In addition, the frequency of EML tended to be lower for the combination group than it did for the group receiving EPLBD alone. However, some recent studies have produced results that contrast our findings. For example, Ito et al. [29] indicated that the success rate for SEST plus EPLBD is higher than for EST alone. The reason for this discrepancy has not yet been adequately explained. Multiple factors, such as study design, the extent of EST, and the size or shape of the stone or CBD may contribute to this discrepancy.

Two approaches for the combination of SEST plus EPLBD, that is EPLBD followed by SEST and SEST followed by EPLBD, were applied in the current study. As far as we know, few articles compare these two approaches regarding the success rate of complete stone clearance. Our results suggest that both approaches were quite similar in terms of the outcomes of stone removal. However, according to the authors' experience, the approach of SEST followed by EPLBD may offer advantages over the approach of EPLBD followed by SEST by improving time efficiency because in the latter approach, initial use of EPLBD sometimes causes peri-papillary edema which consequently obscures the operative field, potentially making the sequent SEST difficult to perform. Therefore, we thought the approach of SEST followed by EPLBD to

Table 2 Outcomes of stone removal in the four treatment groups

Variables	SEST + EPLBD (*N* = 33)	EPLBD + SEST (*N* = 32)	EST (*N* = 31)	EPLBD (*N* = 30)	*p* value for trend	*p* value for SEST + EPLBD versus EST	*p* value for EPLBD + SEST versus EST	*p* value for SEST + EPLBD versus EPLBD	*p* value for EPLBD + SEST versus EPLBD
Complete stone removal, *n* (%)	31 (93.9)	30 (93.8)	30 (96.8)	29 (96.7)	1.000	1.000	1.000	1.000	1.000
Complete stone removal without use of EML, *n* (%)	31 (93.9)	30 (93.8)	30 (96.8)	25 (83.3)	0.316	1.000	1.000	0.243	0.249
Complete stone removal in one session, *n* (%)	26 (78.8)	27 (84.4)	30 (96.8)	20 (66.7)	0.022	0.054	0.196	0.395	0.141
Complete stone removal in more than one session, *n* (%)	5 (15.2)	3 (9.4)	0	9 (30.0)	0.004	0.053	0.238	0.226	0.040
Two sessions, *n* (%)	5 (15.2)	3 (9.4)	0	4 (13.3)	0.493	0.053	0.238	1.000	0.703
Three sessions, *n* (%)	0	0	0	5 (16.7)	0.0017	–	–	0.020	0.020
Required EML for complete stone removal	0	0	0	4 (13.3)	0.003	–	–	0.046	0.049

SEST small endoscopic sphincterotomy, *EPLBD* endoscopic papillary large-balloon dilation, *EST* endoscopic sphincterotomy, *EML* endoscopic mechanical lithotripsy

Table 3 Comparison of short-term complications among the four treatment groups

Complications	SEST + EPLBD (*N* = 33)	EPLBD + SEST (*N* = 32)	EST (*N* = 31)	EPLBD (*N* = 30)	*p* value for trend	*p* value for SEST + EPLBD versus EST	*p* value for EPLBD + SEST versus EST	*p* value for SEST + EPLBD versus EPLBD	*p* value for EPLBD + SEST versus EPLBD
Overall complications, *n* (%)	2 (6.1)	3 (9.4)	5 (16.1)	4 (13.3)	0.572	0.250	0.474	0.412	0.703
Hyperamylasemia, *n* (%)	1 (3.0)	2 (6.3)	0	1 (3.3)	0.748	1.000	0.492	1.000	1.000
Biliary infection, *n* (%)	1 (3.0)	0	0	0	1.000	1.000	–	1.000	–
Mild acute pancreatitis, *n* (%)	0	1 (3.1)	0	3 (10.0)	0.059	–	1.000	0.102	0.347
Significant bleeding, *n* (%)	0	0	2 (6.5)	0	0.114	0.231	0.238	–	–
Biliary reflux, *n* (%)	0	0	3 (9.7)	0	0.026	0.108	0.113	–	–

SEST small endoscopic sphincterotomy, *EPLBD* endoscopic papillary large-balloon dilation, *EST* endoscopic sphincterotomy

Table 4 Comparison of long-term complications among the four treatment groups

Complications	SEST + EPLBD (*N* = 33)	EPLBD + SEST (*N* = 32)	EST (*N* = 31)	EPLBD (*N* = 30)	*p* value for trend	*p* value for SEST + EPLBD versus EST	*p* value for EPLBD + SEST versus EST	*p* value for SEST + EPLBD versus EPLBD	*p* value for EPLBD + SEST versus EPLBD
Total complications, *n* (%)	0	0	3 (9.7)	1 (3.3)	0.066	0.108	0.113	0.476	0.484
Biliary infection, *n* (%)	0	0	1 (3.2)	0	0.484	0.484	0.492	–	–
Recurrence of cholelithiasis, *n* (%)	0	0	2 (6.5)	0	0.114	0.231	0.238	–	–
Biliary reflux, *n* (%)	0	0	2 (6.5)	0	0.114	0.231	0.238	–	–
Biliary stricture, *n* (%)	0	0	0	1 (3.3)	0.238	–	–	0.476	0.484

SEST small endoscopic sphincterotomy, *EPLBD* endoscopic papillary large-balloon dilation, *EST* endoscopic sphincterotomy

be preferable for conducting the combination treatment of SEST plus EPLBD. However, we failed to collect data on operation time. Further study is required to compare time efficiency between these two combination approaches.

In previous literature, the incidence of short-term complications related to the combination of SEST plus EPLBD was reported to be 0–19% [18]. In line with this, the short-term complication rates were 6.1 and 9.4%,

respectively, for the two approaches of the combination which were relatively lower than those of EST and EPLBD alone. For EST, common postoperative complications include bleeding, perforation, acute pancreatitis, biliary reflux, and cholangitis [3, 20]. Bleeding and biliary reflux are most common and are mainly related to papillary damage and impairment of sphincter function when performing EST [30]. In the current study, five patients in the EST group experienced significant bleeding or biliary reflux postoperatively; while in the two combination groups, no patients experienced such complications. This can be attributed to the limited incision of the papilla used in SEST, which minimizes bleeding and impairment of sphincter function [31]. Furthermore, previous studies have pointed out that balloon dilation alone may result in blunt injury of the papilla and sphincter of Oddi, thus possibly causing transient inadequate drainage of the pancreatic duct and consequently lead to an acute transmural inflammatory response [6]. When combined with EPLBD, SEST was able to free access to the common channel, thereby allowing EPLBD to produce less injury to the papilla and sphincter. Therefore, it can be reasonably concluded that the combination of SEST and EPLBD may cause fewer pancreatic complications as compared with EPLBD alone. In the current study, the incidence rate of acute pancreatitis was fairly lower in patients treated with combination therapy than that in those treated with EPLBD alone, which provides rational evidence to support the aforementioned conclusion.

There are few reports comparing the incidence of long-term complications between SEST plus EPLBD and EST or EPLBD alone. During a 1-year follow-up period, long-term complications were only observed in the EST and EPLBD groups. It should be noted that two patients in the EST groups had recurrences of cholelithiasis. Previous studies have indicated that biliary reflux in the early post-operative period is a major cause for this complication [32, 33]. For the combination of SEST and EPLBD, the occurrence of biliary reflux was minimized through limiting the damage of papilla as well as the impairment of sphincter function, thus effectively preventing long-term complications in patients.

Several limitations in the current study should be addressed. First, the single-center clinical trial design may produce potential bias. Second, the small group size may decrease the validity of the study. Third, patients were not blinded to the type of surgery that was performed on them, which may affect patient expectations, thus introducing potential bias to the study results.

In conclusion, a combination of SEST and EPLBD appears to be a safe and effective treatment for patients with large bile duct stones. This combination might have potential safety advantages in comparison with EST or EPLBD alone. Therefore, it may be a good alternative to conventional EST or EPLBD for the treatment of large bile duct stones. However, these conclusions should be treated with caution considering the small patient population in each group.

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Compliance with ethical standards

Conflict of interest
All authors declare they have no conflict of interest regarding the current study.

The study protocol was approved by the institutional ethics committee and all participants provided informed written consent.

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Endoscopic Papillary Large Balloon Dilation With Versus Without Sphincterotomy for the Treatment of Large Common Bile-Duct Stone: a Multicenter, Prospective, Randomized, Controlled Trial

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Background/Aims: Endoscopic papillary large balloon dilation (EPLBD) without endoscopic sphincterotomy (EST) may be comparable with outcomes from EPLBD with EST for the treatment of large common bile-duct (CBD) stone. However, there is no prospective comparative data for both procedures yet. We aimed to compare prospectively safety and efficacy of EPLBD with preceding EST to those of EPLBD without EST for the treatment of large CBD stone. Subjects and methods: Two hundred patients with large CBD stone were prospectively enrolled in four tertiary referral centers from July, 2010 to August, 2014. The patients were randomly allocated into A group (EPLBD with EST) and B group (EPLBD without EST) and each group had 100 patients. The endoscopic procedure was performed according to the protocol (12 mm or more of balloon diameter; 60 seconds of balloon dilation time; single session of EPLBD; minor EST) in each group. Procedure-related adverse events, mortality, and technical success were evaluated in each method, and the clinical outcomes were compared between both groups. Results: Overall adverse event rate was 3% and 1% respectively in A and B groups (P=0.621). The difference of post-ERCP pancreatitis rate between both groups was not significant statistically (3% vs. 1%, P=0.621). Perforation and major bleeding did not occurred in both groups. There was no procedure-related mortality in both groups. Overall success rate was not different in A and B groups (88% vs. 92%, P=0.345) as well as initial success rate (78% vs. 77%, P=0.28). And the difference of mechanical lithotripsy rate in both groups was not significant (8% vs. 6%, P=0.579). Conclusion: The current data show that both EPLBD with preceding EST and EPLBD without EST are safe and effective for the treatment of large CBD stone. It is suggested that implementation of EST first before the procedure is not essential to ensure safety and efficacy of EPLBD.

1060

Can Endoscopic Papillary Balloon Dilation With Minor Sphincterotomy Be a Standard Treatment for the Conventional Bile Duct Stone?

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Background: Endoscopic sphincterotomy (ES) is considered as a standard treatment for bile duct stone (BDS), in which a large incision has a risk of bleeding/perforation, and a small incision can cause incarceration of basket. Endoscopic papillary balloon dilatation (EPBD) has a lower frequency of bleeding/perforation but a higher frequency of post-procedural pancreatitis than that of ES. EPBD definitely widens the distal end of bile duct and can remove a whole BDS with a size of up to EPBD balloon without the crush by mechanical lithotripsy (ML). We considered that EPBD with minor ES may contribute to simplify stone removal in not only large BDS but conventional BDS.Aim: To investigate the feasibility and safety of EPBD with minor ES for conventional BDS. Methods: Between March 2012 and November 2014, a total of 100 patients (55 males; median age 79.5 (30-93)) who had initial BDS with a size of up to 12 mm were randomly assigned to ES alone (n=50) or EPBD with minor ES (n=50). The primary outcome was the stone crush by ML. Secondary outcomes included stone clearance rate, procedural time, and early complications. The patients with intradiverticular papilla, bleeding tendency, past history of ES or EPBD, and altered surgical anatomy except Billroth I reconstruction were excluded. The administration of gabexate and non-steroidal anti-inflammatory drugs, and the pancreatic stent deployment were not performed in all patients. In the ES group, the incision was made in a standard manner with "Endocut" mode. In the ES+EPBD group, minor ES was followed by EPBD, and the EPBD balloon size was selected from 8, 10, 11, and 12 mm. The median of stone size, stone number, and bile duct size was 8 mm (range: 5-12), 2 (range: 1-35), and 12 mm (range: 7-22), respectively. Results: There were no differences in the demographic characteristics in both groups. The stone clearance rate was similar between both groups (100% in each), and it was accomplished at single session except 4 patients in the ES group. Stone crush by ML was performed in 13 patients (26%) in the ES group and in 3 patients (6%) in the ES+EPBD group (P=0.005). The median procedural time was 24.5 minutes (range: 9-94) in the ES group and 19 minutes (range: 5-53) in the ES+EPBD group (P=0.12). In early complications, hyperamylasemia was observed in 3 patients (6%) in the ES group and in 2 patients (4%) in the ES+EPBD group (P=0.65). Mild acute pancreatitis occurred in 1 patient (2%) in the ES+EPBD group (P=0.23). No bleeding, perforation, and incarceration of basket occurred in both groups. Conclusions: In the initial endoscopic treatment for conventional BDS, EPBD with minor ES can reduce stone crush and simplify stone removal without increasing early complications risk compared to ES alone.

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Efficacy of Radiofrequency Ablation (RFA) for the Management of Occluded Biliary Metal Stents

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Background and Aims: Insertion of a self-expanding metal stent is the therapy of choice for decompression of malignant biliary obstruction (MBO) in patients who are not good candidates for surgery. Stent occlusion due to tumor in-growth causes recurrent MBO and cholangitis. Traditional endoscopic management of an occluded metal stent consists of plastic stent placement within the metal stent. We have examined the possibility of using radiofrequency ablation therapy to achieve eradication of tissue ingrowth. The aim of this study was to compare stent patency rates in patients managed with plastic stent placement versus radiofrequency ablation therapy. Methods: All patients with MBO who underwent endoscopic therapy of metal stent obstruction were entered into this retrospective four year study. We used clinical records to determine if and when stent occlusion occurred. The RFA group consisted of patients who underwent RFA (10 watts for 90 seconds) using the Habib endoprobe (EMcision, London) applied to the tissue ingrowth within the metal stent during ERCP. A plastic stent was inserted into the metal stent after the RFA to promote biliary drainage if the stenosis was not eradicated completely. The control group consisted of patients who were treated only with insertion of a plastic stent into the metal stent. The demographic, clinical and follow-up data of all patients for the patency of biliary stents and survival were recorded. The end-points for interim analyses were: the time until a second ERCP for stent re-occlusion and stent patency rate at 90 days. Results: 21 patients with MBO (11 pancreatic, 7 bile duct, 1 gallbladder, and 2 metastatic carcinoma) underwent RFA of an occluded metal stent during the study period. 25 patients with MBO (15 pancreatic, 5 bile duct, and 5 metastatic carcinoma) were managed with plastic stent placement alone. Both groups were matched for age, gender and diagnosis. The procedures were technically successful in all, and immediate biliary drainage was restored in all patients. In the RFA group, the focal stenosis was eradicated completely in 13 and partially in 8 patients. A plastic stent was inserted into the metal stent after the RFA in these 8 patients. In the control group, only a plastic stent was placed across the stenosis. The mean follow-up time was 264 days (range 19-918) for RFA and 290 days (range 139-918) for the control group. The stent patency rate at 90 days was 62% (13/21) and 24% (6/25) in the RFA and control groups, respectively (p=0.02). The mean stent patency time until the re-occlusion was significantly longer in RFA group compared to controls (98.5 vs. 57.6 days, p=0.03). Conclusion: The application of RFA for occluded metal stents in MBO improved stent patency time and 90 days' stent patency rates compared to plastic stenting alone. RFA is an effective treatment of tissue ingrowth in MBO.

1062

Outcome of Referral to an Endoscopic Mucosal Resection Center As an Alternative to Surgery in Patients With Large and Flat Colon Tumors

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Introduction & Aims: Patients (pts) with large & flat lesions of the colon are at high risk for bleeding, perforation, & incomplete resection with traditional snare resection. Hence, these pts are referred to surgery. However, advances in endoscopic imaging as well endoscopic hemostasis & clip closure allowed us to perform endoscopic mucosal resection (EMR) of large & flat lesions to avoid surgery. The aim of this study was to describe their current management to provide insight into optimal management in pts referred to an EMR center. Methods: This retrospective/prospective observational study identified pts with large sessile or flat lesions referred to our EMR Center (2009-2014). Resection techniques, subsequent management & outcomes were recorded. The main outcome measures analysed were: presence of cancer at presentation, success of EMR, need for surgical treatment, complications, residual or recurrent polyp at 6 months, & total polyp burden. Results: 205 pts with presumed benign pathology were referred to our EMR Center (mean age: 64.08 years; range: 29 to 88 years; men: 100 & women: 105). Table 1 shows morphology of polyps. Outcome of patients referred to EMR: a. Cancer: 8 (3.8%) pts with optical diagnosis of cancer underwent biopsy confirmation & were referred to surgery without EMR (biopsies negative outside); b. EMR Failure: 40 (19.3%) pts could not undergo EMR (Difficult access: 16; Failure to lift the lesion due to scarring from prior resection: 13; Multiple & large polyps: 10; unable to identify the lesion: 1); c. EMR Successful: 159 (76.8%) pts underwent EMR successfully

management strategy. Results: Forty-five (8.2%) of 552 patients who underwent ERCP had indeterminate ERCP findings that required further evaluation with biliary IDUS. IDUS was technically successful in all cases. The mean age was 60.7 years (range: 33 - 92), with 62.2% male. ERCP showed apparently normal CBD in 22 (48.9%), dilated CBD of unclear etiology in 8 (17.8%) and a CBD stricture in 15 (33.3%) patients. Among the patients with either apparently normal CBD or dilated CBD of unclear etiology, an occult CBD stone (mean size 2.5mm; range: 1.1 - 6.6) was found in 27/30 (90%), with the remaining cases being normal. Among patients with strictures, Mirizzi syndrome was diagnosed in 7/15 (46.7%), cholangiocarcinoma in 4/15 (26.7%), malignant IPMN in 1/15 (6.7%) and benign fibrotic stricture in 2/15 (13.3%). One patient with biliary stricture was wrongly diagnosed as biliary hydatid disease based on a cystic appearance; subsequent surgery revealed hepatobiliary cystademona. Overall biliary IDUS had a positive clinical impact in 39/45 (86.7%). Conclusion: Biliary IDUS increases the diagnostic accuracy of ERCP. It is a very useful adjunctive test when ERCP findings are indeterminate.

S1341

Blind Laser Lithotripsy Using a Balloon Catheter Combined with Endoscopic Papillary Large Balloon Dilation for Difficult Bile Duct Stones

Hyun Jong Choi, Jong Ho Moon, Bong Min Ko, Hyun Cheol Koo, Hyung Ki Kim, Jong Kyu Park, Young Koog Cheon, Young Deok Cho, Joon Seong Lee, Moon Sung Lee, Chan Sup Shim

Background and Aims: Techniques of stone fragmentation are used in the small percentage of bile duct stones that are difficult or impossible to extract by conventional method including mechanical lithotripsy. Laser lithotripsy (LL) with FREDDY is very effective and safe for stone fragmentation. Direct visual control is required during LL because of radiolucent laser fiber. And endoscopic papillary dilation with large balloon after sphinterotomy is useful procedure to remove multiple, large stones. The aim of this study was to evaluate the feasibility and efficacy of balloon catheter for laser lithotripsy combined with endoscopic papillary large balloon dilation without cholangioscopic control in patients with difficult bile duct stones. Patients and Methods: FREDDY LL using a balloon catheter under fluoroscopy without peroral cholangioscopy was performed in twelve patients with difficult CBD stones in whom conventional endoscopic stone removal including mechanical lithotripsy had failed. A laser fiber was inserted through a double-lumen balloon catheter onto the stone surface. Stones were targeted under fluoroscopy and then the balloon was inflated. LL was performed under fluoroscopy until possible to capture of fragmented stone into the basket. Endoscopic removal of fragments was attempted within the same session after endoscopic papillary large balloon dilation. Results: Stone fragmentation and complete removal was performed successfully in 11 of 12 patients (91.6%). Additional session after first LL was required in 3 patients for complete stone removal. The average number of endoscopic treatment sessions was 1.3. Mechanical lithotripsy was applied in 3 patients (27.3%). Stone removal without endoscopic papillary large balloon dilation was possible in 2 of 11 patients. No significant procedure-related complication was occurred. Conclusions: FREDDY laser lithotripsy using balloon catheter combined with endoscopic papillary large balloon dilation seems to be safe and effective method for difficult CBD stones. This allows "blind" fragmentation of CBD stones under fluoroscopic control. We are expecting the results with a new generation of laser system with higher energy and new accessories for laser lithotripsy.

S1342

Is It a Coin Toss or Can We Predict Which Patients with An Abnormal Intraoperative Cholangiogram Will Have a Confirmed Stone At ERCP?

David S. Wolf, Dharmendra Verma, Frank J. Lukens

Objective: An abnormal intraoperative cholangiogram (IOC) is an indication for endoscopic retrograde cholangiopancreatography (ERCP) for the evaluation of suspected choledocholithiasis. This study evaluated ERCP findings of patients with abnormal IOCs and analyzed pre-operative clinical and radiological factors to predict choledocholithiasis on post-operative ERCP. Methods: Retrospective chart review of patients who underwent ERCP for an abnormal IOC in two tertiary care centers from September 2007 to November 2008. Univariate and multivariate analyses were performed to determine predictors of choledocholithiasis at post-cholecystectomy ERCP. Abnormal IOC was defined as: lack of contrast in the duodenum, small stone in common bile duct (CBD), large stone in CBD, multiple stones in CBD, dilated CBD and poorly visualized distal CBD. Pre-ERCP factors analyzed included: abnormal liver function tests, elevated pancreatic enzymes $>$ 3 times upper limit of normal, abnormal white blood cell count and abnormal imaging study with CBD diameter of $>$8mm. Results: 38 patients (32 females) with average age of 38.5 yrs (14-83 yrs) were referred for ERCP for an abnormal IOC. All procedures were successfully performed and greater than 90% of ERCPs were done within 48 hours post-cholecystectomy. Indications for cholecystectomy included acute cholecystitis (78.9%), acute suspected gallstone pancreatitis (28.9%), and cholelithiasis (13.2%). The IOC was interpreted by the surgeon in all 38 cases and by a radiologist in 31 cases. All 38 IOCs were interpreted as abnormal by the surgeon, whereas only 25/31 of these were confirmed abnormal by a radiologist using the same criteria. Overall, 19/38 (50%) of patients with positive IOCs interpreted by a surgeon, and 12/25 (48%) of patients with positive IOCs interpreted by a radiologist had confirmed choledocholithiasis at ERCP. On univariate analysis, interpretation of large stone on IOC by the surgeon was the only statistically significant factor able to predict the presence of a stone at ERCP in 9/12 ($p=0.033$). No additional significant factors were found on multivariate analysis. Conclusions: There is a poor correlation between abnormal IOCs and ERCP findings. Only half of patients with an abnormal IOC had confirmed choledocholithiasis on post-operative ERCP. Large stone on IOC was the only factor significantly associated with the presence of a stone at ERCP. Alternative, less invasive tests, such as endoscopic ultrasound or magnetic resonance imaging could be used to better select patients with abnormal IOCs who would benefit most from ERCP.

S1343

Endoscopic Sphincterotomy Plus Large-Balloon Dilation Versus Endoscopic Sphincterotomy for Removal of Large Common Bile Duct Stones

Gun Young Hong, Sang Wook Park, Kang Seok Seo, Hyeongcheol Moon

Background: Endoscopic sphincterotomy (EST) is a conventional procedure used for extraction of bile duct stone. Recently, endoscopic papillary large-balloon dilatation (EPLBD) was introduced to facilitate stone extraction. There are few reports that compares EST plus EPLBD versus EST only for removal of bile duct stones. Aims and Methods: Authors sought to determine the safety and efficacy of EST plus EPLBD in comparison with those of EST only for large common bile duct stones. Seventy patients with large($>$15mm in diameter) common bile duct stones who underwent EST plus EPLBD were compared to sixty five patients who underwent EST only. Papillary dilatation was performed with 15-mm or 20-mm balloon after EST. Stones were extracted by basket or retrieval balloon. Additional mechanical lithotripsy was done when stone removal was unsuccessful. Results: There was no significant difference between the two groups in baseline characteristics. Complete stone removal was successful in all patients of both groups. EST plus EPLBD group required significantly less frequent session of procedures and mechanical lithotripsy. Complications were similar between the two groups. Conclusion: EST plus EPLBD is safe and effective method for treatment of large common bile duct stones. This method reduces the procedure time, number of session and obviate the need for mechanical lithotripsy.

	EST + EPLBD (n=70)	EST (n=65)	p Value
Complete removal	70/70	65/65	NS
Mechanical lithotripsy (%)	13/70 (18.6%)	47/65 (72.3%)	$<$0.001
Mean number of session	1.77	2.73	0.001

Comparisons of the complications between EST plus EPLBD and EST only group

	EST + EPLBD (n=70)	EST (n=65)	p Value
Pancreatitis	4 (5.7%)	9 (13.8%)	NS
Hyperamylasemia	7 (10%)	13 (20.3%)	0.026
Bleeding	4 (5.7%)	10 (15.4%)	NS
Infection	0	0	NS
Perforation	0	0	NS

S1344

Evaluation of Computer and Mechanical ERCP Simulators By Endoscopists with Different ERCP Experience - An Update

Joseph W. Leung, Brian S. Lim, Robert E. Wilson, Felix W. Leung, Luk Yiu Wing, Michael Li

Background: We previously reported preliminary data of 7 GI trainees' evaluation of computer (CS) and mechanical (MS) ERCP simulators. Aim: To compare trainees' and trainers' evaluations after practice with MS and CS. Setting: Hands-on ERCP training workshops. Subjects: 15 GI trainees with varying ERCP experience and 3 trainers. Interventions: Participants perform scope insertion, selective bile duct cannulation, guide-wire negotiation of a bile duct stricture, biliary papillotomy and insertion of single biliary stent. Main outcome measurements: Evaluations of each simulator by participants based on modified published criteria (GIE 2003; 57: 886-90). Results: Overall practice with the MS resulted in significantly greater change in understanding [max=20] (4.29 ± 0.93 vs. 2.12 ± 0.80), confidence [max=20] (5.41 ± 1.01 vs. 2.53 ± 0.80) and credibility [max=50] (6.65 ± 1.78 vs. 0.18 ± 2.14) scores after the practice, respectively ($p< 0.05$). The scores were significantly higher for the MS in realism [max=80] (58.33 ± 2.18 vs. 42.28 ± 2.70, $p<0.05$) and usefulness as instructional tool/general applicability in ERCP training [max=60]

positive in 5 (FBx histology 4, ERCP FNA 1) but required additional ERCPs if SEMS were needed. Total yield of ERCP tissue sampling was 24/27 (89%). Definitive diagnosis of CCa was established in the 3 negative pts was by EUS, or long-term follow-up. Specificity was 100% in follow-up. Conclusion: ERCP tissue sampling using a forceps biopsy SMASH protocol produced definitive positive intra-procedural diagnosis in 16/21 (76%) patients. Comprehensive ERCP techniques increased positives to 24/27 (89%) overall. Efforts at new technology to improve diagnostic yield of tissue sampling are unlikely to improve upon these simple and inexpensive techniques during therapeutic ERCP.

T1489

Clinical Applications of the Spyglass Direct Visualization System: A Multicenter Experience

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Background: Single operator peroral cholangioscopy is commercially available with the Spyglass Direct Visualization System™ (Boston Scientific, Natick MA). The system consists of a fiberoptic probe introduced via a 4-way deflectable scope with separate irrigation and instrument channels. Biopsy forceps, SpyBite™, are used for tissue sampling under direct visualization. Aim: To report the clinical applications and technical performance of Spyglass cholangioscopy/pancreatoscopy at 3 tertiary referral centers. Methods: Records of patients undergoing Spyglass procedures were retrospectively reviewed. Clinical and technical data were entered into a database for analysis. Procedures were performed at 3 independent centers by 7 interventional endoscopists. Cases were performed for clinical indications outside of industry sponsored research protocols. Results: A total of 39 Spyglass procedures were performed on 35 patients. The most common indications were indeterminate biliary stricture (62%) and choledocholithiasis (21%). Other indications included pancreatic duct stones, evaluation of IPMN, suspected biliary mass, and surveillance for cholangiocarcinoma. The clinical diagnosis was altered by Spyglass in 24% of indeterminate biliary stricture cases, most commonly from suspected malignant stricture to benign stricture. One patient with biliary obstruction caused by a hepatic lesion suspicious for metastasis, was found to have a hepatic abscess that was treated endoscopically. Management of stones (8 biliary, 1 pancreatic) with laser or electrohydraulic lithotripsy was successful in all cases. Complete clearance in a single session was achieved in all but one case, in which a heavy stone burden necessitated additional sessions. Cholangioscopic visualization alone was adequate for diagnosis in only 7% of cases, while pancreatoscopic visualization alone was adequate in 2/3 cases. Biopsy was performed in 24 cases, and yielded adequate tissue for histologic evaluation in 88%. The endoscopists' impression was that the Spyglass procedure contributed meaningfully to patient management in 86% of cases. Procedure related complications occurred in 5 patients: 1) hemorrhage following sphincterotomy; 2) post-ERCP cholecystitis; 3) pancreatitis following pancreatoscopy; 4) post-procedure abdominal pain; and 5) congestive heart failure. Conclusions: The Spyglass™ system allows single-operator choledochoscopy and pancreatoscopy, high yield, endoscopically directed tissue sampling.and facilitates biliary and pancreatic lithotripsy. The nature and frequency of complications are within the spectrum of those reported with other interventional pancreaticobiliary procedures

T1490

Minor Endoscopic Sphincterotomy Plus Endoscopic Balloon Dilation Is An Effective and Safer Alternative for Endoscopic Sphincterotomy During ERCP in Patients with Peiampullary Diverticula and Bile Duct Stones

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Background/Aim: Periampullary diverticulum poses technical challenges and may lead to endoscopic sphincterotomy (EST) related complications during ERCP. Empirically minor EST plus endoscopic papillary balloon dilation (EPBD) could be a safe alternative by causing less thermal injury. However, little has been reported about its effectiveness and safety in patients with periampullary diverticula. Our study was designed to compare the effectiveness and safety of minor EST plus EPBD with those of EST alone in patients with periampullary diverticula and bile duct stones. Methods: All patients in two groups were prospectively enrolled in a large tertiary referral center from January 2006 to November 2007. Less than 1/3 of the regular EST incision length and 3 minute dilation using 8-mm-diameter balloons were applied in the minor EST plus EPBD group. Results: Eight-three (49 male, 34 female) patients underwent minor EST plus EPBD, and 72 patients (40 male, 32 female) underwent EST. There were no statistically significant differences between the two groups in gender ratio, number and size of diverticula, number and size of bile duct stones, and diameter of bile ducts prior to the interventions. Average age was however different in two groups (57.83 vs. 67.69). Most patients had multiple bile stones with the average number of stones in two groups being 2.43 vs. 2.67 and the average size of stones being 12.51 mm vs. 13.06 mm. Minor EST plus EPBD compared with EST alone resulted in similar outcomes in terms of overall successful stone removal (100% vs. 100%), stone clearance at first attempt (78% vs. 72%, $p = 0.379$), and the use of mechanical lithotripsy (ML) (12% vs. 21% $p = 0.138$). Complication rate in the EST plus EPBD group was significantly lower than the EST group (4% vs. 21%, $p < 0.05$). Pancreatitis occurred in 3 patients and 2 patients in two groups respectively. Twelve patients developed bleeding and 1 patient developed cholangitis in the EST group. No perforation or death occurred in either group. Logistic regression showed both age and method (EST or. EST plus EPBD) were insignificant in predicting stone clearance rate at first attempt and rate of ML usage. Age was not significant in predicting complication rates, while the use of EST plus EPBD was significantly associated with reduced risk of complication rate at 0.05 level (OR = 0.29, 95% CI = (0.1106, 0.7683)). Conclusion: Minor EST plus EPBD was found to be as effective as EST in bile duct stone removal for patients with periampullary diverticula. In addition we found minor EST plus EPBD has a better safety profile than traditional EST for these patients.

T1491

Is Therapeutic Endoscopic Retrograde Cholangiopancreatography Safe and Effective During Live Demonstrations?-A Large Multi-Center Study from China

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Background and Objective: Live demonstrations of endoscopic retrograde cholangiopancreatography (ERCP) have a high educational value and contribute significantly to endoscopy development and training. It has been suggested that the pressure for endoscopists to succeed during live demonstrations might lead to lower success rate and higher complication rate. We report a multi-center retrospective analysis to evaluate the success rate and complications of therapeutic ERCP among patients participated in live demonstrations in China. Patients and Methods All patients who underwent therapeutic ERCP during live demonstrations at gastrointestinal endoscopy conferences in China between January 2002 and December 2006 were included. The matched control for each patient was the patient admitted to the same ERCP unit with similar indications, which received ERCP by endoscopists with similar experience as those who performed live demonstrations. Clinical and endoscopic characteristics including age, gender, indication, therapeutic intervention, success rate, and complication were collected and compared with matched controls. Differences in ERCP outcomes between domestic and foreign experts were compared. Risk factors associated with complete failure and post-ERCP complications were analyzed. Results: Thirty-four conferences (386 patients) involving live ERCP demonstrations were held in 14 endoscopy centers. There were no significant differences in gender ratio, age, indication, and therapeutic intervention among live demonstration and controls. The therapy was less successful in live demonstrations than controls (94.0% vs. 97.4%, $p = 0.0207$). There was no statistically significant difference in overall complication rates among patients in live demonstrations and the controls (10.9% vs. 8.0%, $p = 0.1761$). ERCP performed by foreign endoscopists was as safe and successful as domestic ones. Multivariate analyses showed first-time demonstrators had more complete failures (OR 3.255, 95% CI: 2.3-8.4) and higher post-ERCP complications (OR 2.9, 95% CI: 1.3-6.3) as were demonstrations performed on the same day of arrival (OR 5.7, 95% CI: 1.5-21.8). Conclusion: The success rate of therapeutic ERCP performed during live demonstrations was lower than routine procedures, but the overall complication rate of ERCP was comparable to controls. Lack of prior performing experience during live demonstration accounted for a higher failure rate and increased complications.

T1492

Can MRCP Replace ERCP for the Diagnosis of Autoimmune Pancreatitis?

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Background and Aim: Autoimmune pancreatitis (AIP) is currently diagnosed based on a combination of clinical, laboratory, and imaging studies. Since AIP responds dramatically to steroid therapy, it is most important to differentiate AIP from pancreatic cancer to avoid unnecessary surgery. Irregular narrowing of the main pancreatic duct is a characteristic finding in AIP; it is useful for differentiating AIP from pancreatic cancer stenosis. In many pancreatobiliary diseases, magnetic resonance cholangiopancreatography (MRCP) is replacing diagnostic endoscopic retrograde cholangiopancreatography (ERCP). This study evaluated the usefulness of MRCP for the diagnosis of AIP and assessed whether MRCP could replace ERCP for diagnosing AIP. Methods: The MRCP and ERCP findings of 20 AIP patients (diffuse (n = 6); segmental in the head (n = 4), body (n = 3), and tail (n = 2); two skipped in the head and body or tail (n = 5)) were compared. Results: On ERCP, the length of the narrowed portion of the main pancreatic duct was longer than 3 cm in 18 patients, while it was 2 cm in length in 2 patients. Stenosis of the bile duct was detected in 14 patients, and all of them showed stenosis of the lower bile duct. Furthermore, 2 patients also had stenosis of the intrahepatic bile duct. After steroid therapy, both narrowing of the main pancreatic duct and stenosis of the bile duct improved markedly in all 18 patients. On MRCP of patients with diffuse-type AIP, the entire main pancreatic duct was non-visualized in 3 patients and incompletely visualized in 3 patients. On MRCP of patients with segmental-type AIP, the narrowed portion of the main pancreatic duct was not visualized, while the non-involved segments of the pancreatic duct were visualized. Although upstream dilatation of the proximal main pancreatic duct was detected in the 7 segmental-type AIP patients, the degree of dilatation was milder than that in pancreatic cancer patients. In patients with skipped-type AIP, only skipped narrowed lesions were not visualized on MRCP. Stenosis of the lower or intrahepatic bile duct was similar on MRCP and ERCP. After steroid therapy, the non-visualized main pancreatic duct became visualized on MRCP. Conclusions: MRCP cannot replace ERCP for the