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DIFFERENT TECHNIQUES FOR MANAGEMENT OF COMMON BILE DUCT STONES: A SINGLE CENTRE EXPERIENCE

BY

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Abstract

Local experience on the combined technique of endoscopic sphincterotomy followed by endoscopic balloon dilation is scarce. This study clarified whether this combined technique will offer any advantages, with respect to therapeutic outcome and complications rate, as compared with endoscopic sphincterotomy (ES) and endoscopic balloon dilatation (EBD) alone for the extraction of large and/or multiple common bile duct stones. For a total of 76 patients, extraction of large and/or multiple common bile duct (CBD) stones during endoscopic retrograde cholangiopancreatography was performed. According to the used technique, they were categorized into 3 groups; Endoscopic sphincterotomy, endoscopic balloon dilatation or combined technique. The success rate of complete stone removal and the incidence of procedure-related complications were compared among the three groups. Success rate after one session was recorded to be comparable among the three groups. Relative Risk Ratio assessment of success rate after single session among the three groups showed no statistically significant difference. Regarding bleeding, only 3 (10%) cases were recorded in the ES group with no cases in the other 2 groups. No significant difference was noted among the three groups regarding other complication. The combined technique of ES followed by EBD is an effective and safe technique enables extraction of multiple and/or relatively large stones. It could be a reasonable alternative option when standard techniques are inadequate to remove bile duct stones.

Key words: Common bile duct, Gall stone, Endoscopic balloon dilation, Endoscopic sphincterotomy.

Introduction

The prevalence of cholelithiasis is 10%-15% in adult population. Calculi are detectable in the biliary tract in 17% of patients with symptomatic cholelithiasis (Rhodes *et al*, 1998). The advantages of endoscopic retrograde cholangiopancreatography (ERCP) over open surgery make it the predominant method of treating the choledocholithiasis (Binmoelle and Schafer, 2001). Endoscopic sphincterotomy (ES) has gained wide acceptance in the treatment of common bile duct stones since described in 1974 (Classen and Demling, 1974). Endoscopic sphincterotomy was widely considered the approach of choice for most cases of bile duct stones. However, the complication rate after an ES is not negligible. Complications in ES include hemorrhage, pancreatitis, cholangitis, and perforation of the duodenal wall (Freeman *et al*, 1996). The potential advantage of EBD over ES was the avoidance of short-term complications of bleeding and perforation (Weiberg and Gavin, 2004). Also, EPBD may preserve sphincter of Oddi function (Kawabe *et al*, 2003). However, EPBD appeared to be associated with an increased risk of pancreatitis (Attam and Freeman, 2009). The final success rates for ES and EBD are comparable; Randomized trials suggest that EBD is at least as effective as ES in patients with small to moderate-sized bile duct stones (Vlavianos *et al*, 2003). Extraction of common bile duct stones at ERCP can be technically challenging when the size of the stone exceeds that of an ES (Maydeo and Bhandari, 2007). Concerns still exist about the size and number of stones in ES, especially difficult to remove large and multiple stones. Endoscopic papillary dilation combined with small ES addresses these concerns and is indeed necessary for complete clearance of the bile duct (Minami *et al*, 2007).

This combined technique involves ES followed by large EBD, would theoretically combine advantages of sphincterotomy and balloon dilation by increasing efficacy at stone extraction while minimizing complications of both EBS and EBD (Attam and Freeman, 2009).

The aim of this study was to clarify whether combined technique of ES followed by EBD offered any advantages, both with respect to therapeutic outcome and complications rate, as compared to ES and EBD for the management of large and/or multiple common bile duct (CBD) stones.

Patients and Methods

Design and Duration: This is a prospective study carried out from January to December 2013.

A total of 76 patients with large and/or multiple bile duct stones were included in this study. All of them were admitted to the Tropical Medicine or Internal Medicine Departments, Ain Shams University Hospitals. After signing a written consent, the enrolled patients were randomly subdivided into 3 groups according to the used technique: G1: 30 patients underwent endoscopic sphincterotomy. G2: 30 patients underwent endoscopic balloon dilatation. G3: 16 patients underwent small endoscopic sphincterotomy followed by endoscopic balloon dilatation.

Inclusion criteria: Patients with large and/or multiple common bile duct stones included in this study were candidates for ERCP unless there is a cause for exclusion. Exclusion criteria: Patients refused to undergo the procedure or to sign the consent. We excluded patients with acute pancreatitis, previous biliary surgery, bile duct stricture or intra-hepatic stones and pancreatic or biliary malignancy. Also patients with severe hemorrhagic diathesis or severe co-morbid conditions were excluded.

Ethical Considerations: This study was performed in accordance with the ethical standards. Signed consent was obtained from all patients before enrollment in the study. Right to refuse participation was emphasized.

Patients were fasting for at least six hours. All procedures were performed by standard video-duodenoscopes (Olympus TJF240, Pentax ED-344OT and Pentax ED-363OT). ES was done by using a wire-guided sphincterotome in a conventional manner with the use of a variety of papillotomes (Microvasive, Boston and Wilson-Cook). ES is performed with the electrosurgical "blend" current. Dilatation of the duodenal papilla was done by using a papillary balloon dilator. A guidewire was placed in the bile duct, after removal of the ERCP cannula, a balloon catheter was advanced over the guidewire and located at the papilla. The balloon was expanded gradually over 1 minute and kept at pressure for 15 seconds then collapsed and removed. Stones were removed with a Dormia basket and/or an extraction balloon catheter. Mechanical lithotripsy was performed as necessary.

Two different balloon diameters were used, 10 mm and 15 mm. Patients in the group of combined technique underwent a small sphincterotomy followed by endoscopic balloon dilatation as described above.

Clinical, laboratory and radiological evaluation: 1- Full history taking and thorough clinical examination. 2- Laboratory Investigations included complete blood picture (CBC), Prothrombin time (PT) and INR, Liver profile (AST, ALT, total bilirubin, direct bilirubin, gamma-glutamyl transferase and serum albumin), Renal functions (serum creatinine and blood urea nitrogen) and baseline serum amylase. 3 Radiological investigations included abdominal ultrasound and abdominal computerized scan if needed.

The patients were followed at the outpatient clinic for one month after the procedure to record any complication occurring within this period. Complications were defined and graded according to the 1991 consensus guidelines (Cotton *et al*, 1991).

Statistical analysis: The SPSS statistical software package (V. 17.0, Echo soft Corp.,

USA, 2008) was used for data analysis. Data were expressed as Mean±SD for quantitative measures and both number and percentage for categorized data. The following tests were done: 1- Comparison between 2 independent mean groups for parametric data using the Student t test. 2- Comparison between two independent groups for non-parametric data using Wilcoxon Rank Sum test. 3- Chi-square test to study the association between each 2 variables or comparison between 2 independent groups as regards the categorized data. 4- Calculated Relative Risk Assessments (Relative Risk Ratio or RRR) that measure how many times the risk was present among diseased individuals as that among non-diseased ones, calculated as absolute figures and as a standard error of estimate (95P).

Results

A total of 76 patients with large and/or multiple bile duct stones were 39 males and 37 females, their ages ranged between 20-80 years without significant difference regarding ages and sex among the three groups. In all patients, the main presenting complaint was jaundice. The clinical findings of the included patients were listed (Tab. 1). No ascites was detected in our patients. Laboratory investigations showed no significant difference among the three groups regarding the hemoglobin concentration, white cell count, platelets count and PT. Total serum bilirubin was elevated in the 3 groups with no significant difference among them, the same was noted regarding levels of ALT and AST (Tab. 2). Abdominal sonogarphic examination revealed dilated CBD in most of the included patients (72/76; 94.7%). The largest stone diameter was exceeding 10mm in (31/76; 40.8%) with no significant difference among the three groups. The mean stone size was 10.8 and 9.7 mm in ES and EBD groups respectively, while it was 12.44 mm in the group of combined technique. Multiple stones, more than 3, were detected in totally 31 out of 76 patients (40.8%) but with no significant difference among the three groups.

Success rate, as indicated by CBD clearance, after one session was recorded to be comparable among the three groups with no statistically significant difference. Mechanical lithotripsy was used in ES and EBD groups for only one case in each. The diameter of used balloon for dilatation was mainly 15mm, in 73.3% and 81.2% of EBD and combined groups respectively. The length of sphincterotomy in ES group was mainly medium followed by large sphincterotomy, while small sphincterotomy was performed for all cases in the combined group (Tab. 3). Relative Risk Ratio (RRR) assessment of success rate after single session among the three groups showed no statistically significant difference (Tab. 4). Post procedure complications were recorded. Regarding bleeding, only 2 cases of mild bleeding and one case of severe bleeding were recorded in the ES group with no cases in the other 2 groups. No significant difference was noted among the three groups regarding other complications (Tab. 5).

Table 1: Demographic and clinical characteristics of the studied patients in each group

Characteristic	Sphincterotomy ES (n=30)	Balloon EBD (n=30)	Combined (n=16)	P value
Age in years.	52.63±16.86	50.53±14.64	5±14.79	[a]p 0.64* [b] p 0.85† [c] p 0.46‡
Males Females	14 (46.7%) 16 (53.3%)	18 (60%) 12 (40%)	7 (43.8%) 9 (56.3%)	[a] p 0.30 [b] p 0.29 [c] p 0.85
Jaundice (clinically)	23 (76.6%)	20 (66.7%)	11 (68.8%)	[a] p 0.02 [b] p 0.88 [c]p 0.56
Right hypochondrial tenderness	9 (30%)	11 (36.7%)	7 (43.8%)	[a] p 0.58 [b] p 0.63 [c] p 0.35
Hepatomegaly	6 (20%)	8 (26.7%)	0	[a] p 0.54 [b] p 0.02 [c] p 0.05
Splenomegaly	3 (10%)	2 (6.7%)	0	[a] p 0.54 [b] p 0.64 [c] p 0.19

*[a] p = P value for balloon dilatation versus sphincterotomy, †[b] p = P value for balloon dilatation versus combined, ‡ [c] p = P value for sphincterotomy versus combined.

Table 2: Laboratory and U/S data among groups prior to procedure

Characteristic	Sphincterotomy	Balloon	Combined	P value
ALT (Mean, IU/l)*	128±127	134±126	126±137	[a] p 0.7‡ [b] p 0.5§ [c] p 0.7‖
AST (Mean, IU/l)†	108±139	111±135	123±142	[a] p 0.8 [b] p 0.6 [c] p 0.4
Total bilirubin (Mean, mg/dl)	6.3±5.7	6.6±5.5	6.7±4.9	[a] p 0.7 [b] p 0.6 [c] p 0.5
Gall bladder stones	14 (46.7%)	21 (70%)	7 (43.8%)	[a] p 0.06 [b] p 0.12 [c] p 0.38
CBD diameter: ≤8mm CBD diameter: >8mm	2 (6.7%) 28 (93.3%)	2 (6.7%) 28 (93.3%)	0 16 (100%)	[a] p 1 [b] p 0.29 [c] p 0.29
Largest stone diameter: (Mean) ≤10mm >10mm	 20 (66.7%) 10 (33.3 %)	 16 (53.3%) 14 (46.7%)	 9 (56.3%) 7 (43.8%)	[a] p 0.29 [b] p 0.48 [c] p 0.85
Stone number: ≤3 stones Stone number: >3 stones	21 (70%) 9 (30%)	15 (50%) 15 (50%)	9 (56.2%) 7 (43.8%)	[a] p 0.83 [b] p 0.68 [c] p 0.35

*ALT (Normal up to 41 IU/l), †AST (Normal up to 36 IU/l), ‡[a] p= P value for balloon versus sphincterotomy, §[b] p= P value for balloon versus combined, ‖[c] p= P value for sphincterotomy versus combined.

Table 3: Success rate among three groups

Variants	ES (n=30) No	ES (n=30) %	EBD (n=30) No	EBD (n=30) %	Combined (n=16) No	Combined (n=16) %	P value
Removal after one session	22	73.3	22	73.3	13	81.3	[a] p 0.27* [b] p 0.29 † [c] p 0.69‡
Use of lithotripsy	1	3.3	1	3.3	0		[a] p 0.10 [b] p 0.64 [c] p 0.29
Balloon diameter: 10mm 15mm			 8 22	 26.7 73.3	 3 13	 18.7 81.3	 [b] p 0.54
Length of sphincterotomy: Small Medium Large	 3 16 11	 10 53.3 36.7			16	100	[c] p.000 Sig.§

*[a] p = P value for balloon versus sphincterotomy, †[b] p = P value for balloon versus combined, ‡[c] p = P value for sphincterotomy versus combined, §Sig.: significant

Table 4: Relative Risk Ratio regarding success rate after one session among groups

Variable	O.R	95% CI	Significance
EBD vs. Es	1.000	0.318 -3.140	NS
Combined vs. EBD	1.576	0.354 – 7.017	NS
Combined vs. ES	1.576	0.354 – 7.017	NS

Table 5: Reported complications after procedure among groups

Variable	ES (n=30) No	ES (n=30) %	EBD (n=30) No	EBD (n=30) %	Combined (n=16) No	Combined (n=16) %	P value
Bleeding No Mild Moderate Severe	27 2 0 1	90 6.7 3.3	30 0 0 0	100	16 0 0 0	100	[a] p 0.20‡ [b] p 0.00§ [c] p 0.00‖
Pancreatitis No Mild Moderate Severe	 25 3 1 1	 83.3 10 3.3 3.3	 25 3 2 0	 83.3 10 6.6	 12 2 1 1	 75 12.5 6.3 6.3	[a] p 0.72 [b] p 0.56 [c] p 0.90
Abdominal pain	14	46.7	14	46.7	6	37.5	[a] p 0.59 [b] p 0.55 [c] p 0.59
Cholangitis	3	10	2	6.7	0		[a] p 0.64 [b] p 0.29 [c] p 0.19
Cholecystitis	0		0		0		
Septicemia	2	6.7	0		0		[a] p 0.15 [c] p 0.29
Contrast nephropathy	2	6.7	0		0		[a] p 0.15 [c] p 0.29
Perforation	0		0		0		
Haematemesis	0		0		0		
Melena	1	3.3	0		0		[a] p 0.31 [b] p 0.00 [c] p 0.46
ICU Admission	2	6.7	0		1	6.3	[a] p 0.15 [b] p 0.16 [c] p 0.95
Asymptomatic hyperamylasemia (>375 mg %)	3	10	7	23.3	3	18.8	[a] p 0.16 [b] p 0.72 [c] p 0.40

*P>0.05= NS,†P<0.05=significant, ‡[a] p = P value for balloon versus sphincterotomy, §[b] p = P value for balloon versus combined, ‖[c] p = P value for sphincterotomy versus combined.

Discussion

Endoscopic sphincterotomy (ES) was the standard treatment of choledocholithiasis, but not exempt from risks such as bleeding, perforation and pancreatitis in an early phase (Miller *et al,* 1988; Sherman *et al,* 1991). In addition to complications derived from the loss of function of the sphincter of Oddi in a late phase, early complications incidence after sphincterotomy was 6%-10%, with a mortality of 1% (Mugica *et al,* 2007).

It was hypothesized that the dilation of the papilla could become the treatment of choice in younger individuals as it transitorily increases the diameter of the papillary orifice, allowing the extraction of calculi while preserving its architecture and function (Mugica *et al,* 2007).

In the present study, the success rate after single session was similar for both ES and EBD groups (73.3%). Regarding the complications, 3 patients (2 with mild bleeding and 1 with severe bleeding) in ES group compared to none in EBD group suffered from bleeding. While pancreatitis was recorded in 5 patients (16.7%) in each group (P=0.72).

Accordingly, both techniques are comparable but EBD may be preferable and safer in patients with coagulopathy to avoid bleeding complication of ES. Similarly, the fully published randomized controlled trials (RCT) have shown similar success and short term complication rates between EBD and ES (Bergman *et al,* 1997; Cho *et al,* 1999). Also Lin *et al*. (2004) reported complete stone removal in one session in 47 patients (88%) among ES group and 41 patients (81%) among EBD group (P>0.05). They concluded that the various bile duct clearance rates may be due to the dilating effect of the balloon catheter and the size of stones as they used 8-12 mm balloons and excluded patients with stones larger than 2 cm.

In contrary to the present study, Arnold *et al*. (2001) reported higher outcome among ES group which was significantly different, being 100% (30 patients) compared to 53% (16 patients out of 30) among EBD group. They explained this difference by the fact that larger stones are more difficult to remove using balloon dilatation because the biliary opening is enlarged to a greater degree with endoscopic sphincterotomy and their inclusion criteria included stones up to 2 cm. Also another factor contributing to this outcome is none usage of mechanical lithotripsy in this study.

In agreement with the present data, the results of the meta-analysis by Mugica e*t al*. (2007) showed no hemorrhage after papillary dilation, thus favoring this procedure in patients with a coagulopathy and in those who require re-initiation of anticoagulation within a period of 72 hours. Balloon dilation is highly effective, with extraction of the calculi and complete clearance of the biliary tract achieved in 80%-100% of cases, comparable to the success rate after sphincterotomy (96%). They concluded that balloon dilation of the papilla is highly effective, the complication rate is comparable to that of sphincterotomy, and the clinical importance of the complications is low.

According to modified Cotton's criteria, the incidence of postoperative pancreatitis was significantly higher in the EBD group (16.7%) than in the ES group (6.7%). Bleeding was encountered in one patient (1.1%) in the ES group, but in none in the EBD group. No fatal complication occurred in either the EBD or the ES group. They conclude, although EBD appears to be comparable to ES for removal of small common bile duct stones, mild postoperative pancreatitis is more likely to occur with EBD than with ES (Watanabe ***et al,*** 2007).

Fujita *et al.* (2003) in more than 100 patients using small-diameter balloon dilation (6-10 mm) without ES reported pancreatitis rates from 5% to 15%.

It is worthy to mention that rates of pancreatitis after ERCP and sphincterotomy range from less than 1% to 40%, but rates of

5% or more are typical (Rabenstein *et al,* 2000). This variety in the incidence of post-ERCP pancreatitis mught be attributed to the definition of this complication that remains a matter of debate.

On other hand, Mac-Mathuna *et al.* (1995) reported a 5% incidence of post procedural pancreatitis patients underwent EBD with a rate very similar to the pancreatitis risk after ES. Lin *et al.* (2004) reported that the avoidance of repeated cannulation and an early change to ES or another treatment modality in patients with difficulties to deep cannulation may be the key in preventing post-procedural pancreatitis after EBD. In the present authors' opinion, this wide diverse adverse outcome might be due to presence of more than one risk factor for procedure-related pancreatitis.

As an explanation for this increased incidence of pancreatitis in EBD, it was reported that during dilatation, trauma is applied circumferentially to the sphincter and, therefore, partially in the direction of the pancreatic duct, causing transmural inflammation and intramucosal hemorrhage of the sphincter. Furthermore, EBD was identified as one of the independent risk factors of ERCP pancreatitis in a large prospective multicenter study, including one death related to pancreatitis after EBD (without ES) for stone removal (Freeman *et al,* 2001).

To improve the power of detecting pancreatic irritation, we therefore also compared the rate of asymptomatic hyperamylasemia between the two groups, which reflects to some extent irritation of the pancreas during ERCP. Our study showed a non significant higher rate of hyperamylasemia among EBD group, 23.3% of patients compared to 10% of patients in the ES group ($P>0.05$).

The present results agreed with Bergman *et al*. (2001) who reported that the use of EBD is significantly associated with asymptomatic hyperamylasemia which was evident in 23% of patients in EBD group versus 8% of patients in ES group. Nevertheless, the increased rate of asymptomatic hyperamylasemia in the EBD group may be considered as an indication that EBD is associated with more pancreatic irritation than ES. In addition, mechanical lithotripsy (ML) makes the procedure more laborious, and its manipulation can increase the incidence of pancreatitis (Yasuda *et al,* 1997). In the present study patients, ML was used in 1 (3.3%) patient in each of ES and EBD groups.

The dilation method has some limitations in regard to the size and number of stones. Compared with ES, stone extraction is more difficult as the papillary orifice is narrower after EBD than after ES, so when priority is given to easy and successful stone removal, adequate dilation is required (Takeshi *et al*, 2008).

A technical difficulty may be encountered to extract large and multiple stones from the bile duct by 10 mm balloon dilation. In a new technique, in addition to small ES, large balloon dilation (≥12 mm) was applied to facilitate extraction of large and multiple stones without lithotripsy. Ersoz *et al*. (2001) reported the use of ES followed by large-diameter (12-20 mm) EBD as an alternative to manage ''difficult'' bile duct stones. The authors reported 83% success rate in the first session with a rate of ML use of 7% in 58 patients. The overall complication rate was 15%, including a 3% pancreatitis rate.

The reported series of ES with large diameter EBD (≥12mm) for removal of bile duct stones indicated that; success rate after one session was ranged between 83-100% (Espinel *et al,* 2007; Attasaranya *et al,* 2008). The rate of pancreatitis was 0-6.0%. Cho *et al.* (2007) reported maximum rate (6%) of pancreatitis among patients. The ES+EPLBD therapy may decrease complications associated with the extraction of large and multiple stones (Attasaranya *et al,* 2008; Yang *et al,* 2013).

In the present study, 16 patients underwent small ES followed by EBD for extraction of their stones (mean size of 12.44 mm, range 6-30 mm, showed successful clearance in 13

patients (81.3%); without neither needed lithotripsy nor developed bleeding. However, pancreatitis was reported in 4 patients (25%) without cholangitis.

On the other hand, Minami *et al*. (2007) by using combined therapy reported one patient developed pancreatitis (1%). A small ES frees access to the common channel, and concluded that less injury to the pancreatic duct was produced in the sphincter of Oddi by large balloon dilation when small ES was combined during the procedure. This may cause fewer pancreatic complications compared to ES or balloon dilation alone.

In the present study, pancreatitis was diagnosed in 5 patients in each of ES and EBD groups (16.7%), compared to 4 patients (25%) in the combined technique one without significant difference among all groups. This might be attributed to the use of large balloon diameter (15 mm) in 73.3% and 81.3% pancreatitis in EBD and combined groups respectively. Also, asymptomatic hyperamylasemia was detected in 18.8% in combined group compared to 23.3% in EBD group, indicated less pancreatic irritation in the combined group than EBD group. Moreover, none showed bleeding either in EBD or combined group. Therefore, EST plus EBD should be considered in selected patients with severe coagulopathy and large bile duct stones.

The present study showed that using EBD (10-15 mm) obviated the need for ML for complete stone clearance and in the combined group ML was not needed. This agreed with Teoh *et al*. (2013).

Conclusion

The combined technique of ES followed by EBD is an effective and safe technique enables extraction of multiple and/or relatively large stones (≥10 mm) without much increase in the complication rate. In addition, it can reduce the need for mechanical lithotripsy or large sphincterotomy. It could be a reasonable alternative option when standard techniques are inadequate to remove bile duct stones (Neither funding nor competing interest).

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