



Comparative study between endoscopic papillary balloon dilation and endoscopic sphincterotomy for enlargement of papillary opening during endoscopic removal of common bile duct stones

Dr. Gamal Muammad Soliman¹, Dr. Ibrahim Sabry Bakr², Dr. Ahmad Alwasif³

¹ MD, Department of Tropical Medicine, Al-Azhar University, Egypt

² MD, Department of General Surgery, Al-Azhar University, Egypt

³ MD, Department of Internal Medicine, Egypt

Abstract

Background: Traditionally, endoscopic sphincterotomy (EST) has been accepted as a part of the standard therapy for common bile duct (CBD) stone extraction. However, this procedure is associated with serious complications such as hemorrhage, pancreatitis, perforation, and permanent functional loss of the sphincter of Oddi that predispose to recurrent cholangitis.

Endoscopic papillary balloon dilation (EPBD) of the biliary sphincter was introduced as an alternative to EST, especially for patients with small or moderate CBD stones. By using the wire-guided method, EPBD could be easily performed. EPBD possesses the advantages of preserving papillary sphincter function and reducing the chance of hemorrhage and perforation. On the other hand it is associated with a high risk of pancreatitis.

Combined EPLBD after limited EST was introduced for the removal of large (≥ 10 mm) or multiple bile duct stones. This method increased the efficacy of stone extraction and minimized complications compared to both standard EST and EPBD.

The present study aimed to compare the success and complications rates between endoscopic papillary balloon dilation and endoscopic sphincterotomy for widening of the papillary opening during endoscopic removal of common bile duct stones.

Methods: A case control study was conducted on one hundred and forty eight patients who presented with calculous obstructive jaundice eligible to undergo therapeutic ERCP procedure. Patients were divided into two groups, Group I: eighty six patients who underwent EST combined with balloon catheters and/or baskets, and Group II; sixty two patients who underwent EPLBD technique combined with balloon catheters and/or baskets for stone extraction.

Results: Complete CBD stones clearance among the patients of group I; EST was effective in (96%) of patients with the stone sized < 1 cm, while stone clearance occurred in (56%) in patient with stone size > 1 cm, (overall clearance rate=79%). Overall adverse effects of patients of group I was (18.5%)

Whereas complete extraction CBD stones among the patients of group II; EPLBD was effective for clearance of (92.5%) of CBD stones in patients with the stone sized < 1 cm and in (83%) of patients with stone size > 1 cm, (overall clearance rate=87%). Overall adverse effects of patients of group II was (29%).

Conclusion: Endoscopic papillary large balloon dilation is an adjunctive safe tool to endoscopic sphincterotomy for removing large or difficult CBD stones.

Keywords: common bile duct (CBD) stones, ERCP, endoscopic papillary large balloon dilation (EPLBD) and endoscopic sphincterotomy (EST)

Introduction

During endoscopic retrograde cholangiopancreatography (ERCP), the removal of common bile duct stones involves the destruction or dilatation of the bile duct orifice. Endoscopic sphincterotomy (EST) has been the standard method of management for removal of stones from the common bile duct (CBD) since it was described in 1974 [1]. However, when faced with more challenging situations, for example, in patients with large or multiple stones and tapered or tortuous distal common duct, additional techniques such as mechanical lithotripsy may be utilized [15, 17]. Furthermore, EST and stone removal can result in adverse events, including bleeding, pancreatitis, perforation, and cholangitis [18, 20].

As an alternative method to EST, endoscopic papillary balloon

dilation (EPBD) was described for the management of CBD stones. Compared to EST, EPBD has been reported to have a lower risk of bleeding but an increased risk of post-ERCP pancreatitis (PEP) [22]. Additionally, removal of large stones may be challenging when using EPBD alone. Thus, in 2003, Ersoz *et al.* [4] modified the technique of EPBD by introducing EST prior to large balloon dilatation for the removal of large bile duct stones, which has now been described as endoscopic sphincterotomy with large balloon dilation (EPLBD). Since then, studies comparing the efficacy and safety of EPLBD with EST have reported mixed outcomes. A previous meta-analysis conducted by Feng *et al.* comparing EPLBD with ES showed EPLBD to have fewer overall adverse events [23]. However, the meta-analysis included pooling of

nonrandomized and retrospective studies, which may have induced bias. Furthermore, additional studies have now been reported in the literature.

Aim of work

This study was conducted to compare the success and complications rates between endoscopic papillary balloon dilation and endoscopic sphincterotomy for dilatation of the papillary opening during endoscopic removal of common bile duct stones.

Patients and Methods

This prospective case control study was conducted between April 2013 and December 2015 at the gastrointestinal endoscopy unit, Alhussien Hospital, Cairo, Egypt. One hundred and forty patients with confirmed calculi obstructive jaundice, subjective to therapeutic ERCP procedures were recruited. They were assigned to either EST or EPLBD according to the availability of the accessories. All procedures were done by a one of two experienced operator; G.M Soliman, and I.S.bakr who each have done > 500 ERCP procedures with a yearly rate of > 50 procedures. Patients were separated into two groups;

Group 1: Included eighty six patients who underwent EST combined with balloon catheters and/or baskets, which is considered as conventional endoscopic technique for stone extraction.

Group 2: Included sixty two patients who underwent EPLBD technique combined with balloon catheters and/or baskets for stone extraction.

Each patients from the two groups were subjected to the following: careful history taking, general and abdominal examination, laboratory investigation including; complete biochemical panel with liver enzymes and pancreatic enzymes, serum calcium PT, PTT, INR. Abdominal ultrasonographic examination, emphasizing on the presence of calculi or removed gall bladder, the diameter of CBD, visible stones in CBD and presence of intrahepatic bile duct dilatation. Computerized tomography "CT" scan abdomen with contrast and or magnetic resonance cholangiopancreatography (MRCP) were undertaken before invasive intervention in certain group of patients whenever necessary to exclude other pathologies.

Exclusion Criteria

Patients with ampulloma, suspected cholangiocarcinoma or pancreatic cancer, acute or chronic pancreatitis and cholangitis were excluded from this study.

ERCP

The duodenum was intubated with a side-viewing endoscope (Olympus OR Pentax Optical) under either general anesthesia or deep sedation with intravenous midazolam and Propofol. The patients were placed in the left semi prone position in almost all cases. During the ERCP, in sedated patients the arterial oxygen saturation, pulse rate and blood pressure were continuously monitored. Oxygen supplementation through nasal cannula or intra-tracheal intubation was used for all

patients.

Endoscopic Sphincterotomy

Sphincterotomy guide wire was inserted through the lumen of the sphincterotome once deep cannulation is confirmed. The incision was made in a stepwise manner in the 11–1 o'clock direction along the longitudinal fold. The electrocautery unit was set to blended mode with a high cutting current and a low coagulation current.

Endoscopic Papillary Large Balloon Dilatation (EPLBD)

A two steps procedure was implemented as a minor endoscopic biliary sphincterotomy (EST) was first performed to direct the orientation of SO dilation during the second step towards the biliary sphincter. Dilatation was performed with a large balloon catheter of 12–20 mm. A guide wire was inserted into the bile duct and the balloon catheter was guided over the wire. We used a balloon catheter that was initially developed for dilation in pyloric stenosis, (CRE wire-guided balloon Boston Scientific, Natick, MA). Another reason for a minor EST is to prevent post-procedure pancreatitis by minimizing the peripapillary edema after dilating the papilla.

Definition of post ERCP complications

We classified post ERCP complications according to the severity into three categories

Mild complications: Required 2 to 3 days of hospitalization.

Moderate Complication: Required 4 to 10 days of hospitalization.

Severe Complications: Required more than 10 days of hospitalization, necessities surgical or invasive radiological intervention or contribute of death.

Statistical Analysis

Data were collected, coded and entered to personal computer (IBM compatible, 3GHz). The collected data were analyzed with the program Statistical Package for Social Science version 16 for the Windows operating system. The following tests were used: calculation of mean values and standard deviation (SD), Pearson Correlation coefficient (r) test, Chi-Square test χ^2 was used to compare qualitative variables between groups. Fisher exact test was used instead of chi-square when one or more expected cell <5. Independent samples t-test was used to assess the statistical significance of the difference between two population means in a study involving independent samples. The test was considered significant if $P \leq 0.05^*$

Results

Comparison between EST and EPLBD

For small stones < 1 cm both procedures recorded nearly similar success rate AS EPLBD was effective for clearance of (92.5%) of CBD, whereas EST was effective in (96%) of patients [$P = 0.65$] [Table 1].

Similarly, hand for larger stones both treatment modalities showed similar success rate. However, despite being statistically insignificant data is suggestive of presence of a

difference as $P= 0.073$. EPLBD was effective for clearance of

(83.4%) of CBD stones in patients with the stone sized $>1\text{cm}$, whereas EST was effective in (56%) [Table 1].

Post ERCP adverse events in EST and EPLBD

Group 1 patients reported an overall complication rate of 18.5%, with post procedure bleeding being the most prevalent of which 6.9%. Mild self-limiting post ERCP pain occurred in 4%. Whereas more serious complications as mild pancreatitis developed in 4.6%, and post ERCP cholangitis in 2.3%. On the other hand, following EPLBD adverse events rate was 29%. And similar to post EST, mild post procedural bleeding was the most prevalent complication with a rate of 9.6% and mild self-limiting post ERCP pain occurred in 8.7%. While more serious complication as melena occurred in 3.2%, and mild pancreatitis occurred in 6.4% [table 3].

Table 1: Comparison between the two groups as regard the complete extraction of stones in patients with stone less than 1 cm

Extraction of CBD stone less than 1 cm	Group 1		Group 2		T test	P value
	Case	%	Case	%		
Complete extraction	48	96	24	92.3	0.87	0.65
Incomplete	2	4	2	8.7		
Sum	50 cases		26 cases			

Table 2: Comparison between the two groups as regard the complete extraction of stones in patients with stone equal or larger than 1 cm

Extraction of CBD stone equal or larger than 1 cm	Group 1		Group 2		T test	P value
	Case	%	Case	%		
Complete extraction	20	56	30	83.4	3.15	0.073
Incomplete	16	44	6	16.6		
Sum	36 cases		36 cases			

Table 3: Post ERCP adverse effects among studied groups

Complication	Group 1		Group 2		T test	P value
	Case	%	Case	%		
Endoscopic bleeding	4	6.9	6	9.6	0.395	0.347
Simple Epigastric Pain	6	4	6	8.7	0.675	0.445
Melena or hematemesis	0	0	2	3.2	0.236	0.419
Post ERCP pancreatitis	4	4.6	4	6.4	0.735	0.560
Post ERCP cholangitis	2	2.3	0	0	0.814	0.666
Perforation	0		0			
Sum of adverse effects	16	18.5	18	29	0.394	0.420

Discussion

EST, which was first introduced in 1974, became the standard therapy for the treatment of CBD stones. Although EST has been proven to be safe in many studies, there are several complications, including pancreatitis (5.4%), hemorrhage (2.0%), perforation (0.3%), cholangitis (1.0%), cholecystitis (0.5%), and procedure-related death (0.4%)^[9].

EPBD has become an alternative to EST for the treatment of CBD stones. EPBD has several advantages over EST. Firstly, EPBD results in fewer traumas to the ampullary sphincter. Secondly, EPBD might preserve the function of the biliary sphincter, reducing late complications such as the recurrence of biliary stones^[19]. Thirdly, EPBD has the advantage of less bleeding and is safer for patients with bleeding tendency. Finally, EPBD is recommended for patients with abnormal anatomy, such as peri-ampullary diverticulae and Bill Roth II

gastro-jejunostomy, in which the margin for cutting is limited or the appropriate cutting direction is not clear^[5, 8]. However, a meta-analysis demonstrated that post-ERCP pancreatitis occurred more commonly in the EPBD group than in the EST group^[8]. The balloon dilation of the sphincter of Oddi might cause its spasm, compression and edema of the distal pancreatic duct, which could result in the restriction of pancreatic juice flow and the occurrence of pancreatitis^[25]. Another disadvantage of conventional EPBD is that it is difficult to remove larger stones because the biliary opening is not enlarged to the same degree as with EST (21, 28); therefore, the application of EPBD is restricted to patients with small stones less than 10 mm in diameter^[11].

EPLBD combined with limited EST, was first proposed to facilitate the removal of large or multiple bile duct stones, and has been proven safe and effective in patients with large bile duct stones^[24]. EPLBD combined with limited EST can enlarge the biliary orifice enough to remove multiple or larger bile duct stones, resulting in an increased success rate of stone removal and in decreased use of mechanical lithotripsy^[26, 27]. This study was conducted to compare the success and complications rates between ELPBD and EST for enlargement of papillary opening during endoscopic removal of common bile duct stones.

In our study regarding complete extraction CBD stones among the patients of group II; EPLBD with balloons sized from^[10-12] to^[12-15] mm combined with balloon catheters and/or baskets for stone extraction was effective for clearance of (92.5%) of CBD stones in patients with the stone sized less than 1cm and in (83%) of patients with stone size equal or larger than 1cm, (overall clearance rate=87%). Whereas complete CBD stones clearance among the patients of group I; EST combined with balloon catheters and/or baskets for stone extraction was effective in (96%) of patients with the stone sized less than 1 cm, while stone clearance occurred in (56%) in patient with stone size equal or larger than 1cm, (overall clearance rate=79%). The comparison between the two groups regarding the extraction of CBD stones revealed that combination of papillary large balloon dilation after EST is not required in patients whose the CBD stone size less than 1 cm as the clearance of CBD stones less than 1 cm among the group I was better than among the group II, This is on the same line with the conclusion of *Liao and his colleagues*^[14] that CBD stones smaller than 1 cm in diameter may be extracted after sphincterotomy using retrieval balloons or baskets without the need of mechanical lithotripsy or balloon dilation of the papilla orifices^[14]. whereas the clearance rate of CBD stones in the patients with stone size equal or large to 1 cm among the group II was (83%) which is better than among the group I which was (56%). Indeed, this difference was of no statistical significant but it was suggestive as P value was 0.07. Our data support the conclusion of *Stefanidis et al.*, 2011,^[20] that EPLBD has been introduced as an adjunctive tool to EST for removing large or difficult CBD stones, the combination of techniques creates a very large orifice, facilitating removal of large or multiple stones with less chance of impaction in the distal bile duct or papillotomy. Theoretically, risk of perforation or bleeding would be reduced by performing a less than maximal sphincterotomy, and risk of pancreatitis from balloon dilation would be

reduced by first separating the biliary and pancreatic orifices with EST^[20].

As regard overall adverse effects, patients of group I reported an incidence of 18.5% and the complications profile included, mild self-limiting post ERCP pain 4 % and mild intra-procedure bleeding 6.9% which stopped spontaneously whereas more serious complications as mild pancreatitis developed in 4.6% and post ERCP cholangitis occurred in 2.3% that required prolonged stay in the hospital with intense antibiotic treatment.

Whereas, overall adverse effects of patients of group II was 29% as mild self-limiting post ERCP pain occurred in 8.7% and mild intra-procedural bleeding occurred in 9.6% which stopped spontaneously or after adrenaline injection. On the other hand, serious complication as melena occurred in 3.2% which required blood transfusion, and mild pancreatitis occurred in 6.4%, that required medical treatment recovered without surgery.

Our study result is not far from the study by *Ersoz et al.*, from Turkey (2003), EPLBD was performed after EST in 58 patients in whom endoscopic removal of biliary stones by standard EST and balloon/basket extraction techniques had failed. EPLBD alone resulted in successful stone clearance in 89% of patients with tapered distal bile ducts. Complications occurred in 15.5% of patients of this study, most (10.3%) were mild and self-limiting. Moderately to severe bleeding developed in 5.2% and all recovered without the need for surgery. Mild pancreatitis developed in (3.4%)^[5].

A myriad of studies worldwide had reported variable degrees of efficacy and safety of EPLBD. In a group of 22 Korean cohorts who underwent limited sphincterotomy followed by large balloon dilation (10–15 mm). Successful stone removal was achieved in (73%) and Pancreatitis occurred in one patient (4.5%)^[2]. In a series of 60 Indian patients, EPLBD combining, maximum sphincterotomy and papillary balloon dilation, ductal clearance was achieved in (95%); (5%) of the patients required adjunctive mechanical lithotripsy for stone extraction. Bleeding occurred in (8.3%) and was managed conservatively in all cases^[16]. Another Indian study reported albeit inferior efficacy of EPLBD as successful extraction of stones without mechanical lithotripsy was achieved in 58% of cases while mechanical lithotripsy was required in (10%). Complication rate also was higher as minor oozing of blood was seen in 32% “almost three fold of that reported in our cohorts”,. Melena occurred in (4%) of patients, and major bleeding requiring surgery occurred in one patient. Mild acute pancreatitis that resolved with conservative management occurred in (8%) of patients^[17].

In a multi-center study, *Attasaranya et al.* (2008), from USA reported potential efficacy of EPLBD using large-diameter balloons (12 mm) after sphincterotomy in 103 patients with large CBD stones at five ERCP referral centers in USA. The combined technique had a success rate of (95%) and a complication rate of (6%). Failure of complete stone clearance occurred in (5%). Short term complications were documented in (5.4%), including a single case of cystic duct perforation. Two patients had complications of hemorrhage including one patient who had severe bleeding. Three other patients were reported as having mild events that would not typically be counted as an overt complication. One had abdominal pain

requiring a 2-day hospitalization without evidence of pancreatitis or perforation, while one other had contrast dissection in the peri-ampullary region^[1].

Conversely, fatal complications had been reported, in two out of 166 patients one due to perforation and the other from massive bleeding. However, the size of balloons used in this study was likely larger than in other studies and may have been larger than the native duct in some cases^[26]. Indeed a similar success rate had been reported 83% in extracting large stones.

Mechanical lithotripsy ML was not used in any of our patients representing an additional benefit of the EPLBD technic. Similarly, Draganov *et al* (2009) reported successful complete stone removal in 84% of difficult stones that had failed stone extraction with standard techniques after full length EST clearance was accomplished without additional ML. Mild complications occurred in 6% of the cases^[3]. An observation that was confirmed in another study where ML was required more often in the EST group than in the EPLBD group (25% vs. 6%) (7). In a similar conclusion, balloon dilation managed to reduce the use of ML in patients with large stones. As Complete stone removal from the first session was accomplished in 87.5% of the patients in the EPLBD group vs. 74% in the EST group. Furthermore, Mechanical lithotripsy for large stones was required in 17.9% for the EPLBD group versus 45.8% for the EST group^[12]

In a systematic review, analyzing eighteen retrospective and prospective studies including more than one thousand, three hundred patients, who underwent EPLBD for large stones. The stone size was up to 35 mm; the EST performed was reported as “limited” in nine, “moderate” in four and “large” in four studies. The balloon dilation ranged from 10-20 mm in diameter and the maximum dilation time lasted from 20 s to 60 s. Overall, 0-33% of the patients required complementary ML when successful stone removal with the first ERCP was achieved in 72%-97% of the patients. The complications were pancreatitis (0-9.6%), bleeding (0-12%) and perforation (0-1%)^[10].

One of the most important limitations of wide usage of EPLBD in Europe is increase of incidence of post ERCP pancreatitis with fatal cases. When balloon dilation is performed in the West, it presents a high risk of pancreatitis that makes it rather an abandoned technique in everyday clinical practice. Pancreatitis resulting after balloon dilation alone could be explained theoretically by the edematous change of the papilla due to forced sphincter rupture, trauma and finally, the resulting obstruction of the pancreatic duct that discharges the inflammatory cascade leading to acute inflammation of the pancreas^[11]. Large balloon dilation after sphincterotomy does not appear to be associated with a high rate of pancreatitis. The most likely explanation would be that pancreatic and biliary orifices are separated following sphincterotomy, which direct the force during balloon dilation predominantly towards the biliary part of the sphincter that is already dissected than towards the pancreatic duct^[15]. Using small diameter balloon during EPBD may be increase the procedure risk as the use of stone extraction instruments through an inadequately widened ampullary orifice can cause injury, peri-ampullary edema and increased incidence of post ERCP pancreatitis^[12, 16].

Conclusion

EPLBD is as safe and effective as EST in extraction of small and large biliary stones. However, we suggest that EPLBD is more effective for larger stones which need further validation.

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