

Comparison of Endoscopic Papillary Large Balloon Dilation and Endoscopic Sphincterotomy for Retrieval of Choledocholithiasis

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ABSTRACT

Background: Endoscopic sphincterotomy (EST) combined with balloon catheters and/or baskets are the routine endoscopic techniques for stone extraction in the great majority of patients. Whereas large common bile duct (CBD) stones are treated conventionally with mechanical lithotripsy, large balloon papillary dilation after endoscopic sphincterotomy (EPLBD) represents the onset of an era in large CBD stone extraction and the management of “impaction”. That is because it seems effective, inexpensive, less traumatic, safe and easy method that does not require sophisticated apparatus and can be performed widely by skillful endoscopists. Studies comparing the efficacy and safety of EPLBD with EST have reported mixed outcomes. The aim of the study to compare the success and complications rates between endoscopic papillary balloon dilation and endoscopic sphincterotomy for enlargement of papillary opening during endoscopic removal of common bile duct stones.

Methods: Randomized prospective comparative study was conducted on seventy four patients with CBD stone(s), subjective to therapeutic ERCP procedures for endoscopic extraction of common CBD(s). The enrolled patients were randomly divided into two groups according to the maneuver for dilate the papillary orifice into: Group I: Thirty one patients underwent EPLBD technique combined with balloon catheters and/or baskets for stone extraction. Group II: Forty three patients underwent EST combined with balloon catheters and/or baskets, which is considered as conventional endoscopic technique for stone extraction in the great majority of patients. **Results:** Complete extraction CBD stones among the patients of group1; EPLBD was effective for clearance of (92.5%) of CBD stones in patients with the stone sized < 1cm and in (83%) of patients with stone size \geq 1cm, (overall clearance rate=87%). Overall adverse effects of patients of group1 was (29%) as mild self-limiting post ERCP pain occurred in (9.6%) and mild intra- procedure bleeding occurred in (9.6%), whereas more serious complication as melena which occurred in (3.2%), and mild pancreatitis occurred in (6.4%). Whereas complete CBD stones clearance among the patients of group 2; EST was effective in (96%) of patients with the stone sized < 1 cm, while stone clearance occurred in (56%) in patient with stone size \geq 1cm, (overall clearance rate=79%). Overall adverse effects of patients of group 2 was (18.5%) as mild self-limiting post ERCP pain occurred in (7%) and mild intra-procedure bleeding occurred in (4.6%), whereas more serious complications as mild pancreatitis developed in (4.6%), and post ERCP cholangitis in (2.3%). The comparison between the two groups regarding the extraction of CBD stones revealed combination of papillary large balloon dilation after EST is not required in patients whose the CBD stone size < 1 cm. Whereas the clearance rate of CBD stones in the patients with stone size \geq 1cm among the group 1 was (83%) which better than among the group 2 which was (56%) with nearly statistical difference (P value=0.07). **Conclusion:** Conventional EST is an effective method for removal of common bile duct stones < 1cm in diameter whereas the use of large papillary balloon dilation after endoscopic sphincterotomy improve the clearance rate of bile duct stones \geq 1cm which is difficult to be extracted by conventional sphincterotomy and extraction devices. Endoscopic papillary large balloon dilation is an adjunctive tool to endoscopic sphincterotomy for removing large or difficult CBD stones.

Key words: common bile duct (CBD) stones, ERCP, Endoscopic papillary large balloon dilation (EPLBD) and Endoscopic sphincterotomy (EST).

INTRODUCTION

Bile duct stone management has changed dramatically in the last two decades when open surgery has been replaced by per-oral endoscopic procedures. Nowadays, therapeutic

ERCP is performed worldwide as the first approach in the management of extra-hepatic bile duct stones and is superior to

surgical or percutaneous approaches, although it can be challenging in some cases ⁽¹⁾.

Endoscopic therapy involves stone extraction using During ERCP, the removal of common bile duct stones involves the destruction or dilatation of the bile duct orifice. EST has been the standard method of management for removal of stones from the CBD since it was described in 1974 ⁽²⁾. However, when faced with more challenging situations, for example, in patients with large or multiple stones and tapered distal common duct, additional techniques such as mechanical lithotripsy may be utilized ^(3,4). Large balloon dilatation after endoscopic sphincterotomy (ELPBD) represents the onset of an era in large CBD stone extraction and the management of "impaction" because it seems that is an effective, inexpensive, less traumatic, safe and easy method that does not require sophisticated apparatus and can be performed widely by skillful endoscopists ⁽⁵⁾.

Studies comparing the efficacy and safety of EPLBD with EST have reported mixed outcomes⁽⁶⁾ EPLBD is a conventional method for extraction of large or difficult CBD stones in Asia ⁽⁵⁾, while European Society of Gastrointestinal Endoscopy suggested EPLBD with limited EST is an alternative to full EST with mechanical lithotripsy for extracting large CBD stones when there were anatomical or clinical contraindications of full EST as coagulopathy or altered anatomy ⁽⁷⁾.

Aim of work

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.

Patients and methods

This study had been done from 2013 to 2015 at Ahmed Maher Teaching hospital. Randomized prospective comparative study was conducted on seventy four patients with common bile duct stone(s), underwent therapeutic ERCP procedures for endoscopic extraction of common bile ducts stone(s). **The enrolled patients were randomly divided into two groups according to the maneuver for dilate the papillary orifice into:**

Group I: 31 patients underwent endoscopic papillary balloon dilatation after sphincterotomy

(EPLBD technique) combined with balloon catheters and/or baskets for stone extraction.

Group II: 43 patients underwent endoscopic sphincterotomy (EST) combined with balloon catheters and/or baskets.

All patients were subjected to careful history taking, general and abdominal examination, laboratory investigation including CBC, AST, ALT, Alkaline Phosphatase, total and direct bilirubin, prothrombin time and abdominal ultrasonographic examination. We were emphasizing of the presence of calculi or removed gall bladder, the diameter of CBD, visible stones in CBD and presence of intrahepatic bile duct dilatation, all of these investigations were aiming for diagnosis of choledocholithiasis, which is considered as an indication for diagnostic and therapeutic ERCP.

Endoscopic Papillary Large balloon dilatation (EPLBD):

The difference from conventional endoscopic papillary balloon dilatation (EPBD) is that endoscopic biliary sphincterotomy (EST) is performed before the balloon catheter is inserted. In most cases, a minor EST is sufficient and a major EST is not required. This is because the purpose of the EST is not to dilate the Sphincter of Oddi (SO), but to direct the orientation of SO dilation. When using a large balloon catheter to dilate the SO without an EST, it is difficult to predict the direction in which the SO will dilate. Therefore, by performing a minor EST, the direction of papilla dilation can be predicted. Another reason for a minor EST is to prevent postprocedure pancreatitis by minimizing the peripapillary edema after dilating the papilla.

After the EST, a guidewire is inserted into the bile duct and a balloon catheter is guided over the wire. The diameter of the balloon catheter should be 12–20 mm. A balloon catheter that was initially developed for dilation in pyloric stenosis, such as a CREwire-guided balloon (Boston Scientific, Natick, MA), can be useful.

Post ERCP complications:

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.

Probability (P) value, P value was used as determinant as significance:

If $P > 0.05$ = statistically Insignificant.

If $P \leq 0.05^*$ = statistically significant.

If $P < 0.01^{**}$ = statistically highly significant.

RESULTS

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	12	92.3	24	96	0.87	0.65
Incomplete	1	8.7	1	4		
Sum	13 cases		25 cases			

No statistical significant difference between the two groups as regard complete extraction of CBD stones sized less than 1 cm. EPLBD was effective for clearance of (92.5%) of CBD stones in patients with the stone sized < 1cm, whereas EST was effective in (96%).

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 large than 1 cm	Group 1		Group 2		T test	P value
	case	%	case	%		
Complete extraction	15	83.4	10	56	3.15	0.073
Incomplete	3	16.6	8	44		
Sum	18 cases		18 cases			

Near statistical significant difference (P value: 0.073) between the two groups as regard complete extraction of CBD stones sized equal or large than 1 cm.

EPLBD was effective for clearance of (83.4%) of CBD stones in patients with the stone sized ≥ 1 cm, whereas EST was effective in (56%).

Table (3): Post ERCP adverse effects among studied groups:

Complications	Group 1		Group 2		T test	P value
	Case	%	case	%		
<i>Endoscopic bleeding</i>	3	9.6	2	6.9	0.395	0.347
<i>Simple Epigastric Pain</i>	3	8.7	3	4	0.675	0.445
<i>Melena or hematemesis</i>	1	3.2	0	0	0.236	0.419
<i>Post ERCP pancreatitis</i>	2	6.4	2	4.6	0.735	0.560
<i>Post ERCP cholangitis</i>	0	0	1	2.3	0.814	0.666
<i>Perforation</i>	0		0			
<i>Sum of adverse effects</i>	9	29	8	18.5	0.394	0.420

There was no statistical significant difference between the studied groups as regard the rate of mild adverse effects.

Overall adverse effects of patients of group1 was (29%) as mild self-limiting post ERCP pain occurred in (9.6%) and mild intraprocedural

bleeding occurred in (9.6%), whereas more serious complication as melena which occurred in (3.2%), and mild pancreatitis occurred in (6.4%).

Overall adverse effects of patients of group 2 was (18.5%) as mild self-limiting post ERCP pain occurred in (7%) and mild intraprocedural bleeding occurred in (4.6%), whereas more serious complications as mild pancreatitis developed in (4.6%), and post ERCP cholangitis in (2.3%).

DISCUSSION

Discovery of choledocholithiasis generally should be followed by Procedures to remove the stone(s) to avoid the susceptible dangerous complications as pancreatitis and cholangitis. Since therapeutic ERCP replaced surgery as the first approach in cases of choledocholithiasis, a plethora of endoscopic techniques and devices appeared in order to facilitate rapid, safe and effective bile duct stones extraction. Endoscopic sphincterotomy (EST) combined with balloon catheters and/or baskets are the routine endoscopic techniques for stone extraction in the great majority of patients. Whereas large CBD stones are treated conventionally with mechanical lithotripsy, the most serious complication of that procedure is "basket and stone impaction" that is predominately resolved surgically⁽⁸⁾. Large balloon dilation after endoscopic sphincterotomy (ELPBD) represents the onset of an era in large CBD stone extraction and the management of "impaction" because it seems that is an effective, inexpensive, does not require sophisticated apparatus and can be performed widely by skillful endoscopists⁽⁵⁾. Studies comparing the efficacy and safety of ELPBD with EST have reported mixed outcomes. **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 1; ELPBD 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 2;

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 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 2 was (96%) which better than among the group 1(92.5%), so adding of balloon dilation after EST had no role of improving the clearance rate of CBD stones less than 1 cm and this supported by the conclusion of **Liao and his colleagues at (2010)** 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⁽⁹⁾. whereas the clearance rate of CBD stones in the patients with stone size equal or large to 1 cm among the group 1 was (83%) which better than among the group 2 which was (56%) with nearly statistical significant difference (P value=0.07) and this support of conclusion of **Stefanidis et al.** that ELPBD 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. The concept is to combine the advantages of sphincterotomy with those of balloon dilation. 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⁽⁵⁾.

Also as regard adverse effects of patients of group 1 was (29%) as mild self-limiting post ERCP pain occurred in (9.6%) and mild intraprocedural bleeding occurred in (9.6%) which stopped spontaneously or after adrenaline injection, whereas serious complication as melena which occurred in (3.2%) which required blood transfusion, recovered without the need for surgery, and mild pancreatitis occurred in (6.4%), required medical treatment recovered without surgery. Whereas, Overall adverse effects of

patients of group 2 was (18.5%) as mild self-limiting post ERCP pain occurred in (7%) and mild intraprocedure bleeding occurred in (4.6%) which stopped spontaneously whereas more serious complications as mild pancreatitis developed in (4.6%) required medical treatment recovered without surgery and post ERCP cholangitis occurred in (2.3%) that required prolonged stay in the hospital with intense antibiotic treatment.

Our study result is not far from the study by Ersoz *et al.* from Turkey, EPLBD was performed after EST in 58 patients in whom endoscopic removal of bile 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%)⁽¹⁰⁾.

Also our study result is not far from the study by Bang and colleagues (2006), reported a Korean series of 22 patients undergoing limited sphincterotomy followed by large balloon dilation (10–15 mm), with success in complete stone removal in (73%). Pancreatitis occurred in one patient (4.5%)⁽¹¹⁾.

Also the study of Maydeo and Bhandari reported a series of 60 patients undergoing EPLBD in India. After 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⁽¹²⁾.

Study of Misra and Dwivedi reported EPLBD performed in India using 15–20-mm balloons in 50 patients after sphincterotomy, and standard balloon and basket techniques failed to remove stones. A Dormia basket or an extraction balloon catheter was required for removal of stones in (58%); mechanical lithotripsy was required in (10%). Minor oozing of blood was seen in (32%), but the ooze stopped spontaneously during the endoscopy. 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⁽¹³⁾.

In a multi-center study, Attasaranya *et al.* 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 periampullary region⁽¹⁴⁾.

Whereas the Korean study of Yoo *et al.* is notable for two fatal complications. They reported the success and complication rates associated with EPLBD for stones measuring 5.4 to 16 mm in 166 patients. In the majority of cases (77%), EPBLD was combined with sphincterotomy and when necessary endoscopic mechanical lithotripsy was also performed. Using 15–18mm balloon for an average dilation time of 1 min, the overall success rate was (83%). However, the rate of complications was (6.6%), including two fatal complications, 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⁽¹⁵⁾.

Draganov *et al.* evaluated the efficacy and safety of EPLBD in patients with difficult stones who had failed stone extraction with standard techniques after full length EST. Successful complete stone removal was achieved in 84% the stone clearance was accomplished without additional ML. Mild complications occurred in 6% of the cases⁽¹⁶⁾.

Itoi *et al.* randomized one hundred and one patients in an EPLBD group and an EST group, the successful stone removal in the first session was 85% respectively, higher for the EPLBD group but not statistically significant. ML was required more often (statistically significant) in the

EST group than in the EPLBD group (25% vs 6%)⁽¹⁷⁾.

Investigating a large series of patients, a Korean group tried to manage the question of whether a small EST followed by large balloon dilation can reduce the use of mechanical lithotripsy in patients with large stones. 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. Mechanical lithotripsy for large stones was required in 17.9% for the EPLBD group and 45.8% for the EST group. The study suggested that EPLBD could reduce the need for mechanical lithotripsy in the case of large stones⁽¹⁸⁾.

Khan et al. analyzing eighteen retrospective and prospective studies including more than one thousand, three hundred patients, published a systematic review regarding 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%)⁽¹⁹⁾.

One of the most important limitation 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⁽²⁰⁾. 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, so that the pancreatic orifice is not effaced with significant force during biliary balloon dilation the mechanical trauma caused by balloon expansion is directed predominantly towards the biliary part of the

sphincter that is already dissected than towards the pancreatic duct⁽⁵⁾. **Also Kim et al.** revealed the risk of injury to the ampullary orifice in EPBD by using small diameter balloon may be increased because of instruments for removal are passed through an inadequately widened ampullary orifice. Ampullary orifice injury is leading to periampullary edema and increased incidence of post ERCP pancreatitis⁽¹⁸⁾.

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