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Endoscopic Balloon Dilatation *vs.* Sphincterotomy in Cases of Calcular Obstructive Jaundice during Endoscopic Retrograde Cholangio Pancreatography

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Abstract

Background: Compared to Endoscopic sphincterotomy (ES), endoscopic balloon dilation (EBD) has been reported to have a lower risk of bleeding but an increased risk of post-ERCP pancreatitis. Additionally, removal of large stones may be challenging when using EBD alone.

Patients and methods: 50 patients with calculary obstructive jaundice was enrolled in our randomized comparative study, ES was done for have of them and EBD for the rest. During ERCP, stone removal was declared as complete if the final cholangiogram showed no residual stones. Clinical evaluation for post ERCP pancreatitis was performed on the following day by symptoms and serum amylase.

Results: There is no statistical significant difference between the two groups, as regard, procedure duration, cannulation trials and time. Success rate was 88% and 80 after ES and EBD respectively. Significant higher rates of endoscopic bleeding were detected with ES. Apart from significant higher rates of post-ERCP bleeding after ES, no difference was detected between the 2 groups at regard post-ERCP complications.

Conclusion: The efficacy of EBD is similar to ES regarding, removal of common bile duct stones, and it can be safely applied particularly in patients with systemic coagulopathy as it carries a lower rate of bleeding. Further study evaluating the combined ES and EBD is highly recommended.

Keywords: Common bile duct stones; Endoscopic balloon dilatation; Endoscopic sphincterotomy

Introduction

Management of patients with suspected choledocholithiasis is technically more challenging and usually requires preoperative or intraoperative visualization of the biliary tree with the aim of detecting the stones in the bile duct [1]. For years, the 'gold standard' for preoperative visualization of the bile duct has been endoscopic retrograde cholangiopancreatography (ERCP) [2].

Endoscopic sphincterotomy (ES) has been the standard method of management for removal of stones from the common bile duct (CBD) since it was described in 1974 [3]. However, when faced with more challenging situations, additional techniques such as mechanical lithotripsy may be utilized. Furthermore, ES and stone removal can result in adverse events, including bleeding, pancreatitis, perforation and cholangitis [4].

As an alternative method to ES, endoscopic balloon dilation (EBD) was described by Staritz et al. for the management of CBD stones [5]. Removal of large stones may be challenging when using EBD alone. Thus, Ersoz et al. modified the technique of EBD 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 (ELBD) [6].

Studies comparing the efficacy and safety of EBD with EST have reported mixed outcomes. The aim of this study was to compare the use of EBD *vs.* ES during ERCP in cases of calcular obstructive jaundice regarding, the procedure duration, success rate and complications.

Patients and Methods

This randomized comparative study was conducted on 50 patients with common bile duct stones subjected to ERCP in AL-Hussin University Hospital, from October 2015 to April 2016. The enrolled patients were randomly divided into 25 patients underwent ES (group I) and 25 patients underwent EBD (Group II). For minimizing selection bias, the studied patients were alternatively selected into the 2 parallel groups under the odd-even role.

Apart from cholecystectomy, any patient with history of pancreatico-biliary surgery, failed and\or repeated ERCP or chronic liver disease was excluded.

Clear written consent was taken from patients according to Al-Azhar university committee. For all patients, full clinical evaluation, routine laboratory investigations (Complete blood count, serum urea, creatinine and electrolytes, liver function tests, coagulation profile and serum amylase) and abdominal ultrasound were done.

ERCP procedure

ERCP was performed in the standard manner using a side-view endoscope (Fujinon ED-250 XT Duodenoscope). After selective cannulation of the common bile duct by the catheter, cholangiography using Urograffine dye was performed to confirm the diagnosis. A 0.035-inch guidewire (Boston Scientific, Corp, MA, USA) was inserted into the bile duct through the catheter. Endoscopic Sphincterotomy was performed with the electrosurgical "cut" or "blend" current (group I).

A dilating balloon (CRE balloon 5.5 cm in length, 1-1.2 cm/1.2-1.5 cm/1.5-2.0 cm in diameter; Boston Scientific) was passed via the pre-positioned guidewire into the bile duct. Using fluoroscopic and endoscopic guidance, the balloon was inflated with sterile saline solution up to the optimal size (at least >10 mm in diameter) and duration (usually 2-6 min) according to the patients' condition and tolerance (group II).

A mechanical lithotripter (BML-4Q; Olympus Optical, Tokyo, Japan) was used to fragment the larger stones. Stone removal was declared as complete if the final cholangiogram showed no residual stones. Clinical evaluation for post ERCP pancreatitis was performed on the following day by symptoms and serum amylase. Number of items; procedure duration, success rate and complications were compared between the 2 groups.

Endoscopic bleeding during the procedure was graded as follows

Ooze: Means just oozing of blood at the site of sphincterotomy.

Minimal: Small amount of bleeding that stops spontaneously.

Significant: Large amount of bleeding that does not stop spontaneously and needs intervention whether by ballooning compression, water washing, cauterization, injection of diluted adrenaline or by any other means.

Post-ERCP complications were graded

Mild complications: required 2 to 3 days of hospitalization.

Moderate complications: required 4 to 10 days of hospitalization.

Severe complications: required more than 10 days of hospitalization, necessitated surgical or invasive radiologic intervention, or contributed to death.

Results

A total of 50 patients with calcular obstructive jaundice were included in the study, divided equally into ES and EBD groups. Male \female ratio was 11\14 and 13\12 in ES and EBD groups respectively. Mean age was 43.8 years in ES *vs.* 46.6 years in EBD group with no difference in between.

Distribution	ES (n:25)	EBD (n:25)
M\F	11\14	13\12
Age	43.8 (33.3-51.6)	46.6 (29.7-55.7)

Table 1: Age and sex distribution.

Acute cholangitis was the commonest clinical presentation (60%) and 10% of patients were accidentally discovered during laboratory or imaging study, with no differences between each group.

	ES (n:25)	EBD (n:25)
Jaundice	5	3
Cholangitis	15	15
Pancreatitis	3	4
Asymptomatic	2	3

Table 2: Clinical presentation.

Clinical characteristics, laboratory data and abdominal ultrasonography were evaluated in the two groups with no differences in between.

Data recorded during ERCP did not differ in ES and EBD groups, most of procedure were performed within 30-60 minutes as 56% of ES and 68% of EBD patients, cannulation by the first 3 trials were done in 52% of ES and 68% of EBD patients with successful cannulation within the first 15 minutes in 80% and 88% of ES and EBD patients respectively. Mechanical lithotripter was used in 3 cases of impacted stone with achieving complete biliary tree clearance and day drainage.

Duration of procedure	ES (n: 25)	EBD (n: 25)	X^2	P
	N (%)	N (%)		
<30 min	8 (32%)	7 (28%)	1.357	0.507
30-60 min	14 (56%)	17 (68%)		
>60 min	3 (12%)	1 (4%)		
Trials for cannulation				
≤ 3 times	13 (52%)	17 (68%)	0.750	0.386
>3 times	12 (48%)	8 (32%)	0.826	0.485
Time for cannulation				
≤ 15 min	20 (80%)	22 (88%)	0.149	0.699
>15 min	5 (20%)	3 (12%)		
Cannulation of Pancreatic Duct				
≤ 2 times	8 (32%)	7 (28%)	0.278	0.598
>2 times	4 (16%)	1 (4%)		
Lithotripsy	2 (8%)	1 (4%)	0.00	1.00

Table 3: Procedure data in each group.

After successful cannulation and full dye injection, the mean diameter of CBD in our study was 11.67 mm and 11.64 mm in ES and EBD patients respectively with no differences in between also, diameter of largest stone was not differed in both groups. Single stone was showed in 10 cases of ES *vs.* 8 cases of EBD, four patients showed 2 stones in the CBD in ES group with same number of patients in EBD group also the same number of patients showed 3 stones in both groups. Multiple stones with variable size were detected in 7 cases of ES *vs.* 9 of EBD patients.

	ES (n:25) N (%)	EBD (n:25) N (%)	X^2	P
Pancreatic Duct opacification	9 (36%)	4 (16%)	1.663	0.197
CBD diameter	11.67 ± 3.71	11.64 ± 3.30	0.042	0.966
Largest stone diameter	8.92 ± 4.68	9.16 ± 3.86	0.286	0.775
Stone number				
≤ 3 stones	18 (72%)	16 (64%)	0.092	0.761
>3 stones	7 (28%)	9 (36%)		

Table 4: Cholaniographic findings in each group.

Significant higher rates of endoscopic bleeding were detected after use of sphinctrotomy in 16 patients of ES (64%) *vs.* 4 patients after balloon dilatation with only 16% of EBD group.

Normal papilla was seen in 80% of both groups patients, peri-papillary diverticulum was detected in 11 patients of ES and 10 of EBD. Success rate was 88% and 80 after ES and EBD respectively with no differences in between, with total success rate of 84% after the first ERCP trial. For failed ERCP cases further imaging, second trial or interventional drainage were done.

Papilla	**ES (n:25)**	**EBD (n:25)**	**X^2**	**P**
	N (%)	**N (%)**		
Normal	20 (80%)	20 (80%)		
Abnormal	5 (20%)	5 (20%)	0.00	1.00
Peri-papillary diverticulum	11 (44%)	10 (40%)	0.00	1.00
Bleeding during the procedure				
Total	16 (64%)	4 (16%)	10.083	0.001*
Ooze	5 (20%)	4 (16%)	0.00	
Minimal	7 (28%)	0 (0%)	5.98	
Significant	4 (16%)	0 (0%)	2.446	
Fair drainage (Success Rate)	22 (88%)	20 (80%)	0.601	0.438

Table 5: Endoscopic findings in each group.

One day after ERCP, clinical, laboratory and in some cases imaging re-evaluation was done for detecting post-ERCP complications, variable forms of abdominal pain with no laboratory or imaging abnormalities were detected in 10 patients of ES *vs.* 11 of EBD, infection predicted with fever, toxic features and leucocytosis was detected in 3 patients of ES and 4 of EBD, transient elevation of urea was seen in one patient of both groups. Three patients were referred to ICU because of haemodynamic instability on top of severe pancreatitis one of them was died. Post-ERCP pancreatitis was seen in 7 cases of 14% (2 mild, 3 moderate and 2 severe), 3 cases from ES group and 4 of EBD.

Significant higher rates of post-ERCP bleeding were recorded within patients of ES group as 6 patients experienced melena; 2 were discharged after 2 days with dramatic spontaneous improvement and 4 cases required longer hospital admission with anti-bleeding medications, no cases required surgical interference. In the other hand, no any form of GIT bleeding was seen within patients of EBD group. Gut perforation or active haematemesis was not recorded.

	ES (n: 25) N (%)	EBD (n: 25) N (%)	X^2	P
Bleeding				
No	19 (76%)	25 (100%)	6.818	0.033*
Mild	2 (8%)	0 (0%)		
Moderate	4 (16%)	0 (0%)		
Severe	0 (0%)	0 (0%)		
Pancreatitis				
Total	3 (12%)	4 (16%)	0.194	0.907
Mild	1 (4%)	1 (4%)		
Moderate	1 (4%)	2 (8%)		
Severe	1 (4%)	1 (4%)		
Abdominal pain	10 (40%)	11 (44%)	0.082	0.774
Infection	3 (12%)	4 (16%)	0.104	0.747
Contrast nephropathy	1 (4%)	1 (4%)	0	1
Melena	2 (8%)	0 (0%)	2.856	0.091
ICU Admission	2 (8%)	1 (4%)	0.361	0.548
Death	1 (4%)	0 (0%)	1.407	0.236
Perforation	0 (0%)	0 (0%)	-	-
Hematemesis	0 (0%)	0 (0%)	-	-

Table 6: Post-ERCP complications among the studied groups.

Discussion

Endoscopic retrograde cholangiopancreatography has become one of the most important techniques for diagnosis and treatment of choledocholithiasis. It is usually combined with sphincterotomy for the extraction of bile duct stones [7]. As a therapeutic maneuver, EBD has been shown to be successful with ductal stone clearance rates of 80% to 100% in several case series. However, many gastroenterologists are hesitant to accept EBD as an alternative to ES primarily for fears of an increased risk of pancreatitis [8].

We aimed from this prospective study to compare ES and EBD concerning their success rate and adverse impacts during and shortly after ERCP procedure in patients with calcular obstructive jaundice. We found that, complete stone removal in one session was done in 22 patients (88%) after sphincter of odd cut *vs.* 17 patients (68%) after balloon dilatation with no significant difference. This is consistent with Vlavianos et al. who conducted their study on 202 patients with complete stone removal in one session in 63 patients from 99 (63.6%)

in ES group and in 65 patients from 103 (63.1%) in EBD group with no statistical difference [9].

We agree with Liu et al. with overall success rate 96% in ES (610 patients from 637) and 95% (215 patients from 227) in EBD), these higher rates may be due to their strategy which excluded patients with stone diameter more than 15 mm and frequent use of lithotripsy [10]. Similarly, Bergman et al. reported comparable failure rates as shown in 3 patients among 18 in ES group (16.6%) and in 2 patients among 16 in EBD group (12.5%) [11].

This disagrees with Fujita et al. who reported lower values of failure rate being 0.7% in ES group (one patient of 144) and 3% in EBD group (4 patients of 138) (P>0.05) [12]. This discrepancy could be explained by, much more use of mechanical lithotripsy in their study being 11.8% of patients in ES group and 14.5% in the EBD group *vs.* 8% in ES patients and 4% in EBD group in our study.

Our study highlighted the endoscopic bleeding during the procedure, which was reported more frequently with ES technique than EBD, presented with blood oozing in 5 patients (20%), minimal bleeding in 7 patients (24%) and significant bleeding in 4 patients (16%) with ES compared to 4 patients (16%) with blood oozing in the EBD group, while minimal or significant bleeding were not recorded among any patients underwent EBD with a high significant difference inspite of normal bleeding profile among the patients (platelet count and prothrombin time) prior to the procedure.

The results of the present study were supported by Nelson and Freeman in their study from the United States in which major hemorrhage was observed in 10 of 189 patients (5 percent) undergoing sphincterotomy [13]. Concerning short term complications, our study showed higher rate of post-procedural bleeding among ES group 24% (6 patients), while bleeding was not reported among patients in EBD group which is highly significant (P<0.001). These results were supported by Liu et al. who conclude that bleeding increased in ES group more than EBD group (4.2% *vs.* 0.1%, P<0.00001) [10].

These results were supported also by Weinberg et al., who reported that endoscopic balloon dilatation appears to have lower rates of bleeding and perforation [8]. While endoscopic sphincterotomy involves cutting and carries bleeding rates of 2% to 5%, balloon dilatation theoretically preserves the biliary sphincter with reported no bleeding and consequently balloon dilatation has shown to be safe even in patients with coagulopathies who normally carry a 6.6% to 14.3% mortality rate with endoscopic sphincterotomy.

This is also in agreement with Arnold et al. and Lin et al. who found higher bleeding rates among ES group involving 26% and 7% respectively and 1.9% and 0% in EBD group respectively [14,15].

Our study showed non-significant changes in rates of pancreatitis among the studied groups, including 3 patients of the ES group (12%) *vs.* 4 patients of the EDB group (16%) with no difference in between (P>0.05). This is consistent with Bergman et al. who reported identical rate of pancreatitis after ES and EBD with no determinants of its occurrence in their study inspite of known important risk factor, either to patient characteristics (young age, sphincter of Oddi dysfunction) and to the ease of cannulation (number of times the pancreatic duct is pacified) [11]. This agrees also with Lin et al. [15].

On the other hand, Liu et al. reported increased rate of pancreatitis in EBD group than ES group (9.4% *vs.* 3.3%, P<0.00001) [10]. Baron and Gain found the risk of pancreatitis to be higher with EBD group compared to ES group even after exclusion of patients with acute pancreatitis [16]. Sario et al. revealed a significantly higher rate of pancreatitis with EBD (10%) than with ES (1%) [17].

It is very important to clarify the fact that, most of the studies which concluded higher rates of pancreatitis following EBD, reported very small number of patients with severe pancreatitis if any, which is the main concern and may danger the patient's life, while most of complicated cases with pancreatitis were either mild or moderate with favorable outcomes.

In our opinion, this wide diverse adverse outcome is most probably due to presence of more than one risk factor for procedure-related pancreatitis like age, presence of peri-ampullary diverticulum, time of procedure, pacification of pancreatic duct, stone size and number, diameter of distal common bile duct, size of the balloon, duration of its inflation, experience of the endoscopist and other factors which were not standardized or constant among all series concerning evaluation of endoscopic balloon dilatation.

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