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Article

Combined sphincterotomy and sphincteroplasty versus sphincterotomy alone in the management of large CBD stones

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Abstract.*Background***:** Endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic sphincterotomy (ES) is the most widely used technique for treating choledocholithiasis. Challenges present with large stones hence additional techniques are needed. The aim of this study was to evaluate the efficacy and safety of combined sphincterotomy (EST) and sphincteroplasty (SP) versus sphincterotomy alone in the management of large common bile duct (CBD) stones. *Methods:*A prospective study included fifty patients with choledocholithiasis subjected to ERCP. Twenty-five patients underwent ES with SP, and twenty five patients were subjected only to ES**.** *Results:* There was a significant statistical difference between the two groups (P= 0.002)regarding the rate of successful stone removal which was significantly higher in the EST with SP group. (96.2% in the ES with SP group versus 62.9% in the ES group) but there was no statistical significant difference between the two groups regarding appearance of complications (p =0.460) (19.2% in the ES with SP group versus 24.2% in the ES group). *Conclusion:*Endoscopic sphincterotomy with sphincteroplasty is effective and safe in the treatment of large CBD stones.

Keywords: Large bile duct stones; Endoscopic Sphincterotomy; Sphincteroplasty

Background

Endoscopic retrograde cholangiopancreatography (ERCP) is a technique that uses a combination of luminal endoscopy and fluoroscopic imaging. ERCP was first reported in 1968 and

became a widely available and accepted as a safe, direct technique for evaluating biliary and pancreatic diseases.[1]

The most common source of biliary obstruction is choledocholithiasis. ERCP with endoscopic sphincterotomy (ES) is the most widely used technique for treating choledocholithiasis since it was described in 1974.[2, 3] However, some circumstances may complicate success of the procedure such as extraction of large CBD stones especially more than 15 mm which considered one of the difficult situations meeting endoscopists, Also several complications were reported from this technique, sphincterotomy causes permanent destruction of the biliary sphincter thus exposing biliary tree to reflux of the duodenal contents leading to bacterial colonization and chronic inflammation of the biliary tree, which theoretically increases the incidence of choledocholithiasis and tumors of biliary origin.[4-6]

More sophisticated procedures could be used for large stone extraction. [7]The ideal method for large stones extraction is that one with higher success rate, least time and lower rate of complications.

In the past, mechanical lithotripsy was more often used, and if this technique failed (basket and stone impaction), surgery was decided. [8,9] The surgical option is more aggressive and involves greater morbidity and mortality than endoscopic treatment.

For these reasons, sphincteroplasty (SP) with dilating balloons was introduced in 2003 as a routine method for expanding endoscopic sphincterotomies that are found to be insufficient. it has been proposed as an alternative to sphincterotomy alone represents the onset of a new era in difficult bile duct stone extraction. The potential advantage of balloon dilatation is that the sphincter may regain some of its function thus reducing long term complications.[9-13] This study aims at evaluation of the efficacy and safety of combined sphincterotomy (EST) and sphincteroplasty (SP).

Patients &Methods

Study design: observational prospective study

This study was carried out after the approval of the Ethical Committee of faculty of medicine, Alexandria University. A signed informed consent was obtained from all patients enrolled in the study. This study included fifty patients had either a single common bile duct stone ≥15 mm or multiple stones. During the period between January 2018 and November 2019 selected from the outpatient clinic of the Medical Research Institute, Alexandria University.

All of the patients were subjected to ERCP, twenty five of them ES alone and the other twenty five patients underwent SP after ES. Indomethacin suppository was given to all the patients to guard against pancreatitis. The procedure was carried out under sedation with propofol.

All patients were subjected to complete history taking, thorough clinical examination, ultrasound abdomen, laboratory investigations including: liver enzymes, liver function tests and serum amylase and lipase and complete blood picture were done for all patients before the start of the procedure. Magnetic resonance cholangiopancreatography (MRCP) which was done to determine

the presence of CBD stone/s, detection of dilated bile ducts and IHBR and to exclude other possible causes of dilated CBD.

ERCP was done using side viewing duodenoscope (TJF160VR, Olympus Corporation, Japan). Electrosurgical unit (UES-30, Olympus Corporation, Japan) was used at a setting of blended current with power setting of 40W for both cut and coagulation. Wire cannulation was performed over a 0.035 guide wire (Hydra Jagwire guide wire, Boston Scientific Corp.)

Patients were selected and classified into two groups (EST and EST plus SP groups), after CBD access was gained and a cholangiogram confirmed the presence of stones in a dilated CBD and the diameters of the bile duct and stones were measured during ERCP and corrected for magnification using the external diameter of the duodenoscope's distal end as a reference.

In group I (EST only group) after deep cannulation was achieved, a complete sphincterotomy was done to its full length by extending the incision to major horizontal fold crossing the intramural portion of bile duct with a 25-mm pull-type sphincterotome (Clever Cut 3; KD-V411M, Olympus, Tokyo, Japan), a complete sphincterotomy was defined by the free passage of a fully bowed sphincterotome and the presence of spontaneous bile drainage.

In Group II (EST plus SP group) underwent limited sphincterotomy (minor sphincterotomy) measuring up to one-third to one-half of the size of the papilla. This was followed by dilation of the sphincter with a 5.5-cm-long controlled radial expansion balloon (Boston Scientific, Natick, MA) over guidewire. The balloon was centered at the sphincter and was gradually inflated to 12-18 mm with diluted contrast media according to the size of the largest stone and the maximal diameter of the distal bile duct on the cholangiogram. The biliary sphincter was considered adequately dilated when the waist of the balloon completely disappeared in the fluoroscopic image. The fully expanded balloon was maintained in position for 60s and then deflated and removed, however, if any physical resistance was encountered during dilation, additional inflation was not performed to prevent perforation.

After the procedures, the stones were retrieved with a dormia basket (extraction basket, Wilson-Cook Medical Inc) or extraction balloon (Multi-3 extraction balloon;Olympus Co Ltd). Stone removal was considered successful when no remaining radiolucent stones were visible on contrast enhanced imaging after occlusion with a retrieval balloon.

A mechanical lithotripsy by using a per-oral Soehendra lithotripter was used to fragment the stones when standard methods failed to remove the stones, even after SP.

The primary efficacy endpoint is the success rate regarding complete clearance of the CBD was defined as the absence of filling defects on occlusion cholangiogram as noted by the endoscopist. Secondary end points include other efficacy criteria (number of ERCP sessions till achievement of complete stone/s extraction, duration of the procedure, use of mechanical lithotripsy, biliary stenting and cost).

Statistical analysis

Data were checked, entered and analyzed using SPSS version 20 for data processing and statistic. Data were expressed as number and percentage for qualitative variables. Each variable was statistically analyzed using the chi square test, Fisher's exact test, or Student's t-test. A value of $p < 0.05$ was considered statistically significant.

Results

Table 1 shows the characteristics of the 50 patients in the study whom received endoscopic treatment for a stone/s ≥15 mm.Age, sex, mean number of stones, mean diameter of stones, mean diameter of the bile duct. No statistically significant differences were observed between the two groups for any of these factors.

Table1: comparison between the two studied groups according to patient data

	Group I (n = 25)	**Group II (n = 25)**	**P VALUE**
Sex(M/F)	17/8	12/13	0 .152
Age (years, mean ± SD)	48.64±12.82	47.48±17.42	0.790
CBD diameter mm (Mean ± SD).	16.56±2.20	16.56±2.02	1.000
CBD stone/s number			
Single	13 (52%)	9 (36%)	0.254
multiple	12 (48%)	16 (64%)	
CBD stone size			
Mean ± SD.	16.60±1.85	16.24±1.59	0.464

Successfulextraction rate: **(Table 2, 3,4)**

In first session In group I complete CBD stone/s extraction achieved in 17 patients (68%) however, **in group II** complete CBD stone/s extraction achieved in 24 patients (96.0%).**There was a significant statistical difference between the two groups (P=** 0.023**).**

In thisstudyrepeated sessions of ERCP wereneeded to achieve complete clearance of the CBD; In group I the totalnumber the ERCP proceduresweredone once for 17 patients (68%), twice 6 patients (24%) and threetimes for 2 patients (8%), however in group II the procedure wasdone once for 24 patients (96%) and twice for onlyonepatient (4%).Therewas a statisticallysignificantdifferencebetweengroup I and II (p=0.031).

The overall successful extraction rate per session; In group I complete CBD stone/s extraction achieved in 22 sessions (62.9%) however, **in group II** complete CBD stone/s extraction achieved in

25 sessions (96.2%).**There was a significant statistical difference between the two groups (P= 0.002).**

Complete stoneremovalwasachieved in all 25 patients in the EST + EPSP group (100 % stoneremoval rate) but in only 23/25 patients in the EST group (92%). Thisdifferencewasnotstatistically significant (p = 0.245). So comparableresultsbetweenbothgroupsbut with significanthigher rate of complete stoneremoval in the first session in EST + EPSP group and significantlowernumber of sessions.

Table 2: comparison between the two studied groups according to successful extraction rate

Successful extraction	Group I (n = 35#)		Group II (n = 26#)		P
	No.	%	No.	%	
No	13	37.1	1	3.8	0.002*
Yes	**22**	**62.9**	**25**	**96.2**	

#: No. of session

Table 3: comparison between the two studied groups according to successful extraction rate from the first session

Successful extraction	Group I (n = 25)		Group II (n = 25)		FEp
	No.	%	No.	%	
No	8	32.0	1	4.0	0.023*
Yes	**17**	**68.0**	**24**	**96.0**	

Table 4: comparison between the two studied groups according to the number of ERCP sessions

ERCP (no of sessions)	Group I (n = 25)		Group II (n = 25)		p
	No.	%	No.	%	
1	17	68.0	24	96.0	MCp= 0.031*
2	6	24.0	1	4.0	

3	2	8.0	0	0.0	
Mean ± SD.	1.40± 0.65		1.04± 0.20		0.010*

Between sessions plastic stent was inserted to keep flow of bile; In group I stent was inserted in 13 patient (37.1%). In group II stent was inserted in only one patient (3.8%).There was a statistically significance difference between both groups (p = 0.002). (**Table 5**)

Table 5: comparison between the two studied groups according to stent insertion

Stent	Group I (n = 35#)		Group II (n = 26#)		P
	No.	%	No.	%	
Stent					
No	22	62.9	25	96.2	0.002*
Yes	13	37.1	1	3.8	

1. Time of the procedure:

In group I, the total time of the procedure ranged between 12 and 90 minutes with a mean **34.0 ±16.67** minutes, In group II, the total time of the procedure ranged between 23 and 46 minutes with a mean **35.08±6.61** minutes There was no statistically significant difference between the two studied groups (p=0.469) in (**Table 6**).

Table 6: comparison between the two studied groups according to time of the procedure

Time of the procedure (minutes)	Group I (n = 35#)	Group II (n = 26#)	p
Total			0.469
Mean ± SD.	34.0 ±16.67	35.08±6.61	

There was statistically significant relation between CBD number of stone/s and time of the procedure in total sample (p =0.032) and in group I (p = 0.008), however no statistically significant relation between CBD number of stone/s and time of the procedure in group II (p= 0.426).

In group I emergencylithotripsywasdone for 5 cases (14.3%)**, in group II** onlyone case (3.8%) neededemergencylithotripsy. Althoughitislower rate in group II but with no statisticallysignificancedifference (p= 0.227) (in **Table 7**).

Table (7): Comparison between the two studied groups according to lithotripsy

Lithotripsy	Group I (n = 35#)		Group II (n = 26#)		FEp
	No.	%	No.	%	
No	30	85.7	25	96.2	0.227
Yes	5	14.3	1	3.8	

2. **Regarding complication** rate no cases of perforation reported in eithergroups and nosignificantdifferenceswereobserved in the incidence of bleeding, postoperativepancreatitis and cholangitisbetween the twogroups.
   Pancreatitiswasmild in allpatients with the exception of twopatientswhohad moderate pancreatitis, asclassified by Cotton'scriteria[4]. Allcases of pancreatitisresolved with medical treatment. Bleedingwasmild and successfullytreated and none of the patientsrequiredangiography or surgery.

3. **Regarding the cost,** in EST group the cost was 7040.0 ± 3201.30 pounds however in EST + SP group the cost was 7812.0 ± 1560.0 pounds with statistical significance difference between both groups (P=0.012).

Table (8): Comparison between the two studied groups according to cost

Cost	Group I (n = 25)	Group II (n = 25)	P
Mean± SD.	7040.0 ± 3201.30	7812.0 ± 1560.0	1200.

Discussion

ERCP with endoscopic sphincterotomy (ES) is the most widely used technique for treating choledocholithiasis since it was described in 1974.[2,3] Standard techniques not always successful in clearance of a large stone so multiple procedures and additional interventional techniques are needed. ES with SP is a very good alternative that minimizes the need for lithotripsy and surgery.

Several studies have compared the usefulness of EST and EST + EPSP [8,14-18]. Some showed no significant difference in treatment results, whereas others reported that EST + EPSP reduced the operative time, increased the rate of successful stone removal, and reduced the rate of ML use.

In our study complete stone/s removal was achieved in the first session in 17 patients (68%) in group I, versus 24 patients (96%) in group II with a statistically significant difference between both groups (P= 0.023). This was similar to the results of Kuo et al [19] who stated that the success rate of the first session treatment for ≥15 mm bile duct stone removal was 83.7% in the EST group and 98.3% in the limited EST- SP group. The limited EST- SP group exhibited a higher success rate of the first-session treatment compared with the EST group (P = 0.032) which can be illustrated by the fact that limited EST-SP can dilate both the duodenal papilla opening and the distal CBD simultaneously, facilitating large bile duct stone removal.

Tsuchida et al.[20] showed significant difference in stone removal rates, in first session the limited EST-SP group showed a higher rate of complete stone removal (limited EST-SP: 88.2 % vs. EST: 55.6 %; p = 0.003) and a lower mean number of sessions required for complete stone removal (limited EST-EPSP: 1.12 sessions vs. EST: 1.47; p = 0.002) however according to their study no significant difference between both groups regarding complete clearance of the CBD per patient .

Also according to Kim et al [16] the success rates of the first-session treatment for ≥15-mm bile duct stone removal were 55.6–87% in the EST group and 83– 88.2% in the limited EST-SP group .

In contrast in a retrospective analysis according to Itoi et al [14] who studied one hundred and one patients in a limited EST-EPSP group and an EST group, successful stone removal in the first session was 96% vs 85% respectively which was not statistically significant.

In EST group, the ERCP procedure done once for 17 patients (68%), twice for 6 patients (24%) and three times for 2 patients (8%), however in (limited EST-EPSP) group the procedure done once for 24 patient (96%) and twice for only one patient (4%) which was statistically significant, the number of sessions in the (EST) group was 35 session versus 26 session only in the (limited EST-EPSP) group, according to the total number of sessions the success rate was (62.9%) for the EST group vs (96.2%). For the (limited EST-EPSP) group with significant difference between both groups (p = 0.002)

This was in agreement with Paik et al [21] who concluded that the need for repeated sessions of ERCP to achieve complete removal of biliary stones were significantly required in EST group than in limited EST-SP group (1.7±0.2 times vs 1.3±0.1 times; p=0.03).

In contrast to our study according to Shahriyar et al [22] who studied a prospective non-randomized descriptive study, a total of 84 patients where the biliary calculus was greater than 15 mm uderwent ERCP using combined endoscopic sphinncterotomy and large balloon dilatation for stone/s removal, the success rate was (61.9%) in the first session, (64.4%) in the second session while (100%) in the third session.

Also Kuoet al.[19] showed that the overall success rate for ≥15-mm bile duct stone removal was 93.5% in the EST group, 98.3% in the limited EST- SP group. There was no significant difference between the two groups regarding complete stone removal.

Another study; Kim et al [15] showed no significant differences between limited EST-SP and EST groups in stone extraction .

According to Heo et al[18] who studied patients with large stones (over 15 mm in diameter), in an EST- SP group the reported successful stone removal was 94.4% and for the EST group successful extraction rate was (96.7%) with no significant difference between both groups.

In our study the need for emergency mechanical lithotripsy is lower in EST-SP group but still with no statistical significance; (only one case (3.8%) versus 5 cases (14.3%)), Kuo et al[19] and Heo et al [18] were in agreement with our study, In the former study the need for ML decreased in the limited EST-SP group (3.4%) compared with the EST (12.9%) but this difference exhibited no statistical significance (P = 0.215) and in the latter study ML for stone extraction after failure of the conventional methods was required in 8% of the EST- SP group and in 9% of the EST group.

In contrast, according to Teoh et al [9] the EST - SP reduce the need for lithotripy – as the range of lithotripsy was 30-50% - also Itoi et al[14] said that ML was required more often (statistically significant) in the EST group than in the EST- SP group (25% vs 6%).

Regarding the complications rate, in this study no significant difference was noted in post-procedure pancreatitis, bleeding and sepsis (P = 0.642,. 227, .629) respectively between both groups. No cases of perforation occurred in both groups.

In agreement with our study the rate of major adverse events, mainly pancreatitis, bleeding and perforation, between the two groups was similar in 5 RCTs.(9,15,18,23,24)

According Tsuchida et al [20] the complications rates did not differ significantly between the EST and EST + EPSP groups, also similar to our results Kuo et al [19] showed that no significant difference was noted in post-procedure pancreatitis (P = 0.852) or cholangitis (P > 0.99) among the two groups however in contrast to our results post-procedure bleeding rate in the EST group (9.7%) was higher than that in the limited EST-EPSP group (0%; P = 0.038). Perhaps, this difference could be attributed to the complete extent of the incision in the EST group and balloon dilation with compression of a possibly bleeding vessel after EST in the limited EST-SP group. Hence, they recommended limited EST-SP is for the treatment of large bile duct stones in patients with an underlying coagulopathy or the need for anticoagulation following ERCP because of lower risk of bleeding than EST.

In another systematic review (30) studies considered), the rate of overall adverse events (pancreatitis, bleeding, perforation) was lower for endoscopic sphincterotomy with EST- SP than for endoscopic sphincterotomy alone (8.3% vs. 12.7%, OR 1.60;

P <0.001) and the incidence of pancreatitis was 2.4 % (0–13.2 %), consisting mostly of mild-to-moderate pancreatitis .[25]

Also according to Feng et al [26] a recent meta- analysis of 7 randomized controlled trials that included 790 patients, comparing EST-SP with EST, EST- SP was associated with fewer overall complications than EST (5.8 vs 13.1%, P = 0. 007). In particular, bleeding occurred less frequently with EST- SP than with EST (P = 0.002), suggesting that compression by ballooning may be effective for haemostasis. The authors did not find significant differences in post-ERCP pancreatitis, perforation and cholangitis. The risk of duodenal perforation during EST-SP seems quite low, possibly due to the fact that EST guides the orientation of the dilation and controls the impact of its radial force, which is furthermore monitored in real time by the endoscopist, both endoscopically and fluoroscopically.[26]

In another meta analysis of EST -SP compared with EST alone included six RCT involving 835 patients. [27] Results of this meta-analysis found that EST-SP caused fewer overall complications

than ES alone (OR 0.53, 95% CI 0.33–0.85, P = 0.008), a significantly lower risk of perforation (OR 0.14, 95% CI 0.20–0.98, P = 0.05).

According to Rosa et al [28] in a retrospective single center study over two years, from February 2010 to January 2012. This combined technique has been shown to potentially reduce the complications typically associated with the performance of EST.

Also the combined EST with SP approach does not appear to increase significantly the risk of post-ERCP pancreatitis which is similar to our results. This may be due to the fact that EST guides the orientation of the dilating balloon towards the common bile duct, thus preventing the pressure overload on the main pancreatic duct. Also Probably, the inflammatory reaction caused by SP, which can affect drainage of the pancreatic duct, is mitigated by the effect of previous ES, which separates the pancreatic and biliary orifices.[29]

A meta-analysis including three trials, and six retrospective studies showed equivalent complication rates in both groups (OR = 0.61, 95% CI 0.17–2.25, P = 0.46), including pancreatitis (OR = 1.11, 95% CI 0.37–3.35, P = 0.86), but with less bleeding in the limited EST-EPSP group (OR = 0.10, 95% CI 0.03–0.30, P ≤ 0.001).[30]

In contrast to our study, according to Paik et al.[21] EST-SP was more cost effective in the end. Also according to Teoh et al.[9] showed lower costs with limited EST-SP (p = 0.034).

Limitation of the study

Small sample size of the study, usage of stents in between session which itself could affect the success rate, also the recurrence of the CBD stones should be studied with long term follow up of the cases.

Conclusion

The results of the present study show that EST + SP is an effective and safe method for large CBD stone extraction that allowed complete stone removal in fewer sessions and without increasing the complication rate. Future studies with larger sample sizes for more detailed examination including assessment of long-term outcomes, are necessary

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Conflict of interest

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