

Role of Limited Endoscopic Sphincterotomy (ES) and Endoscopic Papillary Large-Balloon Dilation (EPLBD) in the Management of Difficult Common Bile Duct Stones: A Single-Center Experience

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Abstract: Difficult common bile duct (CBD) stones provide challenges in their therapeutic management, especially per endoscopic treatment. In this study, the author would like to show the effectiveness of limited ES and EPLBD in the management of patients with difficult CBD stones in their center. This is a retrospective study from June 2020 to April 2024, in which patients with difficult CBD stones received endoscopic management with limited endoscopic sphincterotomy and EPLBD. Length of procedure, success rate, morbidity, and mortality rate were recorded and evaluated. The results showed that a total of 98 patients were included in the study, ages ranging from 23 to 83 y.o. The length of the procedure was 44 + 11 minutes, with the success rate of CBD stone retrieval and duct clearance at 70.4%. Etiologies of difficult CBD stones consist of stone size > 1.5 cm (47.96%), combined cause (27.55%), multiple CBD stones less than 1.5 cm (13.26%), and tapering of distal CBD (11.22%). Morbidities such as melena (5.1%), post-ERCP pancreatitis (PEP) (3.06%), cholangitis (1.02%), and duodenal perforation (1.02%) occurred. One mortality incidence occurred due to severe cholangitis and sepsis. The mean period of EPLBD performed was 2.7 + 1.57 minutes. The pressure strength of the CRE balloon dilator commonly used was 4.5 atm. In conclusion, limited ES and EPLBD offer quite satisfactory results in the management of difficult CBD stones, with the success rate as high as 70.4% and an acceptable morbidity rate.

Keywords: endoscopic papillary large-balloon dilation (EPLBD); difficult CBD stones

INTRODUCTION

Gallstones remain a common problem for people in developing countries, with 10-25% of the patients suffering pain or complications because of stones migrating into the common bile duct (CBD).¹⁻³ GallRiks study stated that common bile duct (CBD) stones must be removed to reduce complications because a quarter of cases would develop complications (pancreatitis, cholangitis, obstruction of the bile duct) in a four-year follow-up study.⁴ Suspected CBDS would undergo Liver Function Test (LFTs) and Abdominal Ultrasound (USG) to determine further evaluations. LFTs such as total bilirubin, ALP, AST-ALT, and GGT are recommended for patients with suspected CBD stones. In five studies, USG findings of CBD dilatation were considered positive findings for CBD stones.⁵⁻⁸

Specific consideration for patients aged more than 55 years old with normal LFTs, because there were two studies documenting CBD stones in patients of that specific character^{10,11}. Difficult biliary stones are defined by their diameter (>1.5 cm), number, unusual shape (barrel-shaped), or location (intrahepatic, cystic duct), or because of anatomical factors (such as narrowed bile duct, distal stone, sigmoid-shaped CBD, impacted stone, short distal CBD, or acute angulated distal CBD).^{12,13} Common bile duct stones usually undergo endoscopic retrograde cholangiopancreatography (ERCP) or surgical cholecystectomy.

Visualized bile duct stone is the indication to perform the EPLBD alone or in combination. Perforation and CBD stricture are among its complications. There is no specific size selection of the balloon dilation; in most studies, distal CBD diameter is used as the parameter¹⁴⁻¹⁸. When CBD stones cannot be removed, a plastic stent is often placed to relieve the obstruction for 3-6 months to prevent biliary cholangitis. Laparoscopic cholecystectomy would be the next therapy following ERCP to be performed two weeks after ERCP to prevent biliary events like cholangitis, pancreatitis, jaundice, and biliary colic. In this study, the author would like to show that limited endoscopic sphincterotomy and EPLBD are effective in terms of reduced risk of complication, preservation of sphincter function, and high success rate.

METHODS

This was a retrospective study from June 2020 to April 2024, in which patients with difficult CBD stones received endoscopic management with limited endoscopic sphincterotomy and EPLBD. Length of procedure, success rate, morbidity, and mortality rate were recorded and evaluated.

RESULTS

Figure 1 showed that from June 2020 to April 2024, Prof. Dr. R.D. Kandou General Hospital conducted 502 ERCPs, with CBD stones being the predominant cause in 349 cases (70%), malignancy in 118 cases (24%), and other causes in as many as 35 cases (7%). Figure 2 showed that for CBD stones, out of 349 cases, there were 251 patients (72%) with simple CBD stones excluded from the study and 98 patients (28%) with difficult CBD stones included in this study.

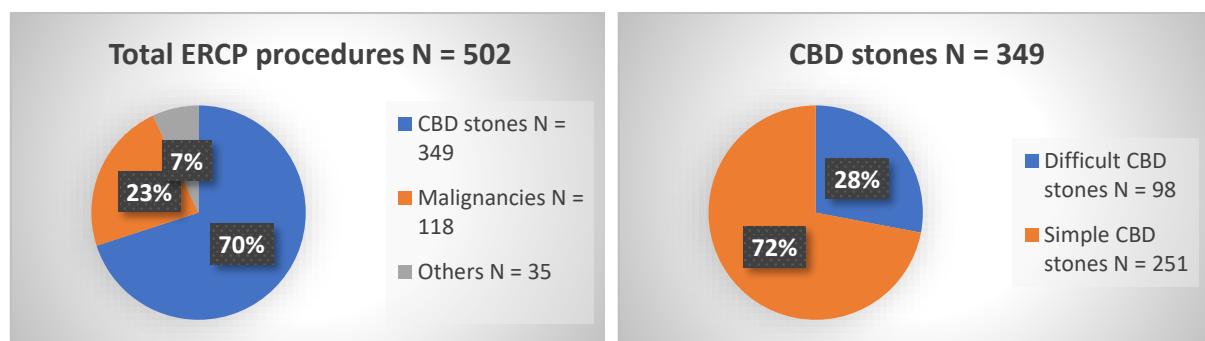


Figure 1. Total ERCP procedures

Figure 2. Total CBD stones

Table 1 showed that sample ages ranging from 23 to 83 y.o. As seen in table 1, etiologies of difficult CBD stones consist of stone size > 1.5 cm (47.96%), combined cause (27.55%), multiple CBD stones less than 1.5 cm (13.26%), and tapering of distal CBD (11.22%).

Table 1. Characteristics of patients with difficult CBD stones in this study

Characteristics of patients	Total (N = 98)
Age range	23-83 years
Male, N (%)	52 (53.06%)
Female, N (%)	46 (46.94%)
Etiologies of difficult CBD stones	
Stone size > 1.5 cm	47 (47.96%)
Multiple CBD Stone with stone size <1.5 cm	13 (13.26%)
Tapering of Distal CBD	11 (11.22%)
Combined Causes	27 (27.55%)

Table 2 showed that the length of the procedure was 44 + 11 minutes, with the success rate of CBD stone retrieval and duct clearance at 70.4%. The mean period of EPLBD performed was 2.7+1.57 minutes. The pressure strength of the CRE balloon dilator commonly used was 4.5 atm.

Table 2. Average intraoperative characteristics

Intraoperative characteristics	Length of procedures
Mean length of procedure	44 + 11 minutes
Mean period of EPLBD	2.7 + 1.57 minutes
The most common pressure strength used for controlled radial expansion (CRE) balloon dilator	4.5 ATM

Table 3 showed that morbidities such as melena (5.1%), post-ERCP pancreatitis (PEP) (3.06%), cholangitis (1.02%), and duodenal perforation (1.02%) occurred. One mortality incidence occurred due to severe cholangitis and sepsis.

Table 3. Morbidities and mortality

Morbidities and mortality	Total (%)
Morbidities	
Melena	5 (5.1%)
Post ERCP pancreatitis	3 (3.06%)
Duodenal perforation	1 (1.02%)
Mortality	
Cholangitis	1 (1.02%)

DISCUSSION

The European Society of Gastrointestinal Endoscopy recommends an adequate extraction for stones should be provided according to papilla-stone size and its common bile duct anatomy. The procedures are biliary cannulation (papillary balloon dilatation/basket catheters) and endoscopic sphincterotomy.¹⁹⁻²¹ The critical step is to determine whether to use endoscopic balloon dilation alone, endoscopic dilation alone, or a combination.^{18,20} There are seven randomized control trials (RCTs) and five meta-analyses that showed the superiority of combined endoscopic sphincterotomy and balloon dilatation over sphincterotomy alone to reduce the need for mechanical lithotripsy. Although conventional ERCP, which includes endoscopic sphincterotomy followed by balloon or basket extraction for common bile duct stones, is a routine procedure, about 10% to 15% of bile duct stones fail to be removed, especially because of bile duct stones with a diameter of > 15 mm.²²

In comparison with ES alone, results from a 2018 study conducted in Taiwan by Kuo et al. reported that limited ES-EPLBD showed a high success rate but required a longer procedure time during the first session treatment.²³ Different results were reported in Japan by Hirofumi et al. in 2020, who concluded that EPLBD without ES for the treatment of large CBD stones obtained greater stone-free results in a single operation without any increase in side effects compared to EPLBD with ES.²⁴

Regarding the high success rate of the EPLBD procedure with ES, it can be caused by the combination of the procedure itself which is able to increase the diameter of the papilla and distal CBD at the same time.

When comparing endoscopic sphincterotomy (ES) and the combination of limited endoscopic sphincterotomy with EPLBD in terms of pancreatobiliary reflux, ES alone can reduce function of the sphincter while limited ES with EPLBD allow preservation of papillary sphincter function and reduce the risk of pancreatobiliary reflux.^{25,26}

During this study, one patient died due to severe cholangitis and sepsis. This mortality is related to the length of the patient's illness, visit to the hospital when the jaundice is getting worse, and the stone is large. In contrast to the study done by Hossam et al. in 2023, who reported no single mortality case during their study.²⁷

The mean period of EPLBD in our study is 2.7 minutes, with the complication rate of post-ERCP pancreatitis being 3.06%. This result is in line with a study from Liao et al. in 2012, which stated that a dilation duration of <1 minute increases the risk of post-ERCP pancreatitis, so that an adequate dilation duration of >1 minute is recommended compared to EST because of the lower complication rate.²⁸

Complications of bleeding after the procedure were higher in an ES alone compared to the combination procedure. Result by Guo et al. in a 2014 study conducted in China, the rate of bleeding was significantly higher in an ES-alone group than in the EPLBD group [1/64 (1.6%) vs. 5/89 (5.6%), $P < 0.05$].²⁹

According to Ishii et al., this is because the nature of limited EST which entails a smaller incision in the sphincter of Oddi than a full sphincterotomy.³⁰

Also the use of a balloon to dilate the papilla is less traumatic than full cutting, which further reducing the risk of bleeding.³¹

There were several limitations in our study. This result comes from a single center with a population that is limited. To eliminate these two limitations, it is better to conduct a multicenter study. The morbidity and mortality in this study only observed in short period of time, not a long-term which also important to determine the safety of procedure and stone recurrence. Future studies with long-term evaluation should be conducted.

CONCLUSION

Combination of limited endoscopic sphincterotomy and endoscopic papillary large balloon dilatation can be used as a first-line approach to treat visualized large bile duct stones that were defined as difficult biliary stones with an acceptable morbidity rate.

Conflict of Interest

The authors affirm no conflict of interest in this study.

REFERENCES

1. Everhart JE, Khare M, Hill M, Maurer KR. Prevalence and ethnic differences in gallbladder disease in the United States. *Gastroenterol*. 1999;117(3):632–9. Doi: 10.1016/s0016-5085(99)70456-7
2. Shaffer EA. Epidemiology of gallbladder stone disease. *Best Practice & Research Clinical Gastroenterology*. 2006;20(6):981–96. Doi: 10.1016/j.bpg.2006.05.004
3. Tazuma S. Epidemiology, pathogenesis, and classification of biliary stones (common bile duct and intrahepatic). *Best Practice & Research Clinical Gastroenterology*. 2006;20(6):1075–83. Doi: 10.1016/j.bpg.2006.05.009

4. Prat F, Meduri B, Ducot B, Chiche R, Salimbeni-Bartolini R, Pelletier G. Prediction of common bile duct stones by noninvasive tests. *Ann Surg.* 1999;229(3):362–8. Doi: 10.1097/00000658-199903000-00009
5. Halldestam I, Enell EL, Kullman E, Borch K. Development of symptoms and complications in individuals with asymptomatic gallstones. *Br J Surg.* 2004;91(6):734–8. Doi: 10.1002/bjs.4547
6. Fein M, Bueter M, Sailer M, Fuchs KH. Effect of cholecystectomy on gastric and esophageal bile reflux in patients with upper gastrointestinal symptoms. *Digestive Diseases and Sciences.* 2008;53(5):1186–91. Doi: 10.1007/s10620-007-9989-8
7. Gracie WA, Ransohoff DF. The natural history of silent gallstones. *NEJM.* 1982;307(13):798–800. Doi: 10.1056/NEJM198209233071305
8. McSherry CK, Ferstenberg H, Calhoun WF, Lahman E, Virshup M. The natural history of diagnosed gallstone in symptomatic and asymptomatic disease patients. *Ann Surg.* 1985;202(1):69. Doi: 10.1097/00000658-198507000-00009
9. Manes G, Paspatis G, Aabakken L, Anderloni A, Arvanitakis M, Ah-Soune P, et al. Endoscopic management of common bile duct stones: European Society of Gastrointestinal Endoscopy (ESGE) guideline. *Endoscopy.* 2019;51(05):472–91. Doi: 10.1055/a-0862-0346
10. Wilcox CM, Kim H, Trevino J, Ramesh J, Monkemuller K, Varadarajulu S. Prevalence of normal liver tests in patients with choledocholithiasis undergoing endoscopic retrograde cholangiopancreatography. *Digestion.* 2014;89(3):232–8. Doi: 10.1159/000358384
11. Qiu Y, Yang Z, Li Z, Zhang W, Xue D. Is preoperative MRCP necessary for patients with gallstones? An analysis of the factors related to missed diagnosis of choledocholithiasis by preoperative ultrasound. *BMC Gastroenterol.* 2015;15(1):158. Doi: 10.1186/s12876-015-0392-1
12. Trikudanathan G. Endoscopic management of difficult common bile duct stones. *World J Gastroenterol.* 2013;19(2):165. Doi: 10.3748/wjg.v19.i2.165.
13. Kim HJ, Choi HS, Park JH, Park DI, Cho YK, Sohn CI, et al. Factors influencing the technical difficulty of endoscopic clearance of bile duct stones. *Gastrointest Endosc.* 2007;66(6):1154–60. Doi: 10.1016/j.gie.2007.04.033
14. Stefanidis G, Viazis N, Pleskow D, Manolakopoulos S, Theocharis L, Christodoulou C, et al. Large balloon dilation vs. mechanical lithotripsy for the management of large bile duct stones: a prospective randomized study. *Am J Gastroenterol.* 2011;106(2):278–85. Doi: 10.1038/ajg.2010.421.
15. Heo JH, Kang DH, Jung HJ, Kwon DS, An JK, Kim BS, et al. Endoscopic sphincterotomy plus large-balloon dilation versus endoscopic sphincterotomy for removal of bile-duct stones. *Gastrointestinal Endoscopy.* 2007;66(4):720–6. Doi: 10.1016/j.gie.2007.02.033
16. Teoh AYB, Cheung FKY, Hu B, Pan YM, Lai LH, Chiu PWY, et al. Randomized trial of endoscopic sphincterotomy with balloon dilation versus endoscopic sphincterotomy alone for removal of bile duct stones. *Gastroenterology.* 2013;144(2):341–345.e1. Doi: 10.1053/j.gastro.2012.10.027
17. Park SJ, Kim JH, Hwang JC, Kim HG, Lee DH, Jeong S, et al. Factors predictive of adverse events following endoscopic papillary large balloon dilation: results from a multicenter series. *Digestive Diseases and Sciences.* 2013;58(4):1100–9. Doi: 10.1007/s10620-012-2494-8
18. Paspatis GA, Konstantinidis K, Tribonias G, Voudoukis E, Tavernarakis A, Theodoropoulou A, et al. Sixty-versus thirty-seconds papillary balloon dilation after sphincterotomy for the treatment of large bile duct stones: a randomized controlled trial. *Digestive and Liver Disease.* 2013;45(4):301–4. Doi: 10.1016/j.dld.2012.10.015
19. Testoni P, Mariani A, Aabakken L, Arvanitakis M, Bories E, Costamagna G, et al. Papillary cannulation and sphincterotomy techniques at ERCP: European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline. *Endoscopy.* 2016;48(07):657–83. Doi: 10.1055/s-0042-108641
20. Dumonceau JM, Andriulli A, Elmunzer B, Mariani A, Meister T, Deviere J, et al. Prophylaxis of post-ERCP pancreatitis: European Society of Gastrointestinal Endoscopy (ESGE) Guideline – Updated June 2014. *Endoscopy.* 2014;46(09):799–815. Doi: 10.1055/s-0034-1377875
21. Carr-Locke DL. Difficult bile-duct stones: cut, dilate, or both? *Gastrointestinal Endoscopy.* 2008;67(7):1053–5. Doi: 10.1016/j.gie.2008.02.003
22. Oh CH, Dong SH. Recent advances in the management of difficult bile-duct stones: a focus on single-operator cholangioscopy-guided lithotripsy. *Korean Journal of Internal Medicine.* 2021;36(2):235–46. Doi: 10.3904/kjim.2020.425
23. Kuo CM, Chiu YC, Liang CM, Wu CK, Lu LS, Tai WC, et al. The efficacy of limited endoscopic sphincterotomy plus endoscopic papillary large balloon dilation for removal of large bile duct stones. *BMC Gastroenterol.* 2019;19(1):93. Doi: 10.1186/s12876-019-1017-x
24. Kogure H, Kawahata S, Mukai T, Doi S, Iwashita T, Ban T, et al. Multicenter randomized trial of endoscopic

papillary large balloon dilation without sphincterotomy versus endoscopic sphincterotomy for removal of bile duct stones: MARVELOUS trial. *Endoscopy*. 2020;52(09):736–44. Doi: 10.1055/a-1145-3377

- 25. Soliman GM, Bakr IS, Alwasif A. Comparative study between endoscopic papillary balloon dilation and endoscopic sphincterotomy for enlargement of papillary opening during endoscopic removal of common bile duct stones. *International Journal of Multidisciplinary Research and Development*. 2018; 5(4):55–60. Available from: <https://www.allsubjectjournal.com/assets/archives/2018/vol5issue4/5-3-27-103.pdf>
- 26. Sugiyama M. Does endoscopic sphincterotomy cause prolonged pancreatobiliary reflux? *The American Journal of Gastroenterology*. 1999;94(3):795–8. Doi: 10.1111/j.1572-0241.1999.00953.x
- 27. Mohammed HI, Nada ASE, Seddik RM, ElGazara AR. Combined endoscopic large balloon dilation with limited sphincterotomy versus sole sphincterotomy for removal of large or multiple common bile duct stones. *Egyptian Liver Journal*. 2023;13(1):1. Doi: <https://doi.org/10.1186/s43066-023-00235-1>
- 28. Liao W, Tu Y, Wu M, Wang H, Lin J, Leung JW, et al. Balloon dilation with adequate duration is safer than sphincterotomy for extracting bile duct stones: a systematic review and meta-analyses. *Clinical Gastroenterology and Hepatology*. 2012;10(10):1101–9. Doi: 10.1016/j.cgh.2012.05.017
- 29. Guo SB, Meng H, Duan ZJ, Li CY. Small sphincterotomy combined with endoscopic papillary large balloon dilation vs sphincterotomy alone for removal of common bile duct stones. *World J Gastroenterol*. 2014;20(47):17962–9. Doi: 10.3748/wjg.v20.i47.17962
- 30. Ishii S, Fujisawa T, Ushio M, Takahashi S, Yamagata W, Takasaki Y, et al. Evaluation of the safety and efficacy of minimal endoscopic sphincterotomy followed by papillary balloon dilation for the removal of common bile duct stones. *Saudi J Gastroenterol*. 2020;26(6):344–50. Doi: 10.4103/sjg.SJG_162_20
- 31. Sadeghi A, Dooghaie Moghadam A, Jamshidizade S, Norouzinia M, Jamshidfar N, Hosseini P. Comparison of endoscopic balloon dilatation potency using balloons size more or less than 15 mm in the treatment of large bile duct stones: a clinical trial study. *Gastroenterology and Hepatology from Bed to Bench*. 2021;14(Suppl1):S112–7. Doi: <https://doi.org/10.22037/ghfbb.vi.2288>