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Efficacy and Safety of Endoscopic Papillary Large Balloon Dilatation (EPLBD) for the Extraction of Common Bile Duct Stones

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ABSTRACT

Endoscopic Papillary Large Balloon Dilatation (EPLBD) is an endoscopic technique which combines limited endoscopic sphincterotomy followed by balloon dilation, leading to increased stone extraction rate with minimum complications of Endoscopic Biliary Sphincterotomy (EBS), Endoscopic Balloon Dilatation (EBD) alone and more advanced Mechanical (ML) and Laser Lithotripsy. **Objectives:** To evaluate the efficacy and safety of EPLBD procedure by using balloon size of 12-20 mm to remove difficult CBDS of ≥15mm. **Methods:** A total of 105 patients fulfilling the inclusion criteria underwent ERCP with EBS at the Endoscopy Department, Lahore General Hospital, Lahore. EPLBD was done with gradual balloon expansion from 12 to 20 mm till the disappearance of the waist under fluoroscopy. Technical success was recorded as complete stone removal. Patients were observed for 24 hours post-procedure for any complications. The data were processed on SPSS version 23.0. Descriptive statistics were employed to calculate means and standard deviation for age, size and number of stones, bilirubin level, CBD size and size of EPLBD in mm and time of balloon inflation in seconds. Success rate and complications were expressed in percentages. **Results:** Data of total 105 patients were collected. The mean age of patients was calculated to be 52.28 years, with female gender predominance (F=62, M=43). The average size of the balloon used was 15.32 ± 1.93mm. The overall success rate for stone extraction, irrespective of the number of sessions or the use of ML, was 95 (90.5%). Post EPLBD complications percentage was 7 (6.7%) (3.8% Bleed, 1.9% pancreatitis, 1% perforation). **Conclusion:** EPLBD is a safe and effective method for the removal of large bile duct stones of ≥15 mm.

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is the standard, often considered first-line treatment for CBDS [1]. It includes several techniques for this purpose, such as endoscopic biliary sphincterotomy (EBS), laser, mechanical lithotripsy or cholangioscopic assisted lithotripsy, endoscopic papillary balloon dilatation (EPBD) and endoscopic papillary large balloon dilatation (EPLBD) [2]. EBS is so far the most commonly practiced method for the removal of CBDS. However, this technique has certain procedural risks, such as perforation, ascending cholangitis, bleeding and recurrence of CBDS [3]. Lithotripsy is a stone fragmentation procedure which helps in the removal of large biliary or pancreatic stones by reducing their size after breaking them or by dislodging impacted stones [4]. Endoscopic papillary balloon dilation (EPBD) is used as an alternative to endoscopic sphincterotomy for the management of CBDS and was first reported by Staritz *et al.*, [5]. In this procedure, an endoscopist uses a balloon of less than 10mm in diameter to expand the ampullary orifice, without performing an endoscopic sphincterotomy. The main side effect of EPBD is an increased risk of pancreatitis. Furthermore, it is

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difficult to remove large stones of more than 15 mm as the papillary opening is small, for which wide EBS combined with Mechanical Lithotripsy (ML) is frequently required [6]. Ersoz *et al.*, described the technique of EPLBD to overcome these limitations in the management of difficult stones, including multiple or large-sized stones [7]. The success rate mentioned in the study was 95%. EPLBD is the procedural technique to dilate the biliary sphincter by using large-sized balloon ranging from 12 to 20mm in diameter after performing limited sphincterotomy. The length of sphincterotomy varies substantially between centers. However, mostly endoscopists, before performing large balloon dilation, do small or moderate size sphincterotomy up to the midpoint starting from the ampullary opening till the roof of the papilla; this way, they tend to reduce the bleeding risk usually linked with large sphincterotomy [8]. The preferred balloons for EPLBD are controlled radial expansion balloons (CRE) that provide gradual inflation. Although the preferred balloon size varies among studies but many suggest that the maximum balloon size should not be more than the size of the native distal common bile duct [9]. The balloon inflation is continued till the waist of the balloon disappears under fluoroscopic guidance. The balloon inflation time differs from 30 seconds to 2 minutes. During the balloon inflation, if the waist is persistent despite reaching 75% of its target pressure or continued resistance is experienced, further expansion of the balloon should be avoided and this way complications like perforation can be prevented [10]. Perforation, being the most feared complication, is commonly seen in patients with a distal CBD stricture. Therefore, it is important to carefully select candidates for EPLBD, likely those who have dilated CBD but without stricture [11]. Similarly, CBD diameter is a guide for balloon size, which should not exceed the maximum diameter of the bile duct. EPLBD is also an excellent option for the management of difficult CBDS and is considered as first line procedure in patients with periampullary diverticulum, cholangitis, coagulopathy or those who are not the candidate for wide EBS or EPBD for any other reasons, due to the small incision required in it, early procedure completion, reduced need for ML and the lower complications rate [12]. There is no increase in pancreatitis associated with EPLBD. The reason behind it is that the pancreatic opening gets separated from the biliary opening due to prior sphincterotomy, therefore dilated balloon is oriented towards the CBD, which leads to minimal pressure on the pancreatic duct [13]. The alternative explanation could be chronic bile duct stones, which eventually leads to a continuously open ampllary orifice and CBD dilatation. It has been suggested that duration of balloon dilatation or small sized CBD is most commonly linked with post procedure pancreatitis rather than large sized dilation balloon [14]. Bleeding is the most common adverse event of the procedure. However, one meta-analysis showed comparable incidence between EST and EPLBD [15]. Moreover, most bleeding episodes are either self-limiting or mild, which can easily be managed conservatively with either blood transfusion or endoscopic intervention. The incidence of cholangitis stays unchanged after EPLBD. This is because the ampullary orifice is wide open with excellent drainage after its dilation with a large balloon, thus preventing ampullary stenosis or edema in contrast to sphincterotomy stenosis seen in the EST group [16].

This study aims to evaluate the efficacy and safety of EPLBD by using a relatively large sized balloon (12-20 mm) for the extraction of difficult common bile duct stones. Moreover, post-EPLBD complications were also evaluated.

METHODS

This was a cross-sectional study carried out at the Endoscopy Department of Lahore General Hospital, Lahore, Pakistan, for 1 year and 7 months from October 2021 till May 2023. The study was started after approval of the Ethical Committee of Ameer ud Din Medical College/ Lahore General Hospital, Lahore (reference No. AMC/PGMI/LGH/Article/Research No/00/20/21). A total of 105 patients were included after informed consent from each participant. The initial sample size of 91 patients was determined for a 95% confidence level, a 93.7% success rate [12] and a 5% margin of error. To account for potential attrition, 105 patients were enrolled, providing an approximate 15% buffer to compensate for possible dropouts. Patients with a diagnosis of CBD stone based on patient history, clinical examination and abdominal Ultrasound/CT/ MRCP with dilated CBD (≥ 10 mm), large-sized stones (≥15 mm) or ≥3 bile duct stones were selected through a non-probability purposive sampling technique. Patients with CBD stricture and malignant obstructive jaundice were excluded from the study. All patients who met the selection criteria underwent an ERCP. The procedure was performed by an endoscopist who had performed >200 ERCPs independently. The size, number of stones and CBD diameter were calculated using the index diagnostic cholangiogram. EPLBD was performed by using a CRE balloon with diluted contrast. The balloon was slowly inflated to a diameter of 12-20 mm by using the corresponding pressure per square inch (PSI) for 30-120 seconds after the waist of the balloon disappeared. If the balloon waist was not resolved or an extensive narrowing was observed along the balloon, further increase in inflation pressure was avoided to prevent perforation. Patients were observed for 24 hours for post-ERCP complications such as hemorrhage, perforation, and pancreatitis. The technical success of EPLBD was defined as the clearance of CBD after removing all stones in the first stage, regardless of procedural time. However, if the patient had to undergo stenting, lithotripsy, another ERCP session or surgery, the procedure was labelled as a failure.

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Pancreatitis, cholangitis, hemorrhage and perforation were considered as complications, and they were defined as follows [10]. Pancreatitis: Development of new abdominal pain or worsening of already present pain along with a three-fold rise in serum amylase level ≥24 hours after ERCP. It was further graded based on severity by using the classification system mentioned in a report of an ASGE workshop [17]. Minimal: If abdominal pain lasts for 12-24 hours. Mild: Clinical pancreatitis requiring 1-3 days of treatment. Moderate: Requiring 4-10 days of treatment. Severe: Requiring more than ten days of medication, or percutaneous or surgical intervention. Cholangitis: Subtotal or complete obstruction of the biliary system, causing fever of a minimum 24-hour duration after ERCP. Hemorrhage: Bleeding causing hemoglobin drop of 2gm/dl that occurred during or immediately after ERCP. Perforation: Plain abdominal X-ray taken immediately after the procedure showing contrast or air outside the confines of the bile duct and duodenum. Data were entered and processed on SPSS version 23.0. Descriptive statistics were employed to calculate means and standard deviation for age, size and number of stones, bilirubin level, CBD size and size of EPLBD in mm and time of balloon inflation in seconds. Success and failure rates of CBD Stone removal were expressed in percentages. Similarly, complications like post-ERCP pancreatitis, Cholangitis, bleeding and mortality were expressed in percentages.

RESULTS

Data of 105 patients was collected. Pre-procedural descriptive statistics of patients' age, stone size, and balloon size are mentioned. According to the data, the mean age of patients was 52.28 ± 15.39 years, with female dominance (F=62 [59%], M=43 [41%]). The average size of the balloon used was 15.32 ± 1.938mm (Table 1).

Table 1: Descriptive Statistics for Age, Stone Size and Balloon Size (n=105)

Variables	Min	Max	Mean ± SD
Age (Years)	20	80	52.28 ± 15.394
Stone Size (mm)	15	33	17.10 ± 3.54
Balloon Size (mm)	12	20	15.32 ± 1.938

The frequency statistics of number of sessions, use of basket, risk factors, technical success and overall success of EPLBD and complications are mentioned. According to it, the basket was used in 09 (8.6%) patients regardless of the outcome of stone extraction. Stone extraction in 1st session without additional use of ML was possible in 90 (85.7%) patients. The overall stone extraction success rate, regardless of the number of sessions or use of ML, was 90.5% (95 out of 105 patients). The total complication rate was 7 (6.7%). Among complications, major and minor bleed was noted in 4 (3.8%), pancreatitis 2 (1.9%), and perforation 1(1%) of patients (Table 2).

Table 2: Clinical Factors and the Success Rate of EPLBD (n=105)

Variables	Frequency (%)
No of Sessions	
1	89 (84.8%)
2	14 (13.3%)
3	02 (1.9%)
Basket Used or Not	
Yes	09 (8.6%)
No	96 (91.4%)
Risk Factors (n=18)	
Cholangitis	05 (4.8%)
Periampullary Diverticulum	10 (9.6%)
Pre cut	03 (2.9%)
Technical Success of EPLBD	
Yes	90 (85.7%)
No	15 (14.3%)
Overall Success of EPLBD	
Yes	95 (90.5%)
No	10 (9.5%)
Complications (n=7)	
Minor Bleed	02 (1.9%)
Major Bleed	02 (1.9%)
Perforation	01 (1%)
Pancreatitis	02 (1.9%)

DISCUSSION

EST and EPBD are established techniques for removal of CBD stones via ERCP, especially for stones of small to moderate size (≤10mm). However, there are certain limitations of both procedures as far as the removal of difficult and large bile duct stones (≥15mm) is considered, for which both techniques require increased use of ML. Moreover, EPBD is linked with increased pancreatitis risk, and EST is considered to be the risk factor for bleeding, perforation and sphincter dysfunction. EPLBD is nowadays being considered for large CBD stones as it is thought to be safe and also reduces the need for ML use [18]. Current study was conducted on 105 patients to assess the efficacy of EPLBD by using a balloon size of 12 -20 mm (mean 15.32 ± 1.938). The technical success in terms of complete duct clearance in 1st session without the additional use of mechanical lithotripsy was achieved in 90 (85.7%) of patients. JA BB et al reported it to be 84.75% [19], showing results closer to our study. However, literature showed varied results from as low as 76% [20] to 98.3% [21]. The difference might be due to factors like sample size, shape of stones, distal CBD stricture and endoscopist expertise. The overall duct clearance in our study was 90 (90.5%). There was a literature review which reported it to vary between 94.4% to 100% [21, 22]. A study by Mohammed *et al.*, reported a 94% duct clearance rate, slightly higher than our results [23]. However, the mean stone size in their study was smaller (13.5mm) as compared to our study, where it was 17.10 mm ± 3.54mm (range: 15–33 mm).

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According to our study, EPLBD was not successful in 15 (14.3%) patients and among these, 10 (9.5%) patients could not get their duct cleared even after the use of ML or repeating the session. The main reason for failure was the very large size of the stone and the possibility of underlying distal stricture, which was evident only after failure of the balloon waist to disappear. Periampullary diverticulum was noted in 10 patients (9.5%). The failure of the procedure was observed only in 2 patients. In one patient, bleeding occurred that was managed by placing a metallic stent. In another patient stone size was >3cm, which was not retrieved even after the use of mechanical lithotripsy. Overall, patients with periampullary diverticulum can be effectively managed for large CBD stones by using EPLBD, as supported by the literature too [13]. EPLBD is an effective procedure for extraction of large bile duct stones but at the same time is linked with different side effects like bleeding, perforation and pancreatitis, rendering many endoscopists reluctant to use this. In our study, the overall complication rate was 7 (6.7%). A 10-year study by Urena *et al.*, reported it to be 10.38% [19]. One of the most feared complications of EPLBD is pancreatitis. Many proposed hypotheses explaining the underlying mechanism of post-ERCP pancreatitis are mentioned in the literature. According to the most famous one, a dilated balloon causes compression of the pancreatic duct, leading to its closure and ultimately an increase in PD pressure. This can be overcome by doing a small EST before EPLBD. Another common reason is multiple failed cannulation attempts, which can lead to mucosal edema and ultimately closure of the PD orifice [8]. In current study, pancreatitis was observed only in 2 patients (1.9%). It was of mild intensity and managed conservatively. Another common complication is bleeding. The incidence of bleeding reported in our study was 3.8% (n=4). These results were comparable to those reported in a literature review, showing it to be 3.5% (18). In our study, among 4 patients with bleeding, 2 patients had minor bleeds, which were controlled with injection of adrenaline or balloon tamponade. However, the other two required the placement of a fully covered self-expandable metallic stent (SEMS). Patients with cholangitis may have underlying coagulopathy. Therefore, literature favors EPLBD alone without endoscopic sphincterotomy in patients with coagulopathy, as the latter is mostly linked with bleeding [21]. Only one patient had a perforation in our study, which was managed by placing a fully covered SEMS.

CONCLUSIONS

It was concluded that EPLBD is a safe and effective technique for extracting common bile duct stones of size >15mm. Current study also supports it to be a preferred technique of stone removal in patients with anatomical variations like periampullary diverticulum and coagulopathy. Limited endoscopic sphincterotomy along with large balloon dilatation has overcome the complications linked with full size EST or EPBD alone like bleeding and pancreatitis respectively. However, more controlled studies from different centers are required to support our data.

Authors Contribution

Conceptualization: SR, MAF, MAH, AD, IUH, GUNT
Methodology: SR, MAF, MAH, AD, IUH
Formal analysis: MAH, GUNT
Writing review and editing: SR, MAF, MAH, AD, IUH
All authors have read and agreed to the published version of the manuscript

Conflicts of Interest

All the authors declare no conflict of interest.

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