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Research Article

Efficacy and Safety of Extracorporeal Shock Wave Lithotripsy (ESWL) for Difficult Common Bile Duct Stones: A Prospective North Indian Study

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Abstract

Background/aims: About 5%-10% of patients with common bile duct stones cannot be cleared with conventional endoscopic retrograde cholangiopancreaticography (ERCP). Alternative therapeutic options for these 'difficult stones' include surgery, intraductal laser lithotripsy and extracorporeal shock wave lithotripsy (ESWL). ESWL leading to stone fragmentation with subsequent endoscopic extraction of residual fragments is safe and effective alternative to surgery for difficult CBD stones. Our study was undertaken to investigate the efficacy and safety of ESWL in clearance of difficult bile duct calculi.

Methods: The study population consisted of 90 patients who had difficult bile duct stones documented on MRCP or ERCP and were subjected to ESWL sessions with or without placement of an endoscopic nasobiliary drainage (ENBD) till stone got fragmented. CBD clearance was attempted by ERCP and outcome was assessed by CBD clearance.

Results: 1926 patients underwent ERCP for choledocholithiasis during the study period. Out of them 150 patients were classified as difficult CBD calculi. 60 (40 %) patients opted for surgery and 90 (60 %) patients were enrolled for ESWL protocol. There were 35 males and 55 females. Mean age of the study population was 51.9± 17.1 years (range 22-75 years). CBD was cleared in 82 patients (91 %) and in 8 patients (9%) complete clearance of CBD could not be achieved and they needed surgery. We found that there was no statistically significant association with age, gender, stone size, stone number, CBD size, ESWL shocks, number of sessions and disease presentation.

Conclusions: ESWL is an effective and safe alternative method for clearance of difficult CBD calculi.

Keywords: Extracorporeal shock wave lithotripsy, Difficult common bile duct stones

Introduction

Endoscopic sphincterotomy first introduced in the 1970s has been an important intervention for the management of common bile duct (CBD) stones [1]. Conventional therapy involving sphincterotomy and stone extraction using a balloon catheter or Dormia basket clears between 80% and 90% of CBD stones [2-4]. Difficult bile duct stones were defined as stones larger than 15 mm in diameter and which could not be removed during ERCP including sphincterotomy, sphincteroplasty or mechanical lithotripsy. These usually include large stones (> 15 mm diameter) and/or impacted stones in patients with narrow distal CBD.

Mechanical lithotripsy is advocated for stones of a larger diameter [5], and failure is generally due to inability to grasp the large stones in the basket [6]. In approximately 10% of patients it is not possible to clear the bile duct stones using the above mentioned techniques [7,8]. Only 12% of these could be extracted by routine endoscopic techniques [9]. Balloon dilation of the papilla followed by extraction has been described as a good option for difficult bile duct stones [10-13]. Alternative therapeutic measures for these 'difficult stones' include medical dissolution [14], electro hydraulic lithotripsy [15], intraductal laser lithotripsy [16] and extracorporeal shock wave lithotripsy (ESWL).

Extracorporeal shock wave lithotripsy is a novel technique which uses shock waves to fragment calculi. This was first used successfully to fragment renal calculi [17]. Sauerbruch, et al. [8] demonstrated the efficacy of ESWL in achieving CBD stone disintegration in over 90% of patients with minimal side effects [8]. Besides in resource poor nations, the cost of setting up ESWL programme at a particular hospital can be shared with the urology departments.

The aim of the present study was to assess the efficacy of ESWL on fragmentation of large CBD stones not amenable to routine endoscopic procedures. The secondary aim of the study was to assess the factors that aid in fragmentation of the calculi and the associated complications.

Materials and Methods

Data source

This prospective study was conducted in the Department of Gastroenterology, Sheri-Kashmir Institute of Medical Sciences Soura and Superspeciality Hospital Srinagar, Kashmir, from June 2015 to December 2018. The study was started after obtaining informed consent from the enrolled patients and approval by the Institutional Ethical Committee.

Study population

During this period 1926 patients underwent ERCP for choledocholithiasis. Out of them 150 patients were classified as difficult CBD calculi. Sixty (40%) patients opted for surgery and ninety (60%) patients were enrolled for ESWL protocol. It was based upon the patient preference after explaining the merits and demerits of both the procedures. Secondly whether patient had previously undergone cholecystectomy or not. Thirdly the associated comorbidities and fitness for the surgery were taken into consideration.

Endoscopic Nasobiliary Drainage Tube (ENBD) was deployed in the patients with difficult CBD stones on ERCP and was followed by ESWL using a 3rd generation lithotripter, which uses electromagnetic shock waves as a source of energy (Delta Compact, Dornier Medtech, Wessling, Germany) giving shock waves at the rate of 90/min. 4000 to 5000 shock waves were given per session. Procedure was carried out in the supine position under epidural anesthesia. Repeat ESWL sessions were done on consecutive days till satisfactory fragmentation i.e when the calculi were broken down to less than 5 mm diameter. Number of sessions needed was determined by size, number and nature of stones. After ESWL patients were taken for ERCP and bile duct clearance.

We excluded pregnancy and severe irreversible coagulopathy before enrolling patients.

Definitions used

Complete CBD clearance: fragmentation of CBD calculi to < 5

mm size and clearance of the bile duct using a balloon or basket.

Partial clearance: fragmentation of calculi to 5 mm or more and clearance of > 50% of the stone volume. Use of an additional device such as mechanical lithotripter is required to clear the large fragments.

Failure of clearance: Patients who did not achieve CBD clearance after ESWL and endoscopic extraction attempts.

Study outcomes and variables

The primary objective of the study was to assess the efficacy of ESWL for clearance of difficult CBD stones. The secondary outcomes were the factors promoting the stone fragmentation and the complications associated with ESWL.

Statistical analysis

It was a prospective, hospital based study. Data analysis was performed using the IBM SPSS version 22.Continuous variables are expressed as mean ± standard deviation, whereas categorical variables are shown as numbers and percentages. For Univariate analysis, a Chi-square test or Student's t-test was used when appropriate. And for multivariate analysis, logistic regression was used. $P < 0.05$ was regarded as statistically significant.

Results

Demographics

A total of 1926 patients underwent ERCP for choledocholithiasis from June 2015 to December 2018.150 patients were having difficult CBD calculi. 60 (40%) patients opted for surgery and 90 (60%) patients were enrolled for ESWL protocol. Mean age of the study population was 51.9 ± 17.1 years (range 22-75 years).35 patients (39%) were males and 55 patients (61 %) were females.63 (70%) patients presented with biliary pain followed by recurrent pyogenic cholangitis in 18(20%) patients and 9(10%) patients were asymptomatic.

Stone number in CBD ranged from single to multiple (>2) with mean 2.5 stones. The stone size ranged from12-30 mm with mean 18 mm. Majority of patients 56 patients (68.2%) had stone size greater than 2 cm. We found no correlation between number of stones and bile duct clearance. 40 patients (44.4%) had 1 stone, 32 patients (35.5%) had 2 stones and 18 patients (20%) had multiple stones.

Mean CBD diameter was 18.38 ± 5.48 mm. Maximum patients 52 (57.7%) had CBD diameter in range of 10-20mm. Mean stone number was 1.45 ± 0 (Table 1).

Mean ESWL shocks needed were 8295.4 ± 3212. Majority of patients 50 (50%) needed ESWL shocks in range of 7000-12000 and only 4 patient (2%) needed ESWL shocks more than 15000. Mean number of ESWL sessions were 2 ± 0.75.We found in our study that patients who achieved maximum bile duct clearance received only two ESWL sessions. 44 patients (48.8%) received 2 sessions, 10 patients (11.1%) received 1 session and 24 patients (26.6%) received 3 sessions. There was no statistically significant correlation between number of sessions and bile duct clearance (Table 2).

CBD was cleared in 82 patients (91%) and 8 patients (9%) failure of complete clearance and needed surgery. Maximum patients 58 (70.74%) needed only one session of ERCP for CBD clearance, 18 patients (21.96%) needed 2 sessions and 6 patients (7.3%) needed 3 sessions.

CBD could not be cleared in 8 patients (8.8%) either because of recurrence of stones because of OCH in 6 patients (6.6%) or because of difficult duodenal anatomy like pulled up papilla in 2 patients (2.2%) (Table 3).

Complications

There was no post-procedure complication in majority of the patients (84.4%). Complications occurred in 20 patients (22.2%). Major complications were echymosis which occurred in 12patients (13.3%) abdominal pain in 3 patients (3.3%), mild pancreatitis in 2 patients (2.2%), hemobilia in 3 patients (3.3%). Majority of patients had only one complication but 5 patients developed two complications including Hemobilia and echymosis in three patients and abdominal pain and hemobilia in two patients.

Discussion

About 90–95% of bile duct stones are amenable to endoscopic extraction after EST using Dormia basket or a balloon extraction and mechanical lithotripsy. For the remainder 5–10% of the cases in which the anatomical conditions, size or location of the stone, do not allow for its removal, techniques have been developed which allow for the fragmentation through shock waves both internally (using electrohydraulic lithotripsy or laser) or externally through ESWL. The choice of treatment technique depends to a

Table 1: Baseline characteristics: patient, stones, and bile duct.

		Frequency	Percentage
Age (years) mean ± SD.		51.9 ± 17.1	
Gender (Male: Female)		35:55	39 : 61
Symptomatology	Biliarypain	63	70%
	Asymptomatic	9	10%
	Recurrent pyogenic cholangitis	18	20%
Size of stones (mm)	11-20 mm	34	37.7%
	21-30 mm	49	54.4%
	>30 mm	7	7.7 %
Stone number (s)	1 stone	40	44.4%
	2 stone	32	35.5%
	Multiple	18	20%
CBD diameter (mm)	11-20 mm	60	66.6%
	21-30 mm	23	25.5%
	>30 mm	7	7.7 %
Location of stones	CBD	70	77.7%
	Hilum	6	6.6%
	CBD+ hilum	14	15.5%

Table 2: ESWL Characteristics.

		No.	% Age
No. of ESWL sessions	One	10	11.1%
	Two	44	48.8%
	Three	24	26.6%
	Four	12	13.3%
No. of ESWL shocks	2000-7000	18	20%
	7001-12000	50	55.5%
	12001-15000	18	20%
	>15000	4	4.4%

large extent on experience and local equipment availability, since such techniques have all shown equal efficacy [19,20].

Extracorporeal shockwave lithotripsy (ESWL) with subsequent endoscopic extraction of residual fragments is an established treatment option if other endoscopic means are not successful. CBD stone fragmentation rates leading to final ductal clearance rates of 71% to 95% have been reported with ESWL [18].

In this study, we are reporting our four years experience in the treatment of ninety patients with difficult CBD Stones managed with ESWL in a high volume tertiary care centre in Northern In-

Table 3: CBD clearance rates and causes of treatment failure.

Outcome		No. of patients	Percentage
Complete clearance	1 ERCPsession	58	70.74%
	2 ERCPsessions	18	21.96%
	3 ERCPsessions	6	7.3%
	Total	82	100.00%
Failure	Recurrence/OCH	6	75.0%
	Pulled up papilla (post D1ulcer sequelae)	2	25.0%
	Total	8	100.0%

dia.

We achieved bile duct clearance in 82 patients out of 90 patients with ductal clearance rate of 91% which is slightly higher as compared to other studies which may be due to soft nature of stones in our patient population because increased prevalence of oriental choangiohepatitis in our population. In addition, all the procedures were done under regional (epidural) anesthesia which may have minimized patient movements and hence better focusing. Majority of the ESWL sessions were performed with simultaneous saline irrigation via ENBD tube which has also been identified a factor which increases clearance rates.

Tandan M, et al. [21] achieved complete CBD clearance in 84.4% patients with large CBD stones were subjected to ESWL. Cecinato P, et al. [12] and Sauerbruch, et al. [2] reported a CBD clearance rate of 89.0% and 76%respectively. Improvements in the ESWL machine kinetics might be responsible for higher clearance rates compared to the study of Sauerbruch, et al. [2].

In our study in 8 patients (8.8%) CBD could not be cleared and all patients underwent surgical intervention. Failure rate of our study was less as compared to other studies which may be due to less number of patients, good analgesia, and use of third generation lithotripter. Tandan M, et al. [8] reported a failure rate of 15%. Cecinato P, et al. [12] in 2012 reported a failure rate of 11%.

Ductal clearance was slightly more in patients with singe stone than multiple stones but was not statistically significant. 40 patients (44.4%) had 1 stone, 32 patients (35.5%) had 2 stones, and 18 patients (20%) had multiple stones. We found no statistically significant correlation between bile duct clearance and age, gender, presentation, number of stones, stone size, number of ESWL shocks, number of sessions, bile duct diameter. Sauerbruch, et al. [2] also found that location and number of stones had no significant influence on the success rate. In a study conducted by Amplatz S, et al. [22] in 2005 on 376 patients found no statistical relevant differences between the group of patients who underwent successful ESWL and those who did not, as far as number of stones, maximum diameter of the largest stone, location of the stones (intra–extrahepatic), age and sex . Only bile duct stenosis has shown to be a limiting factor in the successful treatment with ESWL ($p < 0.01$).

We found in our study that patients in whom bile duct clearance was achieved, majority (55.5%) of patients received ESWL shocks in range of 7000-12000 and in 44patients (48.8%) bile duct was cleared after 2 sessions followed by 10 patients (11.1%) by 1 session and 24 patients (26.6%) by 3 sessions, there was no statistically significant correlation between number of sessions and bile duct clearance. In majority of our patients CBD was cleared after mean of 2 sessions and mean shocks of 8295 which was slightly higher than other studies and may be due to less mean size of stones. In addition OCH is seen quite commonly in our region and stones are less harder and easily fragmentation leading to lesser number of required.

In a study done by Sauerbruch, et al. [2] in 1987 on 113 patients with difficult choledocholithiasis treated with ESWL. Ninety-five

patients (84%) received only one ESWL session. In 16 (14%) two sessions with a median time interval of 8 days [range 2-63 days) were performed. Muratori R, et al. [13] in 2010 conducted a study on 214 patients who underwent ESWL, the mean number of sessions and shock waves were 3.5 ± 0.13 and 3477.06 ± 66.17, respectively.

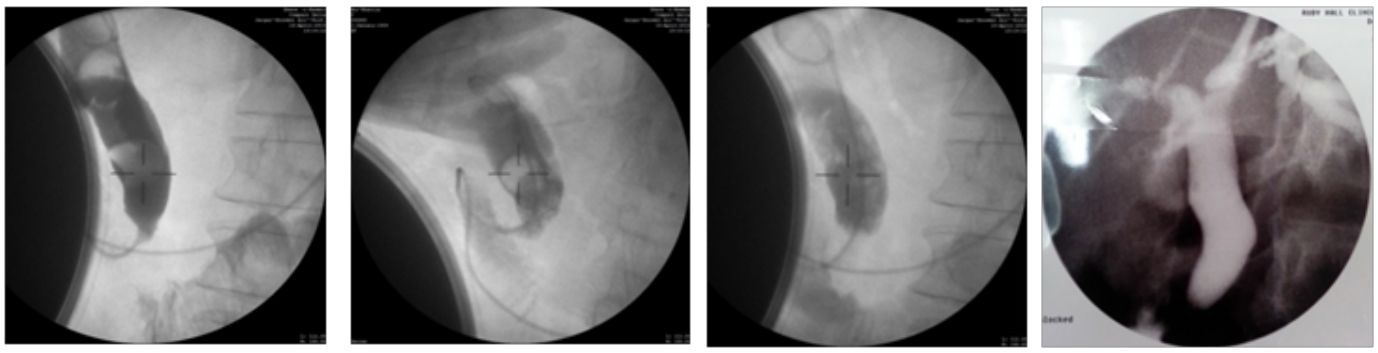
In our study 82 patients achieved bile duct clearance, out of them 60 patients (66.6%) had bile duct diameter in range of 11-20 mm and there was no statistically significant difference between bile duct diameter and bile duct clearance. Similarly disease presentation also had no statistically significant effect on bile duct clearance. In a study done by Cecinato P, et al. [12] in 2012, CBD clearance was achieved in 349 patients (89.0%).The multivariate analysis did not identify any factors influencing the CBD clearance. Age, gender, single or multiple stones, stone diameter, number of ESWL sessions, number of shock waves administered, and type of lithotripter used were not independently related to the CBD clearance.

Epidural anesthesia, shock frequency of 90/min, radiolucent calculi and presence of fluid around the calculus helped in better fragmentation are the factors which have been found to correlate with the CBD clearance in ESWL by Tandan, et al. [14].

In our study post procedure complications occurred in 20 patients (22.2%). Commonly observed complication were echymosis in 12 patients (13.3%) abdominal pain in 3 patients (3.3%), pancreatitis in 2 patients (2.2%), hemobilia in 3 patients (3.3%). In a study by Tandan, et al. [14] in 2009 on 283 patients with large CBD stones who were subjected to ESWL, complications were seen in 45 (15.90%) patients and were mostly mild with no serious consequences. Thirty-four (12.01%) had mild haemobilia. Eleven (3.88%) patients had cholangitis after ESWL, which resolved with antibiotic therapy. Purpuric spots were seen on the skin in 21% of patients at the site of contact with the ESWL coupling unit. Cecinato, P et al. [12] observed complications 9.4% cases, 3 patients reported vomiting, 9 patients had transient palpitations 13 patients had bradycardia. One case of hemobilia and 1 case of lower GI bleeding. In addition Amplatz S, et al. [22] experienced complications like symptomatic cardiac arrhythmia, haemobilia, cholangitis, haematuria, dyspnea.

Although the adverse events in ESWL are mostly mild in severity but serious adverse events, such as necrotizing pancreatitis, cholangitis, perirenal hematoma, bowel perforation, splenic rupture, and death, have also been described [10,27,28]. But with the availability of third generation lithotripter machines and improvement in stone focusing and near zero patient movements have greatly reduced the incidence of adverse events, particularly the incidence of serious adverse events (Figure 1).

In resource limited countries like ours ESWL offers a safe, effective and cost-effective alternative for managing these patients. Firstly ESWL set-up can be used by different medical staff like urology



Before ESWL	After one session of ESWL	Post-ESWL Fragmented stones mimic sludge	Clear CBD

Figure 1: Cholangiogram showing steps in ESWL clearance.

and orthopedics in the same hospital thus reducing management costs. Secondly laser lithotripsy require a more invasive approach, including the use of a choledochoscope for direct visualization of the stones making it more complicated and requires more expensive equipment and expertise.

Conclusion

We found in our study that ESWL is highly effective in clearing difficult CBD stones. The rate of clearance is independent of age, gender, number of stones, size of stones, number of ESWL sessions and number of shocks. ESWL can be used as first-line treatment modality in this group of patients. Besides ESWL has been found to have good safety profile.

Conflicts of Interest

The authors have no financial conflicts of interest.

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