

Extracorporeal Shock Wave Lithotripsy for Large Common Bile Duct and Pancreatic Duct Stones: Efficacy, Safety and Analysis of Factors That Favor Stone Fragmentation

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Abstract

Background Extracorporeal shockwave lithotripsy (ESWL) with subsequent endoscopic extraction of residual fragments is an established treatment option in technically challenging situations for extraction of pancreatic and common bile duct calculi. Common bile duct (CBD) stone fragmentation rates of 71 to 95% have been reported with ESWL, leading to final duct clearance rates of 70 to 90%. While complete clearance of 76% and partial clearance of 17% of pancreatic duct calculi have been documented with ESWL, our study was undertaken to investigate the efficacy and safety of ESWL in clearance of difficult bile duct and large pancreatic duct calculi.

Methods The study population consisted of 61 patients who had either large or difficult bile duct calculi or large pancreatic duct calculi documented on ultrasonography abdomen or magnetic resonance cholangiopancreatography (MRCP). All patients were subjected to ESWL sessions with endoscopic nasobiliary drainage (ENBD) placement till stones got fragmented.

Results A total of 1,284 patients underwent ERCP for either choledocholithiasis or pancreatic duct calculi during the study period (June 2015 to December 2016). Out of them 61 patients had either large or difficult CBD calculi or large pancreatic duct calculi. Forty (65.57%) had choledocholithiasis (Group-A) and 21 (34.42%) had chronic calcific pancreatitis (Group-B). CBD was cleared in 37 patients (92.5%) and 3 patients (7.5%) underwent surgical intervention. Main pancreatic duct (MPD) was cleared in all patients with clearance rate of 100%.

Conclusions ESWL is an effective and safe method for clearance of difficult CBD and pancreatic duct calculi. Combined efficacy of duct clearance is >90%. Complications are minimal and managed conservatively.

Keywords

- Common bile duct
- Extracorporeal shock wave lithotripsy
- Main pancreatic duct

Introduction

Between 80% and 90% of common bile duct (CBD) stones can be extracted by sphincterotomy and stone extraction using a balloon catheter or Dormia basket.¹⁻⁴ Mechanical lithotripsy is advocated for stones of a larger diameter, and failure is generally due to inability to grasp the large stones in the

basket.^{5,6} In approximately 10% of patients it is not possible to clear the bile duct stones using the above-mentioned techniques.^{7,8} Stones bigger than 15 mm in size are considered as large CBD stones. Only 12% of these could be extracted by routine endoscopic techniques.⁹ This is mostly due to a difficult anatomy, large size of the calculus, or impaction of the stone in the CBD. 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 electrohydraulic lithotripsy, intraductal laser lithotripsy, and extracorporeal shock wave lithotripsy.¹⁴⁻¹⁶ Extracorporeal shock wave lithotripsy (ESWL) is a novel technique which uses shock waves to fragment calculi. This was first used successfully to fragment renal calculi.¹⁷ The third generation lithotripter uses electromagnetic generator and focus shock waves to smaller zones, thus minimizing damage to surrounding soft tissue. First generation lithotripter was based on electrohydraulic shock wave generator; the shock waves were focused via an ellipsoid metal water-filled tub in which both the patient and the generator were submerged. Second generation lithotripters use piezoelectric or electromagnetic generators as energy source. It is coupled with a focusing device to concentrate shockwaves on smaller focal zone. Intraductal lasers used for bile duct stones include pulsed solid-state lasers (q-switched neodymium YAG, alexandrite, and holmium YAG lasers) or flashlamp-pumped pulsed dye lasers (coumarin dye and rhodamine-6G lasers). Single operator cholangioscopy is the most convenient approach for effective biliary laser lithotripsy.

Approximately 50% of patients with chronic pancreatitis (CP) have developed pancreatic stones. Removal of the pancreatic duct stones with ERCP alone is often unsuccessful; thus, pancreatic extracorporeal shock wave lithotripsy (P-ESWL), an effective and safe micro minimally invasive method is needed to facilitate stone clearance and improve the success rate of MPD drainage via ERCP.¹⁸ Pancreatic duct stones develop during the natural course of longstanding chronic pancreatitis and are observed in 50% to 90% of patients during long-term follow-up.¹⁹ Majority of pancreatic calculi are radio opaque while a few are radiolucent or mixed.²⁰ Pain remains the commonest and the most distressing of symptoms associated with CCP. Relief of pain is the most important goal of therapy in patients with CCP. Surgical decompression of the main pancreatic duct (MPD) with clearance of calculi leads to relief of pain in most patients.²¹ Ductal decompression can also be achieved by endoscopic techniques. Endoscopy and surgery are complimentary forms of therapy for relief of pain in patients with chronic calcific pancreatitis (CCP) Small pancreatic ductal calculi can be extracted using a basket after an endoscopic pancreatic sphincterotomy. This technique may not be successful for large stones in the MPD. The problem can be overcome by fragmenting the calculi.²² Extracorporeal shock wave lithotripsy (ESWL) is an established modality in the management of large pancreatic ductal calculi.²³ The aim of the present study was to assess the efficacy of ESWL on fragmentation of large CBD and pancreatic duct stones not amenable to routine endoscopic procedures.

Methods

Study Design

The study was conducted in the department of Gastroenterology at Sheri-Kashmir Institute of Medical Sciences, from June 2015 to December 2016. It was a prospective study and involved patients of difficult bile duct and large pancreatic

duct calculi. The study was approved by the institutional ethical committee. All patients of biliary calculi and pancreatic duct calculi who attended the outpatient department or were admitted in the hospital were screened. Informed consent was obtained from all patients. The patients who had difficult biliary calculi or large pancreatic duct calculi on ultrasonography (USG), MRCP, or ERCP were enrolled in the study to receive ESWL for fragmentation of calculi and subsequent clearance by ERCP. Inclusion criteria involved all patients with difficult CBD stones which includes stones (>15 mm diameter); impacted stones in patients with narrow distal CBD and/or difficult anatomy; and all patients with large pancreatic duct stones (>5 mm) in head or body region.

All patients were subjected to USG abdomen followed by either MRCP or ERCP. The patients who had definite stone in CBD and /or common hepatic duct on USG were subjected to ERCP directly. MRCP was performed in patients who had doubtful calculi or biliary tree was not properly visualized on USG abdomen. All patients with biliary calculi on USG abdomen or MRCP were subjected to ERCP. Endoscopic Nasobiliary Drainage Tube (ENBD) was deployed in the patients with large or difficult CBD stones followed by ESWL for stone disintegration. The patients who had pancreatic duct stones in head and body region were taken first for MRCP followed by ESWL for stone disintegration followed by ERP for main pancreatic duct clearance and/or stent deployment if needed. ESWL was performed under local anesthesia using epidural catheter. Bupivacaine 0.25% was used to block the segments D6 to D12. DORNIER COMPACT DELTA II ESWL (Munich, Germany) machine was used for giving shock waves at the rate of 90/min and per session 4,000 to 5,000 shock waves were given. Number of sessions needed was determined by size, number, and nature of stones. Usually three to four sessions were needed to crush the stones. After ESWL patients were taken for ERCP to clear CBD or MPD. PD stent was deployed if needed and was removed after 3 months. Patients in whom we could not clear CBD/ PD calculi were referred for surgical intervention. Pain relief after clearance of PD calculi with ESWL was assessed in terms of improvement on visual analog scale and need for analgesia.

End Points

1. Evaluate the role of ESWL in the clearance of difficult CBD and large pancreatic duct calculi.
2. Evaluate the effect of ESWL on pain management in chronic pancreatitis patients.
3. Secondary outcome: Identify factors that promote stone fragmentation and assessment of complications, morbidity, and mortality associated with fragmentation of CBD and MPD calculi using a third-generation lithotripter.

Statistical Analysis

Data analysis was performed using the IBM (Statistical software USA) SPSS version 22.

Difficult CBD stones were defined as stones that could not be extracted by ERCP with sphincterotomy, Dormia basket,

and/or balloon catheter. Stone fragmentation was defined as the rupture of stones because of ESWL treatment, as fluoroscopically documented. CBD/ PD clearance was defined as complete stone removal after ESWL sessions followed by ERCP. Patients who did not achieve CBD/PD clearance after five sessions of ESWL and endoscopic extraction attempts were considered treatment failures.

Results

A total of 1,284 patients underwent ERCP for either choledocholithiasis or pancreatic duct calculi during study period. Out of them 61 patients had either large or difficult bile duct calculi or large pancreatic duct calculi. Forty patients had choledocholithiasis and were labeled as group A and 21 patients were suffering from chronic calcific pancreatitis with calculi in MPD and were labeled as group B.

Group A—Choledocholithiasis

This group constituted 40 patients with age range from 22 to 75 years and mean age of 51.9 ± 17.1 years. Fourteen patients (35%) were males and 26 patients (65%) were females. Twenty-eight (70%) patients presented with biliary pain followed by nonsuppurative cholangitis in 8 (20%) patients and suppurative cholangitis in 4 (10%) patients (1). CBD diameter ranged from 8 to 30 mm with mean 18.3 mm. Stone number in CBD ranged from 1 to 4 with 26 patients (65%) who had 1 stone, 8 patients (20%) who had 2 stones, 2 patients (5%) who had 3 stones, and 1 patient (2.5%) who had 4 stones. Mean ESWL shocks needed were 8295.4 ± 3212 . Majority of patients (20 [50%]) needed ESWL shocks in range of 7,000 to 12,000 and only 1 patient (2%) needed ESWL shocks more than 15,000. Thirteen patients (32.5%) received shocks in range of 2,000 to 7,000, 19 patients (47.5%) received ESWL shocks in range of 7,000 to 12,000, 4 patients (10%) received 12,001 to 15,000 shocks, and only 1 patient (2.5%) received more than 15,000 shocks (► Fig. 1). Seventeen patients (42.5%) received 2 sessions, 10 patients (25%) received 1 session, and 10 patients (25%) received 3 sessions. Dilated CBD was seen in majority of patients, maximum patients 17 (42.5%) had CBD diameter in range of 16 to 20 mm. CBD was cleared in 37 patients

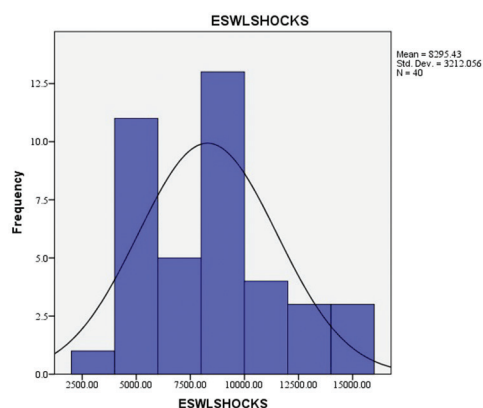


Fig. 1 (Group A-Choledocholithiasis) - Mean ESWL shocks needed were 8295.4 ± 3212 . Majority of patients 20 (50%) needed ESWL shocks in range of 7000-12000 and only 1 patient (2%) needed ESWL shocks more than 15000.

(92.5%) and only in 3 patients (7.5%) CBD could not be cleared and all three patients had undergone surgical intervention. We found no statistically significant correlation between bile duct clearance and age, gender, clinical presentation, number of stones, size of stones, bile duct diameter, number of ESWL sessions, and number of shocks.

Complications

Group A: Complication occurred in nine patients (22.5%), echymosis occurred in four patients (10%), abdominal pain in one patient (2.5%), pancreatitis in one patient (2.5%), and hemobilia in one patient (2.5%). Majority of patients had only one complication but two patients developed two complications including hematemesis and echymosis in first patient and abdominal pain and hemobilia in second patient (► Fig. 2).

Group B—Chronic Pancreatitis

This group constituted 21 patients with age range from 21 to 55 years and mean age of 40.76 ± 9.63 years. Out of 21 patients, 5 patients (24%) were males and 16 patients (76%) were females. Seven patients (33.3%) were diabetic and 14 patients (66.6%) were nondiabetic. Mean stone size was $7.38 \text{ mm} \pm 3.5 \text{ mm}$. Mean ESWL shocks needed for pancreatic clearance was $7,903.33 \pm 4830$ (► Fig. 3). Fourteen patients (66.6%) had multiple MPD stones, three patients (14.2%) had two stones, and four patients (19%) had one stone. Mean stone size was 7.38 ± 3.51 . Out of 21 patients, 10 patients (47.6%) had stone size in the range of 5 to 10 mm, 6 patients (28.6%) 11 to 15 mm, and 5 patients (23.8%) greater than 15 mm. Out of 21 patients, 7 patients needed 1 ESWL session, 7 patients needed 2 sessions, 6 patients needed 3 sessions, and only 1 patient needed 5 sessions. Mean ESWL shocks needed for pancreatic clearance was $7,903.33 \pm 4,830$. Out of 21 patients 12 patients (57.1%) needed 2,000 to 7,000 shocks, 5 patients (23.8%) needed 7,001 to 12,000 shocks, 3 patients (14.2%) needed 12,001 to 15,000 shocks, and only 1 patient

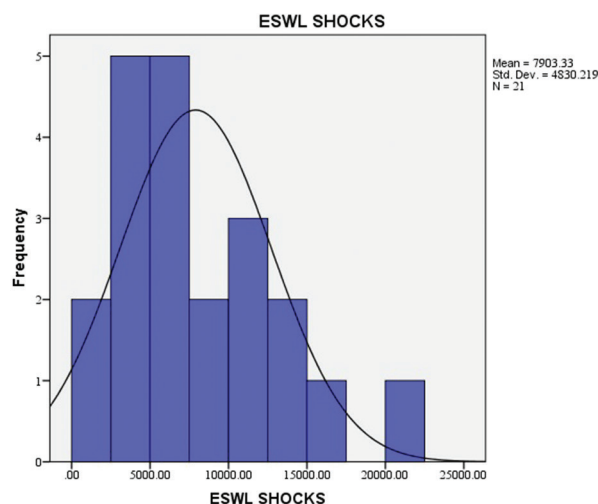


Fig. 2 (Group A-Choledocholithiasis) - There was no post procedure complication in 31 patients (77.5%). Complication occurred in 9 patients (22.5%). Major complication were echymosis which occurred in 4 patients (10%) abdominal pain in 1 patient (2.5%), pancreatitis in 1 patient (2.5%), hemobilia in 1 patient (2.5%).

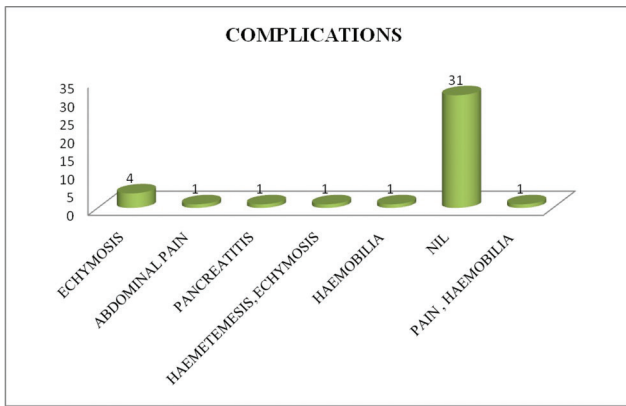


Fig. 3 (Group B - Chronic Pancreatitis)- Mean ESWL shocks needed for pancreatic clearance was 7903.33±4830.

(4%) needed more than 15,000 shocks. Eight patients (38.1%) had pancreatic duct diameter 5 to 10 mm, 8 patients (38.1%) had pancreatic duct diameter 11 to 15 mm, and 5 patients (23.8%) had pancreatic duct diameter greater than 15 mm. Main pancreatic duct was cleared in all 21 patients (100%) and only 1 patient (4%) developed recurrent stones in main pancreatic duct after follow-up of 18 months. Six patients (28.5%) had a stricture in main pancreatic duct on ERCP and all these patients were put on plastic pancreatic duct stent which was removed after 3 months. 71.4% patients of chronic pancreatitis had complete pain relief, while 14.2% patients had some improvement in pain and 14.2% of patients had no relief of pain. In our study we found that there is no statistically significant correlation between pancreatic duct clearance and age, gender, pancreatic duct diameter, stone size, stone number, number of ESWL shocks, and number of ESWL sessions. Complications

Group B: postprocedure complications occurred in five patients (23.8%) and most common complication was abdominal pain in two patients (9.5%) followed by echymosis in one patient (4.7%), bradycardia in one patient (4.7%), and vomiting in one (4.7%) patient (→ Fig. 4).

Discussion

Bile Duct Stones

About 90 to 95% of bile duct stones are amenable to endoscopic extraction after EST using a Dormia basket or a

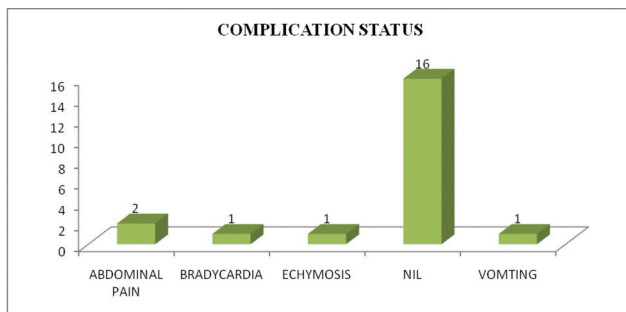


Fig. 4 (Group B - Chronic Pancreatitis) - Post procedure complications occurred in 5 patients (23.8%) and most common complication was abdominal pain in 2 patients (9.5%) followed by echymosis in 1 patient (4.7%), bradycardia in 1 patient (4.7%) and vomiting in 1 patient (4.7%).

balloon catheter and eventually mechanical lithotripsy. For the remainder 5 to 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 electro hydraulic lithotripsy or laser) or externally through ESWL. The choice of treatment technique depends to a large extent on experience and local equipment availability, since such techniques have all shown equal efficacy. ESWL with subsequent endoscopic extraction of residual fragments is an established treatment option if other endoscopic means are not successful. CBD stone fragmentation rates of 71 to 95% have been reported with ESWL, leading to final duct clearance rates of 70 to 90%. In this study, we are reporting our 1.5 years' experience in the treatment with ESWL of 61 patients with difficult CBD or large pancreatic duct stones conducted from June 2015 to December 2016.

Our results suggest that ESWL is a safe, well-tolerated, and effective technique for the treatment of difficult bile duct stones. A study conducted by Ellis et al showed that 69 (83%) of patients achieved complete CBD clearance and 75% of patients required more than one ESWL sessions.⁴ Tandan et al recruited 283 patients with CBD calculi and used ESWL with ERCP for CBD clearance. They achieved complete CBD clearance in 84.4% and partial CBD clearance in 12.3% of patients.²⁴ We achieved bile duct clearance in 37 patients out of 40 patients with clearance rate of 92.5%, which is slightly higher as compared with other studies which may be due to less number of patients or soft nature of stones in our patient population because increased prevalence of recurrent pyogenic cholangitis in our population. Out of them 26 patients had 1 stone, 8 patients had 2 stones, 2 patients had 3 stones, and 1 patient had 4 stones; only in 3 patients, CBD could not be cleared and all 3 patients had undergone surgical intervention. 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, and bile duct diameter. In our study only in 3 patients (7.5%) CBD could not be cleared and all three patients had undergone surgical intervention because of associated gallstones. Failure rate of our study was less as compared with other studies which may be due to less number of patients, good analgesia, and use of third-generation lithotripter.

In our study post procedure complications occurred in 9 patients (22.5%), which is slightly higher than in other studies. It may be due to less number of patients and learning curve of the procedure. Majority of our patients had only one complication but two patients developed two complications including hematemesis and ecchymosis in first patient and abdominal pain and hemobilia in second patient.

Pancreatic Duct Stones

Zhang et al recruited 12 patients in their study; 75% had complete PD clearance after ESWL.¹⁹ Tandan et al had the largest number of patients with PD calculi. Out of 1,006 patients, 76% had complete PD clearance and 17% had partial PD clearance after ESWL.²⁴ Out of 61 patients enrolled in our study,

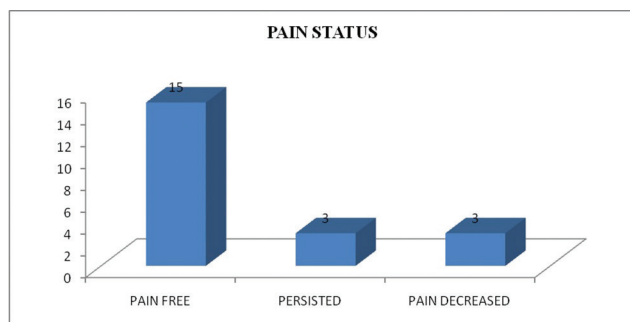


Fig. 5 Pain relief after extra corporeal shock wave lithotripsy for pancreatic duct calculi.

21 patients had chronic calcific pancreatitis with dilated MPD and stones in body and head region. Pancreatic duct clearance was achieved in all 21 patients with duct clearance rate of 100%, which is higher than in above-mentioned studies. It may be due to less number of patients in our study and use of third-generation of lithotripters and use of epidural analgesia in all patients. In only 1 patient (4%) recurrence of stones occurred and in 6 patients (28.5%) there was a stricture in main pancreatic duct on ERCP and all these patients were put on pancreatic duct stent which was removed after 3 months. We found no statistically significant correlation between pancreatic duct clearance and age, gender, pancreatic duct diameter, stone size, stone number, number of ESWL shocks, and number of ESWL sessions. In our study patients were followed-up over a period of one and half years and were assessed for pain status. The study conducted by Zhang et al¹⁹ showed 75% of patients had complete pain relief and 16.7% patients had partial pain relief after ESWL for PD calculi. While the study by Tandan et al²⁴ revealed complete pain relief in 84.4% and partial pain relief in 12.3% patients after ESWL. We found that in majority of patients 15 (71.4%), there was complete pain relief and in 3 patients (14.2%) there was some improvement in pain and in other 3 patients (14.2%) pain persisted (►Fig. 5).

Conclusion

ESWL is an effective and safe treatment which improves the outcome of biliary and pancreatic duct stones. Clearance of difficult and large CBD calculi with duct clearance rate of more than 92.5% and pancreatic duct calculi with duct clearance rate of 100% can be achieved. Major complications included pancreatitis (2.5%) and hemobilia (2.5%) in Group A. Pain in the abdomen in 9.5% and echymosis in 4.7% occurred in Group B. 71.4% patients of chronic pancreatitis had complete pain relief, while 14.2% patients had some improvement in pain and 14.2% of patients had no relief of pain.

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Conflict of Interest

None.

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