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EDITORIAL

Extracorporeal shock wave lithotripsy for pancreatic and large common bile duct stones

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Abstract

Extraction of large pancreatic and common bile duct (CBD) calculi has always challenged the therapeutic endoscopist. Extracorporeal shockwave lithotripsy (ESWL) is an excellent tool for patients with large pancreatic and CBD calculi that are not amenable to routine endotherapy. Pancreatic calculi in the head and body are targeted by ESWL, with an aim to fragment them to < 3 mm diameter so that they can be extracted by subsequent endoscopic retrograde cholangiopancreatography (ERCP). In our experience, complete clearance of the pancreatic duct was achieved in 76% and partial clearance in 17% of 1006 patients. Shortterm pain relief with reduction in the number of analgesics ingested was seen in 84% of these patients. For large CBD calculi, a nasobiliary tube is placed to help target the calculi, as well as bathe the calculi in saline a simple maneuver which helps to facilitate fragmentation. The aim is to fragment calculi to < 5 mm size and clear the same during ERCP. Complete clearance of the CBD was achieved in 84.4% of and partial clearance in 12.3% of 283 patients. More than 90% of the patients with pancreatic and biliary calculi needed three or fewer sessions of ESWL with 5000 shocks being delivered at each session. The use of epidural anesthesia helped in reducing patient movement. This, together with the better focus achieved with newer third-generation lithotripters, prevents collateral tissue damage and minimizes the complications. Complications in our experience with nearly 1300 patients were minimal, and no extension of hospital stay was required. Similar rates of clearance of pancreatic and biliary calculi with minimal adverse effects have been reported from the centers where ESWL is performed regularly. In view of its high efficiency, non-invasive nature and low complication rates, ESWL can be offered as the first-line therapy for selected patients with large pancreatic and CBD calculi.

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Key words: Pancreatic calculi; Extracorporeal shockwave lithotripsy; Common bile duct calculi

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INTRODUCTION

Extracorporeal shock wave lithotripsy (ESWL) was first introduced in the 1980s for the fragmentation of renal and ureteric calculi^[1]. Its application was quickly extended to include large biliary and pancreatic calculi. Over the past three decades, it has been utilized at many centers worldwide for fragmentation of biliary and pancreatic calculi that are not amenable to routine endotherapy^[2-16]. In this review, we briefly highlight the principles of ESWL as well as its place in therapy of biliary and pancreatic calculi.



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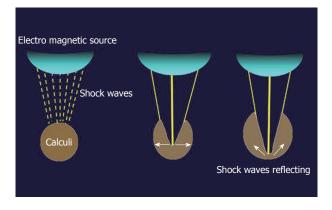


Figure 1 Principle of extracorporeal shockwave lithotripsy. Shockwaves from the source are targeted on the calculi and these induce fragmentation.

PRINCIPLES OF ESWL

ESWL is based on the principle of shock wave energy. Whenever energy is abruptly released in an enclosed space, shock waves are generated. The passage of these shock waves through substances of different acoustic impedance generates compressive stress on the boundary surface. This stress eventually overcomes the tensile strength of the object (in the present case, biliary and pancreatic calculi) and the anterior surface of the calculi crumbles as a result. The shock waves cross to the posterior surface of the calculi and some of them are reflected back and cause further fragmentation^[17] (Figure 1). Modern lithotripsy machines consist of the following basic components.

Shock wave generator

The earlier generation lithotripter utilized electrohydraulic energy or piezoelectric crystals for shock wave generation. The newer third-generation lithotripter utilizes the principle of electromagnetic shock wave generation from an electromagnetic coil. These shock waves are focused on a target (calculi) using an acoustic lens or cylindrical reflector.

Focusing system

Shock waves are focused to the focal point or target in the body. This focal path is conical in shape and all the waves are concentrated at the apex of the cone, which is called the focal point. During ESWL, the focal point targets the calculi. Targeted focusing reduces collateral tissue damage and minimizes the complications.

Localization

Localization of the calculi is basically done by fluoroscopy or ultrasound. All the newer lithotripters are equipped with both these facilities.

Coupling device

The generated shockwaves are transmitted *via* a coupling device, to the skin surface and then through the body tissue to the calculi. The earlier lithotripters used a "water

bath" for this purpose. The newer machines use a small water-filled cushion covered with a silicone membrane to transmit the shock waves to the patient's skin.

ESWL FOR PANCREATIC CALCULI

Chronic calcific pancreatitis (CCP) is a disease of varied etiology that is associated with the development of pancreatic ductal calculi, which result in upstream hypertension, increased parenchymal pressure, and ischemia. Pain is the dominant feature of both alcoholic and nonalcoholic CCP. Decompression of the duct by clearing the stones leads to relief of pain in many patients. Small pancreatic duct (PD) stones can be extracted by the routine technique of endoscopic pancreatic sphincterotomy and basketing. Stones > 5 mm in diameter are often impacted in the main pancreatic duct and require fragmentation to facilitate their expulsion^[15]. ESWL has been successfully used at many centers for fragmentation of large PD calculi followed by spontaneous or endoscopic clearance with resultant relief in pain^[7-15].

Indications and contraindications

ESWL is indicated in all patients of CCP with large PD calculi (> 5 mm) that are not amenable to routine endotherapy - where pain is the predominant symptom. The aim is to break the calculi to fragments of ≤ 3 mm, so that they can be removed by subsequent endoscopic retrograde cholangiopancreatography (ERCP). Calculi in the head and body are targeted during ESWL.

ESWL is not indicated in patients with extensive calculi in the head, body and tail of the pancreas, or in patients with isolated calculi in the tail area because of increased chance of collateral damage to the spleen are high. Patients with multiple stricture, head mass, pancreatic ascites or pseudocysts are not treated by ESWL. Cholangitis or coagulopathy due to biliary stricture are treated before subjecting the patient to ESWL.

Procedure protocol

The protocol followed for ESWL of pancreatic calculi at our institute is depicted in Figure 2.

A third-generation electromagnetic lithotripter (Delta Compact; Dornier Med Tech, Weissling, Germany.) (Figure 3) is used to deliver a maximum of 5000 shocks are delivered per session. Repeat sessions are carried out on successive days until the stone fragments are < 3 mm in diameter. An intensity of 5-6 (15 000-16 000 kV) on a scale of 1-6 with a frequency of 90 shocks per minute is used for fragmentation^[7,8].

A few centers have advocated ESWL alone without any subsequent endotherapy for large PD calculi, stating that good fragmentation is followed by spontaneous expulsion of the fragments^[18,19]. At our center, ERCP, pancreatic sphincterotomy and pancreatic ductal clearance is always performed after ESWL because of the dense nature of the calculi present in patients with idiopathic chronic pancreatitis^[7]. Pancreatic sphincterotomy prior to



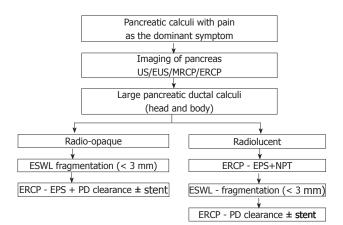


Figure 2 Protocol followed at Asian Institute of Gastroenterology, for extracorporeal shockwave lithotripsy of large pancreatic duct calculi^[7]. EPS: Endoscopic pancreatic sphincterotomy; US: Ultrasound; EUS: Endoscopic ultrasound; MRCP: Magnetic resonance cholangiopancreatography; ERCP: Endoscopic retrograde cholangiopancreatography; PD: Pancreatic duct; ESWL: Extracorporeal shock wave lithotripsy; NPT: Naso-pancreatic tube.

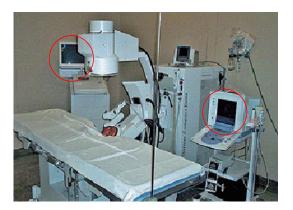


Figure 3 Third-generation lithotripter with fluoroscopic and ultrasound imaging facility.

ESWL is technically challenging because these dense calculi tend to obstruct the pancreatic duct completely and prevent deep cannulation. In our study, the majority of ESWL procedures were carried out under epidural anesthesia $(EA)^{[20]}$. However, general anesthesia or total intravenous analgesia has also been used for this procedure.

Efficacy and pain relief

Over 95% of our patients require three sessions or fewer of ESWL for adequate fragmentation. In 76% of patients, the PD cleared completely, in 17% partially, and there was clearance failure in the remaining 7%^[7] (Table 1 and Figures 4 and 5). Similar results for clearance of the PD, ranging from 37% to 100% have been reported earlier^[9]. Comparative efficacy of ESWL for pancreatic calculi is shown in Table 2. Short-term pain relief was seen in 84% of our patients. This experience is also similar to others who have reported short-term pain in 82%-94% of the patients^[9,10,21-23]. The results of a large meta-analysis have indicated that ESWL has a significant impact on improvement of pain. The mechanism of pain relief is due to decompression of the main PD following clearance of the

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 Table 1 Details of extracorporeal shockwave lithotripsy in

 1006 patients treated at Asian Institute of Gastroenterology

No. of continue	n (%)	Shock waves (n)		
No. of sessions		Mean	Range	
1	292 (29)	4450	(4250-4900)	
2	370 (37)	9270	(8800-9940)	
3	300 (30)	13 250	(11 800-14 700)	
4	32 (3)	18 900	(18 100-19 400)	
≥ 5	12 (1)	23 550	(22 100-27 750)	
Clearance				
Complete cleared	762 (76)			
Partially cleared	173 (17)			
Failed clearance	71 (7)			

Table 2 Efficacy of extracorporeal shockwave lithotripsy for pancreatic calculi

Author	No. of patients	Complete clearance (%)	Pain relief (%)	Follow-up (mo)
Delhaye <i>et al</i> ^[10]	123	59	85	14
Costamagna et al ^[12]	35	74	72	27
Kozarek et al ^[14]	40	-	80	30
Farnbacher et al ^[27]	125	64	48	29
Dumona ceau <i>et al</i> ^[20]	29	-	55	51
Adamek et al ^[16]	80	-	76	40
Tandan et al ^[7]	1006	76	84	6

Table 3 Pain relief and analgesic use, pre- and post-extracorporeal shockwave lithotripsy $^{\left[7\right] }$

	Post-ESWL $(n = 846)$		Pre-ESWL (n = 711)		
Pain relief	(11 -	010)	0	326	
VAS (Scale 0-10)	6/10	212	1/10	161	
· · · ·	7/10	320	2/10	96	D : 0.001
	8/10	204	3/10	85	P < 0.001
	9/10	110	4/10	43	
Analgesic use	0	-	0	326	
Doses/mo	1-5	48	1-5	258	
	6-10	190	6-10	127	P < 0.001
	11-15	385			
	> 15	223			

VAS: Visual analog score; ESWL: Extracorporeal shockwave lithotripsy.

obstruction^[9]. Pain relief was reflected by decreased use of analgesics and of number of hospitalizations during the follow-up period^[7,14] (Table 3). Failure of pain relief, despite adequate clearance could be because of multiple mechanisms of pain in patients of chronic pancreatitis. These include pancreatic inflammation, ischemia, and associated lesions such as duodenal and biliary strictures. Surgery is often considered as the gold standard in the management of chronic pancreatitis. However, even after duodenum-preserving resection of the head of the pancreas, which is considered to be the best surgical approach for chronic pancreatitis, almost 25% of patients experience recurrence of pain^[21]. In addition, there is considerable procedure-related morbidity and mortality. ESWL followed by PD clearance on ERCP is therefore increasingly used in the management of CCP, with results that



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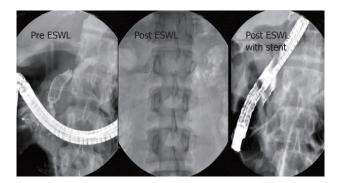


Figure 4 Large pancreatic calculi in head and genu, cleared by extracorporeal shockwave lithotripsy followed by pancreatic stenting. ESWL: Extracorporeal shockwave lithotripsy.

are comparable to surgery^[10-12,19].

Limitations of ESWL in CCP

Long-term follow-up is necessary to evaluate the role of ESWL in PD clearance of patients with CCP. Data on this issue are conflicting. Although no benefit on glandular function and pain has been reported by some workers^[16,24], others have shown a definite improvement in exocrine and endocrine functions^[23]. We feel that more long-term follow-up studies are required to define the role of ESWL in pain and exocrine or endocrine dysfunction, as well as the possibility of carcinoma development, which are all potential sequelae of CCP. This is especially true in tropical regions and in patients with idiopathic chronic pancreatitis in whom the disease begins at a young age.

Although the numbers are small, failure of complete fragmentation has been reported at most centers. It would be ideal to identify this set of patients, so that they can be subjected to surgery directly. Yet another limitation is the failure to prevent recurrence following ESWL, which has been reported in 22%-35% of patients^[22,24].

In conclusion, ESWL is a good technique for extraction of large PD calculi in patients with CCP and offers good pain relief. It is conceivable that ESWL done at a young age, followed by intensive medical therapy could alter the course of the patients with CCP, besides obviating the need for surgery^[8].

ESWL FOR LARGE COMMON BILE DUCT STONES

Conventional therapy for common bile duct (CBD) stones involves endoscopic sphincterotomy and extraction by balloon catheter or Dormia basket. Between 80% and 90% of CBD stones can be extracted using these techniques^[4,5,25]. The rest are categorized as difficult CBD stones and include large stones (> 15 mm diameter), impacted stones in patients with narrow distal CBD and/or difficult anatomy. Large stones can either be fragmented or the CBD passage dilated to facilitate extraction. Fragmentation of large CBD stones can be carried out by me

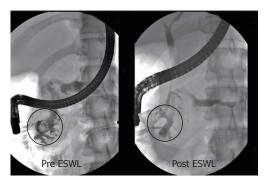


Figure 5 Large pancreatic calculi in head. Post extracorporeal shockwave lithotripsy (ESWL) reduction in diameter of main pancreatic duct.

chanical lithotripsy, electro hydraulic lithotripsy (EHL)^[26], intraductal laser lithotripsy (ILL)^[27], spy scope and holmium laser^[28], and ESWL. The narrow distal CBD can be subjected to balloon dilatation to facilitate extraction of large calculi^[29-31]. Sauerbruch and colleagues first demonstrated the efficacy in achieving CBD stone disintegration successfully and with minimal side effects^[8].

Indications and contraindications

ESWL is indicated all patients with large CBD calculi that are not extractable by routine techniques of sphincterotomy followed by basket or balloon trawl. It is especially useful for patients with post-cholecystectomy retained stones, isolated or primary CBD stones, and in those who refuse or are unfit for surgery.

Acute cholangitis and coagulopathy are relative contraindications and ESWL can be performed once these conditions are treated.

Procedure protocol

The majority of CBD calculi are radiolucent. An initial ERCP is performed and a nasobiliary tube (NBT) is placed in the CBD. This is used to opacify the calculi for targeting and fragmentation. It is also used to bathe the stones in saline - a simple technique that aids fragmentation. ESWL is carried out at an intensity of 4 (in a scale of 1-6) corresponding to 11 000-16 000 kV) at a rate of 90 shocks/min. A maximum of 5000 shocks are given per session. The aim is to break the calculi into fragments < 5 mm in diameter for extraction by subsequent ERCP. Stenting is done if clearance is partial or an associated stricture is present. The protocol followed at our institute is shown in Figure 6.

Efficacy

In our experience, complete clearance was achieved in 84.4%, partial in 12.3%, and failure in 3.1% of patients^[3] (Figure 7). ESWL was useful in clearing intrahepatic calculi also. Similar successful clearance has been reported at other centers (Table 4). Over 75% of our patients needed \leq 3 less sessions of ESWL. Clearance of the CBD in patients with post-cholecystectomy calculi or primary CBD calculi by ESWL and subsequent ERCP



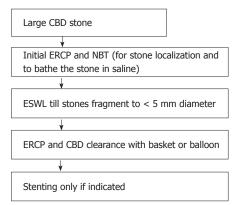


Figure 6 Protocol for extracorporeal shockwave lithotripsy of large common bile duct calculi. CBD: Common bile duct; ERCP: Endoscopic retrograde cholangiopancreatography; NBT: Nasobiliary tube; ESWL: Extracorporeal shockwave lithotripsy.

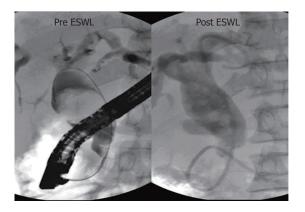


Figure 7 Large common bile duct calculi with narrow distal common bile duct. Good fragmentation achieved with extracorporeal shockwave lithotripsy (ESWL).

obviates the need for surgery^[3]. ESWL was successful in patients in whom mechanical lithotripsy or surgical extraction of CBD stones was unsuccessful^[5]. Non-operative options for removing large CBD calculi include laser lithotripsy, EHL or ESWL. The success rates are similar at between 80% and 95%^[6]. No significant differences in CBD clearance was seen in comparison of ESWL with EHL^[25]. Laparoscopic CBD exploration (LCBDE) is a well-established technique for management of large CBD stones. Despite several studies supporting LCBDE, current surgical practice suggests an overwhelming preference for preoperative ERCP^[33]. Potential explanations for this preference include the challenging nature of LCBDE, lack of necessary equipment, lack of formal training in LCBDE, and increased operative time^[34,35].

Factors that influence fragmentation of CBD stones

Factors that promote better fragmentation and patient compliance have been analyzed at our center^[3]: (1) Use of EA. EA provides good sensory block and reduces patient movement^[20]. This helps with better targeting and reduces the total number of shocks. The same catheter can be used for three sessions of ESWL, which is

Table 4	Efficacy of	extracorporeal	shockwave	lithotripsy	for
large con	nmon bile d	uct calculi			

Author	No. of patients	Complete clearance (%)
Adamek <i>et al</i> ^[27]	79	78.5
Neuhas et al ^[29]	30	73
Binmoeller et al ^[28]	10	70
Ellis et al ^[5]	83	83
Tandan <i>et al</i> ^[3]	283	84
Kocdor <i>et al</i> ^[32]	20	85

often adequate to fragment calculi in the majority of patients; (2) Frequency of shocks at 90/min. At a higher frequency, the ongoing shock waves and those reflected from the surface of the calculus tend to cancel each other out^[17]; (3) The presence of fluid around the calculi aids better fragmentation. Saline irrigation *via* the NBT is carried out during ESWL; and (4) Radiolucent calculi fragment easier compared to radio-opaque ones.

At our center, patients with large CBD calculi undergo ESWL, under EA, at a shock wave frequency of 90/min, with saline irrigation *via* an NBT. Limitations include failure to prevent recurrence, which is reported around 14% at 1 year following ESWL^[36]. The other limitation is failure to identify the calculi that are not amenable to fragmentation, prior to ESWL.

COMPARISON WITH COMPETING STRATEGIES

Mechanical lithotripsy, ILL, EHL and Spy Glass are the other modalities of stone fragmentation for large CBD calculi. Neuhaus *et al*^[27] have reported better clearance with ILL as compared with ESWL, whereas Adamek and colleagues have found no difference between these modalities^[25]. The availability of instrumentation and expertise at a center often determines the choice of the procedure adopted at that center. Very few studies have compared different strategies for fragmentation of large CBD stones.

COMPLICATIONS OF ESWL

A number of rare and serious complications have been reported following ESWL^[37-40]. These occur infrequently and appear to be limited in number. The complications include perirenal hematoma, biliary obstruction, bowel perforation, splenic rupture, lung trauma, and necrotizing pancreatitis. In our experience, as well as in most of the other centers with high patient volume, complications are minimal and mild, and are managed conservatively without extension of hospital stay^[3,7,25,27]. Pain at the site of shock wave delivery, skin ecchymosis, abdominal pain, occasional fever, and hemobilia were observed in some of our patients. No blood transfusion or intervention was required in any of these cases. There is no increased incidence of pancreatitis following ESWL and ERCP. Accurate targeting achieved by the third-generation lithotripter, as well as reduced patient movements with EA, are responsible for reducing collateral tissue damage and minimizing complications^[3,7].

AREAS OF FUTURE RESEARCH

Although fragmentation of pancreatic and biliary calculi by ESWL is satisfactory, there is ample scope for future research to improve results and minimize complications. The long-term results of ESWL in CCP, especially in young patients, are yet to be determined. Data on post-ESWL long-term follow-up are conflicting, with no benefit being shown in some studies^[16], whereas others have revealed good long-term results^[23]. Can intervention at an early age change the course of CCP and help avoid surgery and long-term sequelae^[7]? A long term prospective study in this regard would give us a clearer insight. Another focus of research would be to identify the small percentage of pancreatic and biliary calculi that do not respond to ESWL, so that they can be subjected to alternate modes of endoscopic therapy or surgery. An improvement in the focusing and intensity of shock waves would minimize the failure rate as well as help target pancreatic calculi in the tail region while avoiding splenic complications^[38,39]. Recurrence of pancreatic and biliary calculi after initial successful clearance is known to occur^[22,36]. Identification of this subset of patients and prevention of such recurrences using pharmacological agents would be ideal.

CONCLUSION

ESWL is an excellent therapeutic modality for large pancreatic and CBD calculi. The high efficacy, non-invasive nature of the procedure, along with the low complication rate make it a procedure of choice and can be offered as first-line therapy for selected patients with large pancreatic and CBD calculi.

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