

ESWL for difficult bile duct stones: A 15-year single centre experience

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Abstract

AIM: To evaluate the efficacy of extracorporeal shock wave lithotripsy (ESWL) for the management of refractory bile duct cholelithiasis in a third level referral centre.

METHODS: The clinical records of all patients treated with a second generation electromagnetic lithotripter (Lithostar Plus, SIEMENS) from October 1990 to April 2005 were evaluated. All patients were monitored during the procedure and antibiotics were administered in case of cholangitis. The χ^2 test and logistic regression analysis were performed as appropriate.

RESULTS: Two hundred and fourteen patients (102 males, 112 females; mean age 74.8 ± 0.84 years - single stone 97, multiple stones 117) underwent ESWL. The mean number of sessions and shock waves were 3.5 ± 0.13 and 3477.06 ± 66.17 , respectively. The maximum stone size was 5 cm. Complete stone clearance was achieved in 192 (89.7%) patients. Of the remain-

ing patients 15 required surgery, 2 a palliative stent and in 5 patients stone fragmentation led to effective bile drainage with clinical resolution despite incomplete clearance. Age, sex and stone characteristics were not related to treatment outcome. Major complications occurred in two patients (haemobilia and rectal bleeding) and minor complications in 25 (3 vomiting, 22 arrhythmias). No procedure-related deaths occurred.

CONCLUSION: ESWL is a safe and effective technique for clearance of refractory bile duct stones.

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Key words: Difficult bile duct stones; Extracorporeal shock wave lithotripsy

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INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic sphincterotomy (EST) with or without mechanical lithotripsy followed by stone extraction is the treatment of choice for bile duct stones, and clearance can be achieved in over 90% of cases^[1,2].

Ductal clearance failure by this method (5%-10%) is usually due to characteristics of the stones (shape, size,

number and position, i.e. impacted or proximal to a ductal stenosis) or due to anatomic variants of the biliary tree^[3].

In these cases, alternative therapeutic approaches include surgical exploration, contact dissolution, electrohydraulic and laser lithotripsy, stenting and extracorporeal shock wave lithotripsy (ESWL)^[4].

The prevalence of bile duct stones increases with age and their treatment in older patients is difficult. Common bile duct stones are very common in the elderly and surgical treatment in these patients involves a significant degree of morbidity and mortality. In fact, surgical exploration of common bile duct stones is associated with a mortality of 1% or less in young, fit patients and a mortality of approximate 9%-10% in patients 80 years or older^[5-7].

In many studies it has been demonstrated that ESWL combined with endoscopic procedures represents a safe and effective option for removal of difficult bile duct stones, especially in patients with high surgical risk^[8-12].

In this study, we describe our 15 years of experience with ESWL in the treatment of difficult bile duct stones and evaluate its safety and effectiveness, particularly in elderly patients.

MATERIALS AND METHODS

ESWL treatment is considered for all patients with difficult bile duct stones, defined as stones which did not clear from the papilla after EST and which could not be removed during ERCP (Dormia basket, balloon catheter or mechanical lithotripsy).

From October 1990 to April 2005, 214 patients with lithiasis of the extrahepatic biliary tract not suitable for endoscopic removal underwent ESWL (using a second generation electromagnetic generator, Lithostar Plus, Siemens). The Lithostar Plus generates electromagnetic shockwaves which are focused on the target. Targeting was performed under fluoroscopic control. The injection of contrast medium was carried out through a *naso-biliary* drainage tube, previously fixed during the last ERCP, or through percutaneous transhepatic catheter (PTC) or with a T-tube. Occasionally, targeting was performed under ultrasonography guidance.

All patients who underwent ESWL treatment were selected on the basis of inclusion and exclusion criteria. Before treatment, preliminary tests were performed: blood sampling for hematology, chemistry and coagulation; urine sampling for pregnancy test; chest radiography and abdominal ultrasound. A positive pregnancy test and severe irreversible coagulopathy were absolute contraindications to ESWL treatment, while cirrhosis, portal hypertension, arrhythmias, pancreatitis, thrombosis, abdominal aneurysm, renal failure, voluminous angiomas, gut or lung interposition and voluminous cysts were relative exclusion criteria. All patients gave their written informed consent to the procedure.

The patients with cholangitis and those with associated intrahepatic stones were treated with antibiotic therapy. Patients were fasted for at least 12 h before treatment.

Table 1 Population and stone characteristics

| | |
|---------------------------|------------|
| Study population | |
| <i>n</i> | 214 |
| Age | 74.8 ± 0.9 |
| Sex (M:F) | 102:112 |
| Stone characteristics (%) | |
| Single | 45 |
| Multiple | 55 |
| ≥ 1.5 cm | 94 |
| < 1.5 cm | 6 |

All patients were monitored with pulse oximetry during the procedure. A continuous ECG was also performed in cardiopathic patients.

During treatment the prone position was adopted in the majority of cases. Routine laboratory tests were performed in all patients 6 h after the procedure and the following day, according to the protocol.

When multiple sessions were required, the time interval between sessions was always more than 24 h. During the study period, 214 patients underwent ESWL (102 men and 112 women). The mean age was 74.8 ± 0.84 years (range 29-96); the maximum dimension of the treated gallstones was 5 cm. Ninety seven patients had single stones and 117 had multiple stones (Table 1).

Seven hundred and fifty one sessions were performed (3.5 ± 0.13 sessions for each patient, range 1-14), on average the number of hits per session and per patient was 3477.06 ± 66.17 (range 400-6000) and 13032.41 ± 667.49, respectively.

Every session ended when optimal fragmentation of the stones was obtained or if the maximum number of hits was reached, in order to avoid possible tissue damage (the established limit was 6000 hits per session).

Medium high power (range 1-8) energy was used per session, according to the pain tolerance of each patient. No patient received anesthesia, while 70 patients were sedated with Fentanyl and 12 patients received analgesia with Ketorolac.

Statistical analysis was performed using the MedCalc package. Data are expressed as mean ± SE. The χ^2 test was performed to evaluate differences between the group of patients who were cleared of stones and the group who were not. Logistic regression analysis was used to evaluate the variables correlated with treatment outcome. $P < 0.05$ was considered statistically significant.

RESULTS

A total of 214 patients underwent 751 ESWL procedures during the study period (mean 3.5 ± 0.13, range 1-14 for a single patient). The treatment was stopped in only 8 patients because of pain. Eleven patients (5%) required 6 sessions, 31 patients (14%) 5 sessions, 52 patients (24%) 4 sessions, 47 patients (22%) 3 sessions, 31 patients (14%) 2 sessions and 32 patients (15%) only 1 session; between 7 and 14 sessions were necessary in the remaining patients (Table 2).

Table 2 No. of extracorporeal shock wave lithotripsy sessions required to achieve stone clearance

| ESWL sessions required | No. of patients (<i>n</i> = 214) |
|------------------------|-----------------------------------|
| 1 | 32 |
| 2 | 31 |
| 3 | 47 |
| 4 | 52 |
| ≥ 5 | 52 |

ESWL: Extracorporeal shock wave lithotripsy.

Table 3 Clearance and causes of treatment failure *n* (%)

| Outcome | No. of patients (<i>n</i> = 214) |
|-----------------------------|-----------------------------------|
| Clearance | 192 (89.7) |
| Spontaneous or after 1 ERCP | 178 |
| ≥ 2 ERCP | 14 |
| Treatment failure | 22 (10.3) |
| No cause | 15 |
| Discontinued | 7 |

ERCP: Endoscopic retrograde cholangiopancreatography.

In 205 patients a naso-biliary tube was positioned during a previous ERCP. In 6 patients targeting was performed through percutaneous drainage, in 1 case through a Kehr drainage tube and in 2 cases by ultrasonography guidance.

Endoscopic clearance of the biliary duct was successful in 182 cases, while in 10 cases spontaneous clearance was observed. Fifteen patients required surgery and 7 suspended treatment, in 5 of these cases stone fragmentation led to effective bile drainage with clinical resolution despite incomplete clearance, and 2 received a palliative stent.

Clearance

Clearance of the biliary ducts (both spontaneous or through drainage or ERCP) was observed in 192 of the 214 patients treated (89.7%).

In the vast majority of patients (178, 93%) duct clearance was achieved spontaneously or with only 1 ERCP post-ESWL. Only 14 patients (7%) required two or more ERCP sessions. Most of the patients needed 3 or 4 ESWL sessions (48 and 46 patients, respectively). 15 patients underwent surgery and 7 discontinued treatment (Table 3).

The majority of patients (57%) with clearance had stones with a maximum diameter of 2 cm (range 0.8-5 cm). Usually, stones smaller than 1.5 cm are amenable to mechanical lithotripsy. In fact, in the vast majority of cases (94%) the stones were larger than that. However, in a few cases smaller stones were present together with large stones, and in two patients with single stones (dating before 1997) the endoscopist was unsuccessful in retrieving them. Stone size, number (multiple 55.1% or single 44.9%), sex (52.4% women; 47.6% men) and age did not seem to influence treatment outcome.

Among those without clearance, the majority (51%) had stones with a diameter over 2 cm (range 1-3.5 cm).

Furthermore, in this group none of the variables were

Table 4 Procedure-related complications *n* (%)

| Complications | No. of patients (<i>n</i> = 27) |
|-----------------|----------------------------------|
| Major | 2 (0.9) |
| Haemobilia | 1 |
| Rectal bleeding | 1 |
| Minor | 25 (12) |
| Vomiting | 3 |
| Arrhythmias | 22 |

correlated with a negative outcome: sex (54.5% women, 45.5% men), mean age (71 years) and number of stones (11 patients with multiple gallstones; 12 with a single stone).

Complications

Complications related to the treatment occurred in only 27 patients. Among these, 25 patients (12%) reported minor complications such as vomiting and arrhythmias (mainly extrasystoles and bradycardia). We observed only 2 cases of major complications: haemobilia and rectal bleeding. The haemobilia was mild, without ultrasonographic signs and haematology alterations. The patient with rectal bleeding lost 2 g of haemoglobin which did not necessitate blood transfusion (Table 4). We had to suspend ESWL in only four cases because of minor complications (twice for arrhythmia and twice for pain intolerance).

DISCUSSION

In about 5%-10% of patients with common bile duct stones, duct clearance can not be achieved with traditional techniques such as ERCP and sphincterotomy. These approaches usually fail for reasons related to the stone characteristics: large size, impacted or proximal to a stricture. ESWL is an alternative therapy for difficult duct stones and is also a support to ERCP when it fails to achieve stone fragmentation^[13].

We report our 15 years of experience in the treatment of difficult duct stones with the Lithostar Plus.

Our population was similar to that reported in previous studies. In fact, the vast majority of patients were older than 65 years of age.

Our results suggest that ESWL is a safe, well tolerated and effective technique for the treatment of difficult bile duct stones. Of note, we performed the procedure without the need for anesthesia or flat analgesia in almost all patients. This suggests that careful targeting with the correct focus of the lithotripter allows the execution of ESWL without the need for drugs that may cause side effects in an elderly population possibly already taking different drugs for co-morbidities.

We did not observe any differences in the baseline characteristics between patients with and without stone clearance, probably because of the high success rate. In fact, we did not find any patient or stone characteristics related to treatment failure.

In our population, some smaller stones were present with large stones. It should be noted that in these cases

ESWL was performed on the largest stone in order to achieve subsequent bile duct clearance. However, with our lithotripter, the targeting of stones 1-1.5 cm is easily performed and subsequent stone fragmentation suggests that stone size is not a limiting factor in ESWL treatment. In fact, in two cases, where the endoscopist failed to retrieve the small stones, ESWL was successful.

In our study, no deaths occurred and the few major complications which occurred were immediately treated and resolved rapidly.

We must emphasize that the median age of our patients was 74, and ESWL was performed in 63 patients (29%) aged more than 80 years. For such patients, the mortality rate after common duct bile exploration is still high (around 10%). Furthermore, urgent surgery for biliary stones in elderly subjects has a very high mortality rate ranging from 12% to 21%. Therefore, ESWL is the procedure of choice for difficult bile duct stones in elderly subjects^[5,7,14,15].

In addition ESWL, even when multiple sessions and longer hospitalization are required, has lower costs due to the decreased rate of minor complications compared to surgical treatment.

Other techniques may be employed for the treatment of difficult bile duct stones but they have a lower efficacy or more side effects.

Contact dissolution therapy has been abandoned because of the number of complications and low success rate^[16-18].

Electrohydraulic and laser lithotripsy require a more invasive approach, including the use of a choledochoscope for direct visualization of the stones. They are alternative therapeutic options but have more complications and require more expensive equipment compared with ESWL^[19-21].

ESWL is a valid technique with low cost compared to other therapeutic options for difficult bile duct stones and its utilization can be extended to urology and orthopaedics. Therefore, the same device can be used by different medical staff in the same hospital thus reducing management costs.

Newer generations of lithotripters delivering higher energies and allowing smaller focusing on the target stone are now available; therefore, it is expected that even better results may be achieved.

In conclusion, ESWL is an effective and safe treatment which improves the outcome of biliary duct lithiasis. In association with endoscopy, it is successful in the vast majority of cases and allows surgery sparing in high risk patients, especially in the elderly.

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COMMENTS

Background

Extracorporeal shock wave lithotripsy (ESWL) uses electromagnetic waves to fragment difficult biliary stones when Endoscopic Retrograde Cholangiopancreatography fails. This may prevent surgery which still carries significant morbidity and mortality when the common bile duct is involved.

Research frontiers

The results obtained with second generation electromagnetic lithotripters such as ours are already optimal; however, technological improvements in lithotripters now delivering higher energies and allowing smaller focusing on the target stone may further enhance our performance.

Innovations and breakthroughs

The authors' work emphasizes, in a wide patient population, that ESWL is safe and effective which was also true in elderly patients. In fact, elderly patients are more difficult to treat due to coexisting co-morbidities that frequently contraindicate surgery.

Applications

The study is of interest for physicians dealing with the biliary tree and particularly those managing bile duct stones. Based on these results, ESWL was confirmed to be the first choice for the treatment of difficult biliary stones even in cases outside standard treatment guidelines.

Peer review

Overall, the study helps to evaluate a role of ESWL in difficult common bile duct stones.

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