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# Technology Review

## **EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY**

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<b>Contents</b>	<b>Page</b>
Introduction	1
Objective	1
Methodology	1
Technical features	2
Results and Discussion	3
Conclusion	9
Reference	10

# Extracorporeal Shockwave Lithotripsy

## 1. Introduction

Extracorporeal shock wave lithotripsy was introduced in the early 80s and has since become the gold standard for the treatment of urinary stones. It is the most widely performed procedure for stone treatment, treating all sizes and locations of stones, the results of which have been widely published (Andreas and Fisher, 2005).

## 2. Objective

To determine the effectiveness, safety and cost-effectiveness of the extracorporeal shock wave lithotripsy (ESWL) for the treatment of urinary stones.

## 3. Methodology

Electronic databases like Pubmed, Ovid, Cochrane DSR, Journal @ Ovid full text via OVID and EBSCOHost were searched. The following keywords were used either singly or in combinations: *ESWL, SWL, extracorporeal shock wave lithotripsy, shock wave lithotripsy, urinary calculi, urinary stones, effectiveness, safety, cost-effectiveness, risk and harm*. The search was limited to articles published between the years 2001 and 2006, but not limited to English language only.

In addition, cross-reference searching was carried out from reference lists and bibliographies of the full text articles retrieved.

From the studies and articles reviewed, one was a randomised controlled trial. Others consisted of cross-sectional studies, case series, retrospective studies and retrospective reviews. Not all were available in full text articles. The results of the studies are not directly similar due to the different designs.

#### 4. Technical features



With ESWL, renal and ureteral calculi are pulverized into smaller fragments by shockwaves and can then pass spontaneously as small fragments. The ultimate goal of ESWL is the creation of stone fragments that are smaller than 1 mm, which can pass spontaneously and painlessly from the urinary tract.

The essential feature of a lithotripter is the generation of a shock wave that is focused upon a point (Cartledge et al., 2001). The abrupt release of energy in a small space (air or water) generates high-energy amplitudes that are also called shockwaves. Energy is delivered at that point and fragments the target stone. The shock wave passes readily through water, not air. The physical laws of acoustics regulate the propagation and transmission of shockwaves through water or media of similar density (e.g., soft tissues). The passage of a shockwave through substances of differing acoustic impedance generates compressive stresses at the boundary surface. If the tensile strength of the encountered object (e.g., a stone) is overcome by the produced stress, the anterior surface of the stone crumbles. Part of the energy of the shockwave crossing to the posterior surface of the stone is reflected, causing fragmentation and ultimately implosion of the stone by increasing the tensile stress on the fragment.

The 4 basic components in all lithotripsy machines are:

1. An energy source (the shockwave generator) – shockwave can be generated by electrohydraulic, piezoelectric or electromagnetic energy.
2. A focusing system – lithotripters require a focusing system to direct the energy to a point, allowing the shock wave energy to be concentrated and directed onto a stone, enabling fragmentation of stones to take place.
3. An imaging or localization unit – fluoroscopy or ultrasonography is used to localize the stone and direct the shock waves onto the stone.
4. A coupling mechanism – this system is required to broadcast the energy created by the shock wave generator across the skin surface, through visceral tissues, to the stone. In the past this was done by immersing the patient in a large water bath (first generation lithotripters). Currently the second and third generation devices employ small water-filled drums or cushions to provide air-free contact with patient's skin.

Fragmentation of a stone takes place when the force of the shock waves outweighs the stone's tensile strength. Stone fragmentation can be created by:

1. direct force – the stone splits when the shock waves hit its anterior surface
2. erosion – a pressure gradient causing the stone fragment by erosion when the compressive component of the shock wave advances through the stone
3. cavitation – gaseous bubbles, formed near the stone surface by shock waves in a liquid medium, collapse violently at the surface of the stone, generating a central water jet, eroding the stone.

ESWL is non-invasive, requires less anesthesia than other treatments for renal stones, and may render patients stone free without surgical intervention or endoscopic procedures (Grasso, 2006).

## **5. Results and Discussion**

### **5.1 Effectiveness**

#### 5.1.1 ESWL in adults

Studies have shown that treatment of urinary stones with ESWL to be effective (Abe et al. 2005; Level 8; Keeley et al. 2001; Level 2; Gunawant et al. 2006; Level 9; Al-Ansari et al. 2006; Level 8, Abdel-Khalek et al. 2003; Level 8; Abdel\_khalek et al. 2004; Level 8). Most of these studies measured stone-free rates as well success rates. Stone-free rate is defined as complete removal of all fragments (Shiroyanagi et al. 2002; Level 8), while success rate is largely defined as complete stone clearance or presence, or absence, of clinically insignificant residual fragments (Al-Ansari et al. 2006; Level 8). Factors influencing the outcomes as well as those predicting outcomes were also studied by some.

Keeley (Keeley et al. 2001; Level 2) conducted a randomised controlled trial to determine if prophylactic ESWL is justified as a treatment for small, asymptomatic calyceal stones. Primary outcomes measured were stone-free rate and requirements for additional treatments, while secondary outcomes were symptoms, stone burden, quality of life (QOL) and renal function. It was concluded that prophylactic ESWL did not offer any advantage to patients in terms of stone-free rate, QOL, renal function, symptoms and hospital admission. However, although evidence is weak, prophylactic ESWL may prevent the need for more invasive treatment of calculi and the consequent risk of procedure-related morbidity (Keeley et al. 2001; Level 2).

In managing isolated calyceal stones, success rates were not significantly different with stone location, whether upper, middle or lower calyces, up to a maximum diameter of 2.5cm (Gunawant et al. 2006; Level 9).

In a study on lower pole stones by Sorensen and Chandoke (Sorensen and Chandoke 2002; Level 8), it was concluded that stone size, rather than

calyceal anatomy, influenced the treatment outcome. Sampaio (Sampaio 2001; Level 9) explained that retention of stones in the inferior pole is a consequence not only of the gravity-dependent position of lower calyces but also of the anatomical features of the lower pole collecting system. Infundibulopelvic angle, infundibular length and diameter need to be taken into consideration when considering ESWL for renal stone treatment.

In a large-scale retrospective study, Abe (Abe et al. 2005; Level 8) found the stone-free rate to be 65.1% and success rate 85.7%, while recurrence rate was 28.6%. Stone-free rate was significantly influenced by patient age, history of urolithiasis, pre-ESWL pyuria as well as number, location and composition of the stones. Recurrence of stone, on the other hand, was significantly affected by multiple stones (most significantly related), history of urolithiasis and stone location (in the kidney or both kidneys plus ureter). Morbidity was low while effectiveness was high.

In obese patients with urinary stones, the technique of ESWL may need to be modified. The ability to focus the shock wave deep enough to reach the stone may be limited or impossible, restricting the depth at which the stone fragments. In the morbidly obese patient ESWL may not even be possible. Not even with modification of the technique (Calvert and Burgess 2005; Level 9). Stone-free rate was 73% in a study by Mezentsev (Mezentsev 2005; Level 8). ESWL was most effective in treating pelvic stones in these patients (87% success rate). Secondary procedure post-ESWL was required in 54% patients.

In determining prognostic factors, Al-Ansari (Al-Ansari et al. 2006; Level 8) found stone size, stone location, number of stones and radiological renal features to have a significant effect on the success rate. With regards to stone location, pelvic and upper calyceal stone-free rates were higher compared with lower calyceal stones. In another study, the presence of ureteral stent was also considered to be another significant factor predicting outcome (Abdel-Khalek et al. 2003; Level 8). In this study ureteral stones were the focus and it was found that lumbar ureteral stones had the highest stone-free rate (92.8%), lowest was pelvic ureteral stones (82.7%). Abdel-Khalek (Abdel-Khalek et al. 2004; Level 8) determined the prognostic factors of stone-free rates as patient age, stone size and location, number of stones, radiological renal features and congenital renal anomalies.

In determining factors associated with failure of ESWL for ureteral stones, Shiroyanagi (Shiroyanagi et al. 2002; Level 8) concluded that apart from stone location and stone size, degree of ureteral obstruction was also a factor. Ureteral obstruction was classified subjectively as negative or positive according to morphologic findings of excretory urography. In 39.4% of patients in whom ESWL failed, stone impaction was observed, while 24.2% had ureteral stricture. The authors also found that success rate decreased as the location of the stones moved distally. In a similar study, obesity was also determined as a predictor of unsuccessful ESWL for the treatment of ureteral stones (Delakas 2003; Level 8).

### 5.1.2 ESWL in Children

The incidence of urolithiasis in the paediatric population is on the rise (Minevich and Sheldon 2006; Level 9). Urinary lithiasis affects 5-10% human population, of which 1-3% is children (Desai 2005; Level 9). The majority of stones in children are secondary to metabolic disturbances or anatomical malformations (Landau et al., 2001). Minimally invasive techniques should be used in the treatment of urinary calculi in children because stone recurrence is higher in them compared to adults (Muslumanoglu et al. 2006; Level 8). The options available for treatment of urinary calculi are the same as those for adults, i.e. ESWL, percutaneous nephrolithotomy or a combination of both, as well as surgery (Desai 2005; Level 9). Given its minimally invasive features, ESWL has become a primary mode of treatment for paediatric patients with upper urinary tract stones (Minevich and Sheldon 2006; Level 9). The aim of the management of calculi should be complete clearance of stones, preservation of renal function and prevention of recurrence.

Brinkmann (Brinkmann et al. 2001; Level 8) concluded that ESWL is effective in treating upper urinary tract stones in children. They reported successful fragmentation in all 64 patients, with 54% of them stone-free at discharge. After 3 months 83% stones were completely cleared, remaining fragments being clinically insignificant. Overall success rate was 97.4% in a study of ESWL for ureteral calculi in children (Landau et al. 2001; Level 8). Stone-free rate for stones <10mm after 1 session of ESWL was found to be 100%, regardless of location. Stone-free rate for stones > 10mm after 1 ESWL treatments was 67%. In a retrospective case series by Ather and Noor (Ather and Noor 2003; Level 9), 95% patients were rendered stone-free after ESWL for treatment of renal stones up to 30mm in size. Mean stone sizes were 15.88mm in the treatment failure group and 14mm in stone-free group. In this series it was found that lower pole calyceal stones and those impacted at the ureteropelvic junction have a relatively poorer clearance.

When stratified according to location, it was found that stone-free rates were higher for stones located in proximal and mid-ureter compared to stones in distal ureter (Muslumanoglu et al. 2006; Level 8). The authors found ESWL to be effective in treating urinary tract calculi in children, especially ureteral calculi of 2cm or less. In their retrospective study the overall stone-free rate was 91%. Success rates were 94% for proximal and mid-ureteral stones and 91% for distal ureteral stones. For mid-ureteral stones, the density of bony pelvis is less in children, probably leading to a higher success rate than in adults. In a different study, Minevich (Minevich 2005; Level 8) compared the efficacy of ureteroscopic lithotripsy and ESWL in treating distal ureteral stones in children. It was concluded, however, that the former is more effective than the latter.

In a case control study comparing children (six months to six years old) to adults (above 20 year), it was found that stone-free rate for children was higher than for adults, and children had a quicker stone-free rate than adults (Gofrit et al. 2001; Level 7). Possible explanations for these results would be



that the child ureter is shorter than adult ureter, partially compensating for the narrower lumen, and that the child ureter is more elastic and distensible, allowing easier transmission of stone fragments and preventing stone impaction. Another possible explanation is the damping effect of the shock wave energy while travelling through body tissue – less energy is lost when shock wave is transmitted through the small body volume of the child.

A retrospective study assessing the impact of calyceal pelvic anatomy on lower pole stone clearance suggests that there is no significant relationship between the two (Onal et al. 2004; Level 8).

Afshar (Afshar et al. 2004; Level 8) found that metabolic and anatomical disorders increased the risk of stone formation. Tan (Tan et al. 2004; Level 8) also identified risk factors as metabolic and anatomical abnormalities. They also found patients with large stones less likely to be stone-free.

With regards to staghorn calculi, Lottmann (Lottmann et al. 2001; Level 8) concluded that ESWL is effective in treating these stones. Stone-free rates after one or two sessions in children of age group 5.5 months to 2 years and 6 to 11 years were 87.5% and 71.4% respectively. Another study shows similar findings (Al-Busaidy et al. 2003; level 8). In this study the authors assessed the effect of stent insertion and found that patients who had stents inserted fared better than those without stent insertion, in terms of outcome (shorter hospital stay and recurrence of stones).

Studies have also been carried out to observe the effectiveness of ESWL in infants. In one study on infants (age range 6 to 40 months) from 3 ESWL centres, ESWL was successfully performed in 86% of the patients, using parameters similar to adults (McLorie et al. 2003; Level 8).

Afshar (Afshar et al. 2004; Level 8) studied the outcome of residual fragments in children, factors influencing outcome and if the residual fragments pose an increased risk of adverse clinical outcome in patients compared to stone-free status. They found that in children, small residual fragments after ESWL are significantly associated with an increased risk of adverse clinical outcome, including growth of fragments, haematuria and pain. Therefore, they need to be monitored closely, especially if metabolic or anatomical disorders are present.

According to Desai (Desai 2005; Level 9), several factors need to be taken into consideration when choosing patients for ESWL. For renal calculi, main considerations for ESWL are renal function, stone burden, composition and capability of distal urinary tract to successfully pass the fragments. Children pass well, rarely requiring routine stenting. Shorter duration of stone disease, greater stone fragility and lower impedance to shock waves might be reasons for better stone fragmentation in the paediatric population. In the treatment of ureteral calculi, stone-free rate is dependent on stone size. To aid localisation or stone clearance, ESWL warrants for ureteral stenting in most children with ureteral calculi. Important concerns with paediatric ESWL include radiation hazards, effect on renal function and alteration in renal growth.

### 5.1.3 Stones in abnormally sited kidneys

Congenital abnormalities are very common in urology. The most frequent congenital abnormalities are horseshoe, malrotated, ectopic kidneys and duplex systems. Transplanted kidneys are also considered as one of them and are classified as pelvic kidneys. These abnormally located kidneys are at risk for stone formation. Risk factors for stone formation are urinary stasis and recurrent infections.

Stones in abnormally sited kidneys can be treated by the various procedures used to treat stones in normally sited kidneys. However, each case needs to be individualised, taking into account not only the size and location of the stone, but also the anatomy, function and location of the kidney (Gross and Fisher 2006; Level 9).

It has been reported in the literature that in these cases stone-free rates range from 20%-90%. Stone-free rates of 39% in patients with stones of 2 cm or larger can be achieved with ESWL (Gross and Fisher 2006; Level 9).

Patients with anomalously sited kidneys, however, should be deemed as those at high risk for recurrence and would need to be followed up carefully. ESWL in itself has low complication rates in these patients (Gallucci et al. 2001; Level 8). Use of supportive measures, like stents, is indicated for similar reasons as those for ESWL in normally sited kidneys.

## 5.2 Safety

### 5.2.1 ESWL in adults

Studies have reported similar common post-ESWL complications such as renal colic, steinstrasse and haematuria (Albala et al. 2005; Level 8; Sayed et al. 2001; Level 8; Abdel-Khalek et al. 2003; Level 8; Mokhtari and Salehi 2004; Level 8). Other problems encountered are pain, nausea and urinary symptoms like dysuria, frequency, urgency and bladder pain (Albala et al. 2005; Level 8). Mokhtari and Salehi (Mokhtari and Salehi 2004; Level 8) also reported urinary obstruction in 21 % of their patients early post-operatively.

Abdel-Khalek (Abdel-Khalek et al. 2003; Level 8) reported complications in 3.4% OF patients with static steinstrasse in 2% patients treated for ureteral stones.

The aetiology, prevention and management of steinstrasse were studied by Sayed (Sayed et al. 2001; Level 8). Steinstrasse or “streets of stones” is a well-recognised complication of ESWL. It is a column of sand resulting from fine disintegrated stones passing down the ureter. Aetiology – large stones (> 2.5 cm in kidney, > 1.5 cm in ureter), high energies used during initial treatment (a high initial voltage causes large fragments which pass directly

into the ureter and obstruct it), meatal stenosis or any narrowing caused by subtle stricture (bilharzial infection or previous surgery of ureter), inability to debulk large (> 2.5 cm) before ESWL using percutaneous nephrolithotomy. Prevention - Steinstrasse could be prevented by better selection of patients (those with stones of <2.5 cm in the kidney and <1.5 cm in the ureter); using low energies at the start of treatment (increasing the voltage gradually, thus pulverizing rather than fragmenting the stones; excluding patients with suspected narrowing of the ureter, or treating any stricture endoscopically before ESWL. Management - Conservative management of uncomplicated steinstrasse was effective in about 50% patients; repeated ESWL successful in 23% (ESWL used to disintegrate leading fragment or to mechanically loosen fragment); placing a percutaneous nephrostomy (PCN) in those with obstruction or infection (19%). Ureteroscopy was suggested in non-febrile patients, after failure of ESWL, after placing a PCN and if no progress of steinstrasse, but this comes with disadvantages. Ureteric stenting before ESWL prevents complications of steinstrasse and is considered in patients with large stones (>2 cm), only functioning kidney, faint ureteric stones (esp. those over pelvic bones). Length of the ureter affected by steinstrasse does not affect treatment success.

In a case report by Sare (Sare et al. 2002; Level 9), they reported a rare case of life-threatening perinephric haemorrhage. The patient was on regular clopidogrel for 2 previous myocardial infarcts. Significant haemorrhage after ESWL is unusual with no previously unrecognised or untreated coagulopathies. Furthermore, protocols state that warfarin, and not aspirin or clopidogrel, should be discontinued prior to ESWL.

Another rare complication that was reported was one of acute necrotising pancreatitis (Karakayali et al. 2006; Level 9). A 39 year old man treated with ESWL for a calculus in the right renal pelvic region developed increasing abdominal pain 6 hour post-operatively. The diagnosis was made from laboratory tests and abdominal CT scan.

### 5.2.2 ESWL in children

Most of the studies did not experience significant major problems post-ESWL (Muslumanoglu et al. 2006; Level 8; Brinkmann et al. 2001; Level 8; McLorie et al. 2003; Level 8; Lottmann et al. 2001; Level 8; Ather and Noor 2003; Level 9; Tan et al. 2004; Level 8).

Urinary tract infection and renal colic were the post-ESWL complications observed in the study by Muslumanoglu (Muslumanoglu et al. 2006; Level 8) Steinstrasse was found to be lower in children than adults.

In another study, 21% of the patients who were unstented developed major complications; none of the stented patients had any (Al-Busaidy et al., 2003, level 8). Ather and Noor (Ather and Noor 2003; Level 9), in their retrospective case series, found 8% of patients with complications.

Landau (Landau et al. 2001; Level 8) concluded that none of the patients experienced post-operative urinary infection or ureteral obstruction. Most patients had mild haematuria lasting a few hours post-operatively.

### **5.3 Cost-effectiveness**

Only one article was found on cost-effectiveness of ESWL. From a review by Chandoke (Chandoke 2001; Level 9) on the cost-effectiveness of therapies for urinary calculi, it was found that ESWL is more cost-effective in the treatment of lower pole renal stones less than 1cm in diameter. This was in comparison to percutaneous surgery. Conversely, for stones larger than 2cm, it was less cost-effective. However, studies seem to favour ureteroscopy over ESWL for the treatment of distal ureteral stones when considering cost-effectiveness.

### **Conclusion**

Sufficient evidence was found to support that extracorporeal shock wave lithotripsy (ESWL) to be effective in the treatment of renal and ureteral stones in adults. There was also sufficient evidence to support that renal and ureteral stones in children can be effectively treated with ESWL. There was insufficient evidence to support that ESWL to be effective in treating stones in abnormally sited kidneys.

There was evidence to indicate that ESWL is safe in the treatment of urinary stones in adults. There was also adequate evidence supporting the safety of ESWL when used in children. However, several issues need to be addressed when selecting patients. Important concerns with the use of ESWL in the paediatric population include radiation hazards, effect on renal function and alteration in renal growth.

It was also found that there was insufficient evidence on the cost-effectiveness of ESWL in the treatment of urinary stones in adults or children.

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