

Efficacy of extracorporeal shockwave lithotripsy using Dornier SII in different levels of ureteral stones

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Abstract

Objective: The objective of this study was to evaluate the efficacy and safety of the Dornier lithotripter S II system in the treatment of ureteral calculi.

Patients and Methods: A total of 97 cases which consists of 54 males and 43 females with ureteral stones were treated by extracorporeal shock wave lithotripsy (ESWL). Mean age was 42.6 years. Inclusion criteria were solitary radiopaque ureteral stones of radiological stone size of ≤ 1 cm. The stones were not impacted, with normal kidney functions. Procedure time, number of shocks, energy used, number of sessions and complications were reported. The outcome of ESWL was also recorded.

Results: Stones were in the abdominal (upper ureter) in 50% of patients, in pelvic (middle ureter) in 47% of patients. All patients had unilateral stones and the mean stone size in maximum length was 10 mm). Good dye excretion passing the stone was noted in all patients. Mild hydronephrosis was found in 85% of cases. A total of 49 cases were treated by a single session, while in 35% of cases two sessions were enough and 16% received three sessions. The average number of shocks per session was 3125. The average number of shocks per patient was 5962.5 shocks and average energy was 204.3 Joules. The overall stone-free rate 3 months after lithotripsy was 94%. After a single session of lithotripsy, 49 patients (49%) became stone-free. Stone free rates after ESWL for upper, middle ureteral stones were 94%, 95.7% respectively. Additional procedures were needed in only 6 cases (6%) to render patients stone-free after lithotripsy. No serious complications occurred.

Conclusion: The Dornier lithotripter S II is very effective in the treatment of ureteral calculi with no major complications.

Key Words: Dornier, extracorporeal shock wave lithotripsy, lithotripter, ureteral stones

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INTRODUCTION

Extracorporeal shock wave lithotripsy (ESWL) has become a safe and accepted treatment for urinary tract stones since its introduction in the early 1980s and it was essentially

limited to the management of renal and proximal ureteric stones. Improved technology in ESWL and advancement in lithotripsy design and fluoroscopic imaging has currently allowed successful identification and *in situ* treatment of calculi in the middle as well as the lower ureter.^[1]

A number of reports using the second and third generation lithotriptors support that ESWL is as efficacious for middle and lower ureteric stones as for kidney and upper ureteric stones.^[2] For distal ureteral stones in centers where ESWL and ureteroscopy are available, ESWL should be the preferred treatment for patients with single stones of < 1 cm.^[3]

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PATIENTS AND METHODS

Between May 2010 and January 2013, 97 patients of both sexes with ureteral stones 10 mm or less who were candidates for ESWL were enrolled into this study. All patients were subjected to history taking, clinical examination and laboratory investigations which included urine analysis, urine culture and sensitivity test, complete blood picture, coagulation profile, serum creatinine and blood urea, liver function test, fasting and postprandial blood sugar. Imaging studies included plain X-ray of the urinary tract, intravenous urography and pelviabdominal ultrasound.

Inclusion criteria were age above 18 years old, single radiopaque ureteral stone with radiological size of 10 mm or less, which did not pass in two weeks after conservative management or there is hydronephrosis secondary to the symptomatic ureteral stones. The stones were not impacted and kidney functions were normal.

The exclusion criteria were patients with pregnancy, uncontrolled coagulopathy, severe hydronephrosis, multiplicity or bilaterality of stones, radiolucent stones, renal insufficiency, urinary tract infection (UTI), distal obstruction and those with stone larger than 10 mm.

Patients were categorized into two groups according to the level of the stone. Group I comprised 50 cases with abdominal (upper) ureteral stones and Group II included (47) cases of pelvic (middle) ureteral stones.

Pre-operatively, all patients were given ceftriaxone (1 g) intravenously. Patients with UTI were treated by appropriate antibiotic after culture and sensitivity of the urine. Negative urine cultures were mandatory in every patient before ESWL. Informed consent was taken and instructions of bowel preparation were given to all patients. Patients were fasting for 8 h at least before ESWL and rectal enema was done the night before ESWL.

ESWL procedures were performed in out-patient basis under intravenous analgesia in the supine or prone position according to the level of the stone and under fluoroscopic guidance. All patients were treated with no general or spinal anesthesia. Patients with upper ureteral stones were treated in the supine position; those with mid-ureteric stones were treated either in prone or supine position and patients with lower ureteric stones were treated in the prone position. In all cases, the stone was adequately visualized with fluoroscopy. The stone was fragmented using Dornier lithotripter S II system, which is an electromagnetic lithotripter. Ultrasound gel was used for shock wave coupling and water cushion was adjusted to fit the body contour of patient. We confirmed positioning of the stone and

monitored the progress of fragmentation by fluoroscopy using shot imaging at intervals of 300-500 shock. When satisfactory fragmentation was seen on fluoroscopy or after 4500 shock waves had been delivered the procedure was ended.

Data recording during ESWL included the need for analgesia or anesthesia, the method of localization, procedure time, number of shocks, energy used and number of sessions as well as complications during and early after the procedure and signs of fragmentation during ESWL. Repeat ESWL was done in cases of incomplete stone fragmentation or presence of residual fragments (>4 mm). Patients allowed for maximum 3 sessions with 2 weeks apart.

Evaluation of patients was done 2 weeks after ESWL by clinical assessment of pain, tenderness, fever and hematuria. Laboratory investigations in the form of urine analysis, culture and sensitivity test if needed, blood urea and serum creatinine were done. Plain X-ray of the urinary tract and pelviabdominal ultrasound were repeated to confirm stone clearance after two weeks. The outcome of ESWL was reported as regards to stone clearance, stone disintegration and the signs of fragmentation. Patients having significant residual fragments were scheduled for second session. The same laboratory and radiological investigations, which were carried out after 2 weeks were repeated after 1 month. Patients having non-surgical fragments were evaluated monthly for 3 months.

Definition of success was stone-free state or appearance of insignificant asymptomatic residual fragments <4 mm at 6 weeks or earlier. On the other hand, failed cases were considered as failure of stone expulsion at the end of study, severe hydronephrosis and uncontrollable attacks of renal colic or febrile UTIs, which were in need of further management.

The efficacy of treatment in the three groups was determined by analysis of stone clearance rate and time, steinstrasse formation, frequency of pain episodes, number and dose of analgesia and report of admission for severe pain, hematuria, vomiting or fever. Statistical analysis was performed using statistical package for the social sciences software "version 17." Continuous variables were expressed as mean and standard deviation.

RESULTS

A total of 97 patients were enrolled into this study. There were 54 males and 43 females with mean age of 42.6 years (range: 19-62 years). They had solitary ureteral stones 10 mm or less in size on plain kidneys, ureters and bladder. They were divided into two groups according to stone location where Group I (50 cases) had upper (abdominal) ureteral stones and Group II (47 cases) had pelvic (middle) ureteral stones. They were treated by ESWL

using Dornier lithotripter S II system. Almost, 90% of patients presented with renal colic, 14% with irritative lower urinary symptoms and 3% with gross hematuria. 20% of cases had previous urologic interference for stones in the ipsilateral side. In urinalysis, only 5% had urinary infection, which was treated before ESWL, 23% had microscopic hematuria.

Excretory urography revealed good excretion of contrast passing the stone in all patients and showed duplicated ureters in 2 cases. Mild hydronephrosis was found in 85% of cases. Nearly 49% of patients were treated by single session, 35% of cases received two sessions and 16% had three sessions. The average number of shocks per session was 3125. The average number of shocks per patient was 5962.5 shocks and average energy was 204.3 Joules [Table 1].

There were no differences between the three groups with regard to age, sex, mean stone size, the side affected, fluoroscopic time or maximal shockwave intensity used.

The overall success rate was 94%. Stone clearance was achieved in 87 patients (87%) after 3 months of follow-up and 7 patients (7%) showed insignificant residual surgical fragments (<4 mm). Failure of stone clearance occurred in 6 patients (6%), 4 out of them (4%) showed no change at all in stone size after 3 sessions of ESWL and the remaining 2 patients (2%) showed partial disintegrations. Hence, they underwent ureteroscopy [Figure 1].

Stone free rates after ESWL for upper (abdominal), middle (pelvic) ureteral stones were 94%, 95.7%.

No major complications occurred after ESWL. The most common complication of ESWL in our work was ureteric colic (42%). Transient hematuria for <24 h occurred in 13% of cases. Perinephric and subcapsular hematoma were detected

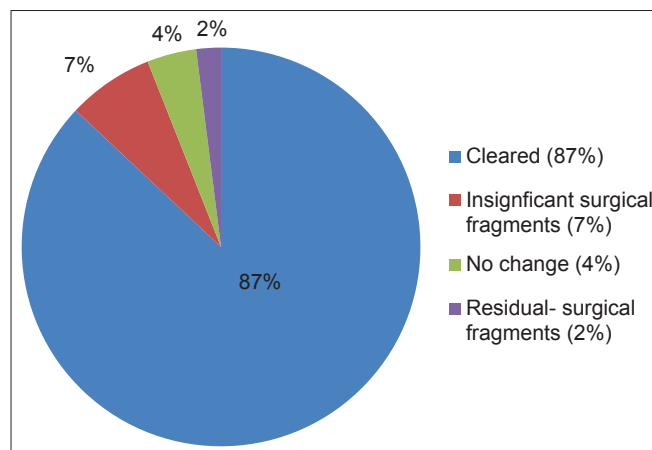


Figure 1: The outcome of extracorporeal shock wave lithotripsy in 100 cases after 3 months

by ultrasound in two patients. Febrile urinary tract infection developed in 8 cases in spite of prophylactic antibiotics given routinely after ESWL. Steinstrasse occurred in one patient and treated conservatively [Table 2].

DISCUSSION

ESWL is one of the most frequently applied procedures for the treatment of urolithiasis. Since the mid-1980s ESWL has been established as a minimally invasive procedure for a wide indication of urinary stones. Since the first generation of shock wave lithotripters, the efficacy of these devices has been almost constant. Technical development mainly improved patient comfort and safety, optimized handling, reduced primary and maintenance costs and provided multiple uses.^[4]

Lithotripters are composed of four essential parts, which differ significantly between the devices – shock wave generator, localization system, shock wave coupling and auxiliary equipment. Shock wave generation is based on electrohydraulic, electromagnetic or piezoelectric sources. Electromagnetic generators work in a way that is comparable to loud speakers. High energy acoustic waves are focused by an acoustic lens or by using a parabolic reflector. The resulting shock wave is constant. The energy is focused to a smaller focal point with higher peak energy. A localization system identifies the stones and guides the positioning of the stone within the focal point; fluoroscopy or sonography can be used for this. Fluoroscopy is the most frequently used system. Stones in all positions of the ureter can be localized, except for very small and less radiodense stones.^[5]

Electrohydraulic and electro-magnetic generators provided the highest disintegrative capacity and could destroy the hardest of

Table 1: Patients and stone characteristics in the study groups

Characteristic	Group I	Group II
Mean age	43.2 (24-67)	41.4 (21-87)
Male/female	28/22	25/22
Right sided stones	29	26
Left sided stones	21	21
Mean stone size (mm)	8.5	8.3
Mean X-ray time (min)	2.83 (0.6-12.1)	2.95 (0.4-9.5)
Average no. of sessions	2.6	2.3
Average energy (J)	212	206.6
Average no. of shocks/session	3100	3342
Average no. of shocks per case	5498	5600

Table 2: Complications after ESWL for ureteral stones

Complications	No. of patients	Percentage
Renal colic	42	42
Transient hematuria for <24 h	13	13
UTI	8	8
Perinephric hematoma	2	2
Steinstrasse	1	1

UTI: Urinary tract infection, ESWL: Extracorporeal shock wave lithotripsy

the natural urinary stones. Electromagnetic sources provided the widest range of energy from very low to very high energy levels. In contrast, piezoelectric generators need more shots to destroy the stones.^[6]

Success rates for ESWL treatment have been reported to be machine-dependent in clinical practice.^[7] Various reports comparing ESWL machines have shown a consistently high stone-free rate and low re-treatment rate with the HM3 lithotripter.^[8]

The most effective device, Dornier HM3, usually requires general anesthesia, but in contrast to the less effective piezoelectric lithotripters – can be applied without any analgesia. In most institutions, preferred lithotripters are those that can be used in analgesation (modified HM3, other electrohydraulic and electromagnetic lithotripters and high-energy piezoelectric lithotripters).^[5] Recent technological developments have resulted in more advanced lithotripters with shorter focal length and more narrow focal breadth, which help reduce the level of pain and ultimately obviates the need for anesthesia and hospital admission for the procedure. In the newer machines, water cushions coated with acoustic gel are substituted for water baths in earlier models. These “dry” lithotripters may deliver less shock-wave energy to the target, but they make up for this in the ease of patient positioning, including the ability to treat them in the prone position.^[9]

The machine used in this study was Dornier lithotripter S II system, which utilizes an electromagnetic shockwave generator and a water balloon coupling mechanism. It has several advantages including small size, a multifunctional cystoscopy table, as well as fewer servicing and cleaning requirements. With regard to efficacy of stone treatment; however, it has several attributes that may make it more difficult to use and might require more practice to master. These machines tend to have much smaller focal areas and may be less powerful. For these reasons, patient positioning and stone localization must be exact. There is no flexibility available in terms of patient movement or severe fluctuations in breathing patterns.^[10]

Intravenous sedation has been employed successfully for shockwave lithotripsy. However, higher retreatment rates have been reported for IV sedation than for regional or general anesthesia.^[11] We did not use general or regional anesthesia for any of the 100 cases included in this study. We used only sedoanalgesia and the procedures were tolerable.

IN spite the intravenous pyelogram (IVPs) carry a definite risk for the patients, but we used only the non-ionic contrasts (ULTRAVIST) which carries very rare risk in the same time still IVP is cheaper than helical computed

tomography, so for financial purposes we used the IVP because all patient are treated free of charge.

The ages of patients in this study ranged from 19 to 62 years with the mean age of 42.6 ± 11.9 years with male to female ratio of 1.08:1. The age range in different studies about ESWL was 4-82 years. The male to female ratio in different studies was 1:1-3:1.^[12,13]

Among the predictors of success, stone location seems to be controversial. Several authors showed that ESWL of lower ureteral stones is not as effective as in stones of the upper urinary tract due to certain difficulties in visualizing stones overlying the sacrum.^[14]

In this study, we performed ESWL monotherapy in patients with stones of a size of less than 10 mm. This fact possibly explains the high overall stone-free rate we had (94%) after ESWL sessions. This rate is comparable to the rates reported by other authors using different machines. It has been estimated that a mean stone free rate of 77.4% (range: 63-100) is achievable for proximal ureter stones, with a retreatment rate of 10%. Data for mid ureteral stones are 80.3% (range: 60-98) and 8.2% and for distal ureteral stones 77.9 (range: 59-100) and 9.4%, respectively.^[15]

For upper ureteric stones (group I), our study achieved fragmentation rate of 94% (47/50). This result is comparable with those reported by other studies. Ghafoor and Halim^[16] treated 17 upper ureteric stones with ESWL. The overall clearance rate for upper ureteric stones was 94%. They also treated 13 patients with mid-ureteric stones with ESWL. The overall clearance rate for the mid-ureteric stones was 92.3%.

The results of ESWL for middle ureteral stones were comparable to those for upper ureteral stones. Coz *et al.*^[17] reported stone free rates of 84.3% and 82.4% for upper and middle ureteral stones respectively. We had similar success rates for upper and middle ureteral stones. Ruckdeschel *et al.*^[18] treated 60 mid-ureteral stone with ESWL and reported 95% stone free rate, a near figure to our result (95.7%).

Di Pietro *et al.*^[19] assessed the short-term efficacy of extracorporeal shockwave lithotripsy with the Dornier Lithotripter S in 19 cases of ureteral stones. The stone-free rate for ureteral stones was 63% at 1 month and 84.2% at 3 months. Analgesia was necessary in 23.5% of cases. No serious complications were seen, except for one steinstrasse.

Zomorodi *et al.*^[20] studied 87 patients with ureteral stone at different levels and treated with ESWL. The treatment protocol included 3500 shock wave per patient in each session, energy of

the shock was 13-9 kV/patient, and the number of sessions was 3/patient. The first group included 43 patients who received only ESWL, while the second group of 44 patients received as well 40 mg of furosemide. Stone fragmentation rate was 81% and 93.1% and stone clearance rate was 68.2% and 88.4% for the first and the second groups, respectively.

Salem,^[21] treated 100 patients with ureteral stones with ESWL and reported stone clearance in 71%.

Verze *et al.*^[22] treated 137 cases with ureteral stones using ESWL and reported that 92.7% of cases were stone free. Ghalayini *et al.*,^[23] Hochrester *et al.*,^[24] Pardalidis *et al.*,^[25] and Wu *et al.*

More recently Aboumarzouk *et al.*^[26] compared the results of ESWL treatment with ureteroscopic stone manipulation of ureteral stones. They found that stone-free rates were lower in patients who underwent ESWL, but re-treatment rates were lower in ureteroscopy patients. ESWL-treated patients had less need for auxiliary treatment, fewer complications and shorter length of hospital stay.

In our study as well as in others, pain was the main complication observed (42%) (Rasool *et al.*, 2009-55%).^[27] This pain was managed by giving injectable diclofenac sodium intramuscularly or even pethidine 50 mg I.V. in severe colic. Regular analgesics were advised to patients in between the session so as to facilitate painless passage of stone particles and gravel. Fever developed in 8% of patients requiring injectable antibiotics treatment and observation after admission with culture and sensitivity of urine. Hematuria observed in 13% of patients and this was transient and mild in majority and settled with increased intake of oral liquids while two of these 13 patients needed admissions and injectable hemostats e.g. Tranexamic acid up to 2-4 g/day doses along with IV fluids. In the work of^[27] hematuria occurred in 14.4% and fever in 12.8%.

Perinephric hematoma happened in two patients the first one aged 62 years had hypertension with hyperlipidemia, which can explain the event, the size of hematoma was small and treated conservatively with ample fluids bed rest and avoid any anticoagulants; the other patient was diabetic type II the size also was small and treated conservatively with the same protocol.

The overall incidence of steinstrasse in literature was 3.97%^[28] which significantly correlated with stone size, site, power level used and radiological features of stone. Steinstrasse was more common in large stones. The small size of the stones in our work <10 mm explains the rarity of steinstrasse (1%).

CONCLUSIONS

ESWL using Dornier lithotripter S II is an effective, non-invasive and convenient way of treatment for ureteral stones regardless the level of the stone.

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