Extracorporeal Shock Wave Lithotripsy success rate for upper and lower ureteric stones in Azadi-teaching (Dohuk) hospital in Kurdistan Region-Iraq

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Abstract

Background: Urolithiasisis a common health problem in our society. Extracorporeal Shock Wave Lithotripsyhas been practiced successfully for treating renal and upper ureteric stones. Few studies, however, have looked on its effectiveness in the treatment of lower ureteric stone.

Objective: To evaluate the effectiveness of ESWL in the management of upper and lower ureteric stones in Duhok.

Patients and Methods: The study was planned and conducted from January 2013 to June 2014 on 294 patients(16-80 years)with ureteric calculi admitted for the initial Extracorporeal Shock Wave Lithotripsytreatment. All patients were underwent lithotripsy with shock wave 1220 to 4000 at the rate of 60-90 impulses per minute in the same place using the Siemens lithotripter. The outcome was evaluated on the 3rdand 7thdays by x-ray and ultrasound and a second Extracorporeal Shock Wave Lithotripsy session was conducted for those have an incomplete clearance of ureteric stone.

Results: Out of the 294 patients, 74.1% were male, 55.8% had left-sided stone and remaining 44.2% had right-sided stone, and 34.4% had stone located in lower ureter. The mean age of the patients was 37.2 (±10.9) years, while the mean stone size was 7.98 (±1.18) mm. The Extracorporeal Shock Wave Lithotripsy has successfully removed the stone from 256 (87.1%) patients and the success rate was significantly higher for lower ureteric and small size stones. The success rate for both sides and genders were comparable in the study. Out of the rest 38 (12.9%) patients who did not obtain the success of stone minimization from the first Extracorporeal Shock Wave Lithotripsy session; 33 of them had stone clearance in the second session while, the rest of 5 patients need surgical intervention. Univariate logistic regression showed that small stone size was the only significant predictor for stone clearance after the first session.

Conclusion: The current study confirmed that the Extracorporeal Shock Wave Lithotripsy technique is the safe and effective method for upper and lower ureteral calculi comminution.

Key words: Extracorporeal shock Wave lithotripsy (ESWL), Lithotripsy, Ureteral calculi,Urolithiasis.

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Introduction

Urolithiasis is a common health problem caused by a variety of metabolic disturbances [1]. Urolithiasiswith an increase incidence of morbidity and a high level of recurrence has been considered as the common occurring disease [2]. Currently, clinical techniques including ureteroscopic lithotripsy [1], Extracorporeal Shock Wave Lithotripsy (ESWL)[3-6],and open surgery [7, 8]are applied to manage renal and ureteral calculi. Of them, ESWLhas been found to be the safest non-invasive technique for treatment of the patients with renal and upper ureteric calculi [9].

The ESWL is a techniquebacks to 1980 decade[10]which has been approved of being as a non-invasive clinical method with a low incidence of complications, a shorter hospitalization period and a non-costly technique[11].

The ESWL successfulness depends on composition, size, and location of stone in the kidney and ureter(it has a low rate of success in stone comminution in lower calicealparts)[12] and operator experience level, number of total shock, energy delivered by patient, frequency of shock, the shock delivery method [13].

Currently, ESWL is used to treat the stones not exceeding 20 mm in diameter in kidney and stones smaller than 10 mm diameter in upper ureteral part. Based on the current available evidence in the literature, the different outcome would be obtained by ESWL due to a number of factors such as application of different types of lithotripters, change in success definition, and post-treatment evaluation of patients and the factor of stone burden resulted in stone-free rates between 14% and 91% [14, 15].

Few studies, however, have looked on its effectiveness in the treatment of lower ureteric stone. The aim of this study is to evaluate the effectiveness of ESWL in the management of upper and lower ureteral stones in Duhok.

Patients and Methods

The study was planned and conducted in kidney Disease and Implantation Center in Duhok city-Iraq from January 2013 toJune 2014.The consent forms were taken of untreated patients with ureteric stones visited the center and admitted for the initial ESWL treatment.

The number of patients included into the study were 300 in a consecutive way in which 6 patients were missed during follow up process,patients were underwent lithotripsy in the same place using the Siemens lithotripter and those patients visited the researcher were included in the study only.The cases included into the study were in the age between 16 and 80 years old, all male patients, female patients with upper ureteric stone only with the radiopaque calculi size between 6 and 12 mm. The females with lower ureteric stones owing to possible adverse side-effects, pregnant women,pediatric population, and patients with acute urinary tract infection, radiolucent stones, ureteral stricture, solitary kidney, and bilateral and ureteral stone in distal part were excluded from the ESWL intervention. All patients recruited for ESWL technique were sent for urine analysis, serum creatinine and coagulation profile.

The patients recruited into the study were given analgesic through intramuscular route in the form of diclofenac Na 30 minutes before lithotripsy only (75 mg, IM). The fluoroscopy was performed in order to monitor the stone location and the supine position was used for the males with lower ureteric calculi. The energy of shock wave was increased gradually to a maximum of 5 joules,and the number ofshock waves depended on thestone fragmentation was between 1200 and 4000 impulses with a rate

of 60-90 impulses per minute with the mean 1848 in the supine position.The shock wave impulses were increased gradually according to the tolerance of the patients to pain. The patients were advised to intake a high amount of water and the outcome of calculi comminution was assessed after 3, 7 days consecutively. The patients following 3 and 7 days were underwent the x-ray and ultrasoundto find out the outcome. The stone-free status or the residual fragments detection equals or less than 3 mm on the final evaluation was considered as the success outcome. Those with remaining stone in ureter were located for a second ESWL session. All patients were treated with the same method and were discharged from the center following one hour surveillance andgiven non-steroidal anti-inflammatory drugs (NSAIDs) and alpha blockers for three days intake postoperatively. The cases with probable complications such as hematuria sever pain and fever was advised to attend the hospital for further intervention despite their recruitment in the study.

Descriptive statistics were generated for all cases included in the final analyses stratified by stone clearance (yes or no) after the first ESWL session. Patient, stone, and ESWL characteristics were compared between patients with vs. without stone clearance using Chi square test for categorical variables and independent sample t test for continuous variables. Univariate and multivariate logistic regression analyses were performed to predict the stone free status after ESWL.

Statistical Analysis

A $p<.05$ was considered statistically significant. All analyses were performed using the Statistical Package for Social Sciences version 23:00 (SPSS 23:00-IBM SPSS Statistics). The ethical approval of the study was obtained from the local Health Ethics Committee of the health directorate.

Results

Table (1) represents descriptive statistics of the study sample stratified by the stone free status after the first ESWL session. Of the 294 patients included in the final analysis, 74.1% were male, 55.8% had left-sided stone, and 65.6% had a stone located in the upper ureter. The mean age of the patients was 37.2 (SD = ± 10.9) years and the mean stone size of 7.98 mm (SD = ± 1.18). In addition, the mean shock wave performed during the ESWL treatment was 1848 ± 408.19 impulses per minute and mean energy applied was 3.53 ± 0.547 joules per minute.

Upon stratification by stone free status, no statistically significant difference between the two groups were noted in terms of sex (p=0.106), age (p=0.251), or stone side (p=0.760), total shock and energy applied for two stone-free and residual groups (p=0.256), and (p=0.733), respectively.However, statistically significant differences between the location (p=0.026) and size (p=0.001) of the stone, and the stone free status were evident.

Table (1): Characteristics of patients and stones.

Characteristics	Overall N (%) ormean ± SD	Stone free state		
		Yes N (%) or mean ± SD	No N (%) or mean ± SD	P value
Total no. of patients	294	256 (87.1)	38 (12.9)	
Sex Male Female	 218 (74.1) 76 (25.9)	 194 (75.8) 62 (24.2)	 24 (63.2) 14 (36.8)	0.106
Age (yr.)	37.21 ± 10.92	36.9 ± 10.6	39.5 ± 12.8	0.251
Stone side Left Right	 164 (55.8) 130 (44.2)	 144 (56.2) 112 (43.8)	 20 (52.6) 18 (47.4)	0.760
Stone location Lower ureter Upper ureter	 101 (34.4) 193 (65.6)	 95 (37.1) 161 (62.9)	 6 (15.8) 32 (84.2)	0.026
Stonesize (mm)	7.98 ± 1.184	7.9 ± 1.1	8.8 ± 1.5	0.001
Total no. of shock wave(impulses)	1848 ± 408.193	1821.6 ± 387.4	2028 ± 496.4	0.256
Energy (Joule)	3.53 ± 0.547	3.5 ± 0.5	3.5 ± 0.5	0.733
*p value from a chi-square tests for categorical variables and independent sample t-tests for continuous variables				

The ureteral calculi of the 256 (87.1%) patients were removed and 38 (12.9%) of 294 patients did not obtain the success in stone comminution including 33 (11.2%) of them planned for the second session and intervention was done for 5 (1.7%) of them in the case of occurred complications.

Table (2) represents stone free success rate after the first ESWL session. The overall success rate in our study sample was 87.1%. The rates were higher among males (89.0%) versus 81.6% for females,the success rate was approximately same in left-sided stone and right-sided stone, 87.8% and 86.2%, respectively. And patients with their stones located in the lower ureter 94.1% versus 83.4% for upper ureter located stones.

Table (2): Clearance rate after first sitting by sex, stone side and stone location.

Characteristics	Clearance rate N (%)
Total no. of patients	256 (87.1)
Sex Male Female	 194 (89.0) 62 (81.6)
Stone side Left Right	 144 (87.8) 112 (86.2)
Stone location Lower ureter Upper ureter	 95 (94.1) 161 (83.4)

Table(3) presents the results from univariatelogistic regression analyses examining the impact of patient's and stone's characteristics on the stone clearance following the first ESWL session. In the univariate analysis, only the size of the stone significantly predicted the stone clearance, in other words, the patients with smaller stone size in the ureter were more likely to have the stone clearance after the firstsitting of ESWL (p=. 004).

Table (3): Predictors of success rate after the first clearance after first sitting.

Variables	P value
Sex (Male, Female)	0.160
Stone side (Right, Left)	0.820
Stone location (Lower ureter, Upper ureter)	0.296
Age (yr.)	0.121
Size of the stone (mm)	0.004
Total no. of shock wave (impulses/minute)	0.293
Energy (joule)	0.950

Approximately 38 patients (12.9%) had residual stones after the first session, which accordingly necessitated either a second ESWL session (33 patients) or a surgical intervention (5 patients) (Table 4). Those who required a second ESWL session were mostly males (22 cases), had upper ureteric stone (27 cases), and had a mean stone size of 8.9 (SD = ± 1.5) mm. Patients required surgical intervention had a mean stone size of 8.0 (± 0.7) mm and all of them had an upper ureteric stone.

Table (4): Management of residual stone post first session ESWL.

Variables	2nd ESWL N (%) ormean ± SD	Surgical intervention N (%) ormean ± SD
Total no. of patients	33 (11.2%)	5 (1.7%)
Sex		
Male	22 (66.7)	2 (40.0)
Female	11 (33.3)	3 (60.0)
Age (yr)	42.88 ± 18.75	22.00 ± 0.00
Stone side		
Left	18 (54.5)	2 (40.0)
Right	15 (45.5)	3 (60.0)
Stone location		
Lower ureter	6 (18.2)	0 (0.00)
Upper ureter	27 (81.8)	5 (100.0)
Size of the stone (mm)	9.12 ± 1.13	7.00 ± 0.00
Total no. of shock wave(impulses/min)	2625.00 ± 694.37	2000.0 ± 0.00
Energy (joule)	3.38 ± 0.58	3.00 ± 0.00

Discussion

The current study was conducted in the Duhok Kidney Center in order to examine the effectiveness of Extracorporeal Shock Wave Lithotripsy (ESWL) on treatment of ureteral calculi. In spite of the very short follow-up time period, the study found a high success rate of 87.1% to upper ureteral stones following the first session of treatment by ESWL anda second ESWL was performed on the rest and all except 5 had a successful commination.

The available evidence of the literature mention that the effectiveness of lithotripsy technique depends on stone size, patient position, calculi location in kidney or ureter, total number of shock wave, stone composition and density, energy, and stone side in kidney and ureter[9], renal morphology, congenital anomalies, stone number, [16], and coupling quality [17, 18]. With this respect, (Wiesenthal, Ghiculete [19]confirmed in univariate analysis that that in spite of calculus location in lithotripsy success, age (p =0.01), body mass index (p=0.01), stone size (p=0.01), mean stone density (p=0.01) and skin to stone distance (p=0.01) are can be predictors of ESWL effectiveness. They developed a

comprehensive nomogramforoutcomes prediction of shock wave lithotripsy for renal and ureteral calculi. In addition, (Elkholy, Ismail [20]found the 94% of overall stone-free rate following three month period with only 35% and 16% of them required two and three settings of the Dornier lithotripter S II for ureteral calculi with 94% and 95.7% stone free rates for upper, middle ureteral stones, respectively.

Nonetheless, the current study showed that stone clearance rate is related to the stone location (lower and upper ureter parts) and stone size in ureter, p= 0.026, p= 0.001, respectively and the univariate regression confirmed on the size of stone in ureter as the only stone clearance predictor.

Although the lower and distal ureteral calculi are more difficult than upper ureteral stones to be managed by ESWL, they can be treated as well through the patient position modification in a supine position, as (Ghalayini, Al-Ghazo [21]treated 92 patients with radiopaque distal ureteral calculi with a success rate of 81.5% ($p < 0.0001$) following three month period using Dornier lithotripter S (MedTech Europe GmbH)comparable with the 91% success rate and 9% required for second and third setting of ESWL by (Hochreiter, Danuser [22]. Therefore, the data of the literature show that ESWL can be performed for calculi in lower and distal ureteral in the time of supine position with a high stone clearance and a low rate of complication pre and post treatment. Moreover, the ureteroscopy technique is available for calculi in distal ureteral parts in spite of preference on ESWL treatment of patients with a single stone less than 10 mm in diameter [23].

The patients were followed-up after a very short time period of three days. The outcome of treatment by ESWL for ureteral calculi do not require a long period of time for follow-up due to proximity of the ureter to the bladder in contrast to long distance of renal stonesas a high stone free rate of 63% was obtained by (Hochreiter, Danuser [22] following just one day of ESWL management and close to complete stone clearance of 97% after three month follow-up.

With respect to the energy and shock wave of lithotripsy, a meta-analysis conducted by (Semins, Trock [24] including randomized controlled trials comparing ESWL technique using 60 shocks per minutes to 120 shock per minutes. The data taken from 4 trials pooled together in order to examine the difference in the patients proportion of successful treatment outcome compared between the 60 and 120 shocks per minute groups. They found out that the successful treatment ofthe shock wave of 60 had a substantial greater likelihood(risk difference 10.2, 95% CI 3.7–16.8, p=0.002).(Mazzucchi, Brito [3]assigned the patients with urinary stones into two groups including one with 3000 shocks per minute at a rate of 60 impulses per minute and the other group treated with 4000 shocks at 90 impulses per minute. The results of the study revealed that the success rate for calculi smaller than 10 mm was 60% for the first group (60 impulses/min) and 58.6% for the second group and 34.2% and 45,7% for stone greater than 10 mm, respectively (p=0.483). However, due to not using the same shock in the mentioned study for the different impulses, the obtained results would not be a confirmation on the 60-90 impulses for the ESWL treatment. The shocks 1200-4000 with rate of 60-90 impulses per minute were used in the current study. Anyway, the evidence did not show an evident benefit to reduce the impulses frequency from 90 to 60 for stone clearance for a three-month follow-up study for calculi greater than 10 mm [25].

Conclusion: The current study confirmed that the ESWL technique is safe and effective method of ureteral calculi comminution. Further studies might be needed to evaluate the effect of ESWL treatment in mid ureteric

stone. The technique is highly recommended for smaller and lower ureteric calculi.

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