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ORIGINAL ARTICLE

Extracorporeal shock wave lithotripsy of lower ureteric stones: Outcome and criteria for success

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KEYWORDS

Stones;
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ABBREVIATIONS

DUC, distal ureteric calculi; SFR, stone-free rate; BMI, body mass index

Abstract *Objective:* To evaluate the efficacy of extracorporeal shock wave lithotripsy (ESWL) for distal ureteric calculi (DUC) and to determine variables that could affect the outcome results.
Patients and methods: Between April 2004 and February 2008, 100 patients with a solitary DUC were treated with *in situ* ESWL using a lithotripter (Lithostar Plus, Siemens, Erlangen, Germany). The outcome of treatment was evaluated after 3 months. The patients' clinical and radiological findings, as well as stone characteristics, were reviewed and correlated with the stone-free rate (SFR).
Results: After *in situ* ESWL, 84 patients (84%) were stone-free (after one session in 57 and after two in 27). From a univariate analysis only three factors had a significant impact on the SFR, i.e. the body mass index (BMI), stone length and stone width. The SFR was significantly lower in obese patients than in normal and overweight patients ($P = 0.019$). Stone width $\geqslant 8$ mm was associated with a SFR of 64% (14/22), compared with 89.7% (70/78) for those with a stone width of < 8 mm ($P = 0.007$). The SFR was 86.8% (66/76) for a stone length of $\leqslant 10$ mm and 71% (17/24) for a stone length of > 10 mm ($P = 0.016$). On multivariate analysis, BMI, stone width and stone length maintained their statistical significance.
Conclusion: Primary *in situ* ESWL remains an effective and safe form of treatment for DUC. The length and transverse diameter of the stone, together with the BMI of the patient, were the only significant predictors of the overall success of ESWL.
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Introduction

The optimum treatment for distal ureteric calculi (DUC)-remains controversial. One of the greatest dilemmas facing the urologist is to choose between the two most frequently

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used methods for treating ureteric stones, ESWL and ureteroscopy [1]. The AUA clinical guidelines note that the ability to predict the response of stones to ESWL is one of three major challenges in stone research, besides stone prevention and a uniform system of reporting stones. We present a study of ESWL for 100 sequential patients with DUC, evaluating the outcome and detecting different variables that could affect the success rate of ESWL.

Patients and methods

From April 2004 to February 2008, 100 patients with a solitary radio-opaque distal (i.e. below the lower border of the sacroiliac joint to the vesico-ureteric junction) ureteric stone of $\leqslant 15$ mm were treated with *in situ* ESWL in our stone lithotripsy unit, and enrolled in our prospective study.

Exclusion criteria included pregnancy, uncorrectable coagulopathy, ureteric stent or percutaneous nephrostomy drainage, febrile UTI, multiple or bilateral ureteric calculi, a solitary kidney, and renal insufficiency. All patients had a radiological examination in the form of a plain abdominal film and IVU. In addition, noncontrast CT was used in 40 patients only. The following features of the stone on radiography were evaluated and recorded: side of the stone; length of the stone (the longest diameter); width of the stone (the transverse diameter); degree of stone radio-opacity, classified into low, moderate and highly radio-opaque stones (with use of the iliac bone as a reference point); state of stone impaction (a stone was considered impacted if there was no visualized dye below the stone, or a stone that remained at the same site in the ureter for >2 months); the degree of stone-induced hydronephrosis, categorised as dilation of pelvicalyceal system, mild hydronephrosis, moderate hydronephrosis, or marked hydronephrosis.

All ESWL procedures were administered with the patients prone and under fluoroscopic guidance. The stone was fragmented using the Lithostar Plus lithotripter (Siemens Medical System Inc., Erlangen, Germany) which is a second-generation electromagnetic lithotripter. All patients were treated as outpatients under sedo-analgesia (meperidine hydrochloride plus diclofenac sodium). Shock waves were given at fixed rate of 84 min^{-1} for all patients. The procedure was ended when satisfactory fragmentation was seen on fluoroscopy or after 4000 shock waves had been delivered.

Patients were reviewed at 1 week after the first session using a plain film. Repeat treatment was applied immediately if there was inadequate fragmentation of the stone (either no fragmentation at all or stone fragments of >4 mm). ESWL was considered successful if the plain film showed complete clearance of the stones with no residual fragments. Stones that showed no or poor fragmentation after two sessions of ESWL, and complicated or residual fragments that failed to pass, were considered as a failure of ESWL and referred for ureteroscopy. Those with an equivocal plain film had noncontrast CT as necessary to confirm the stone-free status. Patients were evaluated 3 months after the last lithotripsy session. Abdominal ultrasonography was used as a screening test for silent obstruction.

The data were collected, coded, tabulated, and then analysed after the 3-month visit. Data were expressed as the mean (SD) for quantitative measures, while categorical variables were presented as the number of cases (frequency) and percentage. Between-group and within-group comparisons of numerical values were assessed by an unpaired and paired *t*-test, respectively. Categorical values were analysed using Fisher's exact test. In all, tests, $P < 0.05$ was considered statistically significant and $P < 0.01$ as highly significant. Univariate analysis of all variables was used to assess individually the association between the various factors and the ESWL outcome. Thereafter, the significantly associated variables were further analysed and tested using multivariate analysis (stepwise logistic regression model with forward conditional procedure) to identify those factors that acted independently and to predict the probability of stone-free status after ESWL.

Results

The study included 76 males and 24 females; their characteristics and other features are listed in Table 1. The overall success rate was 84%, of whom 57 patients (67.9%) became stone free after one session and 27 patients (32.1%) needed two sessions of ESWL to become stone-free. Two patients needed auxiliary procedures after ESWL, i.e. JJ ureteric stenting due to symptomatic obstructing fragments, followed by repeated successful ESWL. In 16 patients the ESWL was considered to have failed. The causes of failure were either lack of disintegration (11 patients) or failure of clearance (elimination) of residual fragments (five). Salvage procedures included ureteroscopy and stone extraction in three cases and ureteroscopy with intracorporeal pneumatic lithotripsy in 10. Salvage ureteroscopy failed in two cases; in the first, stone migrated to the kidney during pneumatic lithotripsy, and this was managed by ureteric catheterisation and subsequently one session of ESWL, which rendered the patient stone-free. In the other case, marked prostatic enlargement caused difficulty in identifying the ureteric orifice, and this case was managed by left ureterolithotomy in the same setting. One obese woman (aged 41 years), who had poor fragmentation of her right lower ureteric stone after two sessions of ESWL, refused to undergo salvage ureteroscopy, and thus a third session of ESWL was used and the patient rendered stone-free, although the case was considered as a failure in the results, according to our study protocol.

According to univariate analyses (Tables 2 and 3), only three factors had a significant effect on the SFR, i.e. body mass

Table 1 The characteristics and other variables in the 100 patients.

Variable	Mean (SD, range) or *n*
Age (years)	34.4 (15.1, 14–76)
Side involved (right/left)	33/67
Stone length (mm)	9.24 (2.40, 4–15)
Stone width (mm)	5.51 (1.85, 3–12)
Symptom duration (days)	18 (4, 3–54)
BMI (kg/m^2)	24.8 (3.8, 20–36)
Stone attenuation value (HU)	592 (202, 280–1052)
Treatment time (min)	46 (18, 33–82)
Fluoroscopic time (min)	2.6 (2, 1.4–6.0)
No. of SWs delivered/session	3200 (1750, 2400–4000)
Voltage (kV)	17.6 (1.1, 15–19)
No. of shocks delivered/stone	5060 (2046, 2400–11,000)
No. of sessions/stone	1.4 (1–3)
Time to stone-free status (days)	13.7 (8.2, 2–40)

Table 2 Univariate analysis for categorical variables predicting failure of *in situ* ESWL for DUC.

Variable	No. of cases	*n* (%) stone-free	*P*
Male	76	64 (84.2)	1.00
Female	24	20 (83.3)	
Stone side			
Right	33	29 (87.9)	0.56
Left	67	55 (82.1)	
Stone nature			
De novo	81	68 (84.0)	1.00
Recurrent	19	16 (84.2)	
Degree of back pressure			
Normal	37	32 (86.5)	0.954
Mild	18	15 (83.3)	
Moderate	35	29 (82.9)	
Marked	10	8/10 (80)	
BMI (kg/m^2)			
< 25	57	50 (87.7)	0.019
25–29	32	28 (87.5)	
⩾30	11	6 (54.5)	
Stone length (mm)			
⩽10	76	66 (86.8)	0.016
> 10	24	17 (70.8)	
Stone width (mm)			
< 8	78	70 (89.7)	0.007
⩾8	22	14 (63.6)	
Stone opacity			
Low	14	12 (85.7)	0.586
Moderate	59	51 (86.4)	
High	27	21 (77.8)	
Symptom duration (days)			
⩽7	23	20 (87.0)	0.907
> 7	77	64 (83.1)	
Stone impaction			
Yes	34	28 (82.4)	0.778
No	66	56 (84.8)	

Table 3 Univariate analysis for continuous variables predicting failure of *in situ* ESWL for DUC.

Variable	Outcome	*N*	Mean (SD)	*P*
Stone length (mm)	Failure	16	10.69 (2.52)	0.010
	Success	84	9.00 (2.31)	
Stone width (mm)	Failure	16	6.63 (2.09)	0.008
	Success	84	5.30 (1.73)	
Age (years)	Failure	16	38.5 (19.9)	0.362
	Success	84	33.63 (14.14)	
Symptom duration (days)	Failure	16	17.06 (7.47)	0.580
	Success	84	18.64 (10.89)	

index (BMI), stone length and stone width. The SFRs were nearly the same for normal and overweight patients (50/57; 87.7%) and (28/32; 87.5%), respectively. This was in contrast to obese patients, i.e. those with a BMI of > 30, in which the SFR was six of 11. This difference was statistically significant ($P = 0.019$). A stone width of ⩾8 mm was associated with a SFR of 64% (14/22), compared to 89.7% (70/78) for those with a stone width of < 8 mm ($P = 0.007$). The mean (SD) stone width in the stone-free group and the failed group was 5.30 (1.73) and 6.63 (2.09) mm, respectively ($P = 0.008$). For stone length, the SFR was 86.8% (66/76) for a stone length of ⩽10 mm and 70.8% (17/24) for > 10 mm ($P = 0.016$). The mean (SD) stone length in the stone-free group was 9 (2.3) mm, in contrast to 10.6 (2.5) mm in the failed group, the difference being statistically highly significant ($P = 0.01$).

Table 4 Multivariate analysis (logistic regression) for variables predicting ESWL failure for DUC.

Variable	*B*	SE	Exp(*B*)	95% CI for Exp(*B*)	*P*
BMI (kg/m^2)					
< 25 (reference)	0		1		
25–29	−0.019	0.759	0.981	0.222–4.342	0.980
⩾30	2.480	0.875	11.95	2.15–66.32	0.005
Stone					
Length (mm)	0.303	0.136	1.354	1.038–1.766	0.025
Width (mm)	0.282	0.170	1.326	0.950–1.851	0.010

Exp(*B*) is the odds ratio, i.e. the ratio between the probabilities of failure due to the increase in the predictor value by one to its original probability. *B*, regression coefficient.

Using multivariate logistic regression analysis, the three factors maintained statistically significant effects on the success rate, indicating that these factors act independently and could be used as significant predictors of failure of ESWL in patients having DUC (Table 4).

The final model showed that a BMI of ⩾30, stone length > 10 mm and stone width ⩾8 mm were significantly associated with the failure of ESWL in DUC. A combination of risk factors increased the cumulative risk of failure. The model provides a favourable overall prediction rate of 83% for dependent variables (it can predict 83% of cases in the study) and the predictive value of each significant predictor when applied alone was 84%.

The logistic regression equation is: $y = -6.745 + B$ (of stone length × stone length) + B (of stone width × stone width) + B of the BMI, where (y) is the linear combination, B is the regression coefficient and (−6.745) is the constant of the model.

The probability of failure (P) for a particular individual with a DUC to *in situ* ESWL is $1/(1 + e^{-y})$, where e is the base of natural logarithms. In general, if the estimated probability is > 0.5 then failure of *in situ* ESWL for a DUC is anticipated and alternative treatment (i.e. ureteroscopy) might be a better choice with a higher success rate.

Discussion

In the present series, the overall SFR was 84%; this success rate is within the reported range (73–86%) [3]. Few authors have reported better success rates (96–97%) of ESWL for DUC, but mostly using the HM3 lithotripter (Dornier, Germany) [4–6]. Perhaps only three studies have reported this high SFR (92–93%) with the second-generation Lithostar lithotripter [6–8]. In the present series the re-treatment rate was 27% and auxiliary procedures were required in only 2% of cases. In previous reports the re-treatment rate ranged from 9% using the unmodified Dornier HM3 lithotripter [5] up to 50% in some studies involving second-generation lithotripters [9].

Although from previous reports there is still no consensus on the number of ESWL treatments for ureteric calculi that should be administered before alternative treatments are used, in the present series we considered absent or poor fragmentation after two ESWL sessions as a failure. However, a notable finding in our study was a relatively high re-treatment rate (1.4 sessions/patient). Although not scientifically confirmed, we believe this might be due to the late presentation for ESWL treatment in general and the relatively large number of impacted stones.

In our study we aimed to evaluate factors that could have a significant effect on the SFR after ESWL for DUC, using univariate and multivariate analysis. This objective is lacking in the studies, particularly in the last 10 years with the new era of lithotripters. To our knowledge, this present study is the study reported on a group of Egyptian patients, and addressing the factors affecting the success of *in situ* ESWL for DUC in particular. We defined three factors that had a significant effect on the SFR, i.e. BMI, stone length and stone width. Our threshold values for a statistically significant higher SFR were a stone length of $\leqslant$10 mm, a stone width of $<$8 mm and a BMI of <30 kg/m^2. Similar to our results, most studies found a statistically significant inverse relation between stone dimensions and success rate of ESWL for ureteric stones [9–11]. The AUA Guidelines Panel reported that, for DUC, the success rates were 85% and 76% for stones of $\leqslant$10 and $>$10 mm, respectively [2]. In two studies [3,12], the transverse diameter of the stone per se had a negative effect on the outcome of ESWL. This might be explained by the lower expansion space around the stone and inadequate cavitation bubble formation, and thus poor shock-wave transmission and difficult disintegration. As to the effect of BMI on SFR, we found that obesity (BMI $\geqslant$30) was a significant predictor of ESWL failure (P = 0.019) and the probability that obese patients will not be stone-free after two sessions of ESWL is more than 10 times higher than for patients with a normal BMI. Disintegration failure in those patients and the need for more SWs might be explained by hampered targeting of the stone and dampened SWs because of the excess fat. Few previous studies have addressed the effect of patient BMI on the outcome of ESWL and reached similar conclusions [13,14].

Contrary to common belief, stone radio-opacity on a plain film did not affect the overall SFR in the present series. Unfortunately, using a plain film for reporting the stone density is highly subjective and difficult to standardize. Besides, calculi must have an appreciable diameter to allow the density to be reported accurately, and this was not the case in our series of DUC with a mean stone length of 9.2 mm. The final possible explanation for our result is that although the radio-faint stone might be more fragile, it increases the existing difficulty of locating the DUC during ESWL.

The results of the present study agree with most previous stThe results of the present study agree with most previous studies regarding the absence of associations between the age and sex of the patient, side and nature of the stone and the treatment outcome [3,15]. Also, in our study we did not find a significant correlation between stone impaction and the overall outcome. Although initial studies reported that this was important, recent trials suggested that a macroscopic expansion space around the stone is not necessary for successful fragmentation [16]. Similarly, there was no significant correlation in our study between the degree of stone-induced hydronephrosis and the overall success rate of ESWL. In recent reports the relation between urinary obstruction and ESWL outcome is still being debated [17,18].

Although the duration of symptoms before presentation was the most influential factor in one study for predicting the spontaneous passage of ureteric stones [19], this factor had no significant correlation with ESWL outcome in the present study. However, the mean (range) symptom duration before treatment in our study was relatively long, at 18 (4, 3–54) days. Recently, several investigators studied the effect of symptom duration on ESWL outcome and proposed that emergency ESWL treatment (during or very shortly after the attack of ureteric colic) could be a valuable therapeutic option for ureteric stones [11,20].

In conclusion, *in situ* ESWL is a safe and effective treatment for DUC, with an SFR of 84%, a re-treatment rate of 27%, and auxiliary procedures required in 2% of patients. In our study the length and transverse diameter of the stone, together with the BMI of the patient, were the only significant predictors of the overall success rate of ESWL for DUC, using univariate and multivariate analyses. It is our opinion that ESWL could be offered as a primary treatment for patients having DUC with a stone length of $\leqslant$1 cm, a stone width of $<$8 mm, and a BMI of <30 kg/m^2.

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