Original Article

Role of clinical and radiological parameters in predicting the outcome of shockwave lithotripsy for ureteric stones

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Abstract

Introduction: Shockwave-lithotripsy (SWL) provides a noninvasive and effective option for the management of ureteric calculi. Several factors may affect the success of SWL. Identification of these predictive factors will both increase the efficacy and decrease the cost. This study was designed to identify factors affecting the outcome of SWL for ureteral stones.

Materials and Methods: This study was conducted from March 2012 to November 2014 in patients with solitary ureteric calculi who were managed with SWL. Data were analyzed to identify clinical and radiological factors associated with treatment outcome. Success after SWL was described as complete stone clearance or clinically insignificant residual fragments <3 mm at 3 months after SWL.

Results: A total of 110 patients with ureteric calculi were divided into two groups depending on the outcome of SWL, Group A (successful - 76%) and Group B (failed - 24%). Stone size, Skin to stone distance (SSD), secondary signs of obstruction, and presence of double J (DJ) Stent, all were significantly associated with the outcome of SWL on univariate analysis. On multivariate analysis, stone size, hounsfield unit, SSD, and DJ stent were the independent factors affecting the outcome of SWL. On Receptor-Operator Characteristic curve analysis, a cutoff value of 8.2 mm for the stone size was found which best predicts a successful outcome, with a sensitivity of 54% and specificity of 96%.

Conclusion: The findings of this study suggest that Stone size, SSD, the presence of DJ stent, and stone attenuation values are the significant factors that influence the outcome of SWL in patients with ureteral stones.

Keywords: Outcome, shockwave-lithotripsy, ureteric stones, ureterolithiasis

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INTRODUCTION

Ureteric calculi are common urological disorders. Conventional treatments include ureteroscopic extraction, shock wave lithotripsy (SWL), and open or laparoscopic surgery.

SWL provides a noninvasive, simple, effective and safe option for the management of ureteric calculi.[1] SWL may cause unnecessary exposure of the treated kidney and neighboring organs to radiation and high energy shock waves which may result in tissue damage. SWL is associated with inherent risk of failure in some patients. The patients whose stones may not be fragmented by repeated SWL will require auxiliary procedures. These patients need to be identified beforehand.

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Several prognostic factors of the success of SWL have been studied.[2,3] These include the size of the stone, its location and density, its degree of impaction and the presence of hydronephrosis.

Identification and the use of these predictive factors in clinical setting will both increase the efficacy and decrease the cost by reducing the number of unnecessary treatment sessions as well as hospital visits.

This present study was designed to establish factors predicting the success of SWL, based on a large-scale clinical study focusing on multiple prognostic factors. It is hoped that such a study will benefit both the patients who have the disease and the physicians treating them, in terms of making the right clinical decision.

MATERIALS AND METHODS

This study was conducted in the Department of Urology in tertiary care centre of northeast part of India, from March 2012 to November 2014.

Inclusion criteria were solitary and radio-opaque ureteric stones of size 5 mm to 20 mm. Patients with a history of previous SWL or stone surgery, urinary tract infections, blood coagulation disorders, ureteral stricture, neurogenic bladder, polycystic kidney, or distal ureteric obstruction were excluded.

Data of each patient were prospectively collected. Age, sex, body mass index (BMI), stone size, stone site, laterality, skin-to-stone distance (SSD), Hounsfield unit (HU), presence of double J (DJ) stent, serum creatinine levels, total SWL sessions required, presence of renal colic, and presence of secondary signs (hydronephrosis, renal enlargement, perinephric fat stranding, and tissue rim sign) were noted.

The SSD was measured on computed tomography (CT) scan by three distances from the stone to the skin (0°, 45°, and 90°). The average SSD was measured from these values and was recorded as the representative SSD for each stone. The HU for each stone was determined by using a 5-mm collimation width from the top of the kidneys to the level of the pubic symphysis. Three regions of interest (ROI) were analyzed in the images showing the stones in the largest dimension. All measurements were made with a similar-sized ROI (2.0 ± 0.5 mm^2). The HU average of three ROIs represented the HU for that stone. Secondary signs including the presence or absence of hydronephrosis, renal enlargement, perinephric fat stranding, and tissue rim sign were also assessed on CT scan. Tissue rim sign was recognized as the observation of the annular soft tissue caused by the edematous ureteral wall surrounding the stones. All radiologic factors were reviewed by one specialized uro-radiologist.

The SWL sessions were generated using a Dornier Compact Delta lithotripter. The stones were fragmented under fluoroscopic guidance, and the number of shockwaves and energy level were recorded. Maximum of 3000 shocks were given per session at the rate of 60–80 shocks per minute at an energy level of 8–12 kv. In those patients who had received a DJ stent, the SWL session took place with a minimum of 3 weeks after the stent placement.

Patients were followed up at 1 week after SWL with a plain abdominal film and ultrasonography. If there were significant fragments, the second session of SWL was planned. However, if there were only insignificant fragments, the patients were given medical treatment and re-evaluated after 1 month. Final results were considered after the complete passage of all fragments or after 3 months from the last SWL session.

The outcome of SWL was described as a success when complete stone clearance was achieved or clinically insignificant residual fragments <3 mm with no symptoms at 3 months after SWL. Failure was defined as clinically significant residual fragments >3 mm after three sessions of SWL, as confirmed by a plain film.

Patients were divided into two groups, Group A where SWL was successful and Group B where SWL failed.

Data were analyzed to identify clinical and radiographic factors associated with treatment outcome. Univariate analysis was used to individually assess the association between the various factors and outcomes. Thereafter, the significantly associated variables were tested with multivariate logistic regression analysis to identify the independent predictors of treatment outcome. In all tests, $P < 0.05$ was considered to indicate statistical significance.

RESULTS

A total of 110 patients with ureteric calculi were included in the study. The overall success rate of SWL in this study was 76% ($n = 84$) and the failure rate was 24% ($n = 26$). All the patients were divided into two groups depending on the outcome of SWL, Group A (successful) and Group B (failed).

On univariate analysis, age, sex, BMI, laterality, location, serum creatinine, and history of colic were not statistically significant in terms of the outcome of SWL [Table 1]. HU with a $P = 0.062$ was not statistically significant but was consistently low in the successful group. The mean stone size in the success and failure groups, respectively, was 8.1 mm (5.0–14.9) and 11.3 (7.5–18.0) with a $P < 0.001$. The mean SSD in the success and failure groups was 90.0 (75.0–118.0) and 96.0 (79.0–123.0), respectively, with a $P < 0.001$. The secondary signs of obstruction and DJ stent also showed statistically significant differences between the two groups.

Logistic regression analysis was used to predict factors associated with failure of SWL. In the multivariate logistic regression, larger stone size (odds ratio [OR] - 19.718; 95% confidence interval [CI] - 1.600–243.005), higher HU, higher SSD, and presence of DJ stent were the independent predictors for failure of SWL in the given population [Table 2].

Receiver-operating characteristic curve analysis [Figure 1] was done to determine stone size cut-off that best predicts a successful outcome, and it was found to be 8.2 mm with a sensitivity and specificity of 54% and 96%, respectively, (area under the ROC curve: 0.77995% confidence limit: 0.685–0.872).

A total number of shockwaves and SWL sessions were tabulated and analyzed as per the outcome and location of stone in the ureter [Table 3]. A number of shockwaves delivered and SWL sessions were significantly different between successful and failed SWL for the stones located in upper ureter. Median shock waves delivered for the upper ureteric stones successful on SWL were 2500 (2000–6000) and for failed SWL were 4550 (2000–6500) whereas, the median number of SWL sessions was 1 and 2, respectively. Similarly, for lower ureteric stones the number of shockwaves delivered and SWL sessions were significantly different between successful and failed SWL groups. For mid ureteric stones, the difference was nonsignificant.

When the results were regrouped as Group I (stone size <10 mm) and Group II (stone size >10 mm), the success rates were 84.1% in the Group I and 63.4% in the Group II [Table 4]. The average stone

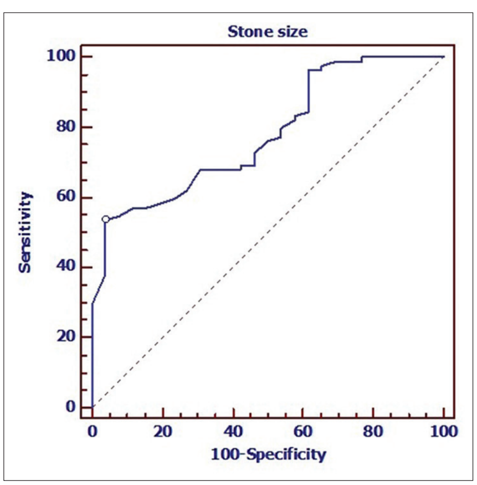

Figure 1: Receiver operating characteristic curve analysis to determine stone size cut off that best predicts a successful outcome of shockwave lithotripsy for ureteral stones

Table 1: Univariate analysis of various factors affecting the shockwave-lithotripsy outcome for ureteral stones

Parameter	Group A (*n*=84)	Group B (*n*=26)	*P*
Age	36.0±1.08	38.0±2.48	0.402***
Sex			
Male	55	17	1.00**
Female	29	9	
BMI	24.0 (21-31)	24.0 (21-30)	0.913*
Laterality			
Left	41	15	0.504**
Right	43	11	
Location			
Upper	65	22	0.722****
Mid	4	1	
Lower	15	3	
Size	8.1 (5.0-14.9)	11.3 (7.5-18.0)	<0.001*
History of colic			
Yes	63	18	0.613**
No	21	8	
Secondary changes			
Yes	27	15	0.023**
No	57	11	
DJ stent			
Yes	3	10	<0.001**
No	81	16	
HU			
A (<750)	29	4	0.062****
B (750-100)	43	16	
C (>1000)	12	6	
Serum creatiinine	1.0 (0.6-2.2)	1.0 (0.7-1.5)	0.093*
SSD (mm)	90.0 (75.0-118.0)	96.0 (79.0-123.0)	<0.001*

*Mann-Whitney U-test, **Fisher's exact two-tailed test, ***Unpaired student *t*-test, ****Chi-square test two-tailed test. BMI: Body mass index, DJ: Double J, HU: Hounsfield unit, SSD: Skin to stone distance

Table 2: Multivariate analysis of various factors affecting the outcome of shockwave-lithotripsy for ureteral stones

Parameter	OR (95% CI)	*P*
Size	19.718 (1.600-243.005)	0.02
SSD (mm)	0.919 (0.863-0.980)	0.009
Secondary changes	0.489 (0.1261-0.905)	0.303
DJ stent	0.048 (0.006-0.401)	0.005
HU		
A	0.104 (0.013-0.750)	0.027
B	0.110 (0.015-0.827)	0.032
C	0.027 (0.002-0.385)	0.008

OR: Odds ratio, CI: Confidence interval, SSD: Skin to stone distance, HU: Hounsfield unit, DJ: Double J

Table 3: Number of treatment sessions and shockwaves as per the location of ureteral stone

Location of stone	Treatment outcome (*n*)	Number of sessions, median (range)	*P*	Shokwaves, median (range)	*P*
Upper					
Success	65	1 (1-3)	<0.001	2500 (2000-6000)	<0.001
Fail	32	2 (1-3)		4550 (2000-6500)	
Middle					
Success	4	2 (1-2)	0.235	4750 (2500-5000)	0.276
Fail	1	3		6000	
Lower					
Success	15	1 (1-2)	0.01	2500 (2000-5000)	0.043
Fail	3	2		4800 (4500-5000)	

Table 4: Univariate analysis of the factors in Group A (stone size<10 mm) and Group B (stone size >10 mm)

Characteristic	Group A (*n*=69) Stone size ≤10 mm (%)	Group B (*n*=41) Stone size >10 mm (%)	*P*
Age (years)	35.16±9.733	38.68±11.633	0.091***
Sex			
Male	46 (66.7)	26 (63.4)	0.729**
Female	23 (33.3)	15 (36.6)	
Results			
Success	58 (84.1)	26 (63.4)	0.014**
Failure	11 (15.9)	15 (36.6)	
Laterality			
Right	35 (50.7)	19 (46.3)	0.657**
Left	34 (49.3)	22 (53.7)	
BMI (kg/m^2)	24.30±2.137	24±2.269	0.482*
Stone size (mm)	7.72±1.07	12.99±1.74	<0.001*
Stone location			
Upper	52 (75.4)	35 (85.4)	0.353****
Middle	3 (4.3)	2 (4.9)	
Lower	14 (20.3)	4 (9.8)	
SSD (mm)			
<100	45 (65.25)	28 (68.3)	0.741**
>100	24 (34.85)	13 (31.7)	
HU			
A (<750)	17 (24.6)	16 (39)	0.166****
B (750-1000)	38 (55.15)	21 (51.25)	
C (>1000)	14 (20.3)	4 (9.8)	
Secondary signs			
Absent	47 (68.1)	21 (51.2)	0.078**
Present	22 (31.9)	20 (48.8)	
Serum creatinine	0.98±0.24	0.98±0.198	0.938*
Shockwave (no)	3095±1079	4746±996	<0.001*
History of colic			
Yes	49 (71)	32 (78)	0.418**
No	20 (29)	9 (22)	
DJ stent	69	41	
Yes	5 (7.2)	8 (19.5)	0.054**
No	64 (92.8)	33 (80.5)	

*Mann-Whitney U-test, **Fisher exact two-tailed test, ***Unpaired student *t*-test, ****Chi-square test two-tailed test. SSD: Skin to stone distance, HU: Hounsfield unit, DJ: Double J, BMI: Body mass index

size was significantly different between the two groups, 7.72 ± 1.07 mm and 12.99 ± 1.74 mm in group I and group II, respectively. A number of the shockwaves delivered (Group I - 3095 ± 1079, Group II - 4746 ± 996) was also statistically significant between the two groups. Remaining variables were not significant. On multivariate analysis, only the Number of the shockwaves delivered was significantly different between the two groups [Table 5].

DISCUSSION

SWL has revolutionised the management of urolithiasis since its introduction in the early 1980s.[4] Less invasive nature and favorable clinical outcome following SWL treatment has made SWL one of the first-line treatment options for patients with ureteric calculi.

Overall stone clearance in our study was 76%. Most studies have reported clearance rates ranging from 84.2% to 88.7% for ureteric stones.[2,5]

Several factors have been reported to influence the stone-free rate after SWL treatment, including patient's demographic characteristics (such as age, sex, and BMI) and stone features (such as stone site, HU, and size).[6,7]

It has been demonstrated that the clinical outcome of SWL for calculi of the upper-third ureter in elderly patients was inferior to that of the younger patients.[8] In addition, the mean age of the patients successfully treated with SWL was significantly lower than that of the failure group, which may be because younger patients had better renal excretion and higher contraction strength of the ureteral muscle. However, this finding has been challenged by other researchers, and patient age was not considered as a significant factor for the success rate of SWL.[9] In our series, age was not a significant factor and does not influence the outcome of SWL.

In several studies, the most important factor in predicting the outcome of SWL for urinary calculi was the stone size, and it was found that the smaller (<8–10 mm) ureteric stones are significantly better cleared than larger ones.[2,5]

Larger stones also required more treatment sessions of SWL. In the present study, the mean stone size was 8.1 mm (5.0-14.9) and 11.3 (7.5-18.0) in Group A (success) and B (failure), respectively. The larger stone size was found to be an independent predictor of failure of extracorporeal SWL on both univariate and multivariate analysis.

Table 5: Multivariate logistic regression analysis of the factors in Group A (stone size <10mm) and Group B (stone size >10 mm)

Parameters[a]	*B*	SE	Wald	df	*P* value	Exp(B)	95.0% CI for Exp(B)	
							Lower	Upper
Age	0.035	0.025	2.020	1	0.155	1.036	0.987	1.087
Results	0.741	0.645	1.320	1	0.251	2.097	0.593	7.422
Secondary signs	−0.251	0.531	0.223	1	0.636	0.778	0.275	2.204
Shockwave	0.001	0.000	26.356	1	<0.001	1.001	1.001	1.002
DJ stent	−0.335	0.834	0.161	1	0.688	0.715	0.140	3.667
Constant	−7.315	1.914	14.610	1	0.000	0.001		

[a]*0.05, P*<0.05 significant, Group B as reference. CI: Confidence interval, SE: Standard error, DJ: Double J

Renal colic has been shown to be a positive factor for the success of SWL.[10] Although the detailed mechanism is not fully understood, it is considered that the occurrence of renal colic is a symptom indicating ureteric calculi does not conglutinate with the ureterovesical junction. In addition, renal colic promotes higher peristalsis frequency, and contraction strength of the ureter, facilitating excretion of the stones. In our study, history of renal colic was not statistically significant for predicting the success of SWL. This may be due to less percentage of patients with a history of ureteric colic in our study, which may have affected the results.

With regard to the hydronephrosis, research indicates that hydronephrosis has a significant influence on the success rate of SWL for treating distal ureteric calculi, although its influence on the overall stone-free rate is not significant.[11] This discrepancy may be due to the interaction between the hydronephrosis and other factors, such as stone size and renal colic, thus, the contribution of the hydronephrosis was somehow weakened.

Choi *et al*.[12] investigated predictive factors for failure of SWL for treating ureteral stones. The patients were divided into two groups: (Group A - 102 patients, stone size ≤10 mm; and Group B - 51 patients, stone size >10 mm). They assessed age, sex, BMI, stone size, laterality, location, SSD, HU, and the presence of secondary signs (hydronephrosis, renal enlargement, perinephric fat stranding, and tissue rim sign). On the univariate analysis of each group, stone size, SSD, and all secondary signs showed statistically significant differences in terms of the outcome of SWL. On the multivariate logistic regression, stone size was an independent predictive factor in group A and the presence of perinephric fat stranding and stone size were independent predictive factors in group B. In the present study, we analyzed secondary changes (hydronephrosis, renal enlargement, perinephric fat stranding, and tissue rim sign) between group A and B. We found that presence of secondary changes was statistically significant ($P = 0.023$) in predicting failure of SWL on univariate analysis but not on multivariate analysis.

Placement of double-J ureteric stent was found to be a significant contributor to the stone-free rate after SWL as observed in a study by Wada *et al*.[13] Although the use of DJ ureteric stent was criticized by other researchers due to a decreased success rate observed,[5] DJ ureteric stent was required in patients for whom the stones caused a severe degree of obstruction. In this study, placement of double-J stent was statistically significant in predicting failure of SWL by both univariate and multivariate regression analysis. This can be explained by the fact that DJ stent was placed in more complicated or larger stones where success of SWL was less likely. Hence, *per se*, the role of DJ stent in influencing results of SWL is not clear.

Several investigators have since shown that SWL is more likely to fail for patients with renal calculi >750–1000 HU and these patients should be considered for other treatment modalities.[14,15] Pareek *et al*.[15] evaluated 50 patients who underwent SWL for 5–10 mm upper urinary tract stones. They reported significant differences with regards to the HU values for the stone-free groups and the residual stone groups and suggested that HU measurement of urinary calculi on CT scan may predict the stone-free rate. In our study, we divided the patients on the basis of HU A (<750 HU), B (750–1000 HU), C (>1000 HU). Increasing HU was not statistically significant in predicting failure of SWL by univariate analysis ($P = 0.62$). However, this came to be significant on multivariate logistic regression analysis, which is in accordance with the findings of previous studies.

The utility of BMI in predicting successful SWL is variable. Higher BMI is found to be a significant factor affecting the success of SWL in some studies.[15,16] Conversely, in another study, BMI failed to predict successful SWL outcomes, whereas SSD remained a significant predictor.[17] Wiesenthal *et al*.[18] suggested that SSD was a significant predictor of lithotripsy success for ureteral stones. In the multivariate analysis, SSD >110 mm (OR, 0.49; 95% CI, 0.31–0.78) was a significant predictor of outcome. Perks *et al*.[19] also supported this finding. They reported that SSD of <9 cm (OR: 2.8; 95% CI: 1.1–7.2) can predict

SWL success. In a recent study by Yazici *et al*.[16] SSD was the only independent predictor of failure or success for the treatment of distal ureteral stones treated with SWL. In our study, BMI was not a significant predictor of the outcome of SWL ($P = 0.913$), whereas, SSD was found to be significant ($P < 0.001$) in predicting the outcome of SWL.

In the present study, we have not found any statistical significance of sex, laterality, location, and serum creatinine on the outcome of SWL.

CONCLUSION

The results of this study clearly show that Stone size, SSD, the presence of DJ stent and stone attenuation values are the significant factors that influence the outcome of SWL in patients with ureteral stones.

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Conflicts of interest
There are no conflicts of interest.

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