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Study of Factors Predicting the Outcome of Extracorporeal Shock Wave Lithotripsy in Patients of Renal and Upper Ureteric Calculi

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ABSTRACT
Extracorporeal shock wave lithotripsy (ESWL) is a safe, effective, non-invasive, and commonly used method for uncomplicated upper urinary tract calculi. The stone-free rate (SFR) is influenced by stone characteristics (stone size, location, density in Hounsfield Unit, degree of obstruction), renal anatomy (congenital anomaly, hydronephrosis, stenosis, calyceal diverticulum), patient-associated factors (Body mass index, skin-to stone distance, and renal function), and efficacy of lithotripter. The present study is conducted with the objective of determining the predictors affecting the outcome (success or failure) of ESWL in renal and upper ureteric calculi. This cross-sectional hospital-based study was conducted in the Department of General Surgery and Urology, Sanjay Gandhi Memorial Hospital, Rewa, India from July 2021 to June 2022, in which 95 patients with renal and upper ureteric calculi were included. All patients were treated with ESWL. We evaluated the role of stone (size, location and density) and patient (sex, age, body mass index and skin to stone distance) related attributions in predicting the clinical outcome of ESWL. After statistical analysis, p-value < 0.05 was taken as the level of significance. A total of 95 cases were selected for the study. The majority of the patients (34.73%) were found in between 18 to 30 years age group, Males were slightly predominant 53 (55.78%) than females 42(44.21%). The most common site of the renal stone was pelvis (34.73%) followed by the lower calyx (18.94%) and most of the stones (83.78%) were ≤10 mm in size. Stone density ≤800 HU was found in 50.52% of patients. Stone-free rate (SFR) was 75.78% after a maximum of 3 sessions of ESWL. Size (≤10 mm), Site (Non-inferior calyceal calculi) skin to stone distance (≤10 cm), and stone density (≤ 800HU) were significant predictors of the success of ESWL ($p<0.05$). Stone size, stone location, stone density, and skin-to-stone distance are important predictors of the SFR of ESWL for both renal and upper ureteric stones. We should take these factors under consideration for proper case selection, optimal results, and patient counselling.

INTRODUCTION

Urolithiasis has a high prevalence worldwide which varies from 1 to 19% with a high recurrence rate[1]. Over the past few years, there has been increasing trend in the incidence of urinary stones, both in developed and developing countries[2]. Kidney stone disease affects 1 in 10 persons at least once in life-time; the global burden of recurrent urinary stone disease is nearly 2%[3]. In India, the rising incidence of urolithiasis is a major concern for healthcare and the economy. In India, the incidence was lower than 40/100,000 in the 1960s, but three decades later, it grew dramatically to 930/100,000[4]. Studies from Asian countries suggest that the recurrence rate is about 6-17% after 1 year and 21%-53% after 3-5 years. The lifetime risk of recurrence is estimated to be 60-80%[5].

Extracorporeal Shock Wave Lithotripsy (ESWL), Ureteroscopy (URS), Retrograde Intra-Renal Surgery (RIRS), Percutaneous Nephrolithotomy (PCNL) and open surgery are various treatment options, if active stone removal is indicated[6].

Chaussy *et al*.[4] introduced ESWL, for the first time in 1980. Though ESWL is a non-invasive and safe procedure compared to other treatment modalities, but it is not free of complications and may cause hemorrhage, steinstrasse, renal hematoma, infection and flank pain[8].

European Association of Urology recommends the use of ESWL as a preferable modality in the treatment of non-lower pole renal calculi (<20 mm), lower pole renal calculi (<10 mm) and ureteral calculi (<10 mm) after excluding unfavourable factors for ESWL[9]. Data from high-volume centres show clearance rates of 86-89%, 71-83%, 73-84% and 37-68% for calculi in the renal pelvis, upper calyx, middle calyx and lower calyx, respectively[10].

The stone-free rate (SFR) is influenced by different factors such as stone factors (stone size, location, composition, degree of obstruction), renal anatomy (congenital anomaly, hydronephrosis, stenosis, calyceal diverticulum), patient-associated factors (Body mass index, skin-to stone distance and renal function) and efficacy of lithotripter[11,12]. Thus, proper case selection is one of the key to improving ESWL efficacy and optimal management.

Aims and Objectives: This study aims to evaluate the various factors predicting the outcome of ESWL in patients with renal and upper ureteric calculi in the Indian population.

MATERIALS AND METHODS

This was a cross-sectional hospital-based study carried out in the Department of General Surgery, in collaboration with the Department of Urology, Sanjay Gandhi Memorial Hospital and Shyam Shah Medical College, Rewa, India from July 2021 to June 2022.Commencement of study was after ,obtaining the ethical approval from the institutional committee.

Inclusion criteria were patient who presented with upper urinary tract stones $\leq$ 20 mm and were in need of active stone removal, age between 18 to 60 years and consented to participate in the study. Patients with acute urinary tract infections, blood coagulopathies, obstructions distal to the stone, lower and middle ureteric calculi and with a history of previous urinary stones surgery were excluded from the study.

Enrollment of total 95 cases of renal and upper ureteric calculi was done in the study. Inclusion and exclusion criteria were applied before enrolling the cases . Non-contrast computed tomography (NCCT) KUB was used in all cases to confirm the size of the stone, location, density and skin-to-stone distance (SSD). Maximal stone length in the imaging study, was the measure of stone size.

ESWL procedure was performed on an outpatient basis. All patients were routinely assessed through a proper history, a thorough clinical examination, urine analysis, urine culture, biochemical parameters, complete blood count and coagulation profile before treatment. Dornier Medizintechnik, German lithotripter was used to treat the patients. After localizing the stone with fluoroscopy, ultrasonic guided piezoelectric lithotripter was used to fragment the stones. Maximum three sessions were planned for fragmentation and clearance of stone . The treatment interval between sessions was 2 to 3 weeks to allow clearance of fragmented stone pieces and recovery of kidney. . Follow-up was planned at 2 weeks, 1 month and 3 months after the last session. X-ray KUB or ultrasonography was used to assess the fragmentation and clearance of stones after each session and follow-up visit. Complete clearance and presence of asymptomatic non-obstructive residual fragments $\leq$ 4 mm in the kidney after a maximum of 3 sessions was considered as successful. We evaluated the role of stone (size, location and density) and patient (sex, age, body mass index and skin to stone distance) related characteristics in predicting the clinical outcome of ESWL.

Statistical Analysis: Statistical software SSPS version 22 was used for data entry and evaluation. The chi-square test was used to analyze the statistical significance of the relation between factors and their effect on the outcome of ESWL. A p-value of less than 0.05 was considered to be statistically significant.

RESULTS

A total of 95 renal calculi patients were enrolled, out of them ESWL was successful in 72 (75.78%) cases

Table 1: Correlation of age and gender factors with the ESWL outcome

	Successful		Failed	
Variables	N (72)	Percentage	N (23)	Percentage
Age group (Years)				
18-30 (33)	25	75.75	8	24.24
31-40 (29)	24	82.75	5	17.24.
41-50 (19)	13	68.42	6	31.57
51-60 (14)	10	71.42	4	28.57
Gender				
Female (42)	32	71.11	10	23.8
Male (53)	40	75.47	13	24.52

Table 2: Stone-related parameters and ESWL outcome

	ESWL Success		ESWL Fail		
Variables	N (2)	Percentage	N (23)	Percentage	p-value
Laterality of Stone					
Right (50)	38	76	12	24	0.9S59
Left (45)	34	75.55	11	24.44	
Stone Site					
Upper Calyx (17)	15	82.23	2	11.76	0.0001*
Middle Calyx (16)	12	75	4	25	
Lower Calyx (18)	6	33.33	12	66.66	
Pelvis (33)	30	90.9	3	9.09	
Upper Ureter (11)	9	81.81	2	18.18	
Stone Size					
≤10mm (72)	60	83.33	12	16.66	0.0023*
>10-20mm (33)	12	52.17	11	47.82	
Stone Density					
≤ 800 HU (48)	41	85.41	7	14.58	0.0268*
> 800 HU (47)	31	65.95	16	34.04	

*p-value <0.05 significant

Table 3: Patient-related parameters and ESWL outcome

	ESWL Success		ESWL Fail		
Variables	N (72)	Percentage	N (23)	Percentage	p-value
Body mass index (BMI) 25 kg m^{-2}					
≤ 25 (62)	50	80.64	12	19.35	0.1299
> 25 (33)	22	66.66	11	33.33	
Skin to stone distance (cm)					
≤ 10 (58)	48	82.75	10	17.24	0.0471*
> 10 (37)	24	64.68	13	35.13	

*p-value <0.05 significant

and failed in 23 (24.21%) cases. The majority of the patients 33 (34.73%) were found in between 18 to 30 years age group, followed by 29 (30.52%) patients falling under the category of 31-40 year age group, mean age was 36.34±10.64 years. Males were slightly predominant 53 (55.78%) than females 42 (44.21%). (Table 1).

Out of 95 cases, 52.63% of stones were located on the right side and 47.36% were located on the left side, but there was no statistically significant difference seen between ESWL outcomes and laterality of the stone. The most common location of the renal stone was the pelvis (34.73%) followed by the lower calyx (18.94%) and most of the stones (83.78%) were ≤10 mm in size. Site and size of the stone were significantly correlated with the ESWL outcome. SFR was 90.9% in renal pelvic stones and 33.33% in inferior calyceal stones (p-value 0.0001). SFR was 83.13% in ≤10 mm calculi and 52.17% in >10-20 mm calculi (p-value 0.0023). The success rate was 85.41% in ≤800 HU and 65.95% in >800 HU calculi which was statistically significant (p-value 0. 0262) (Table 2).

Skin-to-stone distance (SSD) ≤10 cm positively correlated with the success of ESWL. The success rate was 82.75% in ≤10 cm SSD in comparison to >10 cm SSD which was a 64.68% with a significant P-value (0.0471). The success of complete fragmentation was more in normal BMI cases (≤25) which were 80.64% and 64.68% in overweight and obese cases (>25), p-value was 0.1299 which was statistically insignificant. (Table 3).

A maximum of 3 sessions have been planned. In 53 (72.73%) patients stone completely fragmented after a single session, 15 (22.37%) patients required a second session and 4(4.21%) patients required a third session. Complete fragmentation could not be done in 23(24.21%) patients and these cases were considered failures. Ancillary treatments including PCNL, URS and DJ stenting were required in these patients.

DISCUSSION

ESWL is generally considered as treatment modality of choice for uncomplicated renal and ureteral stones less than 20 mm in maximum dimension. It has gained worldwide popularity and added an important dimension to the treatment of stone disease since its introduction in 1980, due to its safe and non-invasive nature[7,13]. Case selection based on stone-related factors (size, site, density) and patient-related factors (Age, SSD, BMI, renal anatomy) is very important for the successful outcome of ESWL; we should identify patients who will benefit the most from ESWL.

Literature have reported the stone free rates ranging from 46 to 91% after ESWL[13] In our study the overall success rate of ESWL for treating renal stones was 75.78%, this is comparable with the Bajaj and Waqas. They have reported stone free rate of 72.2% and 78.37%, respectively[14,15].

Various studies have found that the size of the stone is an important predictor of the outcome of ESWL. There is an inverse relation between stone size and SFR[8,16]. The success rate of fragmentation of stones ≤10 mm is superior to those of stones >10 mm in all regions of the kidney and ureter[14,17] and these results are consistent with our findings.

Inferior calyceal stones have the lowest stone-free rate after ESWL; studies have reported a clearance rate of 52-69%[18]. In our study, the stone-free rate was 33.33% in the inferior calyx, 82.23% in the upper calyx and 90.9% in the pelvis. Stone fragmentation efficacy is similar in all parts of the kidney, but clearance of stone fragments from the inferior calyx of the kidney could be altered by the acute infundibulopelvic angle or a narrow infundibulum after ESWL[18].

Fragmentation of calculi depends on hardness of the stone. Chemical composition of stone determines

its hardness, which can be predicted on the basis of NCCT. Many studies have demonstrated the role of stone density in the Hounsefield Unit (HU) as an important predictor influencing the outcome of ESWL[15,19,20].

Different studies have recommended different stone densities in HU as cut-off value on the basis of computed tomography morphodensitometry. Abdelaziz *et al*.[20] have found ESWL is less likely to be successful when stone density is >800 HU, which is similar to our observation.

Several studies show SSD as an important predictor of success after ESWL with a cut-off value varying from 9 to 11 cm[19,21]. We used the cut-off value of 10 cm and found that the success of ESWL positively correlated with SSD ≤10 cm. Lower SSD is positively associated with ESWL outcome, this is because the intensity of shockwave would be attenuated as SSD becomes longer. Some studies from the Asian population found SSD as a non-significant predictor because of thin body habitus compared to Western populations[22].

Age was not significantly associated with the outcome of ESWL, in concordance with the Cui *et al*.[23]. However, we excluded patients above 60 years, which was one of the limitations of our study. The stone-free rate was poor in the elderly. The reason for the possible poorer SFR in elderly patients is not clearly known. However, sclerotic changes in kidneys with aging may increase the acoustic impedance and lower efficacy of ESWL.

We found that, BMI is not significantly associated with outcome of ESWL success with a cut-off value of 25 kg m^{-2}. Waqas M et al. used a cut-off of 30 kg m^{-2} and concluded that patients with BMI >30 kg m^{-2} have a lower SFR after ESWL[15]. Although SSD is directly related with BMI and SSD is significant predictor of ESWL outcome in comparison of BMI, because BMI does not truly reflect of central body fat distribution[24].

The current study shows that gender is not a significant predictor of ESWL outcome. In the present study, the success rate of ESWL in males and females is almost similar, comparable with Bajaj *et al*.[14] and Lee *et al*.[19].

However some limitations existed in present study. Firstly NCCT KUB was not done in all patients for follow-up imaging. Plain X-ray KUB and USG Abdomen could have underreported residual fragments as compared to NCCT. Secondly we have excluded the patients of age more than 60 years and we have not included the patients with middle and lower ureteric calculi in study.

CONCLUSION

We conclude that the stone size, stone location, stone density and skin-to-stone distance are important predictors of the SFR of ESWL for both renal and upper ureteric stones. Age, gender and BMI do not significantly affect the SFR following ESWL in our study. We should consider these factors for proper case selection, optimal results and patient counselling.

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