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Original Research Article

Study of factors predicting clinical outcomes of extracorporeal shock wave lithotripsy in Indian patients with upper urinary tract calculi

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ABSTRACT

Background: Extracorporeal shock wave lithotripsy (ESWL) is an effective non-invasive method for managing urinary tract calculi. Present study was undertaken to evaluate factors that may influence ESWL clinical outcomes in Indian patients with urinary tract calculi.
Methods: This prospective study was conducted at Department of Urology, Medical Trust Hospital Cochin, India in the period from September 2006 to March 2009. Sixty patients with upper urinary tract lithiasis having stone size between 5 to 25 mm were included and patients with >2 calculi, distal ureteric obstruction (not relieved), renal anomalies were excluded. All patients were treated with DIREX medical system lithotripter. Clinical outcome of ESWL was assessed by factors like site, size, density and skin-to-stone distance. After statistical analysis, p-value ≤0.05 was taken as the level of significance.
Results: The overall success of ESWL was 82%. The final success of ESWL for sites like ureter, pelvis, mid or upper and lower calyx were 94.1%, 84%, 85.7% and 58% respectively (p = 0.095). The rate of fragmentation of stone after one session of ESWL for stone size ≤10 mm, 11 mm - 20 mm and ≥21 mm was 76.5%, 68.4% and 16.7% respectively (p=0.009). For stone density 751-1000 HU, 22.2% patients required ≥2 sessions to achieve stone free status (p<0.0005). Around 15.6% patients in skin-to-stone distance (SSD) ≤10cm required ≥2 sessions to achieve stone free status (p = 0.27).
Conclusions: ESWL should be considered a primary modality of treatment in patients with calculi size ≤20 mm, density ≤ 1000 HU, pelvic, ureteric and upper and/or middle calyceal calculi and for SSD ≤10 cm.

Keywords: ESWL, Factors, India, Urinary tract calculi

INTRODUCTION

Presence of a stone in the urinary tract is one of the most common pathological conditions in human medicine, which is characterized as urolithiasis. This disease affects approximately 1500 to 2000 people per million inhabitants in developed countries.[1] The surgical treatment of stone disease has evolved from open surgical techniques to minimally invasive techniques and non-invasive techniques like Extra Corporeal Shock Wave Lithotripsy (ESWL). The primary goal of surgical stone management is to achieve maximal stone clearance with minimal morbidity to the patient. However, as the armamentarium of treatment modalities available to the urologist has increased, new controversies regarding the indications for these therapies have developed. Currently,

urologists face the challenge of selecting the optimal treatment modality on the basis of the patient's and the stone's characteristics.[2]

ESWL is a non-invasive method for the treatment of urinary tract calculus in adults, and its discovery led to a complete change in the therapeutic strategy for urolithiasis.[1] ESWL has replaced other treatment techniques and become a preferred modality of treatment for the majority of urinary calculi of <2 cm size in the upper urinary tract. It is mainly because of its complete non-invasiveness and its success up to 70% in non-selected urinary stones.[3]

The success rate of this treatment modality is in the range of 60-90% in various series. However, the outcome of ESWL treatment depends on many factors including, stone size, site, composition and the presence of obstruction or infection.[4] It is not certain which factors influence the outcome of ESWL.[5] Therefore the present study was planned to determine the most significant factors that influence on the success of ESWL of ureteric calculi in Asian Indian patients.

METHODS

This prospective study was conducted at Department of Urology of a Medical Trust Hospital at Cochin, India. It was carried out in the period from September 2006 to March 2009. In total 60 patients with upper urinary tract calculi (upper ureteric, pelvic and calyceal) with calculus size between 5 mm to 25 mm having maximum of two calculi.

Patients with more than two calculi, with calculus of more than 25 mm size, non-relieved distal ureteric obstruction, renal or collecting system anomalies were excluded from the study. All patients who were diagnosed as upper tract urolithiasis on either USG or X-ray were admitted for ESWL. A proper written consent was obtained. All patients had initially undergone clinical, biochemical and radiological assessments before ESWL treatment sessions.

Work-up

A calculus was evaluated for its site, size, density, and skin to stone distance (SSD). The average SSD was calculated by measuring three distances from the center of the stone to the skin (0 degrees, 45 degrees, and 90 degrees angles) on non-contrast computerised tomography (NCCT).

Technique of ESWL

After evaluation, patients were posted for ESWL. Preprocedural antibiotics were administered based on urine culture results if required. All patients were treated with DIREX medical System ithotripter, model- compact trigon. All calculi were focused by biplanar fluoroscopically with C-arm. Those calculi which were radiolucent were focused by doing retrograde pyelogram (RGP) after placing a ureteric catheter prior to ESWL. The fragmentation of the calculus during the therapy was monitored by fluoroscopy. A maximum of 3.0 kV was given to each patient, starting at 0.1 kV and increasing gradually stepwise up to 200 shock waves. During each ESWL session 3000 shock waves were given, and an interval of 14 days maintained between ESWL sessions. Shocks were delivered at the rate of approximately 120 shocks/min.

Follow-up

All patients were observed for one day in hospital and were discharged next day. All patients were given diuretics (hydrochlorothiazide), analgesics and α1-blocker (Tamsulosin) and were advised to take plenty of oral fluids. Follow-up was planned after 2 weeks. Follow-up kidney, ureter, and bladder X-ray was taken, or USG was done. If fragments were small (≤5 mm) patients were followed after 3 months with either X-ray or USG. Second session of ESWL was considered in cases with fragment >5 mm or non-fragmented calculus and further follow-up was planned after 2 weeks. A maximum of four sessions were repeated.

ESWL was considered successful when patient becomes stone free or when clinically insignificant residual fragment (CIRF) i.e. <5 mm was present. It was considered unsuccessful when clinically significant residual fragment (CSRF) i.e. >5 mm or unchanged calculus was noted after 3 months follow-up and also if more than 4 sessions were required.

Statistical analysis

The descriptive statistics mean, SD and percentage were used to summarize the data with the help of appropriate charts. Differences among the proportions were tested by using Chi-Square test. In case of 2 by 2 tables fisher's exact test was used for small frequencies. Value of p ≤0.05 was taken as the level of significance.

RESULTS

The study included 60 patients with upper urinary tract calculi. In this study 50 (83.33%) patients were males and 10 (16.67%) patients were females and the patients included were between age 18 to 74 years with mean age of 44 years (SD 14). The Characteristics of ESWL treatment outcome groups are shown in Table 1.

Outcome of ESWL by site of calculus

Site of the calculus does not affect number of session required for fragmentation of the calculus but final success of ESWL i.e. clearance can be determined from the site of the calculus. The final success of ESWL for various sites is shown as in Figure 1.

Table 1: Baseline clinical and radiologic characteristics.

Characteristics	
Number of study subjects	60
Male	50
Female	10
Age range (years)	18-74
Age (Mean±SD, years)	44±14
Stone diameter (Mean±SD, mm)	13.93±4.35
Stone density (Mean±SD, HU)	804.22±206.01
Skin to stone distance (Mean±SD, cm)	9.62±1.13

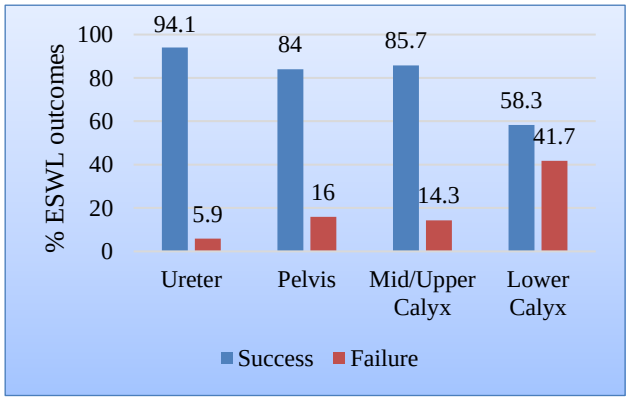

Figure 1: Extracorporeal shock wave lithotripsy treatment outcome according to site of calculi. Differences among the proportions were tested by using Chi-Square test (p = 0.095).

Outcome of ESWL by calculi size

Almost 11.8% patients with stone size of ≤10 mm required ≥2 sessions to achieve stone free status. In comparison to 15.8% and 66.7% patients required ≥2 sessions in 11-20 mm and > 20mm group respectively, (p = 0.009). The rate of fragmentation of stone after one session of ESWL for stone size ≤ 10 mm, 11-20 mm and ≥21 mm was 76.5%, 68.4% and 16.7% respectively (p = 0.025). Overall outcome of ESWL for stone size ≤10 mm, 11-20mm and ≥21 mm is 88.2%, 84.2% and 50% respectively and failure rates were 11.8%, 15.8% and 50% respectively, (p=0.09). This means that stone size is a significant determinant of stone fragmentation, number of sessions required and overall outcome of ESWL.

Outcome of ESWL by calculi density

All patients with stone densities ≤750 HU were cleared in one session. For stone density 751-1000 HU, 22.2% required ≥2 sessions and for density >1000 HU, 60% patients required ≥2 sessions to achieve stone free status (p <0.0005). Similarly, stone fragmentation rate after one session for densities of ≤750 HU, 751-1000 HU and >1000 HU was 87.5%, 66.7% and 10% respectively (p <0.0005). Final outcome of ESWL after 3 months for the densities of ≤750, 751-1000 HU and >1000 HU was 87.5%, 85.2% and 60% respectively.

Outcome of ESWL by skin-to-stone distance

Almost 15.6% patients in SSD ≤10 cm and 31.3% patients in SSD >10 cm group required 2 or more sessions to clear their stone (p = 0.27). And we have stone fragmentation rate of 73.3% for SSD <10 cm as compare to 43.3% of patients having SSD >10 cm (p = 0.063). Percentage of patients cleared of stone after 3 months in SSD ≤10 cm group and in patients with SSD >10 cm is represented in Figure 2.

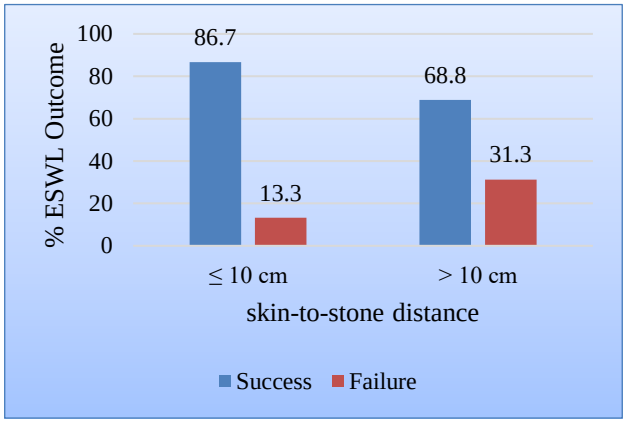

Figure 2: Extracorporeal shock wave lithotripsy treatment outcome according to stone to skin distance, (p=0.137).

The overall success of ESWL was 82% in the present study. 18% patients were failed to clear the stone. Out of these stones, 49 (80.3%) were cleared in one session of ESWL. Around 12 (19.67%) patients required ≥2 sessions.

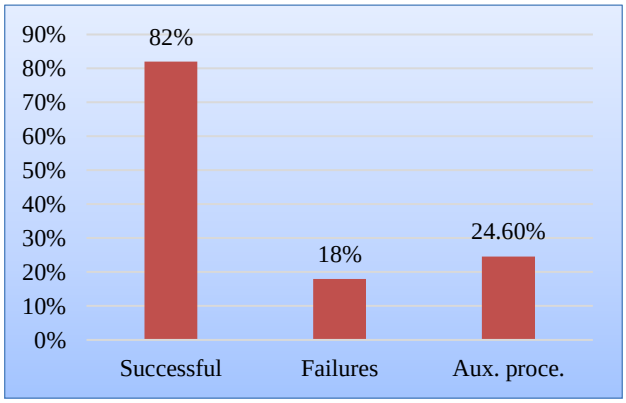

Figure 3: Overall Extracorporeal shock wave lithotripsy treatment outcomes.

The area under the curve (AUC), a frequently used summary measure of predictive accuracy shows that, calculi density, is the best predictor of outcome. Cut-off values were determined for each parameter based upon

receiver operating characteristic curves, and final score (ESWL score) was calculated based on the number of parameters lower than the cutoff values. Parameters that showed significant difference after multivariate analysis were: size (cut off: 14.5 mm), mean density (915 HU), SSD (9.95 mm) (Figure 4).

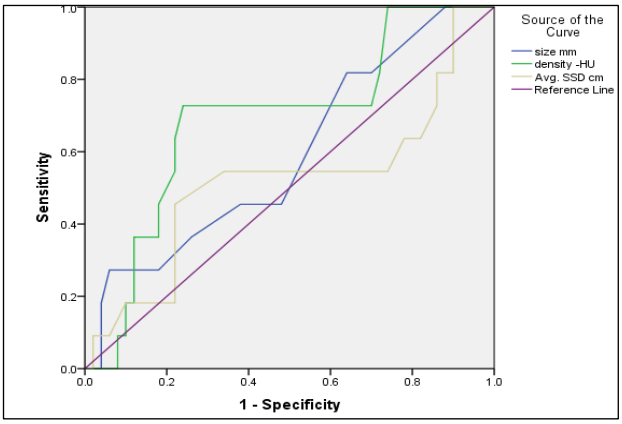

Figure 4: Area under the curve. The area under curve is highest in the calculi density.

DISCUSSION

Extracorporeal shock wave lithotripsy (ESWL) has been a major tool in the treatment of urinary stones. The major draw-back of ESWL may be the need of repeated treatment sessions in a significant number of patients. The outcome of treatment after ESWL is variable due to the close relation between the final result with the different concepts of success.[5] Many studies have demonstrated that the consistency, size, shape, location, and density of ureteral stones and body mass index (BMI) may be predictors of the outcome of ESWL.[6] Therefore it is very important to estimate the probability of stone clearance for each individual so as to determine who will experience maximum benefit from ESWL.

The overall success of ESWL was 82% in the present study. Some of the previous studies have reported overall success rate of 80%, 78% and 86.7%, respectively.[4,7,8] Stone characteristics, such as size and location have been reported as significant predictors of ESWL success by other authors and present study endorse the same. As far as site of calculi is concerned present study results are in comparison with the study of Grace et al who achieved success rate of 92% for upper ureteric calculi.[9] It also matches with the study of Weld KJ et al who found better success of ESWL for calculi in the pelvis and ureter than lower calyx.[10] Stone fragmentation was better for smaller stones. It also matches with the study of Halachmi S et al.[11] ESWL for large ureteral stones in which they got a success rate of 86.5% for ureteric stones. It also matches with the study of Obeke C et al who got success of 63%, 73% and 71%; for lower, middle and upper calyceal stones, respectively (p = 0.1) with ESWL.[12] Present study also matches with the study of Turna B, et al in terms of the stone-free rates for stones in the upper, middle, and lower calices.[13] It also matches with study of Sumino Y et al, who reported an overall stone clearance rate of 54% for lower pole calyceal stones and with the study of Pacik D et al who's success rate of lower pole calculi is 61.3%.[14,15] ESWL success for lower pole calculi is slightly lower than the results of the study of Gupta et al who achieved an overall stone clearance at 6 months of about 72% for lower calyceal stones.[14] This difference may be because of the long follow up of 6 months in their study as compare to our follow up of 3 months.

In the present study the size of the calculi was a highly significant factor in determining the number of sessions required, stone fragmentation rate and overall success of ESWL. The final outcome of the present study matches with the study of Turna B, et al in which success of ESWL for calculi <10 mm and between 11-20 mm was 91.2% and 65.5% respectively (p = 0.001).[13] Abdel-Khalek M et al found that size was significant independent predictor of ESWL outcome (p < 0.001).[8] In the study of Wang L et al.[16] ESWL outcome was not significant for the calculi >12 mm, which is in contradiction to the present results in which outcome for calculi between 11-20 mm was significant at 84.2%. El-Assmy et al found that at 3-month follow-up, the overall stone-free rate was 77.2% for calculi size between 20-30 mm which was higher than that of the present study i.e. 50%.[17] They found repeat sessions were required in 56.9% of cases in this group, which is comparable to our patients who required 66.7% repeat sessions in >20 mm sized stones. Kanao K et al found that outcome of ESWL was highest for solitary proximal ureteral stones less than 5 mm in size (93.8%); and lowest for calyceal calculi >21mm in size (10.55%).[18] This outcome for calyceal calculus >21 mm was far lower than ours for the size of >21mm i.e. 50%. This may be because of their outcome being exclusive for calyceal calculi. Pacik D et al got the success rate with ESWL of about 30% with stones >20 mm.[18] This rate was exclusively for stones in the lower calyx.

Present study results are similar to that of Joseph P et al who found that the rate of stone clearance was 100% in the <500 HU group, 85.7% in the 500-1000 HU group and 54.5% for >1000HU group.[4] The success rate for stones with an attenuation value of greater than 1,000 HU was significantly lower than that for stones with a value of less than 1,000 HU (p<0.01). Patients with >1000HU density required a greater median number of shock waves for stone fragmentation than in other groups. The mean attenuation value and number of shock waves required for calculus fragmentation correlated significantly (p <0.001).

Present study suggests that density of the stone is highly significant factor in predicting stone fragmentation rate and number of sessions required. Kacker R et al found that success of ESWL is highly significant (p<0.0001) for solitary 6 to 10 mm stones with an average stone

attenuation of less than 1,000 and 640 HU for the proximal ureter and renal pelvis, respectively.[19] These results match with the present study results for stone density ≤750 HU. Gupta et al study of patients with calculi of ≤750 HU, 80% needed three or fewer ESWL sessions and 88% had complete clearance.[14] Of patients with calculi of >750 HU, 72% required ≥3 ESWL sessions, and 65% had complete clearance. They found the best outcome was in patients with calculus diameters of < 1.1 cm and mean densities of ≤750 HU; 83% needed ≤3 ESWL sessions, and the clearance rate was 90%. The worst outcome was in patients with calculus densities of >750 HU and diameters of >1.1 cm; 77% needed three or more ESWL sessions and the clearance rate was only 60%. Total clearance rate for ≤750 HU was 88.2% (45 out of 51). These results match with the present study where we have 87% success in one session for density of <750 HU. The results of the study by Cheng G et al shown stone-free status in 69.2% patients and the residual stone group 30.8%.[20] The CT value of the stone-free group was 579.65±194.65 HU, significantly lower than that of the residual stone group (1032.18±270.49 HU, t = 6.842, p <0.01). These results match with the present study where we have success for density ≤750 HU is 87.5% and failure (i.e. residual fragment) for densities >1000HU is 40%. El-Nahas AR et al found that stone density >1000 HU is significant factor in predicting failure to fragment stone by ESWL (p = 0.02).[21] These results matches with the present study where we have density is highly significant factor in determining fragmentation of stone, (p <0.0005). Present results also matches with the study of Pareek G et al where they found BMI and HUs were statistically significant independent predictors of stone-free rates after ESWL (P <0.01 for both).[22] Similarly with Pareek G et al where they found density as a significant predictor factor in determining outcome of ESWL for ureteric as well as renal calculi, (p<0.001).[23]

Wang L et al found that a maximal stone density of more than 900 HU (p=0.0008) is statistically significant predictor of failure of outcome for ESWL.[16] It is also true for our study where we have failure of 40% for density >1000HU. Perks AE et al found that the stone-free rate for stones less than 1,000 HU was 46%; versus 17%; for stones 1,000 HU or greater (p = 0.01) this is less than our study where we have stone rate of 50% for stone density >1000HU.[24]

From the present study results it is concluded that SSD <10 cm is predicting factor for fragmentation of stone by ESWL as well as it predicts outcome of ESWL. Present study results i.e. 31.3% failure for SSD >10 cm as compared to 13.3% for SSD <10cm. matches with the study of Pareek G et al where they found SSD greater than 10 cm predicted treatment failure.[23] These results also match with Weld KJ et al who found higher stone free and ESWL success rates with a shorter SSD among calyceal stones.[10]

There are several strengths in the present study. This work was designed as a prospective study. We could arrange a standardized follow-up protocol for the patients. This study is able to interpret the effects of certain factors such as size, site, and density of calculi in upper ureter which commonly affects the success of ESWL. Also, there are several limitations in the present study; we did not routinely perform abdominal computed tomography of patients, which may have helped us to understand the stone density. We did not have stone component analysis. Different stone components could influence the stone-free rate after ESWL.

CONCLUSION

ESWL remains one of the most commonly utilized treatments for patients with upper urinary tract calculi. The size and density of the calculi are the most important predictors determining clearance after ESWL of ureteric calculi. Low success of ESWL is found if calculi size is >20mm. Highest clearance rates were achieved in patients with calculi densities <1000 HU. Better results were obtained in patients with SSD ≤ 10cm. ESWL should be considered a primary modality of treatment in patients with favourable factors with lesser size (≤20mm), density (≤ 1000 HU), SSD ≤10cm calculi and calculi located at pelvic, ureteric, upper and/or middle calyx.

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