MEDICO RESEARCH CHRONICLES
ISSN NO. 2394-3971
DOI No. 10.26838/MEDRECH.2021.8.1.478
Contents available at www.medrech.com
OPEN ACCESS

AN OBSERVATIONAL STUDY ON THE PREDICTABILITY OF THE TRIPLE-D SCORE IN THE SUCCESS RATE OF EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY IN RENAL STONES 1 – 2 CM IN DIAMETER

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ARTICLE INFO | **ABSTRACT** | **ORIGINAL RESEARCH ARTICLE**

Article History
Received: January 2021
Accepted: February 2021
Keywords: Computed tomography, Efficacy, Extracorporeal shock wave lithotripsy, Hounsfield unit, Predictability, Score, Stone free status.

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Introduction: Evaluation of Triple-D scoring system to assess the stone free rate (SFR) in individuals who were given extracorporeal shock wave lithotripsy (ESWL) for renal stones measuring 10-20 mm in diameter. **Materials and methods:** The study subjects were 120 patients who presented to the urological outpatient department with complaints of renal stones. Systemic Random Sampling technique was applied to select study subjects for study population with a Sampling Interval of 2. Prior to ESWL, Triple-D scoring comprising of three CT based metrics-stone dimension (volume), stone density (HU) and skin-to-stone distance (SSD) was done as described by Tran et al. The score ranged from 0 (worst) to 3 (best). Treatment efficacy was studied by plain abdominal radiography three weeks after ESWL. Complete clearance was considered the "stone free status". **Results**: In the study population, stone dimension, stone density and stone location were positive predictors of stone free rate after ESWL whereas age, sex and BMI of the patients, laterality of the stone and skin to stone distance were not. The area under the curve (AUC) of Triple-D scoring system was 0.598.**Conclusion:** Triple-D scoring system has been successfully validated as the SFR showed a parallel increase with every positive component

INTRODUCTION

Numerous factors affect the SFR after ESWL like the stone location and size,[1,3,4] composition of calculi,[5,6] Hounsfield unit (HU) of the stone as determined by Computed tomography (CT),[7] intrarenal anatomy,[1,4]

skin-to-stone distance (SSD) [8,9] and body mass index (BMI).[10] The Triple-D scoring system was proposed by Tran et al.[11] It comprises three CT-based metrics - stone dimension (volume), stone density, and SSD. Its efficacy has been validated in many retrospective studies.[12,13] This study was conducted to evaluate the clinical efficacy of the Triple-D scoring system in routine urological practice for renal stones 1-2 cm in dimension.

MATERIAL AND METHODS

Urinary tract infections and diseases of the prostate are the pathologies most commonly encountered in urological practice. Incidence of renal and ureteral stones is also very common. ESWL was once widely recommended for the treatment of renal stones, but now the first-line management for renal stones has shifted to endourological procedures such as percutaneous nephrolithotomy (PCNL) and ureteroscopy (URS). However, ESWL remains a recommended treatment option for solitary renal stones of < 2 cm in size.[1,2]

It is a prospective observational study conducted on 120 patients who presented to the outpatient department of a reputed tertiary urology care centre in Eastern India. The study was conducted from April 2019 to July 2020. The sample size was calculated using the formula for descriptive study.

Systemic Random Sampling technique was applied to select study subjects for the study population with a sampling interval of two. The study was conducted as per guidelines laid down by the declaration of Helsinki. The study protocol was approved by the institutional ethical committee (No. RKC/577 dated 06/05/2019). Inclusion Criteria were as follows: (1) Age more than 18 years (2) Urine culture-negative patients (3) Patient receiving ESWL for the first time for the targeted stone (4) Patient with no anatomical urinary tract abnormalities. The exclusion criteria were: (1) distal urinary tract obstruction, (2) unavailable CT images before ESWL, (3) pregnant patients, (4) staghorn stones, (5) calyceal diverticular stones, (6) coagulopathy, (7) active urinary tract infection and (8) endourological procedure before ESWL.

Renal stones were evaluated before ESWL with plain abdominal radiography of kidney, ureter, and bladder as well as a helical non-contrast CT scan (NCCT). The coagulation profile and urine culture sensitivity was also evaluated. Stone volume (SV) was measured using the formula SV= $\pi/6$ x (anteroposterior x transverse x craniocaudal diameters).[11,12,13] Stone density was measured in the Hounsfield unit from NCCT and SSD was calculated as the average distance from the body surface to a targeted stone at 0◦, 45◦, and 90◦ on NCCT.[8]

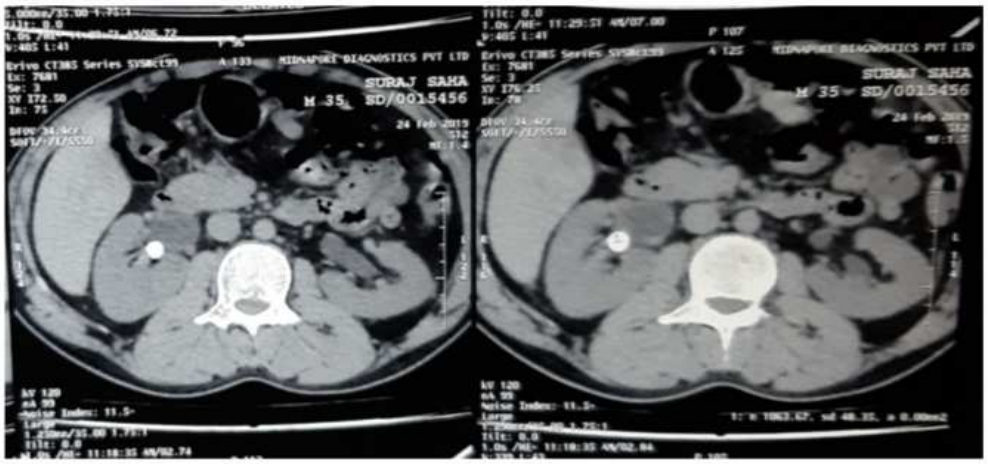
The Triple-D score was calculated as the sum of the number of components matching the cut-offs of < 150 mm^3 for SV, < 600 HU for stone density, and < 12 cm for SSD as described by Tran et al[11]. The score would range from 0 (worst) to 3 (best).

Table 1: Triple-D Scoring System

PARAMETERS	SCORE 1	CUTOFF VALUE	SCORE 0
DIMENSIONS	<150 mm^3	150 mm^3	≥150 mm^3
DENSITY	< 600 H.U.	600 H.U.	≥ 600 H.U.
SKIN-STONE **D**ISTANCE	< 12 cm	12 cm	≥ 12 cm

We used an electromagnetic shockwave lithotripter, ***Dornier Compact Sigma***, manufactured by Dornier MedTech Systems Gmbh. ESWL was performed with a gradual ramping up of shockwave energy at a fixed frequency rate of 60 shocks/minute. The patients underwent just a single ESWL session as part of this study. Treatment efficacy was studied using plain abdominal radiography of kidney, ureter, and bladder approximately three weeks after ESWL.

Figure 1a



Non-contrast CT scan of Kidney showing calculus in right renal pelvis.

984x495mm (72 x 72 DPI)

Figure 1b

Fluoroscopic image from the same patient as Figure 1a. Stone being targeted for extracorporeal shock wave lithotripsy (ESW).

1302x863mm (72 x 72 DPI)

Figure 1c

Stone completely fragmented after ESWL.

1220x864mm (72 x 72 DPI)

All the statistical analysis was done using IBM IPSS 26.0. The student's *t*-test or Mann-Whitney *U*-test was used to compare continuous variables. Their correlation was assessed using Pearson's correlation analysis. Fisher's exact test and Chi-square test were used to analyze the cross charts between the two categories. All *p*-values were based on two-sided statistical analysis. A P-value of <0.05 was considered statistically significant.

Results

In our study, 120 patients formed the study population after complying with the inclusion and exclusion criteria. They were divided into two groups.

Group A: had stone-free status 3 weeks after ESWL.

Group B: had residual stone 3 weeks after ESWL.

The age, sex, BMI, laterality of the stone, and skin-to-stone distance were not statistically significant for the prediction of stone-free status.

The mean ± SD (in mm^3) ellipsoid stone volume was 396.44 ± 163.23 and 395.81 ± 227.52 in groups A and B respectively. Using the independent samples t-test, the p-value was 0.049(<0.05), so the difference in the stone volume in the two groups was statistically significant. Stone volume was a significant predictor of the success rate of ESWL.

The mean ± SD (in HU) stone density was 724.28 ± 210.90 and 814.56 ± 190.63 in group A and group B respectively. Using the student's t-test, the p-value was 0.001(<0.05), so the difference in the stone density between the groups was statistically significant. Hounsfield unit was an important predictor of ESWL success.

The mean ± SD (in cm) skin-to-stone distance (SSD) was 11.39 ± 0.94 and 11.79 ± 0.86 in groups A and B respectively. Using the independent samples t-test, the p-value was 0.422(>0.05). The difference in SSD between the groups was not statistically significant. So in this study, SSD was not a predictor of ESWL success.

Sixty-nine (57.5%), 14 (11.66%), 22 (18.33%), 12 (10%) and 3 (2.5%) patients in

the study population had stones at the pelvi-ureteric junction, renal pelvis, lower calyx, middle calyx, and upper calyx respectively. Fifty (65.78%), 10 (13.15%), 7 (9.20%), 7 (9.20%) and 2 (2.63%) patients in group A had stone at the pelvi-ureteric junction, renal pelvis, lower calyx, middle calyx, and upper calyx respectively. Nineteen (43.18%), 4 (9.09%), 15 (34.09%), 5 (11.36%) and 1 (2.22%) patients in group B had stones at the pelvi-ureteric junction, renal pelvis, lower calyx, middle calyx, and upper calyx respectively. Using Fischer's exact probability test, the p-value was 0.014(<0.05). So, the difference in the two groups concerning stone location was statistically significant. This helps us to conclude that stone location was an important predictor of the success of ESWL.

The mean ± SD (Score) Triple-D score was 1.18 ± 0.58 and 0.93 ± 0.545 in groups A and B respectively. Using the Mann-Whitney *U*-test, the p-value was 0.026(<0.05), so the difference in the Triple-D score in both the groups was statistically significant. So, the Triple-D score can be used as an important clinical tool to predict the success rate of ESWL.

Table 2: Comparison of the study population 3 weeks after ESWL

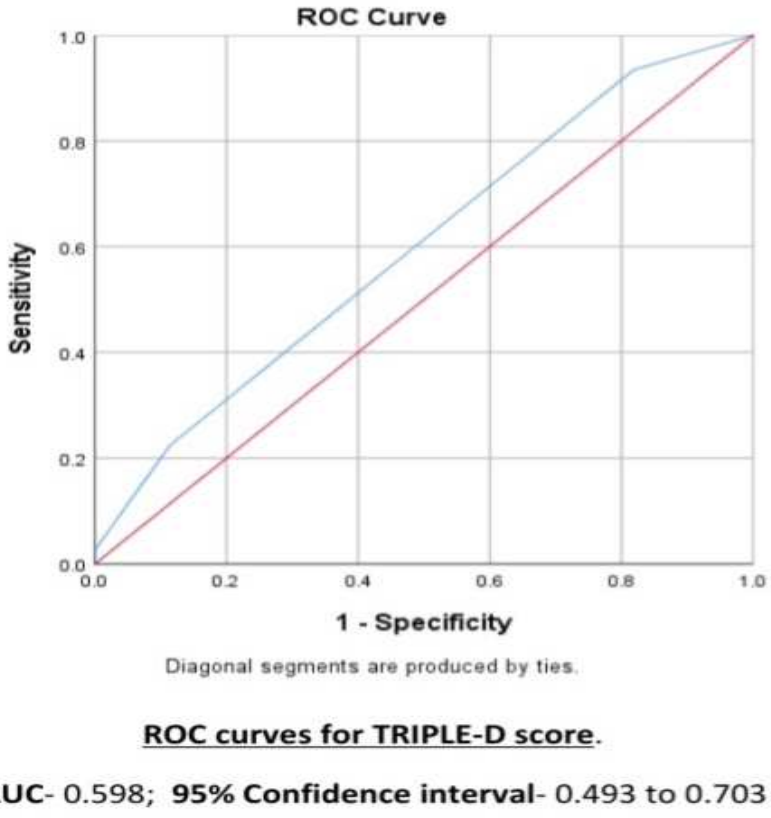
PARAMETERS	**OVERALL(n=120) Mean ± SD**	**GROUP A (n=76) (Stone free) Mean ± SD**	**GROUP B (n=44) (Residual Stone) Mean ± SD**	***p*-value**
Age (years)	40.335 ± 9.77	34.90 ± 9.11	45.77 ± 10.43	0.453*
Sex Male Female	 75(62.50%) 45(37.50%)	 47(61.84%) 29(38.15%)	 28(63.63%) 16(36.36%)	0.845**
BMI (kg/m^2)	24.62 ± 1.06	24.36 ± 1.12	24.89 ± 1.00	0.327*
Laterality Left Right	 67(55.83%) 53(44.16%)	 43(56.57%) 33(43.42%)	 24(54.54%) 20(45.45%)	0.829**
Stone Location Upper Calyx Middle calyx Lower Calyx Renal Pelvis PUJ	 3 (2.5%) 12 (10%) 22 (18.33%) 14 (11.66%) 69 (57.5%)	 2 (2.63%) 7 (9.20%) 7 (9.20%) 10 (13.15%) 50 (65.78%)	 1 (2.22%) 5 (11.36%) 15 (34.09%) 4 (9.09%) 19 (43.18%)	0.014***
Stone volume	396.12 ± 195.37	396.44 ± 163.23	395.81 ± 227.52	0.049*
Mean CT attenuation(HU)	769.42 ± 200.76	724.28 ± 210.90	814.56 ± 190.63	0.001*
SSD (cm)	11.59 ± 0.9	11.39 ± 0.94	11.79 ± 0.86	0.422*

TRIPLE-D Score				0.026****
Total	1.055 ± 0.56	1.18 ± 0.58	0.93 ± 0.545	
Score 0	13 (10.83%)	5 (6.57 %)	8 (18.18%)	
Score 1	85 (70.83%)	54 (71.05 %)	31 (70.45%)	
Score 2	20 (16.66%)	15 (19.73 %)	5 (11.36 %)	
Score 3	2 (1.66%)	2 (2.63 %)	0	

SSD- Skin-to-stone distance, **PUJ**- Pelvi-ureteric junction, **HU**- Hounsfield unit.
*Independent Samples t-test
**Chi-Squared test
***Fisher's exact probability test
****Mann-Whitney *U*-test

The area under the curve (AUC) of the Triple-D score was 0.598 with a 95% confidence interval of 0.493 to 0.703. [ROC curve]. The Triple-D score of 0,1,2 and 3 points showed stone-free rate of 38.46%, 63.52%, 75%, and 100% respectively. (Cochran-Armitage test, p-0.001).

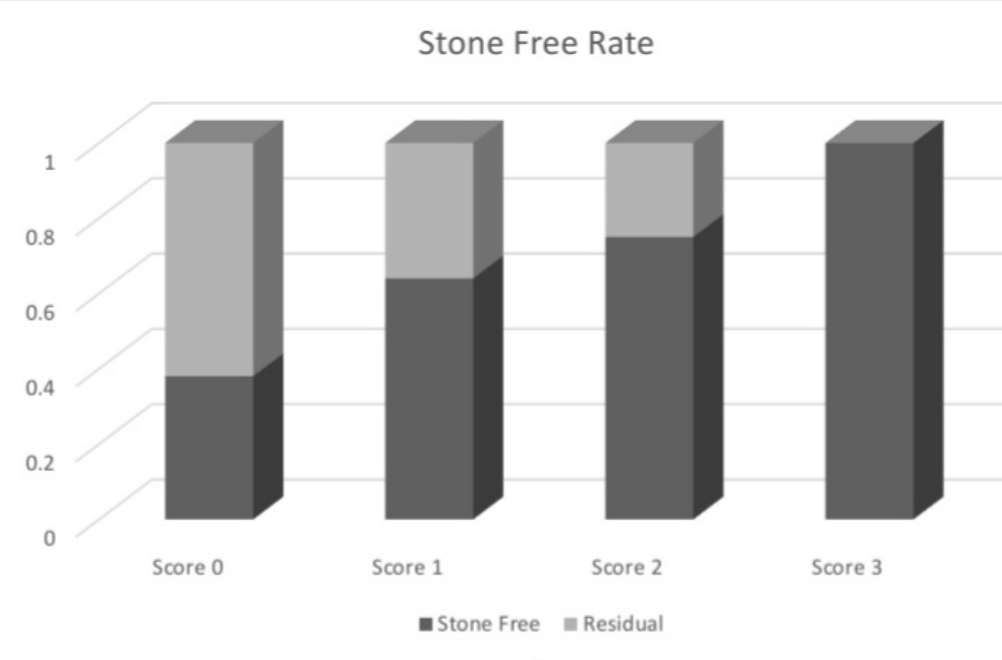
Figure 2



ROC curves for TRIPLE-D score.

AUC- 0.598; **95% Confidence interval**- 0.493 to 0.703

Figure 3



Stone free rate (SFR) based on Triple D score

DISCUSSION

In our study, we find that Triple-D score and lower pole location are independent predictors of stone-free rate (SFR) after ESWL for 1-2 cm renal stones. With increasing Triple-D score, the SFR improved. These findings support the use of Triple-D scoring system to predict the success of ESWL in the Indian population with renal stones between 1-2 cm.

The ROC curve analysis revealed a low AUC (0.598) of Triple-D score for SFR prediction. In a similar study, the AUC of Triple-D score was 0.596. This is because the skin-to-stone distance parameter, a component of Triple-D score, is not a statistically significant factor for determining stone-free or residual stone status after ESWL. SSD was not a significant factor predicting stone-free rate.[14] Contrary to our study, SSD and BMI, which are clinical indicators of obesity, have been reported as significant predictors of ESWL outcome in multivariate analysis.[15,16] Neither SSD nor BMI was related to the SWL outcomes in the present study. It may be because the study population consisted of mostly underprivileged, low socioeconomic status patients (mean BMI of 24.62 ± 1.06 kg/m^2), reflecting racial background different from previous similar studies. [8,15,16,17]

A lower pole location of renal stone was a significant factor related to poor stone-free rate after ESWL. Increased stone burden, lower polar location, and increased SSD, all decrease the success rate of ESWL and URS but have limited influence on percutaneous nephrolithotomy outcomes. [4] So, for 1-2 cm renal calculi, stone and anatomical factors must be carefully studied when considering ESWL as a treatment modality.

In the present study, age is not a significant predictor of ESWL success rate.

Contrary to this observation, age was reported as an independent predictor of ESWL outcome in multivariate analyses. [14, 15, 18] In another prospective study, [16] age and ESWL success rate reached a statistical significance in a univariate analysis but not in multivariate analysis. So, age is not considered a parameter of Triple-D study. There are also other studies where age was not considered as having any significant impact on ESWL outcome. [15, 19, 20, 21]

In a study correlating the age with ESWL efficacy, [22] it was seen that renal stones were difficult to fragment with ESWL in older patients than younger patients. There is also a higher probability of renal hematoma after ESWL, incidence of which increased with age. So age overall might have a negative impact on SFR.

Many nomograms exist to predict successful outcomes after ESWL. [3,11,15, 21, 23,24] Though these have excellent outcomes yet they are often too complex to calculate in clinical settings. In a nomogram by Kim et al, the manual scoring system was formulated using four to six variables on the graphical chart in a CT-dependent or independent manner. Besides the four variables, sex; stone location, number, and maximal diameter; hydronephrosis grade, and stone CT attenuation are included in the CT dependent nomogram. This nomogram and Triple-D scoring system is practical and easy to use in clinical practice and remains externally validated.

There are limitations in the present study. The lower polar location of stone and hydronephrosis were not assessed. Other limitations include a relatively small number of patients. Further studies are needed to confirm the validity of the present findings.

CONCLUSION

The Triple-D scoring system is successfully validated for use in Indian patients with renal stones between 1-2 cm. The SFR showed a parallel increase with every positive component of the Triple-D scoring system. The simple addition of stone location (non-lower polar vs. lower polar) can further facilitate the validation of Triple-D scoring by increasing the stone-free rate, keeping the calculation simple and easy to use.

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