

ORIGINAL ARTICLE

USE OF COMPUTED TOMOGRAPHY-BASED NOMOGRAM IN ADULT AGE PATIENTS TO PREDICT SUCCESS RATES AFTER SHOCK WAVE LITHOTRIPSY FOR RENAL STONES: A SINGLE CENTER EXPERIENCE

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Background: The Triple D score is a novel and easy to use nomogram to predict shock-wave lithotripsy (SWL) outcomes. It is based on Computed Tomography (CT scan) parameters including stone density, skin-to-stone distance, and stone volume. However, its use has not been validated much as studies are sparse regarding its use. Our aim was to validate and evaluate accuracy of the Triple D scoring system in predicting SWL success rates. **Methods:** It was a prospective study of 277 patients who had undergone SWL procedure for renal stones. They were evaluated by using non-contrast tomography, before undergoing SWL. CT scan-based parameters including distance of stone to skin (SSD), stone volume (SV), stone density was assessed. Computation of Cut off values was done with receiver operating characteristics analysis. Score was assigned on the basis of these cut-off values and success rate of SWL was determined. This score ranged from 0 (least favourable score) to 3 (most favourable score). **Results:** Stone-free status was attained in 160 patients (57.7%), and 117 (42.3%) patients were labelled to have failed the procedure. Differences between these two groups in terms of Stone volume, stone density and skin to stone distance were significant. Triple D scores of zero, 1, 2, and 3 had stone-free rates of 3.6%, 52.56%, 53.3%, and 93.1% respectively (p -value < 0.001). **Conclusion:** Shock-wave lithotripsy outcomes can be predicted with use of Triple D score and hence, it's externally corroborated. It may help urologist in appropriate patient selection and hence decision making and patient counselling.

Keywords: Shock wave lithotripsy; Urolithiasis; Nomograms; Hounsfield unit; Tomography

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INTRODUCTION

Extracorporeal shockwave lithotripsy (SWL) had been a marvellous introduction in the armament for treating renal stones. With the passage of time, it sharply gained popularity throughout the world. With gradual technological innovations in technique of SWL, resulted in better treatment outcomes.¹ This was the reason that SWL established itself as having a more concrete role in the context of managing kidney and ureteric stones over the passage of years.² One of the main factors for SWL being an attractive option, when it comes to the renal stone treatment, is because of its non-invasiveness. Secondly, it is day case procedure that can easily be done without use of anaesthesia.^{3,4}

However, it is pertinent to note here that despite all the well-reported literature regarding the success rates and patients' satisfaction with the mode of SWL⁵, there were some obstacles and challenges

that affected its popularity in comparison to other endourologic procedures in past few years⁶. One of these challenges include more variable SWL outcomes when treating renal stones.⁷ Some of the reasons for these variations in results has been associated to technical issues, differences in reporting of SWL outcomes, and suboptimal criteria for patient selection. This divergence seen in treatment results of SWL has also raised concerns about its cost-effectiveness. Current guidelines for renal stones treatment recommend SWL to be used as primary line of option for dealing with renal stones <2 cm. However, in last few years some factors have come into notice of the clinicians such as lesser efficiency of SWL while dealing with stones located at lower pole, multiple calculi, and larger size of stones. After having made these observations, the clinicians are in quest for predictive tools and factors that might improve patient selection and resultantly more efficiency of SWL outcomes. In further quest by

researchers regarding computed tomography-based factors, it was found in recent years that a longer skin-stone distance along with excessive Hounsfield units of stones have been linked to adverse SWL net results.⁶⁻⁷

In the light of all the evolving data in recent years, quest for nomograms has been accelerated in order to help urologists in making the decision of whether or not to use SWL for renal stone treatment. As already discussed earlier, variety different factors are involved and affects the success rate of SWL. Numbers of different studies have shown non-contrast computed tomography-based stone parameters to be effective for predictions of SWL outcomes and resultantly variety of scoring systems/nomograms were developed for this purpose.⁶⁻¹⁰ It is evident from recent experiences of clinical researchers that utilization of information in the light of nomograms in patients' selection led to enhanced success rates of treatment. However, it's also pertinent here that some of these nomograms and scoring systems are not only complex but also confusing at times to use.⁸⁻¹⁰ Triple D scoring system was recently developed which is based on volume of stone (SV) skin-stone length (SSD) and density of stone (HU) from CT scan imaging studies.¹¹⁻¹⁴ The main purpose for developing triple D score was that it might help urologists to take a well thought, clear and calculated decision regarding renal stone treatment as it does not require complex computations. Triple D score can help in proper selection of patients, so the objective of this study was to see predictive efficacy in single center in patient's population >18 years of age with renal stone. Furthermore, we wanted to know the impact of increasing three D score on number of sessions required to get stone free and consequently the costs incurred. No study till date has commented in this regard.

MATERIAL METHODS

Shock wave lithotripsy (SWL) was done for renal stones since October 2015 till December 2018. There were 323 adult age patients that were subjected to SWL for solitary radio-opaque renal stones in a tertiary care hospital. We did charts review and prospectively collected data for variables such as age of patient, gender, stone side (left or right), stone location and body mass index (BMI).

All patients were diagnosed initially after taking their full history and doing physical examination before undergoing SWL. Radiologically assessment was made with kidneys, ureter, and bladder (X-ray KUB) radiography and NCCT. We had included only those patients who had undergone CT scan prior to their procedure. Urine culture was done prior to the procedure to make it sure that urine

was sterile. Apart from this, blood biochemistry, complete blood count and coagulation tests were also done prior to procedure in all patients. Furthermore, patients' informed consent was taken regarding SWL treatment.

Exclusion criteria consisted of patients of less than 18 years of age, active urinary tract infection on urine culture, those having anatomical renal abnormalities, multiple renal calculi, renal insufficiency, patients having solitary kidney and prior history of SWL or ipsilateral renal stone surgery were excluded. In this manner, total of 277 patients were incorporated based on the criteria aforementioned.

To sum up, after evaluation, 277 patients were included in this study. They were divided into two groups based on whether their treatment was successfully completed with SWL or not. So, group 1 comprised of patients who had failure of procedure while group 2 comprised of patients successfully treated with SWL. As mentioned earlier, all patients underwent evaluation with CT (computed tomography) KUB before SWL. In order to prevent the calculation bias, the parameters relevant to our study were examined by two senior urologists (A and B). It was made sure to make them blinded to the SWL outcomes in those patients.

They did CT evaluations of each stone for calculating volume (SV), density (Hounsfield Unit) and skin-stone distance (SSD). Stone volume was assessed by using ellipsoid formula, $SV = \pi/6 * (\text{Antero-posterior} * \text{Transverse} * \text{Cranio-caudal diameters of the Stone in mm})$ and final volume was calculated as mm^3 . Furthermore, for measuring the SSD values, they followed the methodology portrayed by Pareek *et al.*¹²

We calculated Three D scores for all patients as stated in the description of the formula by Tran *et al.*¹⁴ According to their study, the values of stones were to be calculated for the three parameters (SV, SSD and stone density). Points in this computation were based on the cut off values obtained after the ROC curves were generated for volume, Density and skin-stone distance. This Three D score ranged from zero (worst score) to 3 (most favourable score).

These patients were subjected to SWL, using an electromagnetic lithotripter machine (3rd generation; Storz Modulith SLX-MX). Position of the patients was kept supine. To target the stone, we used fluoroscopy (Modulith SLX-MX) aided with an ultrasound (model Aloka SSD-Thousand;1000). Approximate value of frequency the shock waves delivered was set at 90 shocks waves per minute. Initially, 500 shocks to be given were delivered at the energy level 2 and then a gradual ramping up of these

waves was done up to energy level 3 and 4 for the next 2000–2500 shocks. Intravenous nalbuphine (10 mg) was required if patients felt pain during this procedure. Patients underwent Second session of SWL procedure in case of gross residual stones observed on X-Ray KUB and ultrasound abdomen pelvis after 2–3 weeks after the first session. We labelled patients in this study to have attained status of being stone free in case of no evidence of presence of stone fragments or if there were only clinically insignificant residual stone (CIRFs) fragments of size less than 4 mm depicted on plain X-ray (KUB) or abdomen and pelvis ultrasound done after three months of last lithotripsy session.

After collection of data for the variables, it was entered for data analysis in Statistical Package for Social Sciences, version 16 (SPSS Inc.; Chicago, IL, USA). For description of the categorical variables frequency and percentage values were utilized (for example stone failure and stone-free status). While mean values with standard deviation were utilized for describing continuous variables (for example age, skin-stone distance, stone size). Continuous (values) variables were being compared by utilizing Student’s t-test while Chi-Square test was used to compare the categorical (values) variables between stone free and failure groups. A *p*-value of <0.05 (Two-tailed) was gauged to be statistically significant while making these comparisons. We also generated Receiver operator characteristic (ROC) curves to ascertain the cut-off values for the volume, Skin-stone distance, stone density and to reaffirm the predictive capacity of three D score.

RESULTS

There were 277 patients covered in this study. Their mean age was 38±14.17 years. Out of these 277 patients, 201 (72.56%) were male and 76 (27.43%) of the patient were women. Standard deviation and mean of SV, stone density and SSD values of these subjects were 391.50±117.2mm³, 9.74±2.74 cm,

889.2±540.47 respectively. Achievement of successful treatment was seen in 160 (57.76%) of the 277 patients after completion of all SWL sessions. Procedural success rate after single session of SWL session was 72 out of 160 of the successful patients (45.97%), remainder of the patients needed 2 or 3 SWL sessions.

No difference was seen with regards to values of age, gender, BMI and stone laterality across the two groups. (See table 1 for the results of Descriptive statistics). However other factors that were dissimilar between these two groups included number of SWL sessions. Furthermore, it was noted that results for Volume, skin-stone distance and density values were found notably higher in individuals with unsuccessful procedure compared with those who had successful outcomes (Table 1 and 2) with shock wave lithotripsy (*p*<0.001).

Generating ROC curves for volume, stone density and Skin-stone distance demonstrated greater sensitivity and specificity values. Values of AUC, cut-off levels of each of volume (stone), Skin-stone distance and density with respect to the specificity and sensitivity are summed up in Figure 1. ROC curves curve with their coordinates are shown in Figure 1a-d. (For cut off values see table 2)

Stone free rate for Triple D score groups were calculated. Triple D score results shows highly significant results with (*p*<0.001). Success rate of 93.1% Were detected in subjects with Three D score of 3, success rate of 53.26% at triple D score of 2 and 52.56% at Triple D score of 1 and 32.65% at triple D score of zero (Table-3). Hence, a better association between Three D score and stone free rate was found in this study. The number of SWL sessions for attaining status of successful procedure (median numbers SWL sessions) were lesser for higher three D score (favourable score) as compared to lower three D scores (unfavourable score) patients (Table-1).

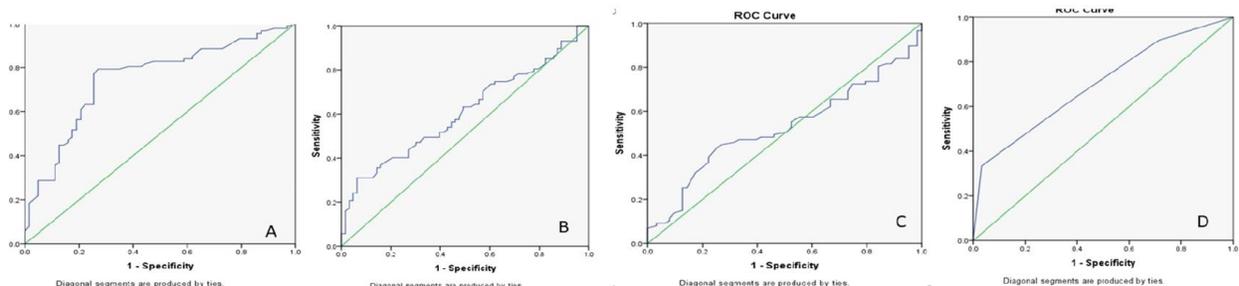


Figure-1: ROC curves for the SV, SSD, stone density in kidney stone patients, (a) ROC curves for SV in kidney stone patients (b) ROC curves for stone density of patients (c) ROC curves for skin to stone distance (d) ROC curves for three D score

Table-1: Demographic characteristics of patients

| Parameters | Unsuccessful | Successful | p-value |
|---------------------------------|---------------|--------------|---------|
| Gender (%) | | | 0.083 |
| Male | 92 (79.4) | 109 (67.8%) | |
| Female | 25 (20.6%) | 51 (32.2%) | |
| Age | | | 0.522 |
| Mean±SD | 37.63±14.17 | 39±14.17 | |
| Stone volume (mm ³) | | | 0.001 |
| Mean±SD | 219.017±56.1 | 121.66±37.2 | |
| Stone density (HU) | | | 0.024 |
| Mean±SD | 969.61±198.63 | 797±281.90 | |
| SSD (cm) | | | 0.017 |
| Mean±SD | 10.8±1.07 | 9.2±1.75 | |
| Stone location, n (%) | | | 0.170 |
| Upper pole | 29 (24.7%) | 49 (30.6%) | |
| Mid pole | 22 (19.0%) | 37 (23.1%) | |
| Lower pole | 43 (36.7%) | 29 (18.1%) | |
| Pelvis | 23 (19.6%) | 45 (28.1%) | |
| Stone laterality, n (%) | | | 0.325 |
| Right | 55 (47.1%) | 68 (42.5%) | |
| Left | 62 (52.9%) | 92 (57.5%) | |
| Number of SWL Sessions | | | 0.001 |
| Mean±SD | 1.285±0.5800 | 1.8046±0.860 | |

Table-2: Results of ROC analysis

| Parameters | Cutoff | Sensitivity | Specificity | AUC (95% CI) |
|---------------------------------|---------------------|-------------|-------------|--------------------|
| Triple D score | 1.60 | 0.897 | 0.714 | 0.69 (0.617,0.782) |
| Stone density (HU) | 685 | 0.65 | 0.55 | 0.60 (0.516,0.696) |
| Stone volume (mm ³) | 197 mm ³ | 0.83 | 0.60 | 0.75 (0.671,0.831) |
| SSD (cm) | 10.7 | 0.65 | 0.66 | 0.52 (0.433,0.618) |

Table-3: Success rates of the patients for triple d score groups

| Triple D score | Triple Unsuccessful (n=117) | Triple Successful (n=160) | p-value |
|----------------|-----------------------------|---------------------------|---------|
| 0 | 33 (67.34%) | 16 (32.65%) | |
| 1 | 37 (47.43%) | 41 (52.56%) | 0.001 |
| 2 | 43 (46.73%) | 49 (53.26%) | |
| 3 | 4 (6.89%) | 54 (93.1%) | |

Table-4: Sessions and costs in the patients for triple d score groups

| Triple D score | Triple Successful (n=160) | Sessions needed to achieve success | Costs incurred | p-value |
|----------------|---------------------------|------------------------------------|----------------|---------|
| 0 | 16 | 2.36±0.70 | 671±83 | |
| 1 | 41 | 1.73±0.41 | 469±27 | 0.001 |
| 2 | 49 | 1.57±0.44 | 389±21 | |
| 3 | 54 | 1.26±0.28 | 307±37 | |

DISCUSSION

In urology we have observed advancements in terms of technological innovations for ureteroscopy (URS) and shock wave lithotripsy (SWL) leading to ease with which these procedures can now be done in many of the centers in world. Nevertheless, a new trend is seen nowadays regarding surgeons' inclination towards use of ureteroscope augmented with lasers fibre mechanics (as with time success rates have expanded for URS). Likewise, there has been noted some decline in SWL results over last few years, which may be ascribed to various technical limitations such as presence of the air bubbles that may sharply decrease in breakage of stone.¹³ Furthermore, modern lithotripters less frequently use

general anaesthesia thereby resulting in enhanced respiratory movement during shockwave delivery.^{14,15} In the face of this developing scenario it's pertinent to choose patients wisely based on certain stone parameters that may help in prediction of stones free rates after SWL.¹⁶⁻¹⁸

Studies in last few years regarding outcomes of SWL have shown much variations of success rates—from as low as 32 to over 95%.¹⁹⁻²¹ Such a wide and diverse outcomes points towards thought provoking factors that might have influence on the overall outcome and the decision-making process by the treating urologist. For example, few important factors were pointed out in past few years. One of Such studies was reported in 2005, which describe that skin-stone distance estimated by NCCT can be a

vital predictive factor with regards to procedural success in patients, this was the first study to evaluate outcomes of ESWL based on skin-stone distance.¹² Later on studies conducted by other authors²¹⁻²³ regarding effects of stone size and stone density on SWL outcomes. With passage of time gradual efforts have been made keeping in view the fact to find durable ways of foretelling post-procedural sequels to help in apposite choice of the individuals who has to be subjected to SWL. Hence, few nomograms have been developed and tried in past. People have tried using them but with little success. Secondly, even few of these nomograms (that included vital parameters, assuring valuable predictability regarding SWL outcomes), have not been welcomed much among the practicing urologists.²¹ Reason for this being their seemingly impractical nature, being too complex and above all confusing for the clinicians as to how to use them. Eventually, Three D score was illustrated by Tran *et al* to prognosticate procedural success and cost productiveness for SWL.¹⁴ This score needs only three simple and important parameters that are reported in routine in CT imaging studies and thus can facilitate urologists regarding use of this simple nomogram. The focus of this study is to endorse the Three D score in individuals >18 years. Results of this study shows Triple D score is effectual in prediction of successful procedural outcomes. The important factors in 3 D score are evaluated through NCCT studies for prediction of SWL outcomes.^{22,23} Unfortunately these factors are not being used in routine bases and not accepted widely.

In this study ROC curves were generated for each stone parameter which gives significant correlation with success rate (Figure-1). Stone size which is an important part of 3 D score, has been inversely correlated with SWL success rate. In past papers stone size is one of the good predictor of stone free rate.²⁴ Various techniques of stone size measurements have been tested in past- the diameter, surface area, and volume.¹⁶⁻¹⁸ In a study, they found smaller volume (SV) was observed in subjects who had attained procedural success following SWL (273 μ L and 464 μ L, *p*: 0.002). In a similar fashion, El-Nahas asserted volume of stone as an anticipating factor for subsequent fragmentation of stones following the SWL procedure.²⁵ In our study stone size was significantly associated with success rate and cut-off value of SV was found to be 197 mm³.

Skin to stone distance (SSD) a vital part of 3 D formula, has been found to be one of the predictors of treatment efficacy of SWL.^{12,13} Perk *et al.* identified SSD <9 cm to be associated with better SWL net results²⁶. Wiesenthal *et al.* identified cut-off value of 11cm³²⁷. Previous studies have proclaimed

optimal values ranging from 10–11 cm.¹³ In present study, remarkable contrast was observed in mean skin-stone distance between those achieving successful outcomes (9.2 \pm 1.75 cm) and those in whom the procedure was a failure (10.8 \pm 1.07 cm).

Likewise, Stone density is an important parameter of 3 D formula. Some of previous studies²⁷⁻³⁰ implicated stones of more than 900 Hounsfield unit to be a cause of SWL failure (30). Ouzaid *et al* inferred that stones of more than 970 HU had higher chances of SWL failure.¹¹ Nakasato *et al.* mentioned SWL procedural success to be strikingly higher where density was lesser than 815.²⁸

Three D score has not been studied extensively (see table 4). First of all, conducted by Tran *et al.*¹⁴ stone free rates of 96%,78%, 41%, 21.4% were attained for Triple D score of 3, 2, 1, 0 respectively. Their results were almost similar to our study (Table-4). In yet another study done, Gokce *et al.*²⁹ found a score of 3 to be associated with success rate reaching almost 95%. On the contrary, these rates plummeted much for patients having Triple D score "0" (success rate of merely 20%). In another study recently, Ozgor *et al.*³⁰ found that, there was marked difference in the Three D scores between SWL successful and failure groups (markedly lower in SWL failure patients: They noted mean score of 1.9 vs. 1.2 for SWL successful and failed groups respectively (with *p*-value <0.001).

We believe that the Triple D score can be helping in favourable patient selection owing to its convenient application. These values (cut-offs) might be of help if disseminated to the radiology colleagues, so as to furnish easily computable scores. If used in routine reports by radiology, this might be of great help in urology clinics. Furthermore, we took into account the impact of increasing three D score on number of sessions required to get stone free and consequently the costs incurred. Cost is an important parameter in order to better counsel patients as to how much will be financial burdens in case of failure to achieve success in single session. Every center and country have different monetary policies and economies. So, it may vary from country to country and also from centre to centre. No study till date has ever commented on effect of three D score in this regard.

Our study had some strengths. Firstly, we had the highest number of patients studied to see validity of 3D score in literature so far. Secondly, it was a homogenous group of patients (renal stones). Thirdly, their results were prospectively followed. To date, no center has prospectively followed so many patients for Triple D score validation. Other centres have included ureter stones as well and so their data was not homogenous. Being a single centre study is

its limitation. No multi-centre study has ever been done till date. So, in future there is a need for multi-centre studies to further see the validity of this simple score.

CONCLUSION

The Three D Score seems to be an efficient tool for prediction of procedural net results including expected costs as well. However, additional appraisal of the Three D Score involving multi-centre prospective study may be needed to gauge its capacity of usefulness and in terms of its predictive capability. It will pave a way to incorporate in daily reporting by radiologists to offer a ready and easy score for the practicing urologists to formulate their decisions and patient counselling in a better and efficient way.

AUTHORS' CONTRIBUTION

NI: Design, Conception, Data collection, Analysis, writing. AH, GS: Data collection, Analysis, Literature review. MH: Data collection, Analysis, Literature review. AN: Literature review, Analysis, writing. MHK: Data collection, Analysis, Literature review. SI: Literature review, Analysis, writing. MA: Data collection, Analysis, Literature review. SA: Design, Conception, critical review. DI: Literature review, critical review, writing. FK: Data Analysis, Literature review.

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