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## A Study on Role of Non-Contrast Computed Tomography scan in predicting the outcome of Extracorporeal Shockwave Lithotripsy in Urinary Calculi

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### Abstract

**Background:** Urolithiasis is a common disease universally and is known to affect patients all over the globe irrespective of race, culture or geographic boundaries. Recent studies have also demonstrated a changing composition of urolithiasis as well as an appreciable increase in the incidence of stone disease in females and younger patients over the last decade.

**Objectives:** To assess the association between value of Hounsfield unit (HU) measurement of urinary calculi as measured on NCCT (KUB) and the skin to stone distance (SSD) as measured on NCCT on the stone free status after ESWL at 4 weeks follow up.

**Methodology:** All patients referred to department of Radiology, Shadan Institute of Medical Sciences, Hyderabad will be screened and those patients meeting the study inclusion criteria will be informed for the study. For the purpose of the study an informed consent, will be obtained. The study proforma will be completed for every patient included in my study

**Results and Discussion:** The mean age of the patients in the study was  $44.0 \pm 13.1$  years. The age of the patients ranged from 19-75 years. Maximum number of patients (30 patients 50%) belongs to the age group of 21-40 years. Out of the 12 patients 4 (33.3%) had successful outcome and 8 (66.7%) had unsuccessful outcome. Among the 30 patients belonging to the group 500-1000 mean HU, 20 (66.6%) had successful outcome and 10 (33.3%) had unsuccessful outcome. Out of 18 patients who had > 1000 mean HU, 10 (55.5%) had successful outcome and 8 (44.5%) had unsuccessful outcome.

**Conclusion:** Lower pole stone was observed in 30.7% of the lithotripsy success group of patients and 69.3% in lithotripsy unsuccessful group. Statistically there was a significant difference between the lithotripsy success and unsuccessful group. Lower pole stones had significantly higher failure rate.

**Keywords:** Urolithiasis, Radiology, successful outcome, lithotripsy

### Introduction

Urolithiasis is a common disease universally and is known to affect patients all over the globe irrespective of race, culture or geographic boundaries<sup>[1]</sup>. It is also one amongst the most commonly encountered problems in urology constituting a significant proportion of any urology practice. Diminished fluid intake, increased oxalate intake, sodium and animal protein intake are. Considered to be the most important lifestyle related risk factors<sup>4</sup>. In the past few decades, there has been an increasing incidence of urinary stone disease both in developed and developing nations due to changes in life style, particularly due to the rising prevalence of obesity. Recent studies have also demonstrated a changing composition of urolithiasis as well as an appreciable increase in the incidence of stone disease in females and younger patients over the last decade. The rising prevalence of urolithiasis poses a major challenge to the healthcare system not only in terms of the direct cost involved but also due to the complications associated with untreated or delayed treatment such as infection and chronic renal failure. Unlike many chronic diseases, urolithiasis primarily affects working age adults between ages 20 and 60<sup>[2]</sup> which contributes to decreased or lost work productivity. It is also shown that urolithiasis is known to recur in two thirds of the patients within 20 years of the first episode<sup>[3]</sup>.

### Objectives

**The primary objective of the study is:**

1. To assess the association between value of Hounsfield unit (HU) measurement of urinary calculi as measured on NCCT (KUB) and the skin to stone distance (SSD) as

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measured on NCCT on the stone free status after ESWL at 4 weeks follow up.

#### The secondary objective of the study is:

1. To assess the impact of location and size of calculus on the outcome of ESWL.
2. To find out the optimum cut off value of HU and SSD beyond which lithotripsy is likely to fail.

#### Material and Methods

1. **Study Location:** Department of Radio-Diagnosis, Shadan Institute of Medical Sciences, Hyderabad.
2. **Study Period:** The study will be conducted for 24 months, from July 2016 to June 2018.
3. **Study Design:** Hospital based Prospective cross sectional analytic study.
4. **Study Population:** All Patients who are diagnosed with Urolithiasis on Non Contrast Computed Tomography (KUB) performed at the department of Radio-Diagnosis in SIMS, Hyderabad and who are later considered suitable candidates for shockwave lithotripsy.

Every effort will be made to include maximum number of patients in the study over and above the minimum required sample size provided they satisfy the Study Inclusion criteria.

#### Inclusion Criteria

1. Patients with Age > 18 years and patients belonging to both genders
2. Patients with Calculi of size between 5mm and 20 mm and located in the Kidney or the Upper Ureter.
3. Patients proposed to be treated by extracorporeal shockwave lithotripsy.

#### Exclusion Criteria

1. Patients with Age < 18 Years.
2. Patients with calculi in locations of the urinary tract other than the kidney or the upper ureter.
3. Patients with calculi of size < 5mm or > 20 mm.
4. Patients with staghorn calculi.
5. Patients with structural abnormalities of the urinary tract.
6. Patients who have absolute contraindications to ESWL such as pregnancy and coagulopathy.
7. Patients who have not undergone pre procedure Non contrast CT scan (K U B).
8. Patients with active Urosepsis.

#### Study Definitions

- Upper ureteric calculi are defined as the calculi which are located between the ureteropelvic junction and the superior aspect of the sacroiliac joint.
- The Hounsfield unit of the calculus shall be calculated as detailed here: Three regions of interest (ROI) with a diameter of 2mm are drawn on the stone at an axial plane of the non contrast computed tomography scan where the stone length is the longest. The mean HU calculated from the 3 regions represents the mean HU of the stone on NCCT.

**For this study purpose we will categorise the patients based on HU of stone as**

- 1) <500HU
- 2) 500 – 1000 HU

- 3) >1000 HU

- The Skin to stone distance (SSD) is calculated by three distances from the stone to the skin at 0, 45 and 90 degrees by using radiographic callipers and the average of these three values was calculated to represent the skin to stone distance. For the purpose of this study we will categorise the patients as
  - 1) Patients with a skin to stone distance less than 10 cm
  - 2) Patients with a skin to stone distance greater than 10 cm
- The size of the calculus is measured in the largest dimension. For the purpose of the study we will categorise the patients as
  - 1) Patients with a calculus size less than 10mm.
  - 2) Patients with a calculus size greater than 10mm.
- Successful outcome of lithotripsy is defined as either absence of any residual fragments or presence of clinically insignificant residual fragments which are fragments less than 4mm in size in the follow up scan (Xray KUB / USG).
- Failure of lithotripsy is considered as presence of residual stone fragments > 4mm in size in the follow up scan.

#### Study Method and Procedure

**Screening of Patient and Inclusion in this Study:** All patients referred to department of Radiology SIMS, Hyderabad will be screened and those patients meeting the study inclusion criteria will be informed for the study. The study proforma will be completed for every patient included in my study.

Every Patient will be followed up for outcome of Extracorporeal shockwave lithotripsy and data entry will be done into proforma master chart.

#### Study Imaging Protocol

Patients with suspected Urolithiasis referred to department of Radiology, SIMS, Hyderabad will undergo Non contrast computed tomography scan of kidney- ureter- bladder (K U B) on 128 slice Multidetector Philips Ingenuity CT scanner. The scan is done from the upper border of T10 vertebral body to the lower border of symphysis pubis with Slice thickness of 5mm followed by 1mm thin reconstruction and Coronal and Sagittal Reformations. No oral or intravenous contrast will be used.

**Collimation:** 64 x 0.625

**Pitch:** 0.797

**Rotation Time:** 0.75

**Scan Time:** 10.9 seconds

**KV:** 120

**mAs (Avg):** 101

After the scan is done, the requisite parameters (size, mean HU, mean SSD) are calculated.

ESWL will be performed using Dornier Medtech Lithotripter machine aided with both fluoroscopy and ultrasound for focussing the cup at the region of the calculus and for assessing the fragmentation of the calculus.

Number of shockwaves in each session ranges from 1000 to a maximum of 2000.

Sedation will be administered only if necessary.

All patients will be administered Inj. Dynapar post procedure for pain control.

Each session lasts for approximately 40 to 45 minutes.

### Study Follow Up for Outcomes

Patients will be followed up 4 weeks later by Kidney, ureter, bladder (KUB) radiograph, ultrasonography and/or Non Contrast Computed tomography (NCCT) KUB.

In our centre majority of the patients are followed up with either an X ray (KUB) or an ultrasound. In patients who undergo a post procedure NCCT scan for follow up, the CT will be used for follow up as it has greater sensitivity in detecting residual fragments.

Patients with absent or clinically insignificant residual fragments (fragments < 4mm) are considered as those with a successful outcome.

Patients with presence of clinically significant residual fragments (fragments > 4mm) are considered as treatment failures.

### Statistical Analysis

1. Statistical analysis will be performed by using Student t test for continuous data (BMI, infundibular length, mean HU and skin to stone distance) and Chi square test for categorical data (gender, location of calculus)
2. Logistic regression analysis is used to determine the impact of factors such as HU, skin to stone distance, and renal cortical thickness on the outcome of shockwave lithotripsy and to determine which among these parameters have a significant association with the outcome of shockwave lithotripsy.
3. Analysis of the outcome of ESWL in different subgroups of patients will be done and p value ( $p < 0.05$  will be considered as cut off for significance) will be calculated for effect of various individual parameters (HU & SSD) on each subgroup.
4. Receiver operator characteristic (ROC) curves will be generated to compare the predictive power of the variables including but not limited to HU, SSD, and to predict a cut off value for each of these individual parameters beyond which ESWL is likely to be unsuccessful.
5. Data analysis will be done using SPSS 23.0 version (Statistical Package for Social Sciences) computer software.

### Results and Observations

**Table 1:** Age Distribution of the patients

Age group In years	Numbers	%
<20	6	10
21-40	30	50
41-60	15	25
>60	9	15
Total	60	100

**Table 2:** Mean age in Years

Age	Years
Mean	44.0
SD	13.1
Range	19-75

The mean age of the patients in the study was  $44.0 \pm 13.1$  years. The age of the patients ranged from 19-75 years. Maximum number of patients (30 patients 50%) belongs to the age group of 21-40 years.

**Table 3:** Gender distribution of patients

Gender	Number	%
Male	40	66.6
Female	20	33.4
Total	60	100

Out of the 60 patients, 45 (75%) were males and 15 (25%) were females.

**Table 4:** Age and gender distribution of patients

Age group in years	Gender			
	Male		Females%	
	Number	%	Number	%
<20	4	10	3	15
21-40	20	50	10	50
41-60	12	30	4	20
>60	4	10	3	15

**Table 5:** Patients who had calculus in kidney and in ureter

Calculus	Number	%
Kidney	20	33.33
Ureter	40	66.67
Total	60	100

Majority of the patients 40 (66.67%) had calculus in kidney followed by 20 (33.33%) in ureter

**Table 6:** Location of the calculus

Location	Number	%
Renal	5	8.3
Upper pole	5	8.4
Midpole	10	16.6
Lower pole	10	16.6
Ureter	30	50
Total	60	100

Maximum number 30 (50%) of the patients had calculus in the ureter followed by mid pole 10 (16.6%) and lower pole 10 (16.6%) in the kidney.

**Table 7:** Presenting the outcome of patients location wise

Location	Success		Un success	
	Number	%	Number	%
Renal				
Upper pole	4	11.7	-	-
Mid pole	5	14.7	10	38.46
Lower pole	8	23.5	13	50
Ureter	17	50	3	11.5
Total	34	100	26	100

From the above table it is evident that in the kidney maximum number 5 (14.7%) had calculus at mid pole followed by 8 (23.5%) at lower pole. But 17 (50%) of the patients had calculus at ureter.

**Table 8:** Showing the outcome of the patients in three groups based on mean HU

Mean HU	Total number	Success		Unsuccess	
		Number	%	Number	%
<500HU	12	4	11.7	8	30.7
500-1000	30	20	58.8	10	39
>1000	18	10	29.4	8	30.3
Total	60	34	100	26	100

As represented in the table 7, 12 patients had mean HU < 500 out of the 12 patients 4 (33.3%) had successful outcome and 8 (66.7%) had unsuccessful outcome. Among the 30 patients belonging to the group 500-1000 mean HU, 20 (66.6%) had successful outcome and 10 (33.3%) had unsuccessful outcome. Out of 18 patients who had > 1000 mean HU, 10 (55.5%) had successful outcome and 8 (44.5%) had unsuccessful outcome.

**Table 9:** Showing the outcome of the patients in the two groups based mean size

Mean size	Total number	Success		Unsuccessful	
		Number	%	Number	%
<10mm	32	20	33.33	12	46.15
>10mm	28	14	66.67	14	53.84
Total	60	34	100	26	100

As mentioned in the above table number 8, out of 60 patients 32 had mean size <10mm among these 32 patients 20 (62.5%) had successful outcome and 12 (27.5%) had unsuccessful outcome. Out 60 patients 28 had mean size >10mm. Among these 14 patients 14 (50%) had successful outcome and 14 (50%) had unsuccessful outcome.

**Table 10:** Showing the outcome of the patients in the two groups based on mean SSD

Mean SSD	Total number	Success		Unsuccessful	
		Number	%	Number	%
<10cm	20	14	41.1	6	23
>10cm	40	20	59.9	20	77
Total	60	34	100	26	100

As represented in table number 9, out of the total 60 patients 20 had mean SSD <10cm. Among these 20 patients 14 (70%) had successful outcome and 6 (30%) had unsuccessful outcome out of the 60 patients 40 had mean SSD>10cm. Among the 40 patients 20 (50%) had successful outcome and 20 (50%) had unsuccessful outcome.

**Table 11:** Showing the mean and SD of Lithotripsy success and Lithotripsy Unsuccess groups with regard to their mean HU.

	Success group N=34	Unsuccess group (N=26)	P value
Mean	785.44	1006.11	P<0.01
SD	212.35	291.44	-

As mentioned in the table number 10 the mean in lithotripsy success group of patients was 785.44±212.35. Mean HU and in lithotripsy unsuccess group it was 1006.11±291.44. Mean HU statistically there was significant difference between the lithotripsy successful group and lithotripsy unsuccessful group of patients. Since  $P<0.05$

**Table 12:** Showing the mean and SD of lithotripsy success and unsuccessful groups in respect of their mean size of calculi

	Success group N=34	Unsuccessful group (N=26)	P value
Mean	7.01	11.15	P<0.05
SD (in mm)	2.16	4.21	-

As presented in table number 11 the mean size of calculi in lithotripsy success group of patients was 7.01±2.16 mm and in lithotripsy unsuccessful group it was 11.15±4.21 mm. Statistically there was significant difference between the

lithotripsy success group and unsuccessful group of patients as the P value is less than 0.05.

**Table 13:** Showing the mean and SD of lithotripsy success and unsuccessful groups in respect of their mean SSD

	Success group N=34	Unsuccess group (N=26)	P value
Mean	10.33	10.01	P<0.05
SD (in mm)	2.51	2.04	-

As mentioned in table 12, the mean SSD in the lithotripsy success group of patients was 10.33±2.51 cm and in lithotripsy unsuccessful group it was 10.01±2.04. Statistically there was no significant difference between the lithotripsy success group and lithotripsy unsuccessful group of patients as p value is > 0.05.

**Table 14:** Comparison of the lithotripsy success and unsuccessful groups with respect to stones at lower pole/lower pole stones

Groups	Number	%	P value
Lithotripsy success	8	30.7	P<0.01
Lithotripsy unsuccess	18	69.3	
Total	26		

As mentioned in table number 13, lower pole stone was observed in 30.7% of the lithotripsy success group of patients and 69.3% in lithotripsy unsuccessful group. Statistically there was a significant difference between the lithotripsy success and unsuccessful group. Lower pole stones had significantly higher failure rate.

## Discussion

ESWL has revolutionized the treatment strategy of urolithiasis worldwide and continues to be a major therapeutic modality for treating a majority of upper urinary tract stones. It is non-invasive in nature along with high efficacy has resulted in outstanding patient and surgeon acceptance. ESWL is the preferred modality of treatment for renal stones <2 cm. However, SFR after treatment has never been near 100% and has been in the range of 65-75%. The success rate of ESWL is determined by factors such as stone size, composition, location, presence of obstructive changes, and anatomical anomalies. Stone composition is one hidden factor which decides the fragility of calculus and its susceptibility to ESWL. The number of shocks required for fragmentation is related not only to the size of the stone but also to its hardness (or) brittleness which largely depends on its chemical composition. CT being an easily available modality of investigation and because of its increased sensitivity to density differences has been used to measure stone densities of various types of calculi, and attempts are made to correlate the density with chemical composition [4-6].

Hillman *et al.* reported 89% overall accuracy of CT scan to categorize uric acid, calcium oxalate, and struvite calculi.11 On the contrary, Kuwahara *et al.* reported that there is no correlation between the attenuation value and the chemical composition of renal stone. Where in this study 12 patients had mean HU < 500 out of the 12 patients 4 (33.3%) had successful outcome and 8 (66.7%) had unsuccessful outcome. Among the 30 patients belonging to the group 500-1000 mean HU, 20 (66.6%) had successful outcome and 10 (33.3%) had unsuccessful outcome. Out of 18 patients who had > 1000 mean HU, 10 (55.5%) had



successful outcome and 8 (44.5%) had unsuccessful outcome<sup>[7]</sup>

Joseph *et al.* reported overall success rate of 80% for calculus up to 2 cm when they assessed the susceptibility of stone fragmentation by ESWL. According to the HU, they found that the success rate for stone with attenuation value <1000 HU was significantly higher than that for stone with value >1000 HU. In their study, they found a significant correlation between number of shocks required for stone fragmentation and the attenuation value of the stone. Where in this study 12, out of 60 patients 32 had mean size <10mm among these 32 patients 20 (62.5%) had successful outcome and 12 (27.5%) had unsuccessful outcome. Out 60 patients 28 had mean size >10mm. Among these 14 patients 14 (50%) had successful outcome and 14 (50%) had unsuccessful outcome<sup>[8]</sup>.

Motley *et al.* concluded that there is no significant difference between density values of calcium oxalate and calcium phosphate calculus. Where in this study 12 out of the total 60 patients 20 had mean SSD <10cm. Among these 20 patients 14 (70%) had successful outcome and 6 (30%) had unsuccessful outcome out of the 60 patients 40 had mean SSD >10cm. Among the 40 patients 20 (50%) had successful outcome and 20 (50%) had unsuccessful outcome<sup>[9]</sup>.

Pareek *et al.* correlated calculus density with clearance in 50 patients. 36% of patients had residual calculi with their mean density of >900 HU compared to 74% clearance with mean density of 500 HU. Where in this study 12 the mean in lithotripsy success group of patients was  $784.63 \pm 253.76$ . Mean HU and in lithotripsy unsucess group it was  $1009.35 \pm 304.36$ . Mean HU statistically there was significant difference between the lithotripsy successful group and lithotripsy unsucessful group of patients. Since  $P < 0.05$ <sup>[10]</sup>.

## Conclusion

Lower pole stone was observed in 30.7% of the lithotripsy success group of patients and 69.3% in lithotripsy unsuccessful group. Statistically there was a significant difference between the lithotripsy success and unsuccessful group. Lower pole stones had significantly higher failure rate.

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