THE ROLE OF NON CONTRAST CT – KUB IN PREDICTING THE STONE FRAGILITY AND ESWL SUCCESS RATE

Dissertation submitted in partial fulfillment of the requirement for the degree of

M.Ch (UROLOGY) – BRANCH – IV

THE TAMILNADU Dr.M.G.R. MEDICAL UNIVERSITY
CHENNAI

AUGUST 2009

DECLARATION

I solemnly declare that this dissertation ***"THE ROLE OF NON CONTRAST CT-KUB IN PREDICTING THE STONE FRAGILITY AND ESWL SUCCESS RATE"*** was proposed by me in the Department of Urology, Government Madras Medical College and Hospital, Chennai under the guidance and supervision of **Prof.R.JEYARAMAN, M.S., M.Ch.,** Professor and Head of the Department, Department of Urology, Government Madras Medical College, Chennai.

This Dissertation is submitted to the Tamilnadu Dr. M.G.R. Medical University, Chennai in partial fulfillment f the University requirements for the award of degree of M.Ch Genitourinary Surgery.

Place: Chennai
Date:

CERTIFICATE

This is to certify that this dissertation entitled ***"THE ROLE OF NON CONTRAST CT-KUB IN PREDICTING THE STONE FRAGILITY AND ESWL SUCCESS RATE"*** submitted by **Dr.S.MANGAIYARKARASI,** appearing for **M.Ch (Urology)** degree examination in August 2009 is a bonafide record of work done by her, under my guidance and supervision in partial fulfillment of requirement of the Tamilnadu Dr. M.G.R. Medical University, Chennai. I forward this to the Tamilnadu Dr. M.G.R. Medical University, Chennai, Tamilnadu, India.

Prof.R.JEYARAMAN, M.S., M.Ch.,
Professor and Head of the
Department of Urology,
Madras Medical College &
Government General Hospital,
Chennai – 600 003.

DEAN
Madras Medical College &
Government General Hospital,
Chennai – 600 003.

ACKNOWLEDGEMENT

I owe my thanks to the **DEAN, GOVERNMENT GENERAL HOSPITAL,** and **MADRAS MEDICAL COLLEGE** for allowing me to avail of the facilities needed for my dissertation work.

I would like to express my sincere gratitude to my beloved Professor and Head of the Department of **Prof.R.JEYARAMAN, M.S., M.Ch.,** for his invaluable motivation and guidance in completing this dissertation.

I am also deeply thankful to **Prof.V. KAMARAJ, M.S., M.Ch.,** and **Prof.RM. MEYYAPPAN, M.S., M.Ch.,** for their valuable suggestions and inputs in preparing this dissertation.

I sincerely thank my Assistant Professors for their help at various stages of this work.

Finally, I will be failing in my duty if I don't thank my patients who have been my greatest source of inspiration in my work.

CONTENTS

INTRODUCTION

Stone disease causes enormous social and economic burden to the society. The lifetime prevalence of kidney stone disease is 1-15% with the probability of having a stone varying according to age, gender, race, and geographic location. Management options for renal calculi has changed dramatically during the past 30 years.

Minimally invasive techniques, especially the introduction and development of Extra Corporeal Shock Wave Lithotripsy (ESWL) has virtually replaced open surgical stone removal. ESWL was introduced by ***Christian Chaussay*** in 1980. Around 80-85% of simple renal calculi can be treated effectively with ESWL.

ESWL is a non invasive therapy for urinary calculi with good success rates and decreased morbidity, length of hospitalization and anaesthesia requirement. According to the AUA guidelines, ESWL is the preferred modality of treatment for renal stones of 2cm size.

Even large and complex renal calculi can be treated effectively with these minimally invasive techniques. For complete staghorn calculi a combined PCNL and ESWL (Sandwich) therapy has been recommended as the first line of treatment.

However, even for the calculi of this size, the stone free rates vary between 66% -

99%. This variation in stone fragmentation is due to factors like stone size, location, chemical composition, BMI, other congenital anatomical anomalies, shock wave generator and presence of obstruction (or) infection.

The renal calyces are the most common location of asymptomatic (or) incidentally discovered urinary calculi. Pelvic calculi, upper calyceal and middle calyceal stones of less than 2cm have been treated with ESWL with stone free rate of upto 99%.

The management of lower calyceal stone is more controversial and in this situation, stone free rate after ESWL range from 44-79%. Lower calyceal Stone with favourable infundibulo pelvic anatomy have good success rate with ESWL.

Stone fragmentation by ESWL is variable. So it is desirable to reduce the number of retreatment (or) limit one definite therapy. In addition to the local effects of ESWL upon renal parenchyma, injury to surrounding organs are also of concern. The long term prevalence rate of HT and change in renal plasma flow following ESWL treatment constitute a further reason for the surgeon to limit the therapy to one stage definite treatment. The success of ESWL has been correlated with the radiodensity of the renal stone on plain X-ray KUB. Overall accuracy of predicting calculi composition from plain radiographs was reported to be only 39%, which is at present insufficient for clinical use.

The Emergence of Non Contrast CT KUB in the assessment of flank pain and the

subsequent availability of the attenuation coefficient measurement has resulted in many studies comparing the attenuation value and stone composition invitro. These studies have determined that stone compositions can be predicted on the basis of the attenuation value determined by NCCT.

The density of stone measured by NCCT Hounsfield Unit (HU) varies with stone composition and determines the fragility of a calculus which ultimately determines the clinical outcome in ESWL. NCCT because of its easy availability, superb sensitivity and very high resolution capability, is a good modality for the measurement of stone density.

REVIEW OF LITERATURE

The prevalence of stone disease is very high in most parts of India because of its geography, dietary habits, temperature and humidity superimposed on their intrinsic factors predisposing to stone formation. Prevalence of stone disease is 1-15% and varies by age, sex and race. For men, incidence begins to rise after age 20, peaks between 40 and 60 years at about 3/1000/y and then begin to decline. For women incidence rates seem to be higher in late 20s (2.5/1000/y) and then decreasing to 1/1000/y age 50. The incidence and prevalence of stone disease is increasing in recent years, may be due to increased detection of asymptomatic stones discovered with the greater use and higher sensitivity of imaging studies.

Stone disease can be easily diagnosed using imaging studies like X-ray KUB, USG KUB and CT KUB. Plain radiography detects radio opaque calculi. The limitations are bowel gas, bone shadow overlapping the stones, and radiolucent stones.

USG KUB can detect calculi in the renal area and associated obstruction and dilatation of pelvi calyceal system. Limitations are obesity, bowel gas and poor sensitivity for ureteric calculi.

Non contrast CT KUB is a simple method to detect renal and ureteric calculi,

stone burden with density and dilatation of pelvicalyceal system.

Various treatment options including non invasive modalities and minimally invasive surgeries have replaced the open stone surgery nowadays. Extra Corporeal Shockwave Lithotripsy is a non invasive treatment option with minimal morbidity.

The word lithotriptor is Greek origin and means stone crusher. Lithotriptors have evolved from many years of research into the physics of flight. Researchers discovered that raindrops striking an air craft during supersonic flight created shockwaves that had disintegrating effects on solid materials. Refinements of these findings led to the intervention of the lithotriptor as a means for treating urinary calculi.

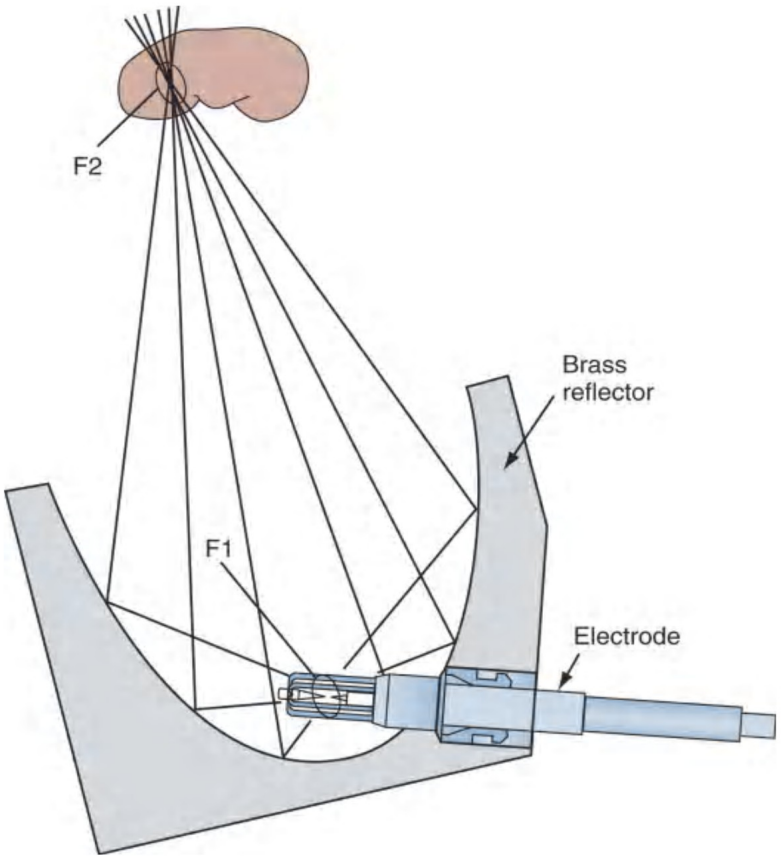
In February 1980 ***Dr. Christian Chaussay, University of Munich*** first used electrically generated focused shockwaves to fragment stones within a human kidney. The first Lithotriptor model HM 1 soon replaced by HM 2 in 1982 and in 1984 by Model HM 3. Each new generation reflects progression of technology and a growing sophistication. Further modification of the generation is the consolidation of fluoroscopic screens and the lithotripsy control into a convenient, efficient and user friendly console. Shockwave lithotripsy technology has advanced rapidly in terms of shock wave generation, focusing, patient coupling and stone localization making it the most widely used treatment for renal calculi.

METHODS OF SHOCK WAVE GENERATION

Lithotriptors, are characterized by the types of shockwave generators they employ. Commercially available lithotriptors use Electrohydraulic (EH), Electromagnetic (EM) and Piozoelectric generators .

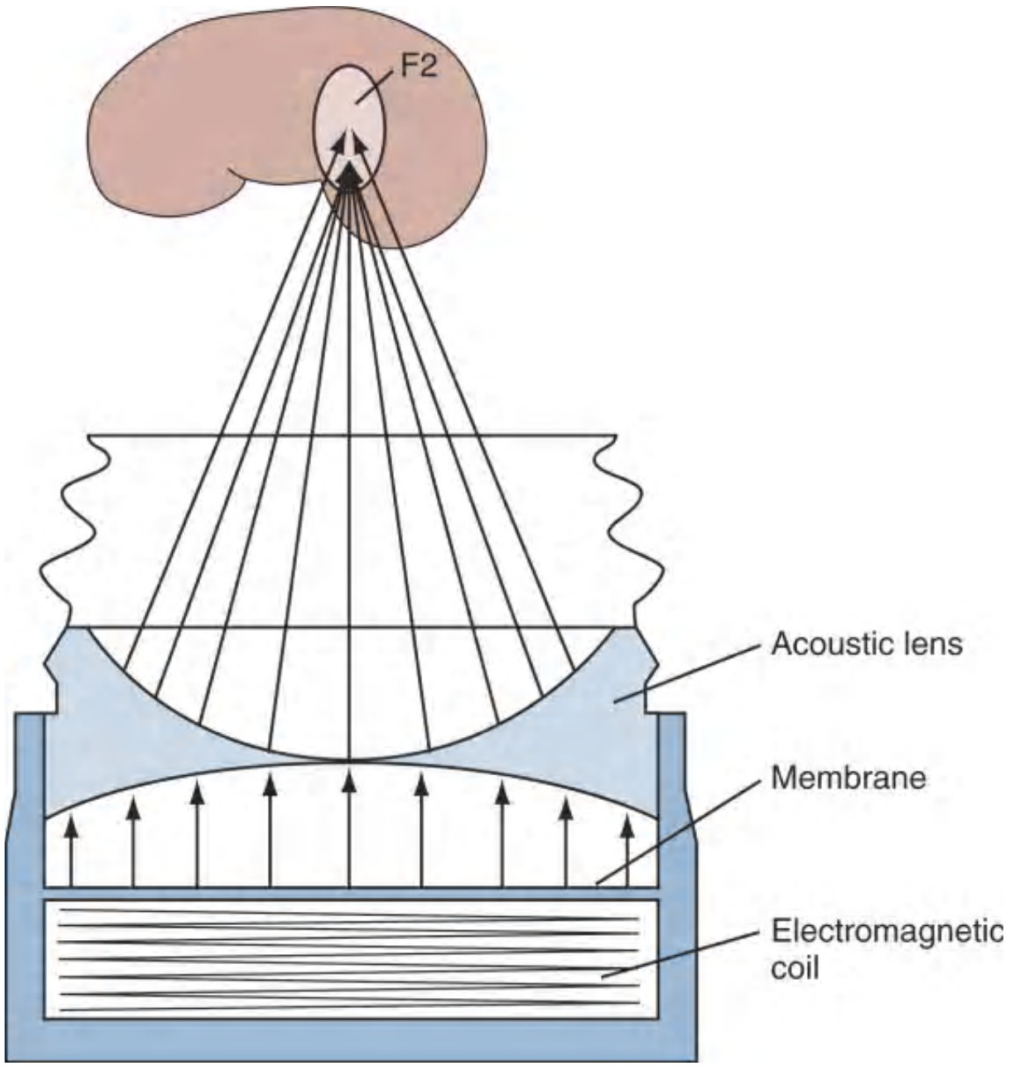
ELECTRO HYDRAULIC (SPARK GAP) GENERATORS

A spherically expanding shockwave is generated by an underwater spark discharge (15000-25000V) Electrode at F1 and focused by hemi ellipsoid reflector on to the calculus at F2. The advantage of this generator is its effectiveness in breaking kidney stones. Disadvantages are substantial pressure fluctuations from shock to shock and a relatively short electrode life.



ELECTROMAGNETIC GENERATORS

EMSE - Electromagnetic shock wave Emitter. This consists of a disk coil that is charged with high voltage pulses (5000-20000V), whereby, the membrane lying directly on the coil is thrust outwards. The shock wave generated is focused by means of an acoustic lens on the stone.

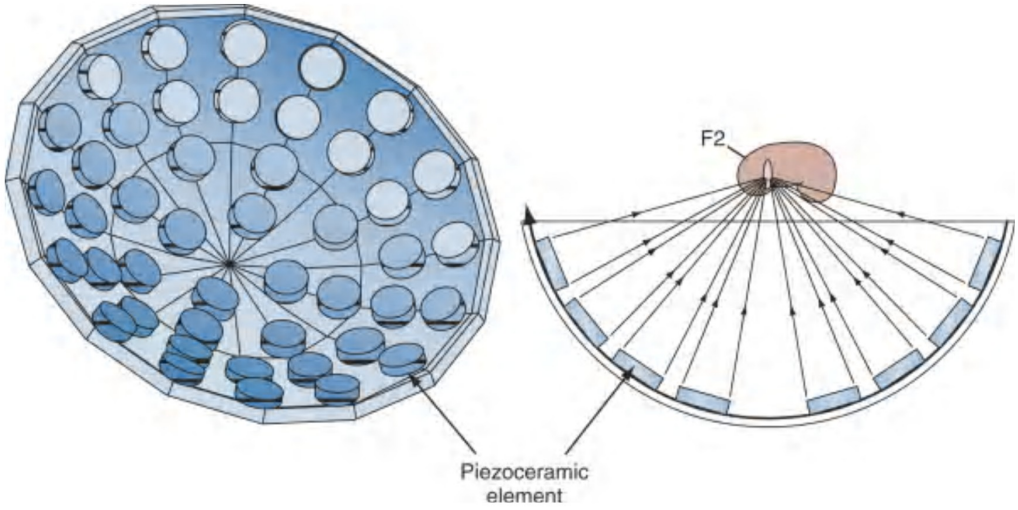


The advantage of electromagnetic generator is that, it is more controllable and reproducible. Introduction of energy into patients body over a large skin area causes less pain. The small focus with high energy densities increases its effectiveness is breaking stones. The disadvantage is also the small focal region of high energy, leading to increased rate of subcapsular hematoma formation.

PIEZOELECTRIC GENERATOR

Piezoelectric energy source uses a spherical array of piezoelectric crystals excited by an electric impulse of 2000-6000V. This results in simultaneous sudden expansion and shockwave generation. These waves are focused on to the stone. The advantages are the focusing accuracy, a long service life, and anaesthesia free treatment.

The major disadvantage is the insufficient power it delivers, hampering its ability to effectively break renal stones.



SHOCKWAVE FOCUSING

Shock wave focusing allows for the concentration of shockwave energy at a focal point. The focal area refers to the volume within which the shock waves are concentrated.

SHOCK WAVE COUPLING

Shock waves can be coupled effectively into the body by degassed water which has a matched acoustic impedance to soft tissues. Current lithotriptors use enclosed water cushion with a coupling medium of ultrasound gel, instead of 1000 L water bath. Shock wave attenuation through the membrane of water cushion amounts to 20% loss of energy.

STONE LOCALIZATION

Stone localization during lithotripsy is accomplished with either fluoroscopy (or)

ultrosonography. Fluroscopy provides the urologist with a familiar modality and the added benefit of effective ureteral stone localization. Disadvantages are the radiation hazard to both the patient, medical staff and the inability to visualise radiolucent calculi.

Ultrasonography based lithotriptors offer the advantages of stone localization with continuous monitoring and effective identification of radiolucent stones without radiation exposure. Disadvantage of ultrasonography is inability to locate ureteral stones.

PHYSICAL PROPERTIES OF RENAL CALCULI AND TISSUE

Knowledge of acoustic and mechanical properties of renal calculi and tissue is important to understand shockwave – stone tissue interaction and the mechanisms of stone fragmentation and tissue injury during ESWL Acoustic properties determine the characteristics of shock wave propagation inside the stone and tissue materials as well as the wave transmission and reflection, at the stone tissue boundary. Mechanical properties dictate the response of the stone and tissue materials to shock wave loadings. Acoustic and mechanical properties of renal calculi depend primarily on the composition of stone.

COMPOSITION AND STRUCTURAL FEATURES OF RENAL CALCULI

The constituents of renal calculi are crystalline (95%) and non crystalline matrix materials (Protein, Cellular debris and organic materials)

Major crystalline components are calcium oxalate (Monohydrate and dihydrate), phosphates (hydroxyapatite, carbonate apatite struvite), uric acid, urate, cystine and xanthine. Renal calculi appear in wide range of shapes, sizes, colors and textures.

ACOUSTIC PROPERTIES OF RENAL CALCULI AND RENAL TISSUE

Acoustic properties are density, wave speed and acoustic impedance. Longitudinal wave propagation (compressional) is characterized by parallel movements of material particles along the wave path. In transverse (Shear) wave propagation, material particles move perpendicular to wave path.

Calcium oxalate monohydrate and cystine stones have higher acoustic impedance. Stones with higher acoustic impedance would produce a stronger reflection of the shock wave at the anterior surface of stone resulting in less of the shock wave energy being transmitted into the stone to cause fragmentation.

MECHANICAL PROPERTIES OF RENAL CALCULI

Dynamic elastic properties of renal calculi depend upon resistance of stone material to elongation (or) shortening, shear deformation and volume change. Most renal calculi are brittle, while cystine stones are ductile (more energy is needed to produce fracture) and the most difficult to fragment during SWL.

MECHANISMS OF VARYING STONE FRAGILITY

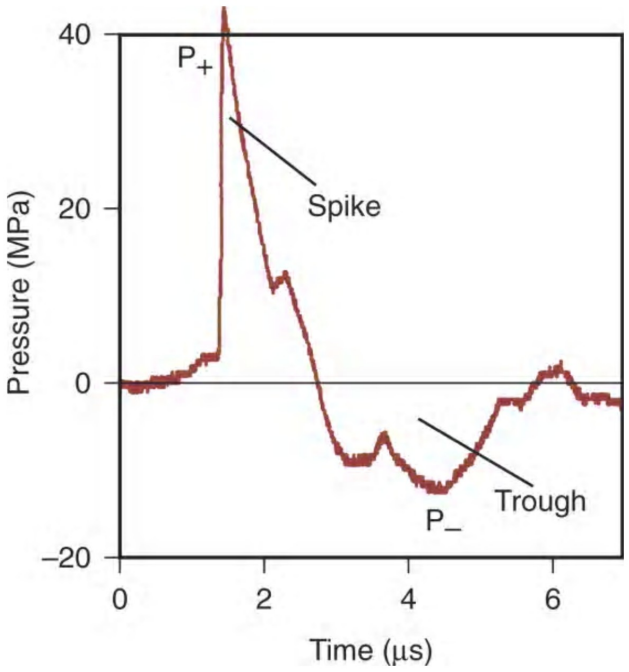
Stone fragility determines the response of a renal calculus to SWL. It varies with composition, size and structural features of stone.

It has been reported that stones with homogenous architecture are less fragile than stones with heterogenous structure. Elastic module determines the stone's resistance to shock wave induced deformation. Hardness determines a stone's resistance to cavitation, microjet impact and fracture. Toughness determines a stone's resistance to spalling damage and crack propagation. COM(Calcium oxalate monohydrate) and brushite stones are less fragile than MAP(Magnesium ammonium phosphates) and CA(Carboxy apatite) stones because COM and brushite stones are stiffer, harder and more resistant to fracture.

MECHANISMS OF STONE FRAGMENTATION

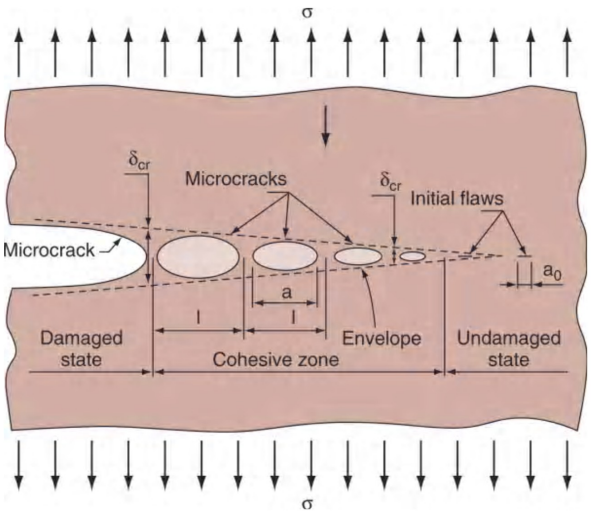
Damage methods are surface erosion at the anterior surface of stone, spalling damage at the posterior surface of stone and layer separation at the interface of adjacent stone laminar surface.

Shock Waves composed of positive compressive waves and negative tensile waves.



Shock waves produce bubbles 100-200 μs size which collapse rapidly near the stone surface, producing high speed microjet (770 m/s) that impinge towards the stone surface to cause damage. On the anterior surface of stone numerous minute pits are formed. It is the specific characteristic of cavitation induced surface erosion.

Spalling damage causes the separation of a spherical cap from posterior surface of stone. This mode of stone damage can be attributed to the reflected tensile waves generated at the layer interface because of acoustic impedance mismatch between stone crystalline structure and surrounding matrix materials. Numerous micro fracture grow and propagate to form large crack lines leading to stone disintegration.



Calculi maintain their form because of innate comprehensive forces. Fragmentation occurs when tensile strength of a calculus is overcome by opposing force created by shockwaves. Stone fragmentation occurs by several mechanisms.

The ultimate goal of ESWL is to fragment renal and ureteric calculi as effectively as possible with minimizing the potential injury to surrounding tissues.

Stone fragmentation varies according to stone composition cystine stones are most ESWL resistant. Next are Brushite, and Calcium Oxalate Monohydrate. Pre treatment determination of stone composition and an ability to predict the probability of fragmentation can reduce the number of fruitless shockwaves and reduce the overall cost of stone management.

Different techniques have been used to assist in determining the chemical composition of urinary calculi in vivo. Such tests include pH, identifying characterizing

urinary crystals, presence of urea splitting organisms, bone densitometry and radiographic studies.

Roentgenography has played a major role in the diagnosis and management of calculus disease. Various researchers have attempted to predict the stone composition by different methods.

Dretler pioneered the work on stone fragility and the magnitude of response of a calculus to stone fragmentation techniques. The author chose 6 calculi with near 100% purity. These were photographed on high resolution roentgenographic paper to compare the crystal structure and allow appreciation of differences in their structure. Small spalls are noted in the calcium oxalate dihydrate COD stone, whereas the appearance of calcium oxalate monohydrate and brushite stones are more uniformly dense. Struvite calculi show alternating lines of dense and less opaque material. Cystine and uric acid calculi have more homogenous structure, without obvious striations. They concluded that except of cystine calculi radiologic density correlated well with stone fragility.

In 1996 ***Dretler and Kolt*** further analyzed radiographic patterns of calcium oxalate dihydrate and monohydrate stones. Smooth edge, denser than bone and homogenous are characteristics of pure calcium oxalate monohydrate stones. Radial striations and superimposed stippling pattern are found in calcium oxalate dihydrate stones. This study is the first proof that radiographic morphology can be related to ESWL stone free rate.

Bone et al demonstrated that a smooth, denser than bone calcium oxalate monohydrate stone, fragments less efficiently than rough less dense calcium oxalate dihydrate stone.

Plain radiographs have many limitations. For distinct outline of the renal stone it should be of more than 1cm size. Moreover the stone may get masked by overlying bowel gas and for obvious appearance it should be located in an area away from bony structures.

Cohen et al showed that an accurate diagnosis of stone composition could be made by an analysis of crystals in post ESWL urine specimen using scanning Electron Microscopy and X-ray energy dispersive spectroscopy (XES). His associates then extended the use of these techniques to include examination of pre treatment urine specimen, and thereby predicting the response to ESWL success. The disadvantage of this method is that electron microscopic urine examination may not be easily available and there is difficulty in predicting the nature of calculi in patients with mixed stones.

Cher Saw et al studied the ability of stone density on non contrast CT to predict the number of shock waves required for fragmentation of stones. The number of shock waves required for fragmentation to less than 3mm was taken as the end point. However due to technical defect of volume averaging with 3mm collimation the correlation was not due to radiological density but rather solely to stone size. They concluded that the

size and not HU which determined the number of shockwaves required for fragmentation.

CT Scan is a relatively simple and non invasive technique that is available in most medical centres. Radio opaque and radiolucent calculi can be detected. Several reports have indicated that with the use of modern instrumentation uric acid and poorly mineralized matrix stones can be identified with certainty.

Hillman and his associates sought to determine the feasibility of using CT to analyse the chemical composition of renal calculi. He concluded that uric acid stone can be differentiated clearly from struvite and calcium oxalate calculi.

(CT number (or) Hounsfield unit is calculated using the formula).

$$\frac{1000 \times \mu\text{tissue} -- \mu\text{ water}}{\mu\text{ Water}}$$

μ - absorption coefficient in kilovoltage. This number is named in honor of ***Godfrey Hounsfield*** the inventor of CT Scanning when HUs are used air has a value of – 1000, water- 0 and dense bone and calcification $\geq +1000$.

Federle et al (30) evaluated 9 Patients and analysed CT HU with stone composition. In this study 1 uric acid stone has an attenuation value between 346-400 HU, Xanthine stone had a value of 391 HU, cystine stone 586 HU, calcium oxalate 500-1000 HU.

Kuwahara et al (31) studied the attenuation value of CT of 50 calculi more than 1cm in diameter to determine its composition. The attenuation of various calculi were measured in HU in 5mm collimation in the region of interest. Values obtained as follows. Mixed calcium oxalate Phosphate 1555±193, Magnesium Ammonium Phosphate 1285±284, calcium oxalate 1690, Calcium Phosphate 1440, Cystine 757±114. Uric acid 480. They concluded that attenuation values ranging from 500-1600 overlapped for various calculi. However uric acid calculi had attenuation value less than 500 and oxalate calculi >1000. They could not find any correlation between the attenuation value and the mineral content.

AIM AND OBJECTIVES

- To study the density of renal stone by Non contrast CT Scan as measured in HU and its correlation with susceptibility of fragmentation by ESWL.

MATERIALS AND METHODS

STUDY DESIGN

This is a prospective study conducted in 100 patients of renal stone disease who underwent ESWL treatment at Madras Medical College, Chennai, during the period January 2008 to January 2009.

INCLUSION CRITERIA

- Patients with renal stones 8mm – 35mm in diameter who have not received any previous treatment for the same.
- All stones located in a satisfactory functioning, non obstructed renal unit.

EXCLUSION CRITERIA

- Bleeding diathesis
- Pregnant females
- Uncontrolled infection
- Ureteric calculi
- Distal obstruction
- Congenital Anomalies
- Patients with cardiac pacemaker
- Lower calyceal stone with unfavourable anatomy.

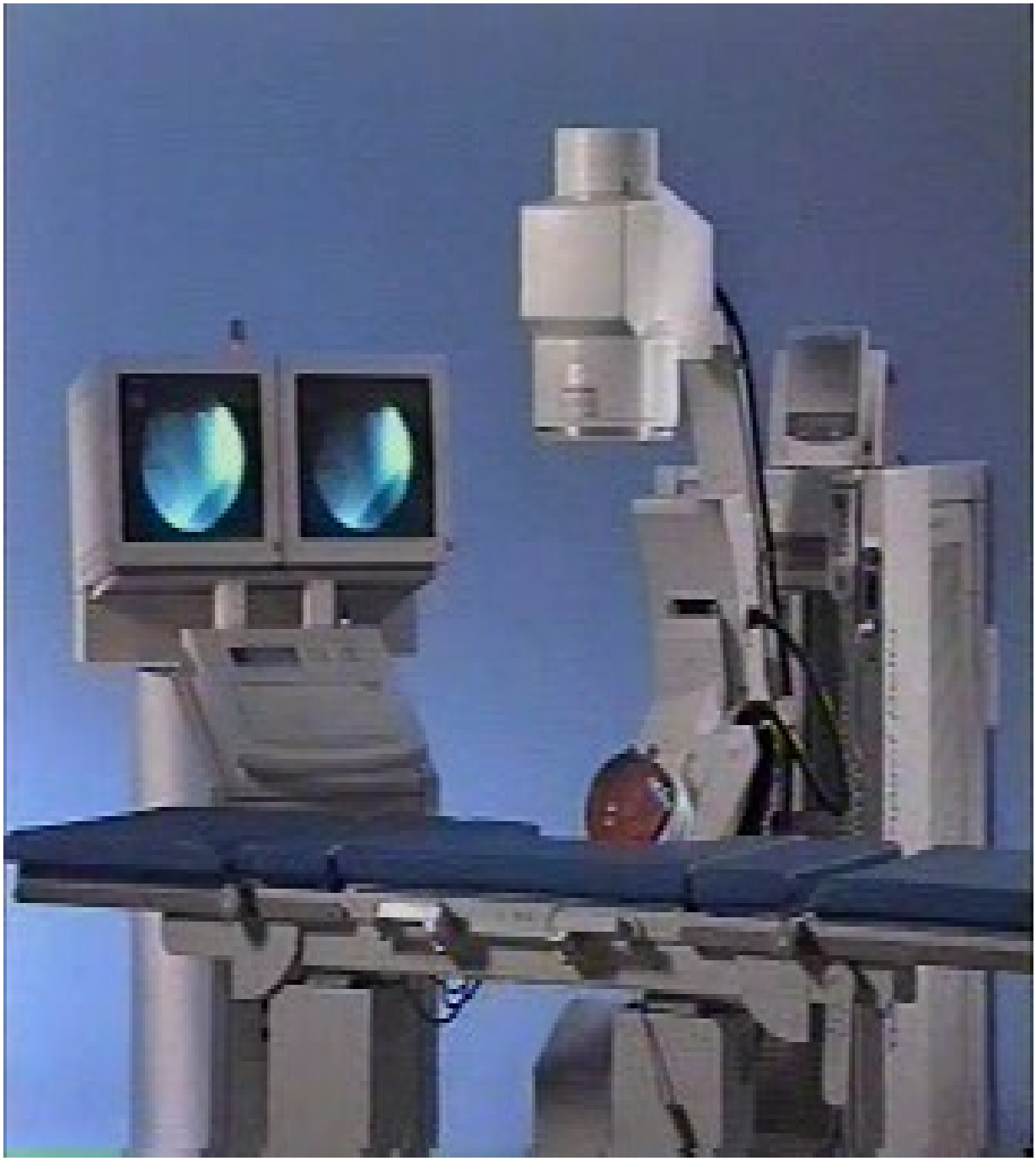
100 patients with renal stones included in the study. In all patients history and physical examination was done. Baseline investigations included were Complete haemogram,

RFT, urine C/S, X-ray KUB, USG KUB and CT KUB.

NCCT Scan was done in 3mm cuts. Stone density in HU was obtained on the particular cut in which the stone was seen in the greatest diameter. Mean stone density was calculated in some cases. Patients were explained about the study, ESWL procedure and informed consent obtained.

ESWL was done as outpatient procedure. Patient datas recorded in the proforma. All treatments were done with ***Dornier Compact Delta*** II (Electromagnetic Generator) Machine. Patients were administered sedation IV Fortwin (20mg), 30 minutes before procedure. In paediatric patients Endotracheal General Anaesthesia was given by anaesthetist. Topical EMLA cream was used in some patients.

ESWL MACHINE



Calculus was focused using ***fluoroscopy, USG probe*** (in radiolucent stones) A maximum of 2500 shocks were given in each sitting. Intensity of shockwaves increased stepwise. Shocks frequency was 60 / minute.

Stone fragmentation was monitored fluroscopically after every 100 shock waves or continuously with USG probe and the procedure was terminated once adequate

fragmentation was observed.

Adequate fragmentation was accepted when following were observed:-

- Increase in stone surface area
- Alteration in configuration
- Irregularity in outline
- Obviously separated fragment
- Decreased over all density

If the stone size is large (> 2.5cm) Pre procedure 5F DJ stenting was done.

After each session of treatment patients were observed for 4-6 hours period and allowed to go home. Patients were explained about the post treatment hematuria, pain and voiding of fragments.

Analgesics were given and patients advised to take around 5-6 liters of fluid /day. All patients were instructed to pass urine through sieve (coffee filter) and to collect stone fragments. This was brought and given to us at the time of review for chemical analysis.

POST PROCEDURE FOLLOW UP

Patients were followed up at 2 weeks with X-ray KUB, USG KUB and CT KUB. For those patients with residual fragments II sitting ESWL was instituted. Second follow

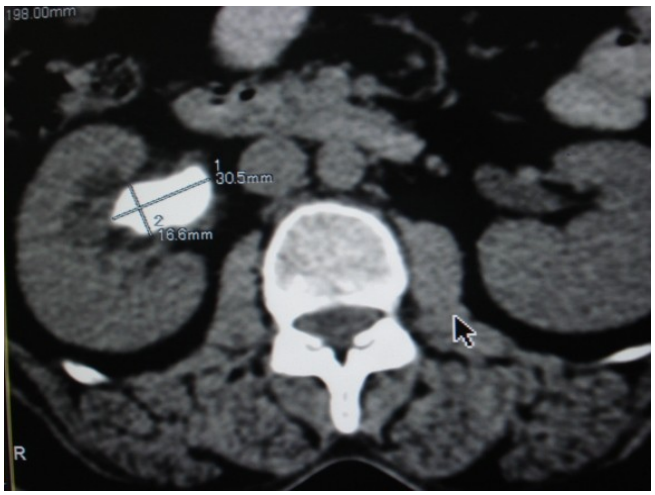
up for those patients who undergone II session of ESWL was done at the end of 4 weeks with X-ray KUB, USG KUB and CT KUB. Those patients with residual fragments, III sitting ESWL was given. After 2 weeks patients were followed up.

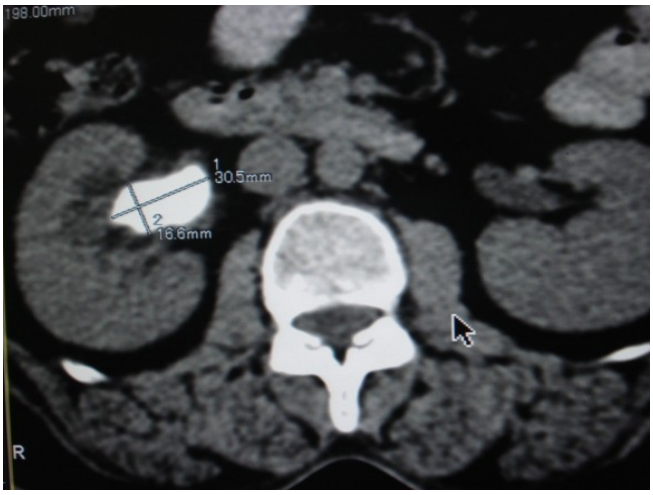
Residual calculi by X-ray KUB, USG KUB and CT KUB <4mm clinically insignificant residual fragment were considered adequately treated. Residual fragments >4mm were considered treatment failures.

The stone fragments brought by the patient were collected, labeled and sent for Chemical Composition Analysis, Biochemistry Department, Madras Medical College. (By Chemical dissolution Method stone composition was detected).

STONE FREE GROUP

PRE ESWL

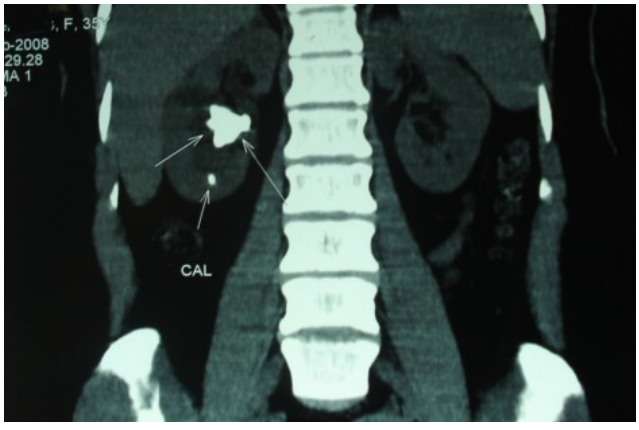




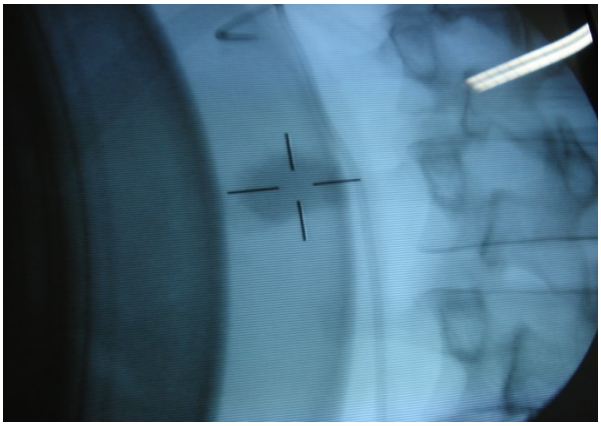
POST ESWL

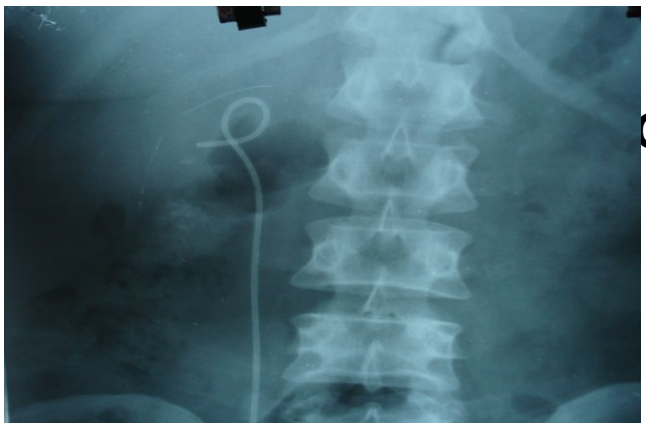
STONE FRAGMENTATION GROUP

PRE ESWL



FLURO FOCUSING





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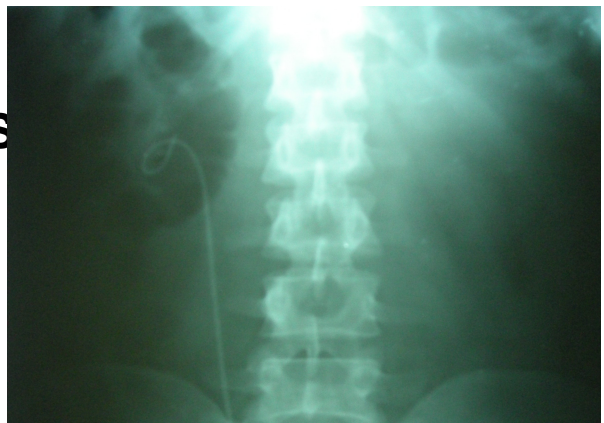
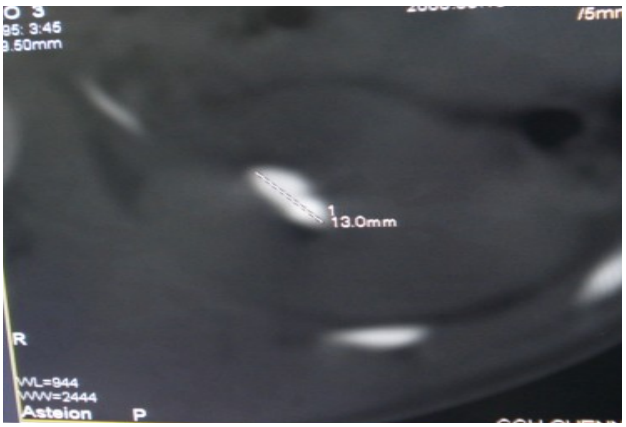
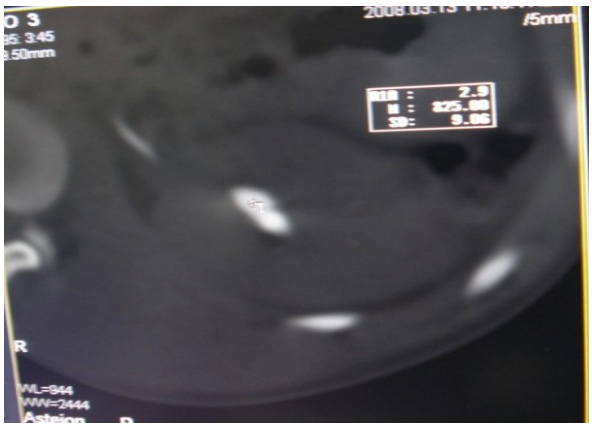


STONE FRAGMENTATION GROUP

PRE ESWL





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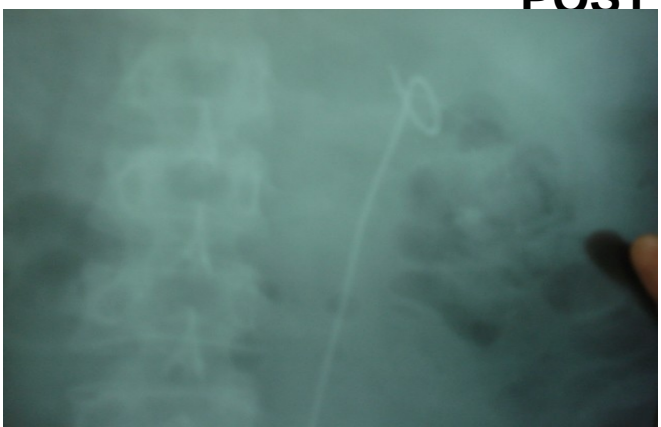
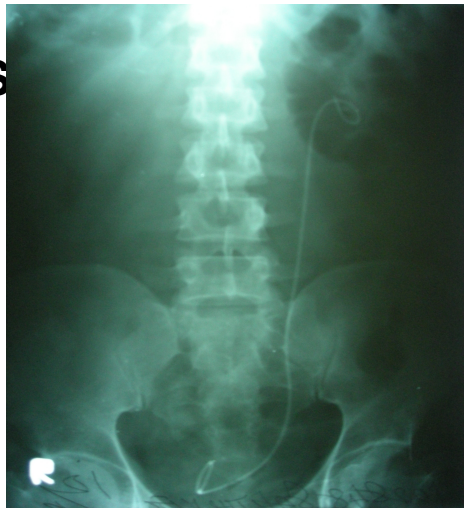
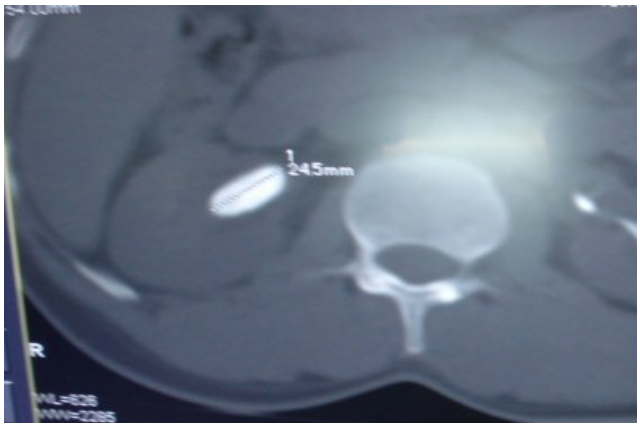
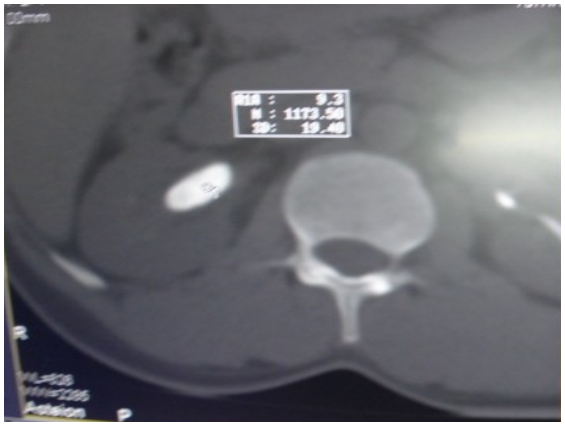


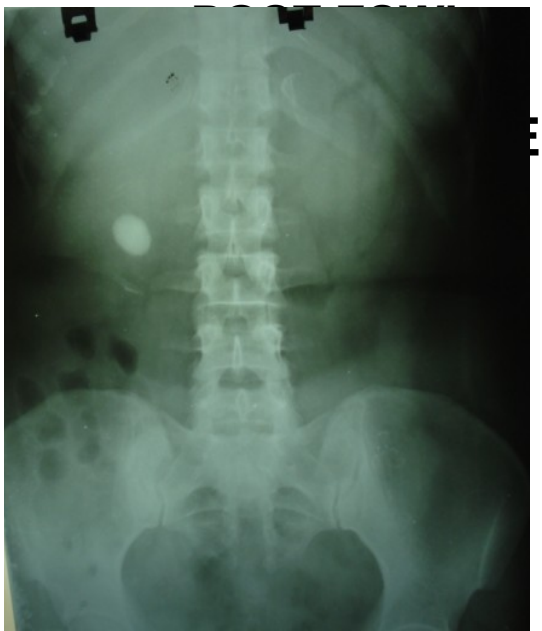


STONE WITH RESIDUAL FRAGMENTS (Failure of Treatment)

PRE ESWL







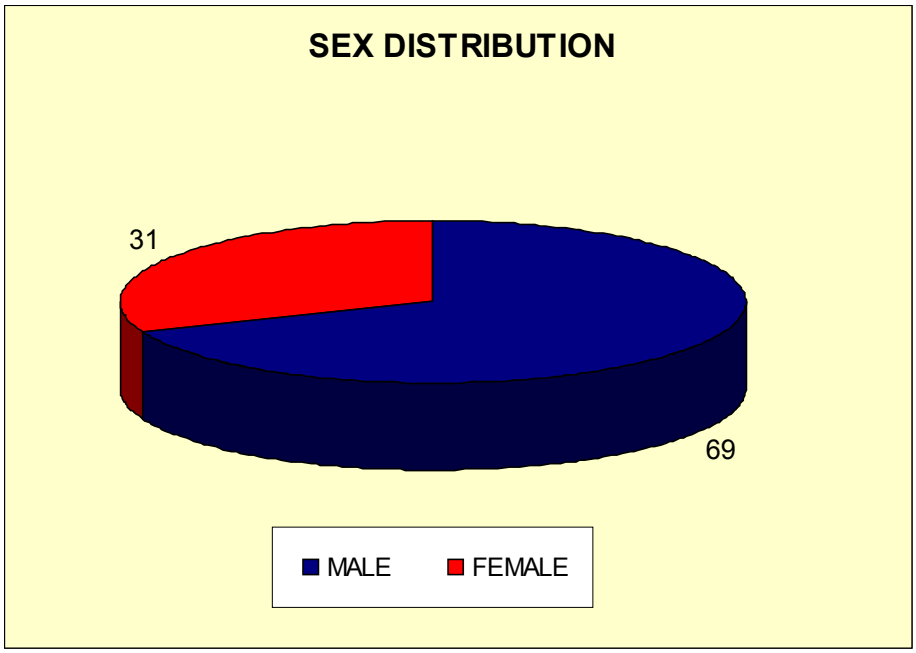
RESULTS

This study comprised of 100 patients who had satisfied the inclusion and exclusion criteria mentioned earlier and later underwent NCCT KUB for assessment of stone density in HU followed by ESWL (Maximum III Sittings 7500 Shock waves)

SEX DISTRIBUTION

There were 69 Male Patients and 31 Female Patients in the study.

MALE	FEMALE
69	31

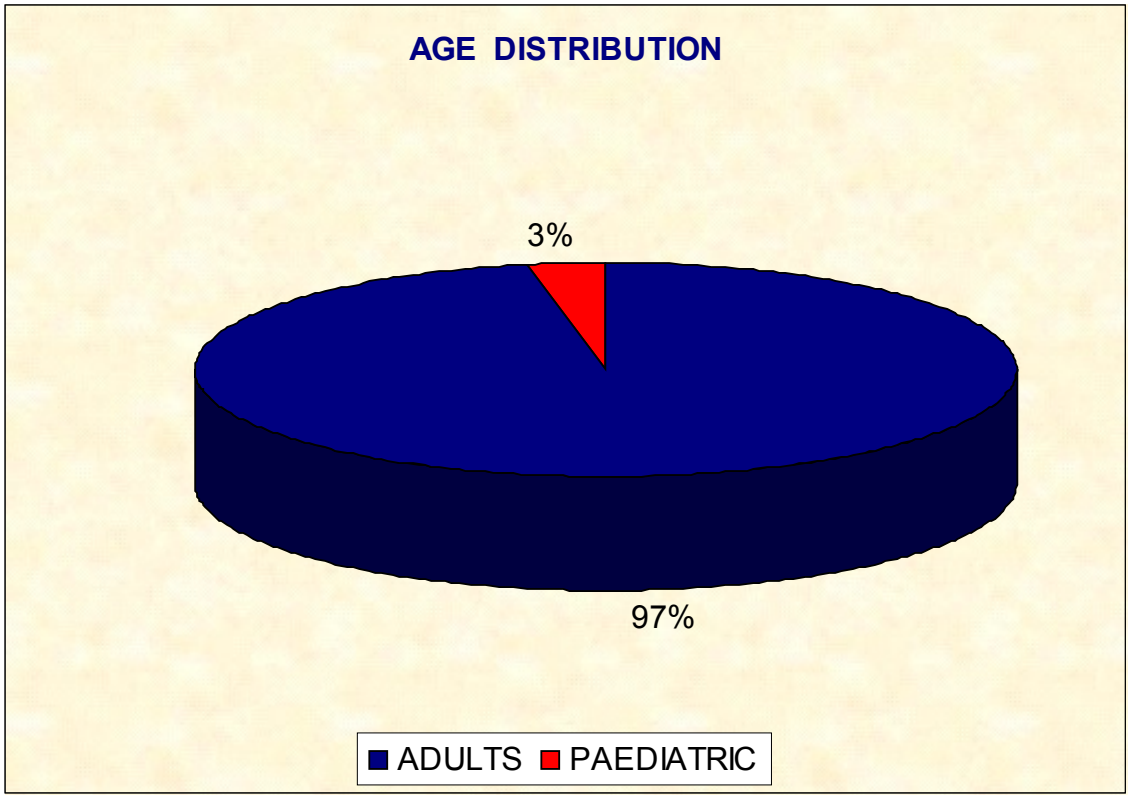


AGE DISTRIBUTION

The age of the patients ranged from Adults 97 patients (20-60 years)

Paediatric age group 3 patiens

ADULTS	PAED
97	3



SYMPTOM DISTRIBUTION

Majority of patients presented with loin pain (80 out of 100 patients) other symptoms were dysuria, Hematuria and UTI. 20 patients were asymptomatic and incidentally detected.

SYMPTOMS	NO. OF PATIENTS	PERCENTAGE
Flank Pain	80	80%
Dysuria	10	10%
Fever	5	5%
Asymptomatic Incidentally Detected	20	20%

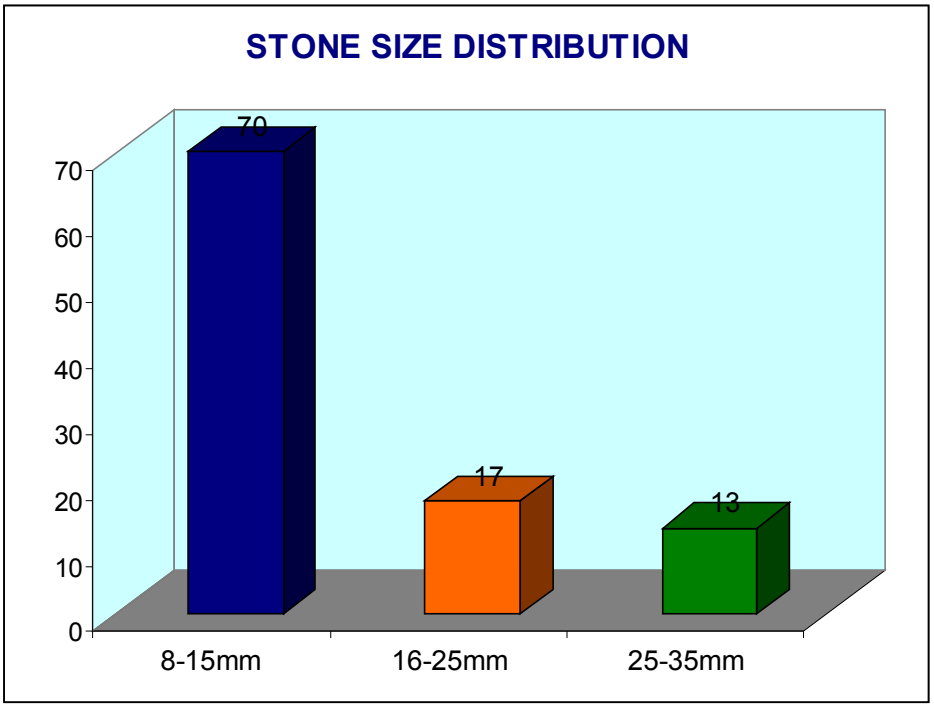
STONE SIZE DISTRIBUTION

The largest calculus was 35mm and smallest was 8mm.

In our study stone of size 8-15mm in 70 patients (70%) 16-25mm in 17 patients (17%)

and 26-35mm in 13 patients (13%).

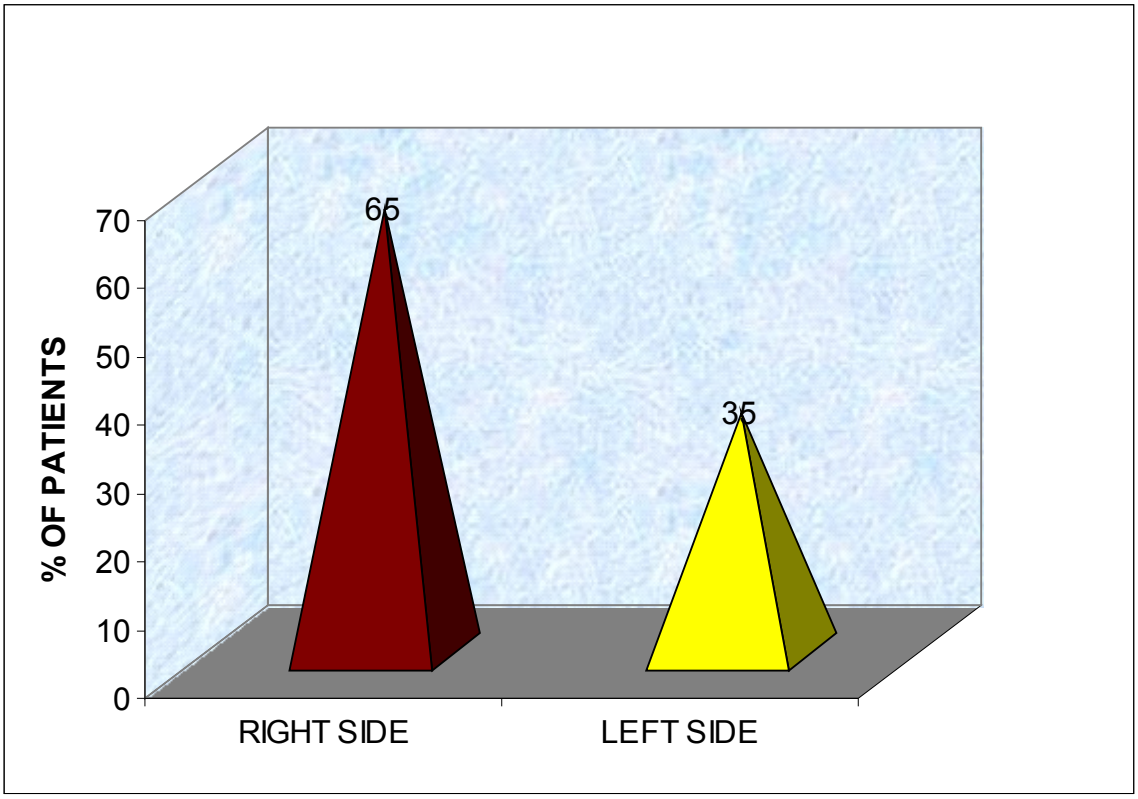
SIZE	NO. OF PATIENTS
8 – 15mm	70
16 – 25mm	17
26 – 35mm	13



SIDE DISTRIBUTION

It was observed that 65 patients had Right sided stones and 35 patients had Left sided stone.

RIGHT SIDE	LEFT SIDE
65	35

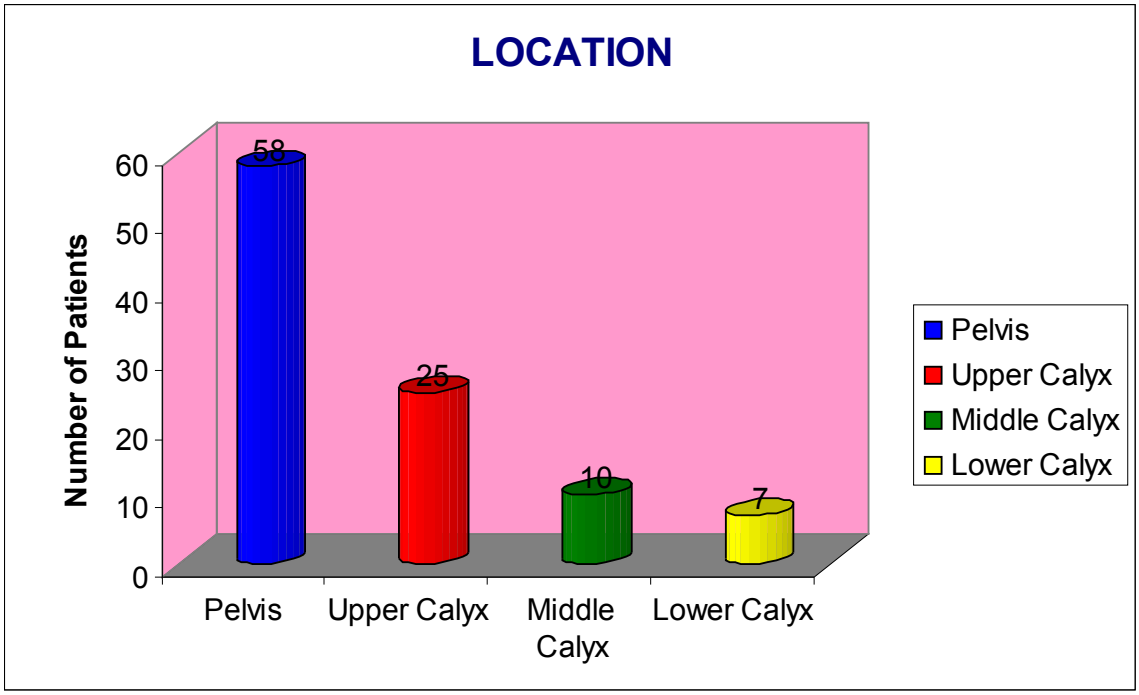


LOCATION

Stone distribution anatomically was 58 patients had stone in renal pelvis, 25 patients had stone in upper calyx, 10 patients had stone in middle calyx and 7 patients had stone in lower Calyx with favourable anatomy.

LOCATION	NO. OF PATIENTS
Pelvis	58
Upper Calyx	25

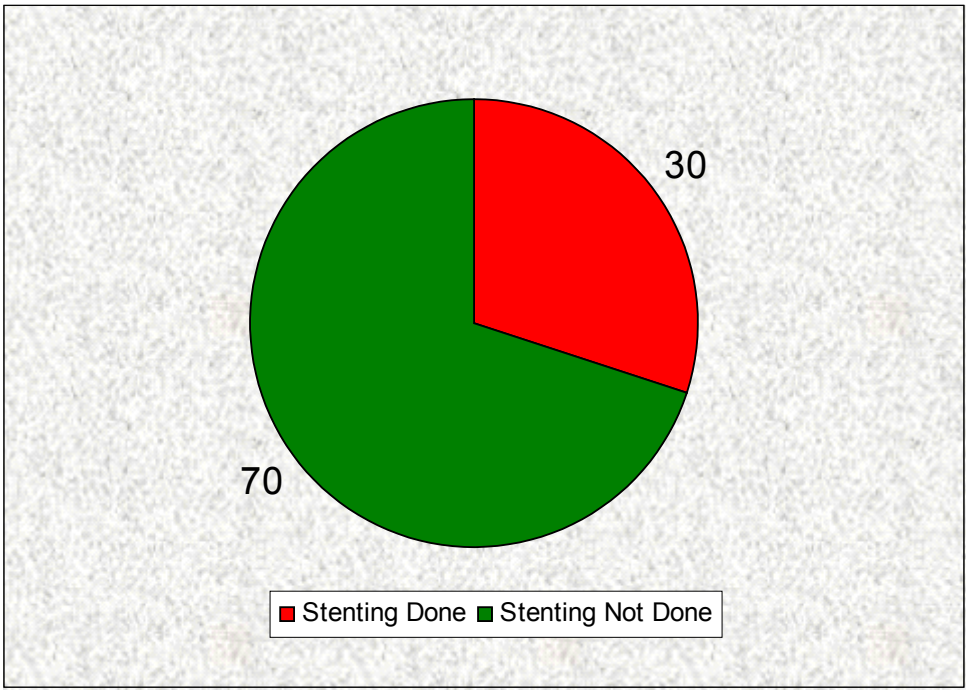
Middle Calyx	10
Lower Calyx	7



STENTING

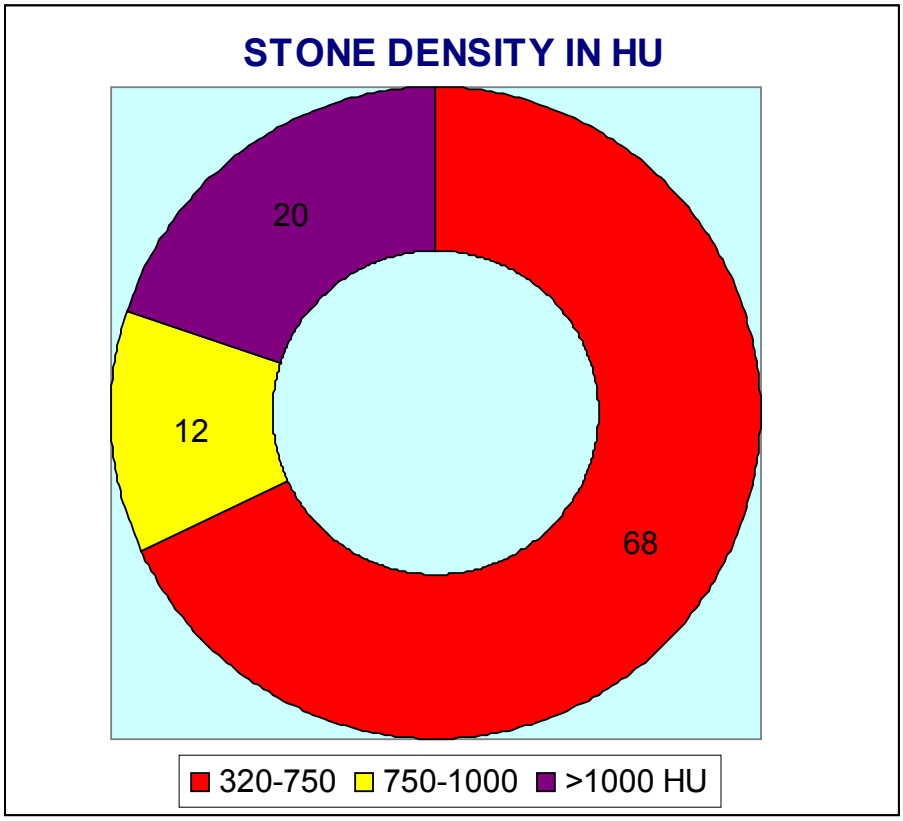
Stone Size >25mm were stented, 30 pateints were stented and 70 patients were nonstented.

STENTING DONE	STENTING NOT DONE
30	70



STONE DENSITY IN CT SCAN

68 Patients had CT HU	320-750
12 patients had CT HU	750-1000
20 patients had	> 1000 HU

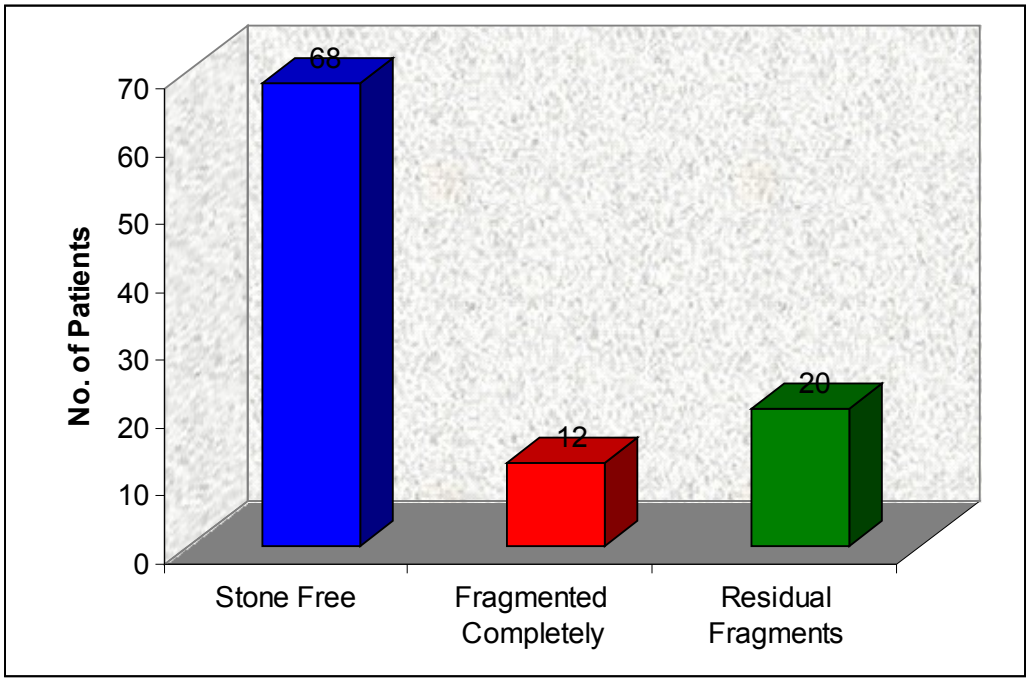


FRAGMENTATION AND CLEARANCE

Out of 100 patients, in 68 patients stone completely disappeared. 12 patients had good fragmentation and 20 patients had clinically significant residual fragment.

DESCRIPTION	STONE FREE	FRAGMENTED COMPLETELY	RESIDUAL FRAGMENTS
No. of Patients	68	12	20
Stone Density	320-750	750-1000	>1000

No. of Shocks	800-2200	2500-6000	5000-7500



68 patients had stone density 320-750. I sitting ESWL done No. of Shocks 800-2200. Stone completely disappeared.

Among the 68 patients 58 patients 8-15mm Size

16-25mm in 6 patients, 4 patients had 26mm – 35mm

Eventhough the size >2.5cm if HU is <750

Stone fragmentation rate is good.

STONE FREE PATIENTS	68		
	58	6	4
Stone Size (Diameter)	8-15mm	16-25mm	26-35mm
Stone Density	320-750		
No. of Shocks	800-2200		

12 Patients had stone density of 750-1000. Among the 12 Patients 7 Patients underwent II sitting ESWL and stone fragmented. 5 Patients underwent, III Sitting ESWL and store completely fragmented. Among 12 Patients 6 Patients had stone size, 8-15mm, 4 patients had stone size 16-25mm and 2 patients had stone size 26-35mm. In the II Group Re-treatment is needed.

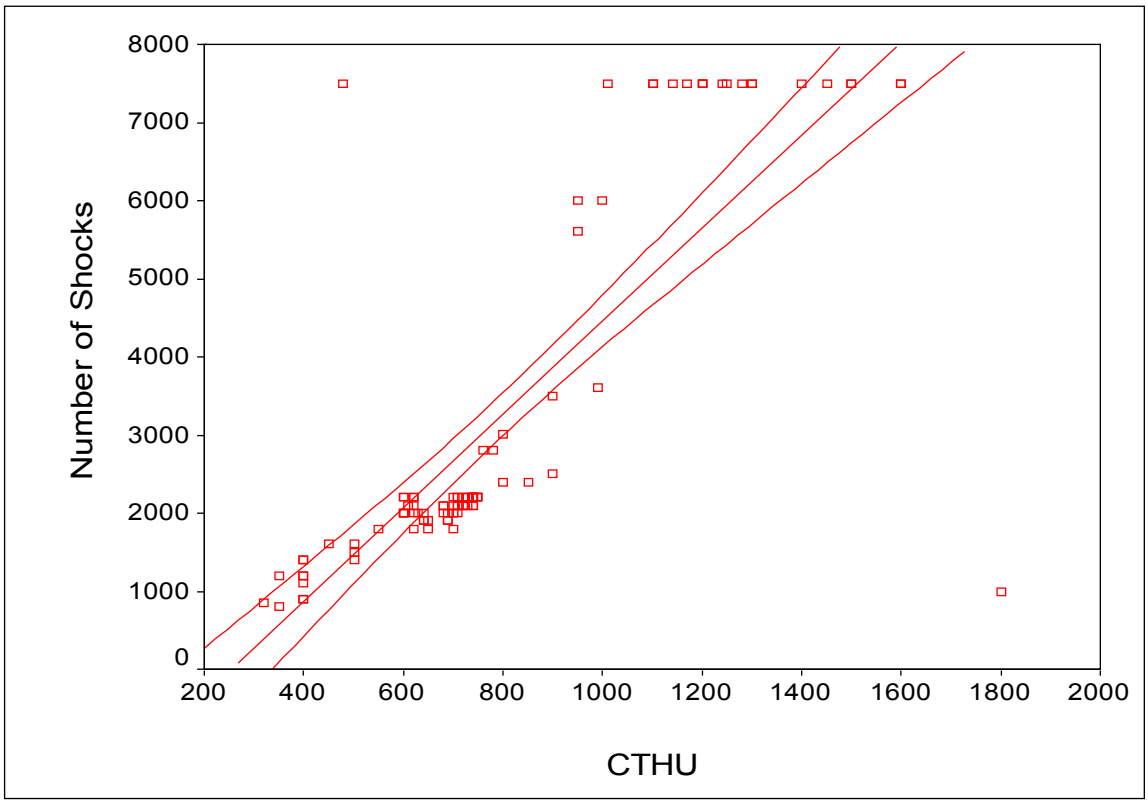
STONE FRAGMENTED COMPLETELY	12		
	6	4	2
Stone Size (Diameter)	8-15mm	16-25mm	26-35mm
Stone Density	750-1000		
No. of Shocks	5000-6000		

- 7 Patients residual fragments at 2 weeks and underwent II Sitting ESWL.
- 5 Patients underwent III Sitting ESWL and became stone free.

20 Patients had stone density of > 1000 HU and received 7500 shocks, III Sitting ESWL patients had clinically significant fragment >4mm. In this group auxillary procedures PCNL, open surgery (or) URS is needed.

STONE WITH RESIDUAL FRAGMENTS	**20**		
	6	**7**	**7**
Stone Size (Diameter)	8-15mm	16-25mm	26-35mm
Stone Density	> 1000		
No. of Shocks	7500		

Among 20 patients 6 patients had stone size 8-15mm. Eventhough the stone size is smaller since the HU > 1000 stone was not fragmented. 7 patients had size 16-25mm 7 patients had 26-35mm.



From the above study it is obvious that size of the stone will not be able to predict the number of shock waves (eventhough moderate correlation) but stone density in HU will be able to predict the number of shocks needed in a better quantitative way.

	MEAN	SD
Age	37.18	12.38

Size mm	15.54	6.88
CT - HU	811.30	419.34
Number of Shocks	3206.50	2300.11

	Karl pearson correlation coefficient	Interpretation
No. of shocks Vs CT - HU	r=0.54 P=0.001	CT - HU increases shocks also increases . There is a moderate correlation between shocks and CT - HU
No. of shocks Vs size mm	r=0.36P=0.001	Size mm increases shocks also increases. There is a fair correlation between shocks and size

CT – HU	No. of patients	Mean shock	Std. Deviation	One way ANOVA F-test
<750	68	1978.99	775.754	F=199.8
750 -1000	12	3690.91	1454.960	
>1000	20	7175.00	1453.444	P=0.001
Total	100	3206.50	2300.106	significant

INTERPRETATION FOR R-VALUE

Pearson correlation coefficient is denoted by “r”

“r” always lies between -1 to +1

0.0 – 0.2 poor correlation

0.2 - 0.4 fair correlation

0.4 - 0.6 moderate correlation

0.6 – 0.8 substantial correlation

0.8 - 1.0 strong correlation

CHEMICAL COMPOSITION

The chemical composition of post ESWL fragments was obtained in 80 patients by chemical dissolution method (qualitative analysis). The following table depicts the various chemical composition.

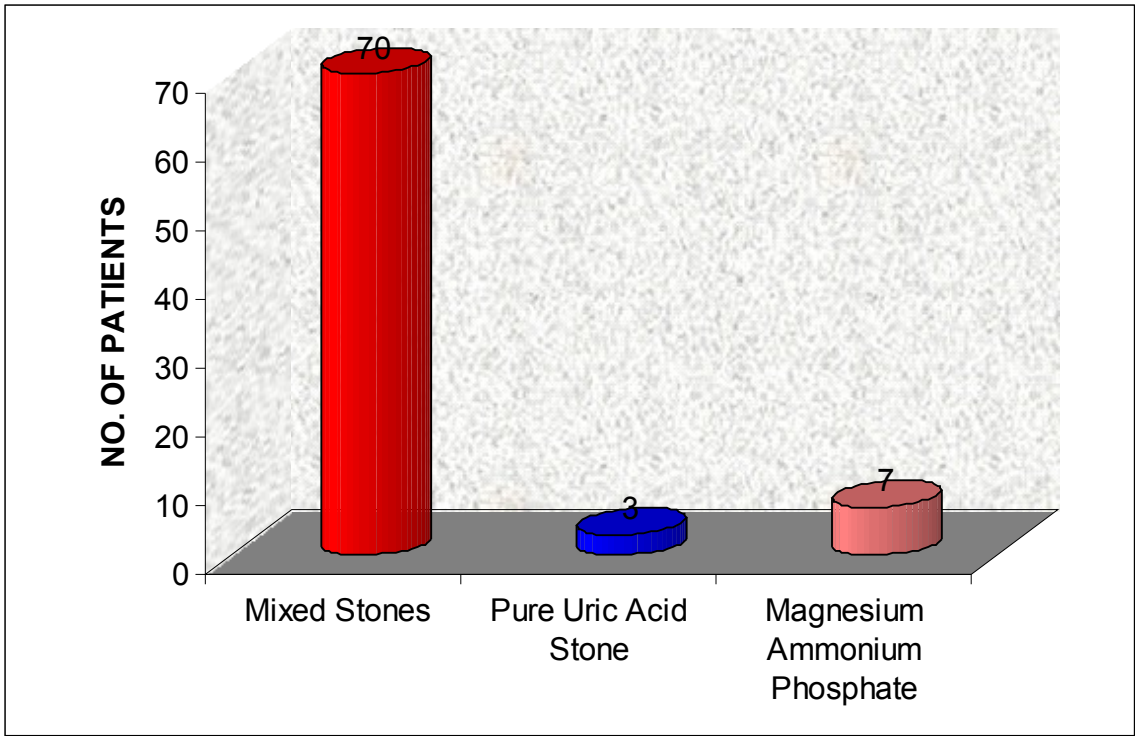
20 patients were not able to retrieve their stones.

TYPE OF STONE	NO. OF PATIENTS	HU
Mixed Stones (Calcium, Oxalate, Phosphate & Uric Acid)	70	400-1600
Uric Acid	3	320-350
Struvite Stones	7	400-600

Uric acid stones completely disappeared in a single sitting with ESWL (HU 320-350). Struvite stones had HU 400-600, stone fragmented and cleared completely. Mixed stones had varying, HU between 400-1600. Stone fragmentation also varies.

STONE COMPOSITION ANALYSIS BY QUALITATIVE CHEMICAL ANALYSIS

	NO. OF PATIENTS
Mixed Type	70
Pure Uric Acid Stones	3
Magnesium Ammonium Phosphate	7



COMPLICATIONS OBSERVED

Hematuria Dysuria	50	Analgesics, adequate oral fluids, observation.
Subcapsular Hematoma	5	Conservative line of Management
Perinephric Hematoma	3	Conservative line of Management
Stent Migration	1	URS/Stent repositioning
Steinstrasse	4	URS/Pathological Lead fragment broken

NO MAJOR COMPLICATIONS

DISCUSSION

ESWL has revolutionized the treatment strategy of urolithiasis world wide and continues to be a major therapeutic modality for treating a majority of upper urinary tract stones. It's non invasive nature along with high efficacy has resulted in outstanding patient and surgeon acceptance.

ESWL is the preferred modality of treatment for renal stones less than 2cm. However stone free rate (SFR) after treatment have never been near 100% and has been in the range of 65-75% (In our study 80%).

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 hardeness (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.

Hillman reported 89% overall accuracy of CT Scan to categorize uric acid, calcium oxalate and struvite calculi. On the contrary ***Kuwahara et al*** reported that there is no correlation between the attenuation value and the chemical composition of renal stone. In our study we also could not find any correlation between CT density and chemical composition of stone. The predominant stone (Mixed stone) of calcium oxalate, phosphate, uric acid had stone HU ranging from 400-1600 and the values were overlapped for various calculi.

Joseph et al reported overall success rate of 80% for calculus upto 2cm. When they assessed the susceptibility of stone fragmentation by ESWL according to 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.

We noted that 80/100 patients with CT density of less than 1000 HU had significantly successful treatment. 68 patients cleared their stone in the I sitting ESWL. 7 patients pulverized their stone in II Sitting ESWL and 5 patients undergone III Sitting

ESWL for complete clearance. 20 patients with CT HU >1000 HU had unsuccessful fragmentation even after 7500 shock waves. Thus the CT density of the renal stone is inversely proportional to the fragmentation and clearance.

$$\text{CT density } \alpha = \frac{\text{|}}{\text{Fragmentation and Clearance}}$$

Patients with CT HU>1000 required more number of shock waves.

The success rate of ESWL is also related to chemical composition of stone. Uric acid and struvite stones having HU < 750 easily fragment. Mixed calcium oxalate and cystine stones are known to fragment with difficulty by ESWL. Though cystine stones have HU <1000, these stones are ESWL resistant because of their greater deformation capability and higher resistance to crack propagation. Ductile stones (Smooth cystine calculi) can absorb the energy of cavitation jet impact through plastic deformation thus preventing the cavitation damage produced on the anterior surface of stone.

Size and Location of stones are the other variables depending on which success of ESWL fairly correlates.

Narmata Gupta et al in their study concluded that NCCT predict the treatment outcome of ESWL. So might help in planning alternative treatment in patients with a likelihood of poor outcome from ESWL. The calculus density was a stronger predictor of ESWL outcome than size of stone.

Joseph et al, in study of 30 patients, those with Calculi < 500 HU had complete clearance in 2500 shocks. Stones with 500-1000 HU had clearance rate of 86% and median number of shock waves 3390. Patients with calculi ≥ 1000 HU had clearance rate of 55% requiring a median of >3000 shock waves.

Motley et al concluded that there is no significant difference between density values of calcium oxalate and calcium phosphate calculus.

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.

100 patients with renal calculi measuring between 8mm – 35mm were included in our study. The stone density measured on NCCT and mean density value obtained. All patients were treated with ESWL and the susceptibility of renal stone to fragmentation was correlated with stone density and its chemical composition.

The overall success rate of ESWL was 80% in our study.

68/100 patients with <750 HU had 100% stone fragmentation and clearance.

12/100 patients with 750-1000 HU had 59% stone fragmentation and clearance in the II Sitting and 41% had stone fragmentation and clearance in III Sitting. ***(Retreatment with ESWL needed).***

20/100 patients with HU > 1000 had significant residual fragment even after III sitting ESWL (***Auxillary Procedures needed)***. (There was a statistically significant difference with P<0.001).

Comparing stone size with ESWL fragility, eventhough stone size > 2.5cm, if the stone density is ***< 750 HU*** stone fragmentation is 100%.

Even if the stone size < 15mm, a stone density of ***>1000 HU*** shows poor fragmentation with ESWL.

On stone composition analysis, uric acid and struvite stones had fragmented completely in the I sitting. The chemical composition of mixed renal stones did not correlate with attenuation value of stone.

CONCLUSION

For stones with HU < 750 and stone size even upto 3.5cm, stone free rate of 100% can be achieved with ESWL.

For stones with 750 – 1000 HU patient may need retreatment (Multiple Sittings ESWL).

For stones with HU >1000 other modalities of treatment (Endoscopic and Open Stone Surgery) are preferable to ESWL.

NON CONTRAST CT estimation of stone density by HOUNSFIELD UNIT predicts the successful outcome of ESWL therapy.

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MASTER CHART

	Name	Age	Sex	Side	Location	Size mm	Stenting Done / Not Done	CTH U	Number of Shocks	Stone composition	Results
	SELVARAJ	28	M	R	P	8	Not Done	720	2100	M	SF - I
	GUNASEKARAN	32	M	R	UC	10	Not Done	750	3200	M	SF - II
	SATHIYA	56	F	R	P	12	Not Done	1200	7500	X	FAIL - III
	JEEVANATHAN	41	M	L	MC	9	Not Done	350	800	U	SF -I
	DHANDAPANI	27	M	R	P	28	Done	1100	7500	X	FAIL - III
	GANDHIPATHI	29	F	R	LC	11	Not Done	400	900	MAP	SF -I
	ANNADURAI	42	M	R	P	27	Done	1010	7500	X	FAIL -III
	SOMU	56	M	L	P	12	Not Done	650	2100	M	SF -I
	RAMNIVAS	55	M	R	MC	32	Done	1200	7500	X	FAIL -III
	SOFIYA	6	F	L	P	14	Not Done	400	900	M	SF -I
	RAMADURAI	27	M	R	UC	33	Done	1400	7500	X	FAIL -III
	RAVI	34	M	L	LC	12	Not Done	600	2000	M	SF -I
	RADHAKRISHNAN	35	M	R	P	14	Not Done	600	2200	M	SF -I
	PALANIAMMAL	35	F	L	MC	34	Done	350	1200	U	SF -I
	BASKAR	32	M	L	P	12	Not Done	400	1200	M	SF -I
	RATHNAMMAL	40	F	L	LC	10	Not Done	500	1400	MAP	SF -I
	ARUMUGHAM	46	M	R	P	14	Not Done	1300	7500	X	FAIL -III
	RAMCHAND	42	F	L	UC	35	Done	400	1400	M	SF -I
	VIKNESH	5	M	R	P	12	Not Done	380	1000	M	SF -I
	GOPAL	24	M	R	P	15	Not Done	680	2000	M	SF -I
	MADHESH	22	M	R	P	12	Not Done	600	2200	M	SF -I

	Name	Age	Sex	Side	Location	Size mm	Stenting Done / Not Done	CTH U	Number of Shocks	Stone composition	Result
	BASKAR	28	M	R	UC	26	Done	1170	7500	X	FAIL -III
	NALINIAMMAL	42	F	L	P	14	Not Done	680	2100	M	SF -I
	BALARAMAN	25	M	R	MC	26	Done	1240	7500	X	FAIL -III
	NARIRAM	26	M	L	UC	13	Not Done	680	2100	M	SF-I
	SAVITHIRI	38	F	R	P	15	Not Done	1140	7500	X	FAIL -III
	PARAMASIVAN	42	M	R	LC	14	Not Done	710	2100	M	SF-I
	VENKATACHALAM	48	M	L	P	13	Not Done	720	2200	M	SF-I
	DEEPA	23	F	R	UC	10	Not Done	740	2200	M	SF-I
	GURUMOORTHY	52	M	R	MC	10	Not Done	690	2000	M	SF-I
	MALA	40	F	L	P	14	Not Done	700	2100	M	SF-I
	SELVAPERUMAL	56	M	R	UC	12	Not Done	600	2000	MAP	SF-I
	LAKSHMANAN	60	M	R	LC	10	Not Done	1250	7500	X	FAIL -III
	INBAJOTHI	27	F	R	P	8	Not Done	620	2000	M	SF-I
	RANI	6	M	L	UC	9	Not Done	630	2000	M	SF-I
	MANGALRAM	40	M	R	MC	10	Not Done	640	2000	M	SF-I
	PARVATHI	24	F	R	P	27	Done	1600	7500	X	FAIL –III
	MAHABUNISHA	52	F	L	LC	12	Not Done	710	2200	M	SF-I
	SATHISH KUMAR	33	M	R	P	13	Not Done	740	2200	M	SF –I
	BASKAR	35	M	R	P	30	Not Done	760	2800	M	SF-II
	MOORTHY	32	M	R	UC	10	Done	610	2100	M	SF-I
	SURESH	34	M	R	UC	12	Not Done	620	2200	M	SF-I
	SELVI	23	F	L	P	13	Not Done	730	2200	M	SF-I
	KANNAN	26	M	R	MC	24	Done	950	6000	M	SF-II
	KUMAR	28	M	R	P	15	Not Done	740	2200	M	SF-I

	Name	Age	Sex	Side	Location	Size mm	Stenting Done / Not Done	CTH U	Number of Shocks	Stone composition	Result
	LOGANATHAN	42	M	L	P	10	Not Done	480	7500	X	FAIL –III
	BHUVANESWARI	32	F	R	MC	9	Not Done	600	2000	M	SF-I
	GURUMOORTHY	40	M	R	P	32	Done	700	1800	M	SF-I
	HAMEED	20	M	L	UC	14	Not Done	750	2200	M	SF-I
	HAMAVATHY	41	F	R	P	9	Not Done	730	2100	M	SF-I
	SATHISH KUMAR	28	M	R	UC	10	Not Done	740	2100	M	SF-I
	LALITHA	57	F	L	MC	33	Done	500	1600	MAP	SF-I
	LOGANATHAN	32	M	R	P	10	Not Done	450	1600	MAP	SF-I
	DEVARAJAN	33	M	R	UC	13	Not Done	800	2800	M	SF -II
	DHANALAKSHMI	38	F	L	P	16	Done	320	850	U	SF-I
	KADAR BABU	52	m	R	LC	14	Not Done	400	1200	MAP	SF-I
	PALANI	55	M	L	P	25	Done	400	1100	M	SF-I
	VEERAPERUMAL	56	M	R	UC	15	Not Done	1500	7500	X	FAIL -III
	GAJALAKSHMI	42	F	L	UC	24	Done	550	1800	M	SF-I
	VENKATESAN	57	M	R	P	18	Done	600	2000	M	SF-I
	SUKUMAR	52	M	R	P	8	Not Done	620	2100	M	SF-I
	KRISHNAN	48	M	R	UC	19	Done	620	2200	M	SF-I
	RANI	32	F	L	P	9	Not Done	710	2100	M	SF-I
	RAMESH	22	M	R	UC	20	Done	750	3200	M	SF -II
	MURUGAN	30	M	R	P	22	Done	780	2800	M	SF -II
	KUMAR	38	F	L	P	12	Not Done	850	3400	M	SF -II
	SELVARAJ	32	M	R	UC	10	Not Done	730	2200	M	SF-I
	KASI	36	M	L	MC	24	Done	800	3000	M	SF -II
	GOMATHI	28	F	R	P	11	Not Done	400	1400	MAP	SF-I

S.No	Name	Age	Sex	Side	Location	Size mm	Stenting Done / Not Done	CTHU	Number of Shocks	S comp
70	SIVARAJA	42	M	R	UC	25	Done	900	3500	
71	SANDANAKRISHNAN	45	M	L	P	14	Not Done	620	1800	
72	PURUSOTHAMAN	47	M	L	UC	12	Not Done	900	6000	
73	JAYAKUMARI	27	F	R	P	17	Done	990	5800	
74	MATHIMOHAN	58	M	R	P	13	Not Done	640	1900	
75	MUNUSAMY	56	M	R	UC	18	Done	1100	7500	
76	JEEVA	46	F	L	P	12	Not Done	650	1900	
77	MURUGESAN	24	M	L	P	17	Done	1200	7500	
78	NAGARAJ	30	M	R	P	16	Done	1300	7500	
79	AMUDHA	27	F	R	P	11	Not Done	710	2000	
80	SOUNDAR	20	M	R	P	10	Not Done	690	1900	
81	DURAI RAJ	42	M	R	P	8	Not Done	640	1900	
82	RAJAGOPAL	40	M	L	P	10	Not Done	650	1800	
83	MOBANA	24	F	R	P	12	Not Done	720	2100	
84	DHANADAPANI	38	M	R	UC	22	Done	1450	7500	
85	ANANDHAN	56	M	L	P	14	Not Done	740	2200	
86	ALAMELU	32	F	R	UC	15	Not Done	750	2200	
87	VELAYUTHAM	58	M	L	P	23	Done	1600	7500	
88	ELUMALAI	55	M	L	UC	10	Not Done	500	1500	M
89	TAMARAJ KANI	48	F	R	P	24	Done	1500	7500	
90	ARUMUGHAM	35	M	R	UC	10	Not Done	700	2000	
91	MOORTHY	37	M	L	P	18	Done	1280	7500	
92	KARPAGAVALI	57	F	L	P	12	Not Done	740	2200	
93	SIVARAMAN	42	M	L	P	11	Not Done	950	5600	

S.No	Name	Age	Sex	Side	Location	Size mm	Stenting Done / Not Done	CTHU	Number of Shocks	Ston compos
94	SUBRAMANIYAN	41	M	R	P	14	Not Done	690	1900	M
95	SARAVANAN	38	M	R	P	15	Not Done	720	2100	M
96	CHINNAPILLAI	50	F	R	P	14	Not Done	710	2200	M
97	PARASURAMAN	36	M	R	P	10	Not Done	1000	6000	M
98	GEETHA	22	F	R	P	12	Not Done	740	2100	M
99	VENKATESAN	28	M	R	P	10	Not Done	740	2200	M
100	SATHISH KUMAR	20	M	R	P	12	Not Done	700	2000	M

COMPARISON BETWEEN STONE HU AND STONE BREAKAGE RATE

S.No

Name Age / Sex I.P.No

Address

Symptoms Duration

Clinical Examinations

Investigations :
Urine culture & Sensitivity

RFT

Basic Metabolic Workup

X –Ray Site Size Side No. of Stones

USG KUB PCS Dilation Y/N
Stone Located

IVU

CT : Plain HU

INSTITUTIONAL ETHICAL COMMITTEE

GOVERNMENT GENERAL HOSPITAL & MADRAS MEDICAL COLLEGE,
CHENNAI-600 003.

Telephone: 044-2530 5000
Fax : 044 – 25305115

K.Dis.No.16328 P & D3/Ethics/Dean/GGH/08 Dated: 8.9.2008

Title of the work : "The role of non contrast CT-KUB in predicting the stone fragility and ESWL success rate"

Principal Investigator : Dr-S. Mangaiyarkarasi

Department : Urology, MMC, Ch-3.

The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 10th September 2008 at 2 P.M in Government General Hospital, Deans, Chamber, Chennai-3.

The members of the Committee, the Secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the principal investigator.

The principal investigator and their term are directed to adhere the guidelines given below:

1. You should get detailed informed consent from the patients/participants and maintain confidentiality.
2. You should carry out the work without detrimental to regular activities as well as without extra expenditure to the Institution or Government.
3. You should inform the IEC in case of any change of study procedure, site and investigation or guide.
4. You should not deviate form the area of the work for which I applied for ethical clearance.
5. You should inform the IEC immediately, in case of any adverse events or serious adverse reactions.
6. You should abide to the rules and regulations of the institution(s)
7. You should complete the work within the specific period and if any extension of time is required, you should apply for permission again and do the work.
8. You should submit the summary of the work to the ethical committee on completion of the work.
9. You should not claim funds from the Institution while doing the work or on completion.
10. You should understand that the members of IEC have the right to monitor the work with prior intimation.

SECRETARY
IEC, GGH,CHENNAI

CHAIRMAN
IEC, GGH,CHENNAI

DEAN
GGH &MMC, CHENNAI

Rkm.5.9(2)

PATIENT CONSENT FORM

Study Title **: "THE ROLE OF NON CONTRAST CT-KUB IN PREDICTING THE STONE FRAGILITY AND ESWL SUCCESS RATE"**

Study Centre **: Department of Urology**

Patient's Name :

Patient's Age :

Identification No :

Patients may tick these Boxes [ ]

I confirm that I have understood the purpose of procedure for the above study. [ ]

I have the opportunity to ask the questions and all my questions and doubts have been answered to my complete satisfaction. [ ]

I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving any reason, without my legal right being affected [ ]

I understand that sponsor of the clinical study, others working on the sponsor's behalf, the ethics committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from study. [ ]

I agree to this access, however, I understand that my identity would not be revealed. In any information released to third parties or published, unless as required under the law. [ ]

I agree not to restrict the use of any data or results that arise from this study. [ ]

I agree to take part in the above study and to comply with the instructions given during the study and to faithfully to cooperate with the study team, and to immediately inform the study staff if I suffer from any deterioration in my health or my well being or any unexpected or unusual symptoms. [ ]

I hereby give consent to participate in this study. [ ]

Signature / Thumb Impression .....
of the patient:

Place : .....
Patient's name and address : .....
Signature of the Investigator :.....Place .....Date .....
Name of the Investigator : .....