ANALYSIS OF EFFICACY OF EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY IN THE MANAGEMENT OF LOWER URETERIC CALCULUS

Dissertation submitted to

THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY

in partial fulfillment of the requirements for the award of the degree of

M.Ch (UROLOGY) – BRANCH – IV

THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY

CHENNAI

AUGUST 2010

DECLARATION

I solemnly declare that this dissertation titled ANALYSIS OF EFFICACY OF EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY IN THE MANAGEMENT OF LOWER URETERIC CALCULUS was prepared by me in the Department of Urology, Government General Hospital, Chennai under the guidance and supervision of Prof. R. Jeyaraman, M.Ch ., Professor & Head of the Department, Department of urology, Government General Hospital, Chennai. This dissertation is submitted to the Tamil Nadu Dr. MGR Medical University, Chennai in partial fulfillment of the university requirements for the award of the degree of M.Ch. Urology.

Place: Chennai

Date: DR.T.GNANASEKARAN

CERTIFICATE

This is to certify that the dissertation titled "Analysis of efficacy of extracorporeal shock wave lithotripsy in the management of lower ureteric calculus" submitted by **Dr.T.GNANASEKARAN** appearing for **M.Ch. (Urology)** degree examination in August 2010, is a bonafide record of work done by him under my guidance and supervision in partial fulfillment of requirement of the Tamil Nadu Dr.M.G.R.Medical University, Chennai. I forward this to the Tamil Nadu Dr.M.G.R.Medical University, Chennai.

Prof.R.Jeyaraman, M.S. M.Ch,
Professor & Head of the Department,
Department of Urology,
Government General Hospital,
Madras Medical College,
Chennai -600003.

The Dean
Madras Medical College &
Government General Hospital
Chennai -600003

ACKNOWLEDGEMENT

First of all, I would like to thank my patients, who subjected themselves for my dissertation work.

I whole heartedly thank **The Dean**, Madras Medical College and Government General Hospital, Chennai for allowing me to avail the facilities needed for my dissertation work.

I would like to express my humble gratitude to **Prof. R.Jeyaraman**, M.Ch, Professor and Head of the Department of Urology for his expert guidance and help rendered for the conduct and completion of my dissertation work.

I would like to thankfully acknowledge **Prof.V.Kamaraj** and **Prof. RM. Meyyappan**, Professors in the Department of Urology, for their constant help in the dissertation work.

I sincerely thank the Director, Barnard Institute of radiology for his help in completing my dissertation.

I sincerely thank the Asst professors in the Department of Urology for their continuous inspiration and support in carrying out my dissertation.

Last, but not least, I thank my fellow past and present postgraduates who helped me in carrying out my work and preparing this manual.

TABLE OF CONTENTS

INTRODUCTION

The indications for intervention in the management of patients with ureteric calculi have clearly been affected by the increased efficiency and lower morbidity of minimally invasive treatment modalities. Although the traditional indications for intervention (intolerable or intractable symptoms, infection, obstruction, and a stone that is unlikely to pass spontaneously) have not changed, the array of technologies currently available allows almost any symptomatic patient to be considered a candidate for stone removal.

Lingeman and associates reported that when a patient requires hospitalization, it is less costly to remove the patient's stone with either SWL or ureteroscopy than to attempt to control the patient's symptoms with pharmacotherapy only. However, many patients will pass the stone spontaneously[1]. A thorough knowledge, then, of the natural history of ureteric stones permits a well-informed judgment of when conservative measures (e.g., observation), rather than intervention, are indicated. Furthermore, such data help the patient consider the spectrum of options and decide whether to try to endure further symptoms or to elect immediate stone removal [3, 4].

In the absence of external ureteric compression or internal narrowing, the width of the stone is the most significant measurement affecting the likelihood of stone passage (Ueno et al, 1977). The likelihood of spontaneous stone passage was directly related to stone size and location at the time of presentation. The rate of spontaneous passage for stones smaller than 4 mm was 38% compared with 1.2% for those larger than 6 mm, irrespective of their position in the ureter at the time of presentation. Calculi discovered in the distal third of the ureter had a spontaneous passage rate of 45%, compared with 22% for the middle third and 12% for the proximal third. Two thirds of all stones that passed did so within 4 weeks after the onset of symptoms.

Segura[5] and associates reported on the management of patients with ureteric calculi that for patients with stones of 5 mm or less, conservative management should be considered, whereas the chance of spontaneous passage for larger stones diminishes considerably, and intervention is recommended.

The factors that must be considered when recommending treatment to patients with ureteric calculi may be grouped into three broad categories: stone-related factors (location, size, composition, duration, and degree of obstruction), clinical factors (the patient's tolerance of symptomatic events, the patient's expectation, associated infection, single kidney, abnormal ureteric anatomy, and technical factors (equipment available for treatment, costs). These factors may be thought of as treatment modifiers; the presence or absence of one or more of these factors may shift the balance toward a certain treatment modality.

Perhaps the greatest dilemma facing the urologist today is "to blast or not to blast" (i.e., to choose between the two most frequently used modalities in ureteric stone treatment—SWL and ureteroscopy).

Success of ESWL has been correlated with radio density of the 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 made several authors comparing attenuation 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 stone Hounsfield Unit (HU) varies with composition and determines the fragility of a calculus which ultimately governs the clinical outcome in ESWL. NCCT because of its easy availability, superb sensitivity and very high resolution capability it is a good modality for the measurement of stone density.

The optimal therapy for patients requiring removal of distal ureteric calculi is controversial. SWL and ureteroscopy are both effective treatments associated with high success rates and limited morbidity. ESWL is noninvasive, associated with less morbidity than ureteroscopy. Moreover ureteroscopy requires specialized training, requires more anaesthesia, and more often requires ureteral stent placement.

A 1997 meta-analysis performed by the AUA Ureteral Stones Clinical Guidelines Panel established that both ureteroscopy and SWL are acceptable treatment options for patients with distal ureteric stones. This recommendation was based on the stone-free results, morbidity, and re-treatment rates for each respective therapy. However, this report used data that were derived from older lithotripsy and endoscopic technology

Continued studies are warranted to better define the roles of ESWL and ureteroscopy in the management of patients with distal ureteric calculi because both are highly effective.

AIM AND OBJECTIVE

The aim of this study is to

1) To analyze the efficacy of Extra corporeal lithotripsy in the management of lower ureteric calculus

2) To find out ideal patients for extracorporeal shock wave lithotripsy in the management of lower ureteric calculus

3) To find out complications of extracorporeal shock wave lithotripsy during the management of lower ureteric calculus

REVIEW OF LITERATURE

The goal of the surgical treatment of patients suffering from ureteric calculi is to achieve complete stone clearance with minimal attendant morbidity. Improvements in surgical technology, such as SWL, rigid and flexible ureteroscopes, the holmium:YAG laser, and basket devices, have greatly augmented the urologist's ability to efficiently treat such patients, regardless of the size or location of the ureteric calculus.

Minimally invasive treatments replaced the open stone surgery nowadays. Extra Corporeal Shockwave Lithotripsy is a non invasive treatment option with minimal morbidity.

The word Lithotripter is Greek origin and means stone crusher. Lithotripters have evolved from many years of research into 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 invention of the Lithotripter 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 experimental treatment began the era of

ESWL. The first Lithotripter 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 and ureteric calculi.

METHODS AND PHYSICAL PRINCIPLES OF SWL

In extracorporeal SWL, shockwaves are generated by a source external to the patient's body and are then propagated into the body and focused on a kidney or ureteric stone. The uniqueness of this device is in its exploitation of shockwave focusing. Relatively weak, nonintrusive waves are generated externally and transmitted through the body. The shockwaves build to sufficient strength only at the target, where they generate enough force to fragment a stone.

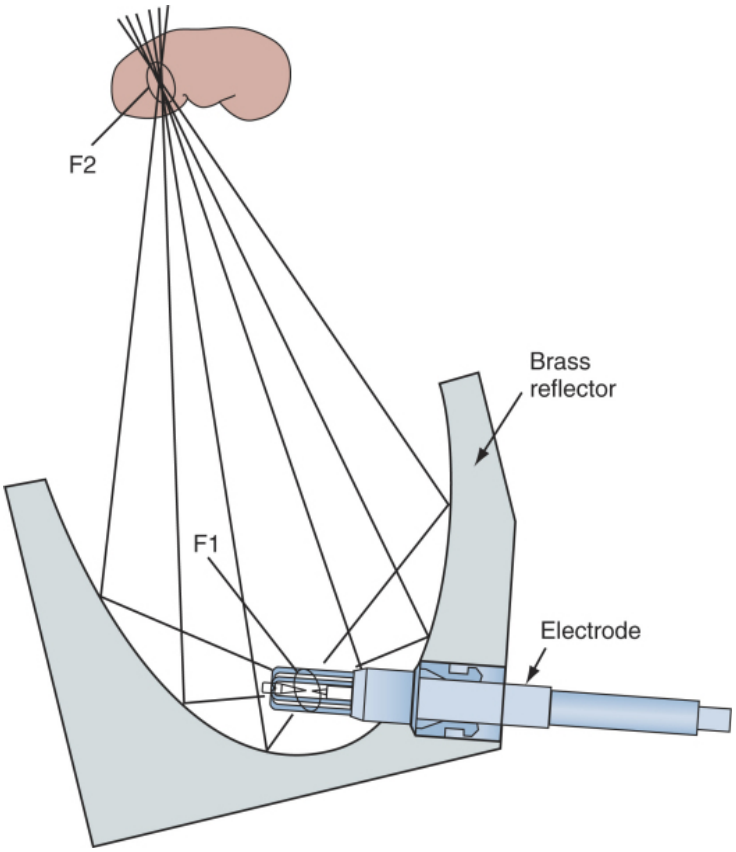
When energy is deposited rapidly into a fluid, a shockwave invariably results. Shockwaves are surfaces that divide material ahead, not yet affected by the disturbance, from that behind, which has been compressed as a consequence of energy input at the source. These waves move faster than the speed of sound, and the stronger the initial shock, the faster the shockwave moves. Their behavior is characteristic of the propagation of nonlinear waves. Although the shockwaves in lithotripters generate large pressures, they are relatively weak in that they induce only slight compression and deformation of a material.

GENERATOR TYPE

There are three primary types of shockwave generators: electro hydraulic (spark gap), electromagnetic, and piezoelectric.

ELECTRO HYDRAULIC (SPARK GAP) GENERATORS

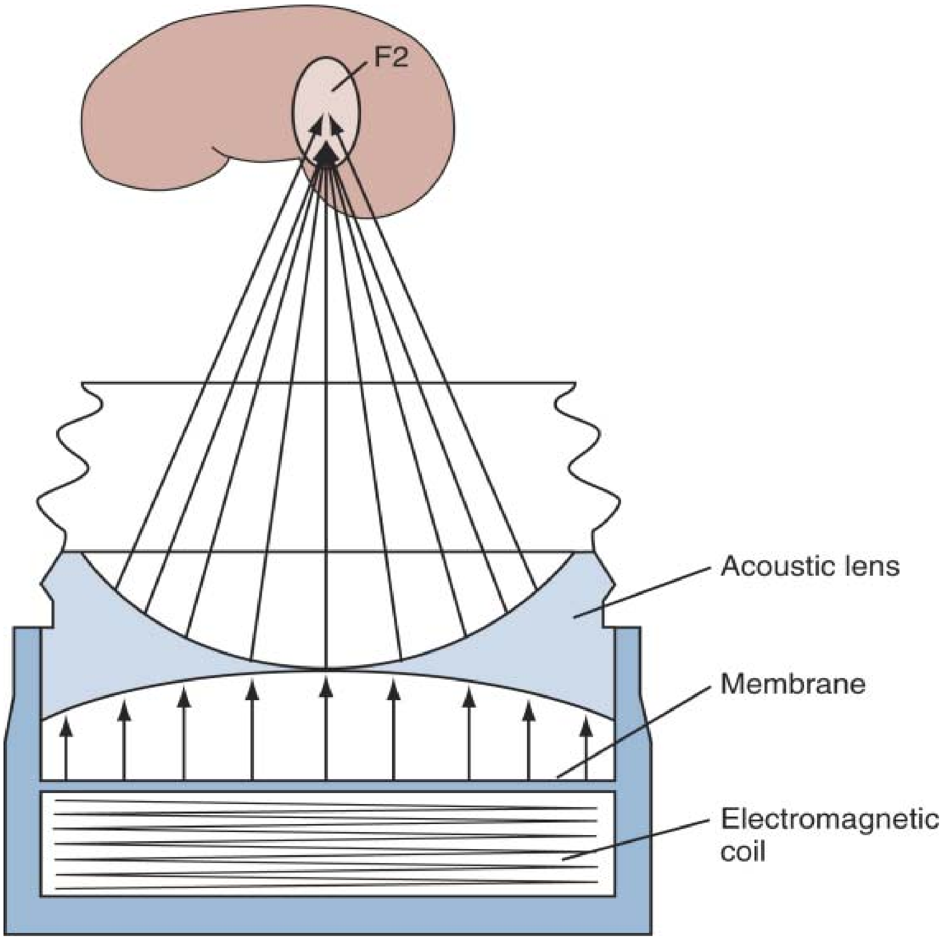
A spherically expanding shockwave is generated by an underwater spark discharge High voltage (15000-25000V) is applied to two opposing electrodes positioned about 1 mm apart. The high-voltage spark discharge causes the explosive vaporization of water at the electrode tip. For the spherically expanding shockwave to be focused onto a calculus, the electrode is placed at one focus (termed F1) of an ellipsoid, and the target (the stone) is placed at the other focus (termed F2)**.** Hemi ellipsoid reflector focuses shockwaves from F1 to target F2. Advantage of this generator is effectiveness in breaking kidney stones. Disadvantages are substantial pressure fluctuations from shock to shock and a relatively short electrode life. Another issue to consider is that as the electrode deteriorates, it wears down, and a 1-mm displacement of the electrode tip off of F1 can shift F2 up to 1 cm off of the initial target.



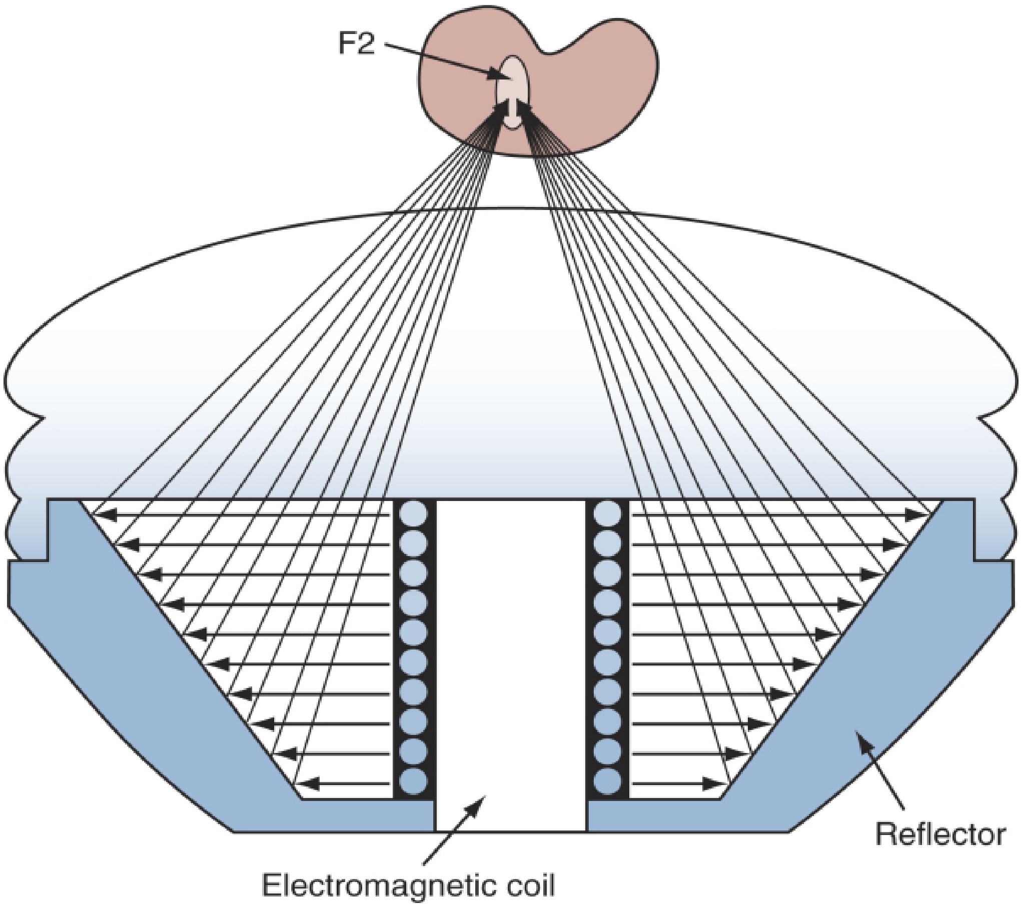
ELECTROMAGNETIC GENERATORS

The electromagnetic generators produce either plane or cylindrical shockwaves. The plane waves are focused by an acoustic lens the cylindrical waves are reflected by a parabolic reflector and transformed into a spherical wave**.**

Basic design of an electromagnetic generator is simple, a water-filled shock tube containing two conducting cylindrical plates separated by a thin insulating sheet. When an electrical current is sent through one or both of the conductors, a strong magnetic field is produced between the conductors, moving the plate against the water and thereby generating a pressure wave. The electromagnetic force that is generated, termed magnetic pressure, causes a corresponding pressure (shockwave) in the water. The shock front produced is a plane wave that is of the same diameter as the current-carrying plates. The energy in the shockwave is concentrated onto the target by focusing it with an acoustic lens.



The electromagnetic system that uses a cylindrical source also has a coil (cylindrical in shape) surrounded by a cylindrical membrane that is pushed away from the coil by the induction of a magnetic field between the two components. In both systems, the pressure pulse has only one focal point (F2) that is positioned on the target.



ADVANTAGES

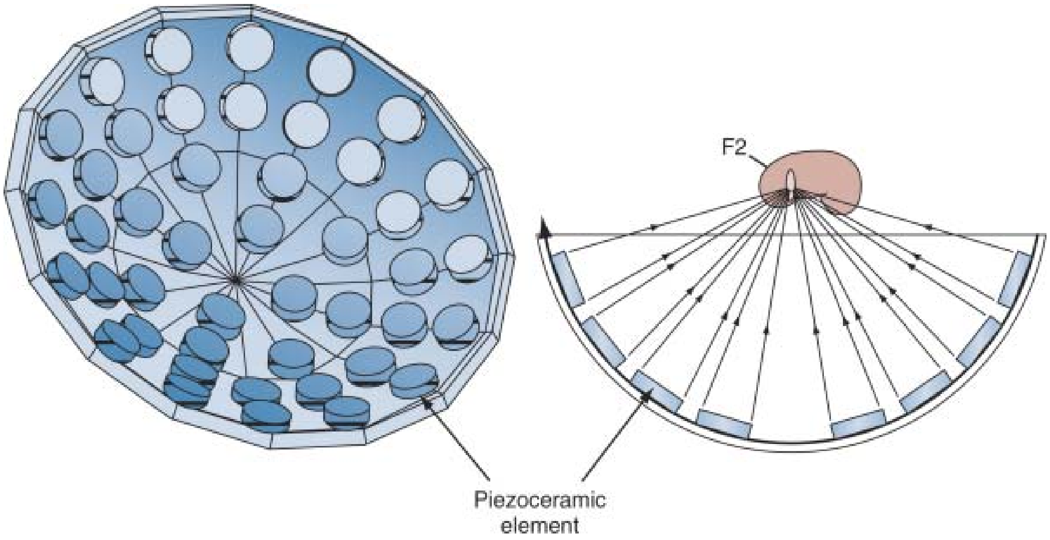
Electromagnetic generators are more controllable and reproducible than electro hydraulic generators because they do not incorporate a variable in their design such as the underwater spark discharge. Other advantages include the introduction of energy into the patient's body over a large skin area, which may cause less pain. In addition, a small focal point can be achieved with high-energy densities, which may increase its effectiveness in breaking stones. This generator will deliver several hundred thousand shockwaves before servicing, thereby eliminating the need for frequent electrode replacement, which is required with most electro hydraulic machines.

DISADVANTAGE

Small focal region of high energy results in an increased rate of subcapsular hematoma formation.

PIEZOELECTRIC GENERATOR

Piezoelectric lithotripter also produces plane shockwaves with directly converging shock fronts. These generators are made of a mosaic of small, polarized, polycrystalline, ceramic elements (barium titanate), each of which can be induced to rapidly expand by the application of a high-voltage pulse. Owing to the limited power of a single piezoelectric element, 300 to 3000 crystals are necessary for the generation of a sufficiently large shock pressure. The piezoelectric elements are usually placed on the inside of a spherical dish to permit convergence of the shock front. The focus of the system is at the geometric center of the spherical dish.



ADVANTAGES

Focusing accuracy, a long service life, and anaesthesia free treatment.

DISADVANTAGES

Insufficient power it delivers hampers its ability to effectively break renal stones.

SHOCK WAVE COUPLING

Shock waves can be coupled effectively into body by degassed water which has matched acoustic impedance to soft tissues. Current Lithotripter 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 provide the urologist with a familiar modality, added benefit of effective ureteric stone localization. Disadvantages are ionizing radiation to both the patient and medical staff, and it is not useful in localizing radiolucent calculi.

Ultrasonography based Lithotripters offer the advantages of stone localization with continuous monitoring and effective identification of radiolucent stones without radiation exposure. Disadvantage of ultrasonography is not able to locate ureteric stones.

PHYSICAL PROPERTIES OF RENAL CALCULI AND TISSUE

Knowledge of acoustic and mechanical properties of renal, ureteric 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 calculi depend primarily on the composition of stone.

COMPOSITION AND STRUCTURAL FEATURES OF 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, cystine and xanthine. Calculi appear in wide range of shapes, sizes, colors and textures.

ACOUSTIC PROPERTIES OF CALCULI AND RENAL TISSUE

Acoustic properties are density, wave speed and acoustic impedance. Longitudinal wave propagation (compression) characterized by parallel movements of material particles along the wave path. Transverse (Shear) wave propagation material particles move perpendicularly 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 CALCULI

Dynamic elastic properties of calculi depends 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) so most difficult to fragment during SWL.

MECHANISMS OF VARYING STONE FRAGILITY

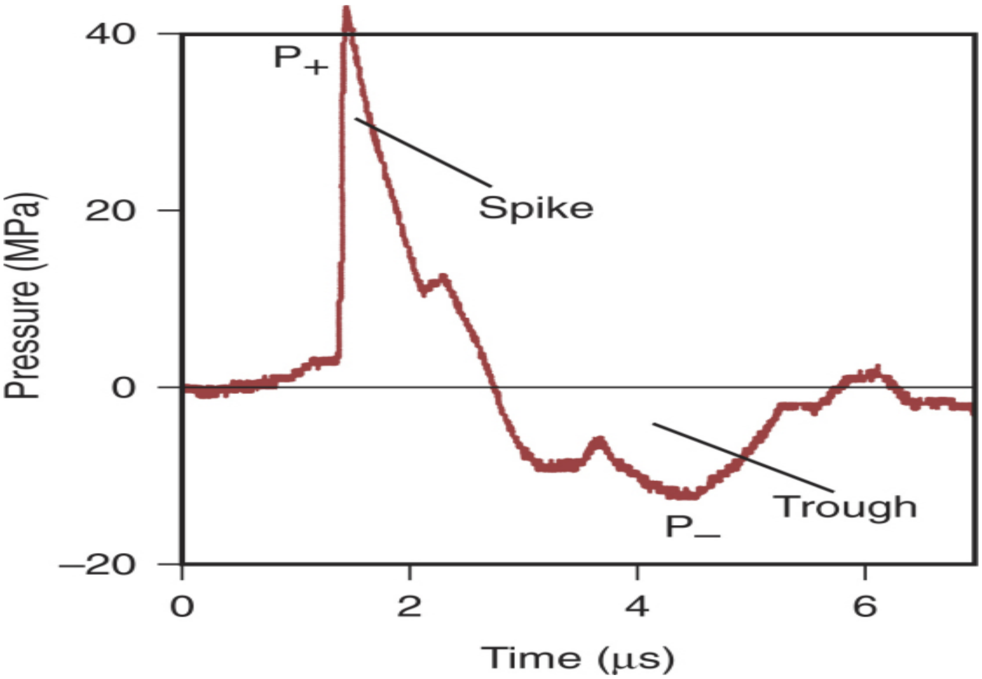
Stone fragility determines the response of a ureteric calculus to SWL. Response varies with composition, size, and structural features of stone.

It has been reported that stone with homogenous structure are less fragile than stones with heterogeneous structure. Elastic module determine a stones resistance to shock wave induced deformation, hardness determine a stone’s resistance to cavitation, microjet impact and fracture toughness determines a stone’s resistance to spalling damage and crack propagation. Calcium oxalate monohydrate and brushite stones are less fragile than MAP (Magnesium ammonium phosphates) and CA (Carboxy apatite) stones because Calcium oxalate monohydrate and brushite stones are stiffer, harder and more resistant to fracture. Based on the above factors cystine stones are most ESWL resistant, next are Brushite, and Calcium Oxalate Monohydrate.

MECHANISMS OF STONE FRAGMENTATION

Present knowledge in the field of SWL suggests that comminution of a renal or ureteric stone in a lithotripter field is the consequence of failure of the stone material due to the mechanical stresses produced either directly by the incident shockwave or indirectly by the collapse of cavitation bubbles. These events could be occurring simultaneously or separately at the surface of the stone or within the interior of the stone. Several potential mechanisms for SWL stone breakage have been described: spall fracture, squeezing, shear stress, superfocusing, acoustic cavitation, and dynamic fatigue.

Shock waves composed of positive compressive waves and negative tensile waves. Initial short and steep compressive front with pressures of about 40 MPa that is followed by a longer, lower amplitude negative (tensile) pressure of 10 MPa, with the entire pulse lasting for duration of 4 μs. Note that the ratio of the positive to negative peak pressures is approximately 5. Pressure measurements near the focal region of a Dornier unmodified HM3 indicate a 6-dB beam, of a width of approximately 15 mm. Since most of renal and ureteric stones are also generally of this dimension, the wave front incident on the stone can be considered a plane wave.



The first mechanism by which a stone might break is through spall fracture. Once the shockwave enters the stone, it will be reflected at sites of impedance mismatch. One such location is at the distal surface of the stone at the stone-fluid (urine) interface (although there could be other internal sites, such as cavities in the stone and interfaces of crystalline and matrix materials). As the shockwave is reflected, it is inverted in phase to a tensile (negative) wave. If the tensile wave exceeds the tensile strength of the stone, there is an induction of nucleation and growth of microcracks that eventually coalesce, resulting in stone fragmentation, which is termed spallation. The failure plane is located perpendicular to the applied tensile stress.

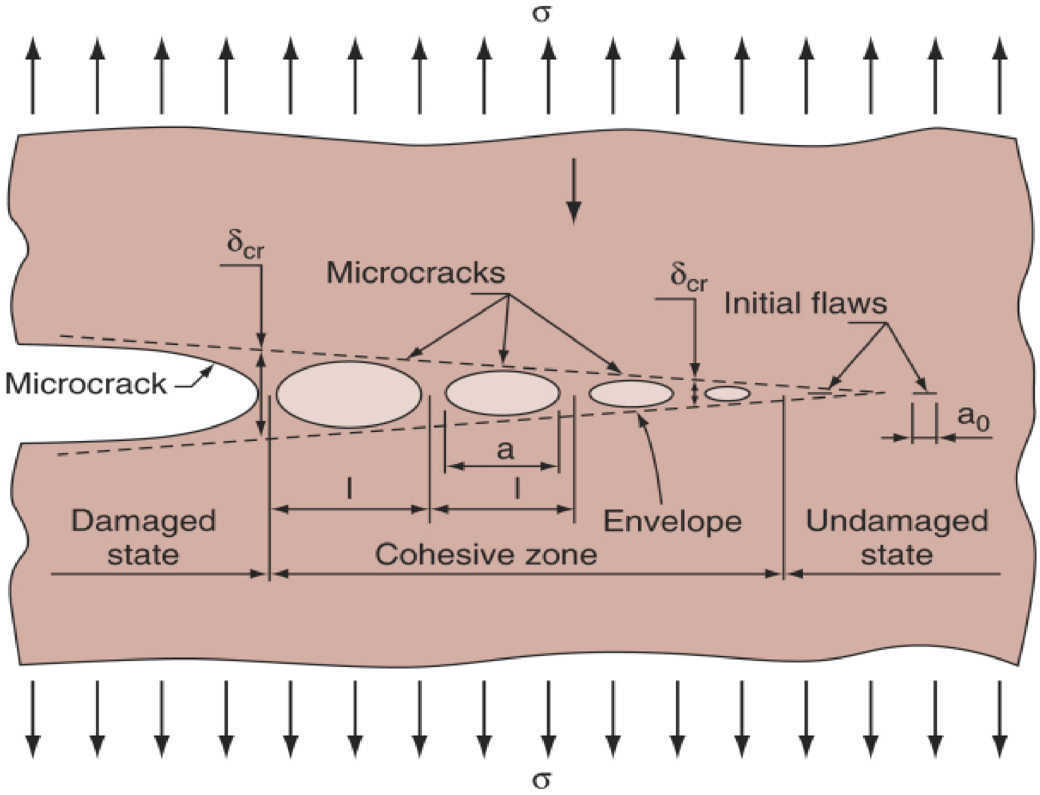
Second mechanism for stone breakage, termed squeezing-splitting or circumferential compression, occurs because of the difference in sound speed between the stone and the surrounding fluid. The shockwave inside the stone advances faster through the stone than the shockwave propagating in the fluid outside of the stone. The shockwave that propagates in the fluid outside of the stone thus produces a circumferential force on the stone, resulting in a tensile stress in the stone that is at its maximum at the proximal and distal ends of the stone. The resulting squeezing force could split the stone either in a plane parallel to the shockwave propagation direction or, depending on the elastic properties of the stone, possibly in a plane parallel to the shockwave front. It has been theorized that squeezing should be enhanced when the entire stone falls within the diameter of the focal zone. Thus, current third-generation lithotripters that have very small focal zones will not make use of this mechanism, as the stone size is typically greater than the focal zone, whereas the original Dornier HM3 machine would.

The third mechanism is shear stress. Shear stress will be generated by shear waves (also termed transverse waves) that develop as the shockwave passes into the stone. The shear waves propagate through the stone and will result in regions of high shear stress inside the stone. In contrast to compression waves, which move the molecules in the direction of propagation, a shear wave results in translation of molecules transverse to the direction of propagation, and therefore the molecules are not compressed but are shifted sideways by the wave. Many materials are weak in shear, particularly if they consist of layers, as the bonding strength of the matrix between layers often has a low ultimate shear stress. Calcium oxalate stones commonly possess alternating layers of mineral and matrix, and the shear stress induced by the transverse wave could cause such stones to fail.

The fourth mechanism for stone breakage, superfocusing, is the amplification of stresses inside the stone due to the geometry of that stone. The shockwave that is reflected at the distal surface of the stone can be focused either by refraction or by diffraction from the corners of the stone.

The fifth potential mechanism for SWL stone breakage is cavitation [14]. Cavitation is defined as the formation and subsequent dynamic behaviour of bubbles. The lithotripter-generated pressure field has been found to induce cavitation in both in vitro and in vivo studies. The negative pressure in the trailing part of the pulse causes bubbles to grow at nucleation sites. A nucleation site is an inhomogeneity in the fluid, which leads to preferential formation of free gas under stress. During the negative pressure wave, the pressure inside the bubble falls below the vapour pressure of the fluid, and the bubble fills with vapour and grows rapidly in size (almost three orders of magnitude). As these bubbles grow, they oscillate in size for about 200 μs and then collapse violently, giving rise to high pressures and temperatures. In the absence of any boundaries, a cavitation bubble remains spherical during collapse, releasing energy primarily by sound radiation, the majority of which is in the form of a shockwave However, in the presence of a boundary, a liquid jet, also termed a cavitation microjet, forms inside the bubble during the collapse. This jet can accelerate to extremely large speeds because it converts most of its kinetic energy from the collapse of the cavity interface to the jet itself. If the liquid jet is near the surface of a stone, it creates a locally compressive stress field in the stone, which propagates spherically into the stone interior.

The final mechanism of stone fragmentation to be considered defines stone breakage in terms of a dynamic fracture process, in which the damage induced by SWL accumulates during the course of the treatment, leading to the eventual destruction of the stone. Essential to this process is nucleation, growth, and coalescence of flaws within the stone caused by a tensile or shear stress. As renal calculi are not homogeneous but rather have either a lamellar crystalline structure bonded by an organic matrix material or an agglomeration of crystalline and noncrystalline material, there are numerous sites of pre-existing flaws (microcracks). All of the fracture mechanisms described have the potential to generate progressive damage to the interior of the stone.



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.

In 1996 ***Dretler***[24]***and Kolt*** further analyzed radiographic patterns of calcium oxalate dihydrate and monohydrate stones. Smooth edge, denser than bone, homogenous are pure calcium oxalate monohydrate stones. Radial striations and superimposed stippling pattern in calcium oxalate dihydrate stones. This study is the first proof that radiographic morphology can be related to ESWL stone free rate.

Hillman[25]and his associate sought to determine the feasibility of using CT to analyze 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).

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

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 ≥ + 1000.

Federle et al [26] evaluated 9 Patients and analyzed CT HU with stone composition. In this study 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 [27]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.

EXTRACORPOREAL SHOCK WAVE TREATMENT OF URETERIC CALCULI

Chaussy and his colleagues initially treated ureteric stones insitu and reported < 50% success rate. Most of the stones had been disintegrated, but the pieces were held together by edematous mucosa. This was seen in patients with stones impacted. This observation led Chaussy to use ureteric catheter or ureteroscope to push the ureteric stone into the renal collecting system. The success of this treatment was 75%-95%**[28]**.

ASSESSMENT OF FRAGMENTATION

One of the troublesome aspect of ESWL is determining the adequacy of fragmentation. One of the best indications is dispersion of sand, but this can occur only if the stone is located in a large cavity such as renal pelvis. **Barr et al 1990** noted that both Calyceal and Ureteric stones may be fragmented satisfactorily, but radiographic appearance may appear unchanged. Hence even if the 24-hour post treatment plain radiograph shows no definite pulverization the patient should be followed for a couple of weeks before considering retreatment.

IMPACTED URETERIC STONES

An impacted stone may be defined as a stone that cannot be bypassed by a wire or catheter or a stone that remains at the same site in the ureter for more than 2 months. The presumed action of shockwaves on a stone is the creation of interacting compressive and tensile forces at fluid stone interfaces. Stone fragment is torn off in layers. Green and Lytton,1985 &Farsi et al, 1994 in their study noticed that impacted stones are often more resistant to fragmentation by SWL .One explanation for this observation is **expansion space theory** the initial shock waves remove an outer layer of stone material, but the surrounding ureteric walls do not allow these particles to fall away. The new fluid –stone interfaces interfere with the transmission of next series of shock waves to the core of the stone, thereby preventing complete fragmentation. This situation can be remedied by push back to kidney with a ureteric catheter or ureteroscope, by bypassing the stone with a ureteric catheter to provide an artificial expansion space, or by irrigating the stone during insitu ESWL using saline to flush the particles away from the solid core. The only disadvantage to ureteric irrigation is that renal pelvic pressure may raise enough to result in forniceal tear and extravesation.

Both Mueller and associates (1986) and Park and colleagues (1998) have performed in vitro studies demonstrating that the confinement of a model stone is associated with substantial reduction in fragmentation, which may be due to the lack of a liquid interface surrounding the stone, thus reducing cavitation activity.

Although these reports suggest that ureteroscopy may be the optimal approach to the impacted ureteric stone, some urologists still favor SWL as the initial approach for stones smaller than 1 cm in the ureter. However, ureteroscopy may be the treatment of choice for patients whose SWL treatment failed, for patients with cystinuria, for patients with distal obstruction, for patients with impacted stones, for obese patients, for patients with bleeding diathesis, and when SWL is not readily available.

Cole and Shuttleworth reported on insitu ESWL on 40 patients juxta vesical uretric stones. Unmodified Dornier HM3 lithotripter was used in the treatment.33 stones ≥ 8mm, one below 5mm.Satisfactory disintegration occurred with one treatment in 90% of patients. At end of 3 months 79% of patients were stone free.

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

AUA guidelines on the management of patients with ureteric calculi that for stones smaller than 5 mm, the spontaneous passage rate in the distal ureter ranged from 71% to 98% whereas stones larger than 5 mm had a lower spontaneous passage rate, ranging from 25% to 53%. These rates have been affirmed by a more recent review of CT imaging of ureteric calculi by Coll et al, 2002. Therefore, for patients with stones of 5 mm or less, conservative management should be considered, whereas the chance of spontaneous passage for larger stones diminishes considerably, and intervention should be more readily contemplated.

Patients with ureteric stones >10 mm could be observed or treated with MET, but in most cases such stones will require surgical treatment. No recommendation can be made for spontaneous passage (with or without medical therapy) for patients with large stones.

For patients requiring stone removal, **AUA recommends**:

Standard: A patient must be informed about the existing active treatment modalities, including the relative benefits and risks associated with each modality. [Based on Panel consensus/Level IV]

Specifically, both SWL and URS should be discussed as initial treatment options for the majority of cases. Regardless of the availability of this equipment and physician experience, this discussion should include stone-free rates, anaesthesia requirements, need for additional procedures, and associated complications. Patients should be informed that URS is associated with a better chance of becoming stone free with a single procedure, but has higher complication rates.

Recommendation: For patients requiring stone removal, both SWL and URS are acceptable first-line treatments. (Based on review of the data and Panel consensus/Level 1A-IV).

El-Faqih et al (1988) studied treatment of juxtavesicular uretric stones. They compared URS and ESWL. The stone free rate in the ureteroscopy group was 93%,while ESWL group was 90%.These authors suggest ESWL should be the primary mode of intervention in patients with distal ureteric calculus.

V.J. GNANAPRAGASAM et al U.K in his study of primary in situ extracorporeal shock wave lithotripsy in the management of ureteric calculi: reviewed treatment outcome in 180 patients with 196 stones who were treated with primary in situ ESWL in all level of ureteric calculus. At 3 months follow up stone free rates were 90% for upper ureteric calculus, 89% for mid ureteric calculus and 86% for lower ureteric calculus. He concluded that where prompt access to ESWL available, primary in situ ESWL remains an effective form of treatment for all ureteric calculi, although stone free rates are lower for larger stones[39].

Mohammad Ghafoor and colleagues from TAWAM hospital, UAE studied the efficacy of extracorporeal shock wave lithotripsy in the treatment of ureteric stones. Based on stone size, the patients were divided into two groups: A (10 mm) and B (11-20 mm). Their results were overall clearance rate for ureteric stones treated with ESWL, irrespective of its site and size was 78.5%. Clearance rate for small stones (<10mm) in the lower third of the ureter was 73.8% and for stones larger than 10 mm in the distal third of ureter, the clearance rate was low with a high retreatment rate[40].

They concluded that for distal ureteric stones <10 mm in diameter, the clearance rate is more than 70% and ESWL can be considered as a primary treatment, while for stones larger than 10 mm in diameter, endoscopic removal should be the preferred treatment.

Guang –Qiao ZENG and Wei-De ZHONG from china compared the efficacy of URS and ESWL in the treatment of lower ureteric calculus .180 patients underwent URS and 210 patients were submitted for ESWL in prone or at a major postero oblique position. Results after 1 month: Stone clearance was achieved in 164 patients (78.1%) ESWL group, 168 patients (93.3%) in URS group (p- 0.05)[29]

Maheshwari PN et al conducted study in R.G stone research institute, Mumbai & New Delhi compared success ,efficacy and complications of URS & ESWL in symptomatic non obstructing lower ureteric calculus .120 patients under went ESWL ,after 3 months 90% of patients were stone free. URS was needed for 12 patients where ESWL failed to achieve stone clearance. Hence they concluded that ESWL can be the primary mode of treatment for symptomatic small non obstructing lower ureteric calculus and URS can be offered to patients who demand immediate failure or when ESWL fails[30].

COMPLICATIONS

The complications of ESWL of uretric stones appear to be related to manipulative procedures done before or after ESWL. There are no confirmed reports of adverse effects associated with insitu ESWL of lower uretric calculi alone [31, 32, 33].

MATERIALS AND METHODS

TITLE OF THE STUDY:

Analysis of efficacy of extracorporeal shock wave lithotripsy in the management of lower ureteric calculus

PERIOD OF STUDY:

January 2008 –April 2010

STUDY DESIGN:

Prospective study

SOURCE OF PATIENTS:

The study was conducted in the Department of Urology; Government General Hospital from the patients those attended for the management of lower ureteric calculus. The institutional review board at our hospital approved the study.

METHOD OF STUDY:

Informed consent obtained from all the patients after explaining all available modalities of treatments –medical expulsion therapy, ureteroscopy &intracorporeal lithotripsy and extracorporeal lithotripsy, their complications in the management of lower ureteric calculus.

PATIENT EVALUATION:

History, Physical examination, Complete hemogram,Urine routine and culture sensitivity, Renal function test, X ray KUB, Ultra sonogram KUB, CECT KUB. Patient's details are entered in a proforma.

Lower ureteric calculus –Stones below sacroiliac joint to vesico ureteric junction. Stone size measurements taken in the study–maximal transverse measurement in C.T and C.T –H.U of stones were measured simultaneously.

Patients included in the study are divided into 2 groups based on stone size. Group 1:≤10 mm and Group 2: >10mm. Patients again divided based on C.T –H.U into Groups A and B, Group A: ≤1000 Group B :> 1000 H.U.

Hence study group contains,

Group 1A: ≤10 mm and H.U:≤1000,

Group 1 B: ≤10mm and H.U > 1000,

Group 2A: >10 mm and H.U:≤1000,

Group 2 B: >10mm and H.U > 1000.

INCLUSION CRITERIA:

1. Patients with unilateral lower ureteric calculus willing for extracorporeal shockwave lithotripsy
2. Patients with normal renal parameters
3. No previous treatments for the same ureteric calculus

EXCLUTION CRITERIA:

1. Not willing for ESWL
2. Bilateral ureteric calculi
3. Ureteric obstruction distal to calculus
4. Coagulation disorder/patients on anticoagulation drugs
5. Pregnancy
6. Sepsis
7. End stage renal disease

PATIENT PREPARATION & ESWL:

Bowel preparation – anti flatulent & laxatives day before procedure

All treatments were done with ***Donier Compact Delta*** II (Electromagnetic Generator) machine as outpatient procedure.

POSITION OF PATIENT:

Prone

ANAESTHESIA/ANALGESIA:

Inj.Pentazocine 30 mgs and Inj. Promethazine hcl 25 mgs intramuscularly 30 minutes before the procedure.

Stone focusing done fluoroscopically

2500 shocks for all patients - 60 shocks/minute, in the intensity 4-5.

POST PROCEDURE:

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, dysuria and passing stone fragment in the urine. Patients advised to take adequate oral fluids.

FOLLOWUP:

Patients were followed in 15 days, 30 days, and 60 days and in 90 days or whenever patients had unusual urinary complaints after the procedure. Failure of ESWL –if any significant residual stone after 3 months.

History, Physical examination, U/S KUB, X ray KUB done during all visits. During the first visit in 15 days, adequacy of fragmentation assessed, if necessary second sitting of ESWL suggested.

Patients follow up terminated if the patient cleared the stone with ESWL or secondary treatment selected for the failure of ESWL.

STUDY ANALYSIS:

Study data analyzed using SPSS (V: 17) software.

OBSERVATION & RESULTS

The study comprised of 50 patients who had satisfied the inclusion and exclusion criteria. 2 patients lost follow up after ESWL procedure, hence results of 48 patients analyzed.

AGE DISTRIBUTION

Age of the patients ranged from 17-70 yrs, most patients were in 21-50yrs

AGE (YRS)	**NO OF PATIENTS**
<20	6
21-30	19
31-40	8
41-50	10
51-60	4
>60	1

SEX DISTRIBUTION

There were 35 male and 13 female patients in our study

SEX	**SIZE**		
	Group 1 **≤ 10 mm**	**Group 2** **> 10 mm**	**Total**
MALE	19 76.0%	16 69.6%	35 72.9%
FEMALE	6 24.0%	7 30.4%	13 27.1%
TOTAL	25 100.0%	23 100.0%	48 100.0%

SYMPTOM DISTRIBUTION

Majority of patients presented with colicky pain and nausea/vomiting, other symptoms were dysuria and loin pain. Duration of symptoms ranged from 4 days to 1month.

SYMPTOM	**NO OF PATIENTS**
COLICKY PAIN	45
NAUSEA/VOMITING	42
DYSURIA	7
LOIN PAIN	2

STONE SIZE DISTRIBUTION

In our study size of the lower ureteric calculus range from 6mm-16mm.Cases are divided into 2 groups based on stone size. Group 1: ≤10mm and Group 2 : >10mm.

SIZE	**NO OF PATIENTS**
Group 1: ≤10mm	25
Group 2: >10mm	23

CT HU DISTRIBUTION

In Group 1(≤ 10mm), 24 patients were with ≤1000 HU - Group 1A and 1 patient with >1000 HU Group 1 B.

In Group 2(>10mm) 16 patients were ≤1000 HU – Group 2 A and 7 patients were with >1000 HU –Group 2 B.

			SIZE		
			Group 1 ≤ 10 mm	**Group 2 > 10 mm**	**Total**
HU	≤1000		24	16	40
		% within SIZE (cms)	96.0%	69.6%	83.3%
	> 1000		1	7	8
		% within SIZE (cms)	4.0%	30.4%	16.7%
	Total		25	23	48
		% within SIZE (cms)	100.0%	100.0%	100.0%

SIDE DISTRIBUTION

In our study left side stones predominated (27pts) over right sided stones (21pts).

Group 1 (≤ 10 mm) -10 patients had right lower ureteric stones, 15 had left side stones, Group 2(> 10 mm) -11 patients had right sided stones and12 patients had left side stones.

SIDE		**SIZE**		
		Group 1 ≤ 10 mm	**Group 2 > 10 mm**	**Total**
RIGHT		10	11	21
	% within SIZE (cms)	40.0%	47.8%	43.8%
LEFT		15	12	27
	% within SIZE (cms)	60.0%	52.2%	56.3%
TOTAL		25	23	48
	% within SIZE (cms)	100.0%	100.0%	100.0%

PRIMARY TREATMENT

In this study one patient in Group 1(≤10mm) required second sitting of ESWL.

5 patients in Group 2 (>10mm) required second sitting.

			SIZE		
			Group 1 ≤ 10 mm	**Group 2 > 10 mm**	**Total**
NO OF PRIMARY	ONE		24	18	42
		% within SIZE (cms)	96.0%	78.3%	87.5%
	TWO		1	5	6
		% within SIZE (cms)	4.0%	21.7%	12.5%
	Total		25	23	48
		% within SIZE (cms)	100.0%	100.0%	100.0%

NO OF PRIMARY CT- HU

No of primary treatment increased when CT HU was >1000(Group 1B & Group 2 B) when compared with CT- H.U < 1000(Group 1A & Group 2A) ,this difference was statistically significant (p-<0.01)

			HU		**Total**
			≤1000	**>1000**	
NO OF PRIMARY	ONE		37	5	42
		% within HU	92.5%	62.5%	87.5%
	TWO		3	3	6
		% within HU	7.5%	37.5%	12.5%
	Total		40	8	48
		% within HU	100.0%	100.0%	100.0%

(P-<0.01)

STONE FREE RATE –SIZE

Stone free rate in ≤10mm group was 22/25patients (88%) and in >10mm group was 13/23 patients (56.5%).This difference was statistically significant (p-<0.01).

ESWL		**SIZE**		
		Group 1 **≤ 10 mm**	**Group 2** **> 10 mm**	**Total**
SUCCESS		22	13	35
	% within SIZE (cms)	88.0%	56.5%	72.9%
FAILURE		3	10	13
	% within SIZE (cms)	12.0%	43.5%	27.1%
Total		25	23	48
	% within SIZE (cms)	100.0%	100.0%	100.0 %

(P-<0.01)

STONE FREE RATE –HU

STONE FREE RATE IN GROUP 1(≤ 10 mm)

In Group 1(≤ 10 mm) stone free rate based on C.T-H.U showed when C.T H.U was ≤1000 success rate significantly higher than > 1000 H.U.

STONE FREE RATE	**≤1000 H.U GROUP 1 A**	**> 1000 H.U GROUP 1 B**	**TOTAL**
SUCCESS	22(91.7%)	0	22(88%)
FAILURE	2(8.3%)	1(100%)	3(12%)
TOTAL	24(100%)	1(100%)	25(100%)

P <0.001

STONE FREE RATE IN GROUP 2(> 10 mm)

In Group 2 (> 10 mm) stone free rate based on C.T –H.U showed when C.T -H.U was ≤1000 success rate was 75%, significantly higher than > 1000 H.U. (P <0.01)

STONE FREE RATE	**≤1000 H.U GROUP 2 A**	**> 1000 H.U GROUP 2 B**	**TOTAL**
SUCCESS	12(75%)	1(14.3%)	13(56.5%)
FAILURE	4(25%)	6(85.71%)	10(43.5%)
TOTAL	16(100%)	7(100%)	23(100%)

When CT-HU increases success rate decreases, when HU was ≤1000 (Group 1A & Group 2A) 34 patients (85%) successfully cleared their stones, failure occurred only in 6 patients (15%).

When HU > 1000(Group 1B &Group 2 B) only one patient cleared the stone (12.5%), failed in 7 patients (87.5%), this difference was statistically significant.

Stone free rate:		**HU**		
		≤1000	**> 1000**	**Total**
SUCCESS		34	1	35
	% within HU	85.0%	12.5%	72.9%
FAILURE		6	7	13
	% within HU	15.0%	87.5%	27.1%
Total	Count	40	8	48
	% within HU	100.0%	100.0%	100.0%

(P <0.001)

COMPLICATIONS

During follow up of post ESWL, few patients presented with minor complications. Dysuria was the major complication in most number of patients-12 patients, hematuria in 5 patients, lower abdominal pain in 4 patients and UTI in one patient.

COMPLICATIONS	**NO OF PATIENTS**
PAIN	4
HEMATURIA	5
DYSURIA	12
UTI	1
STRICTURE	0

All complications were treated conservatively with hydration, antibiotics and analgesics.

DISCUSSION

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

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.

Both recommended treatment options, SWL and ureteroscopy, in ureteric stone have valid advantages and disadvantages. Supporters of SWL claim that it is effective and noninvasive, is associated with less morbidity, requires fewer anesthesias than ureteroscopy, and seldom requires ureteric stents. Critics argue that the success rates are not as high as those of ureteroscopy, equipment availability may be limited, visualization of the stone is often difficult, attainment of a stone-free state requires a longer time and follow-up, re-treatment rates are higher, and costs are higher. Supporters of ureteroscopy claim that it is highly successful and minimally invasive, is associated with minimal morbidity, can be used with larger and multiple stones, and has high immediate stone-free rates. Critics argue that it requires specialized training, requires more anaesthesia, and more often requires ureteric stent placement.

The primary goal in treating patients with ureteric calculi is a stone-free state, and the **AUA/EAU guidelines panel's meta-analytic study** reported that with ESWL in distal ureteric stone <10mm, in 17 groups containing 1684 patients stone free rate was 86% (80-91) % [34]. In our study it was 88%.In >10mm groups containing 966 patients stone free rate was 74 %(57-87) %, in our study it was only 56.5%. All ESWL failure cases in our study underwent ureteroscopy and intracorporeal pneumatic lithotripsy. All patients were stented following the procedure. DJ Stents removed after 3 weeks. During URS &ICL no significant abnormality in either ureteric orifice or distal ureteric narrowing below the stone was noted.

There have been two randomized prospective studies comparing ureteroscopy and SWL for treatment of patients with distal ureteric stones subsequent to the guidelines document. **Peschel** and associates (1999) randomized 80 patients and found that those undergoing ureteroscopy achieved stone-free status more rapidly, regardless of initial stone size, than did those treated by SWL. All of the patients undergoing ureteroscopy were rendered stone free, whereas 10% of the SWL cohort required subsequent ureteroscopy to achieve a stone-free status[35]. **Pearle** and associates (2001) randomized 64 patients and reported that 100% of individuals who completed radiographic follow-up subsequent to either SWL or ureteroscopy became stone free[36].

One possible reason for the difference in this outcome compared with the Pearle et al study is that an **unmodified Dornier HM3 lithotripter**, which is known to fragment stones more efficiently, was used in Pearle's study rather than the **Dornier MFL5000** used in Peschel's study. In our study overall success rate was 72.9%; 27.1% of patients required secondary treatment .The lithotripter used was ***Dornier Compact Delta*** II (Electromagnetic Generator).

Joseph et al assessed the susceptibility of stone fragmentation by ESWL according to HU in renal stone, they found that the success rate for stone with attenuation value < 1000 HU was significantly higher than that for stone with value >1000 HU [37]. In their study they found a significant correlation between number of shocks required for stone fragmentation and the attenuation value of the stone.

Not much of data available in the literature on correlation between HU and stone free rate in lower ureteric calculus. In our study significant failure and retreatment rates in >1000 HU stones, both in Group 1(≤10mm) and Group 2(>10mm), but the number of patients in our study with HU >1000 were small (8/48).

KH Yip,PC Tam,CWF Lee,yl leung studied efficacy of insitu ESWL in ureteric calculi management using Dornier MFL 5000 lithotripter, their overall success rate was 81% [38] ,in our study it was 72.9%. **V.J. GNANAPRAGASAM et al** studied with same machine with success rate of 86%, majority of stone size in this study <10mm[39].

Mohammad Ghafoor et al studied the efficacy of extracorporeal shock wave lithotripsy in the treatment of lower ureteric stones using second generation Siemens Lithostar II. Clearance rate for small stones (<10mm) in the lower third of the ureter was 73.8% , and for stones larger than 10 mm in the distal third of ureter, the clearance rate was low 42.8% , with a high retreatment rate. So Ghafoor et al concluded that for distal ureteric stones <10 mm in diameter, the clearance rate is more than 70% and ESWL can be considered as a primary treatment, while for stones larger than 10 mm in diameter, endoscopic removal should be the preferred treatment [40].

In our study the results were far better than Ghafoor et al study, Clearance rate for small stones (<10mm) was 88% compared with 73.8%.Clearence rate for stones larger than 10mm was 56.5% still better than Ghafoor et al study 42.8%.

In our study total of 48 patients underwent insitu ESWL of lower ureteric calculus, 25 patients with stone size ≤10mm and 23 patients with > 10mm size.

Dornier Compact Delta II was used in this study. All procedures were done as outpatient treatment.

Overall stone free rate was 72.9%, there were 27.1% patients required URS/ICL as secondary procedure.

In patients with stone size of ≤10mm (Group 1) success rate was 88%, when C.T H.U was <1000 (Group 1 A) the success rate increased to 91.7%.

In patients with stone size of >10mm (Group 2) success rate was 56.5%, when C.T H.U was <1000 (Group 2 A) the success rate increased to 75%.

Patients with CT HU >1000 retreatment and failure rate statistically increased when compared to ≤ 1000HU stone patients in both groups.

Overall failure rate in ≤10mm (Group 1) was 12%, only one patient with CT HU >1000 (Group 1 B) failed to clear the stone.

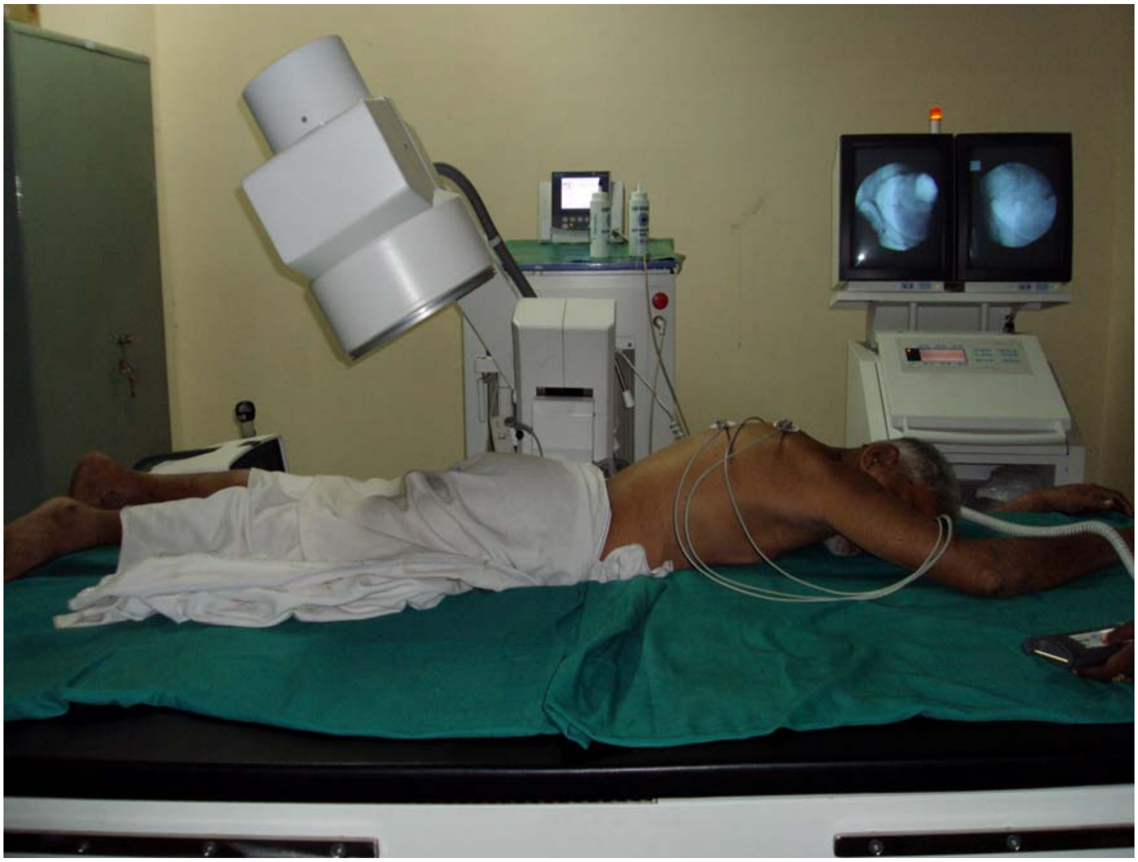
Overall failure rate of insitu ESWL in > 10mm stone size patients were 43.5% (Group 2).when C.T H.U was <1000 (Group 2 A) it was only 25%,in patients with stone size >10mm with C.T H.U (Group 2 B) stone clearance failed in all except one - 85.71%.

Complications during and following insitu ESWL for lower ureteric calculus was minor, no complications required inpatient treatment.

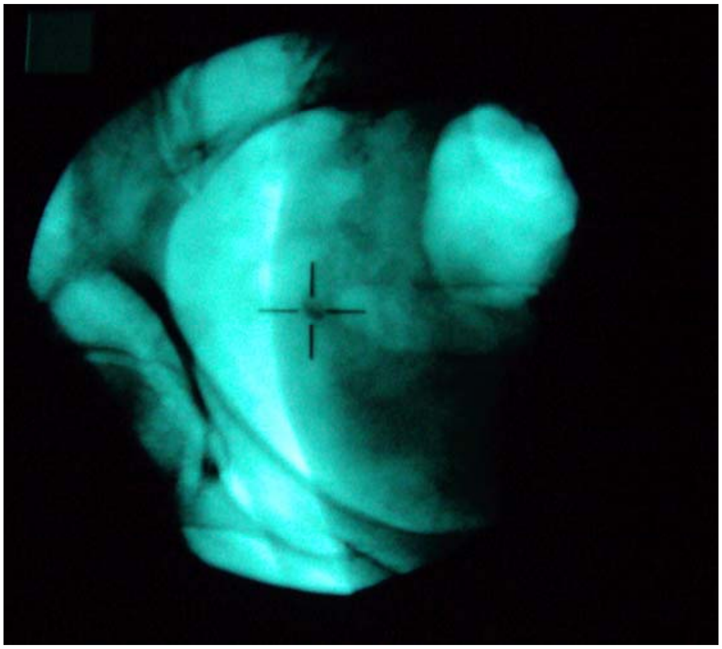
CONCLUSION

1. Insitu ESWL for lower ureteric calculus is an effective, non invasive and a viable treatment option with no major complications.
2. Patients with lower ureteric calculus size ≤ 10 mm and CT – H.U <1000 had high expulsion rate with ESWL. Hence ESWL may be considered as the primary treatment option.
3. Other modalities of treatment may be needed in patients with stone size >10mm and CT-H.U >1000.

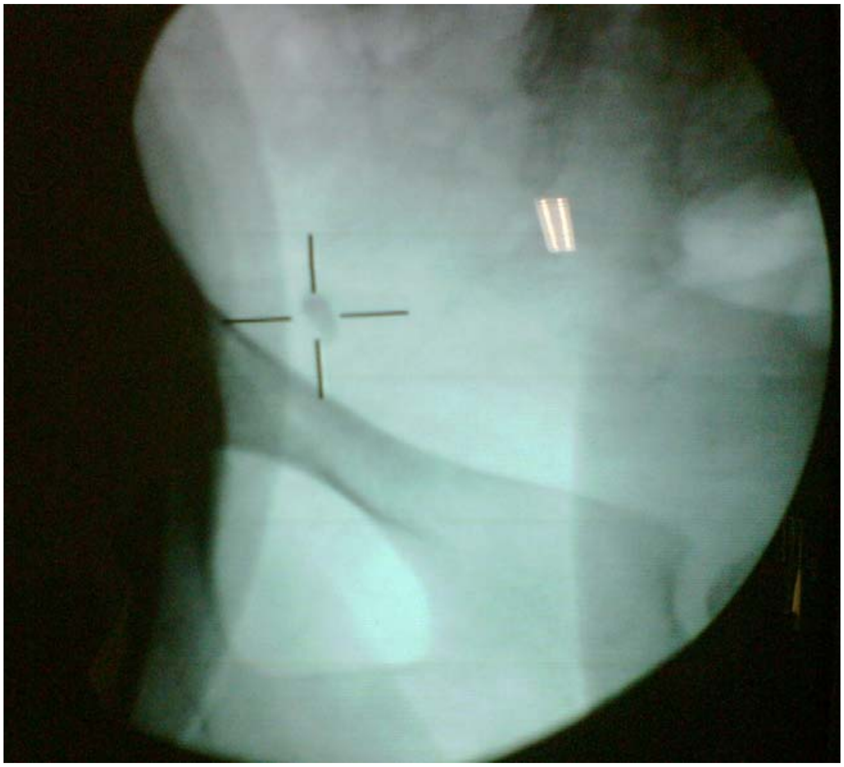
4. Patients with lower ureteric calculus size > 10 mm and CT – H.U <1000, ESWL can be tried with reasonable success.

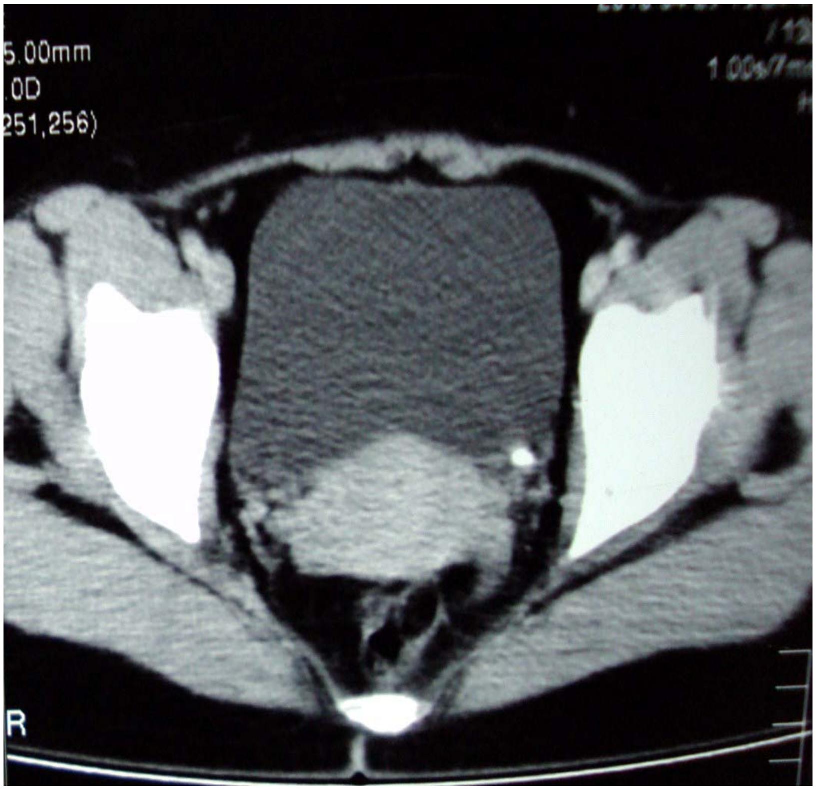


ESWL MACHINE AND POSITION OF PATIENT



LEFT LOWER URETERIC STONE




5.00mm
.0D
251,256)
1.00s/7m
R

PRE ESWL

POST ESWL

BIBLIOGRAPHY

1. Ueno et al., 1977. Ueno A, Kawamura T, Ogawa A, et al: Relation of spontaneous passage of ureteral calculi to size. *Urology* 1977; 10:544-546.
2. Otnes and Sandnes, 1978. Otnes B, Sandnes H: Comparison of radiological measurement and actual size of ureteral calculi. *Scand J Urol Nephrol* 1978; 12:155-156.
3. Morse and Resnick, 1991. Morse RM, Resnick MI: Ureteral calculi: natural history and treatment in an era of advanced technology. *J Urol* 1991; 145:263-265.
4. Hubner et al., 1993. Hubner WA, Irby P, Stoller ML: Natural history and current concepts for the treatment of small ureteral calculi. *Eur Urol* 1993; 24:172-176
5. Segura et al., 1997. Segura JW, Preminger GM, Assimos DG, et al: Ureteral Stones Clinical Guidelines Panel summary report on the management of ureteral calculi. *J Urol* 1997; 158:1915-1921.
6. Coll et al., 2002. Coll DM, Varanelli MJ, Smith RC, et al: Relationship of spontaneous passage of ureteral calculi to stone size and location as revealed by unenhanced helical CT. *AJR Am J Roentgenol* 2002; 178:101-103.

7. The silence of stones: Asymptomatic ureteral calculi.J.Urology.2007;178:1341-1344
8. Sosa et al., 1987. Sosa RE, Riehle RA, Vaughan Jr ED: The management of ureteral calculi. *Semin Urol* 1987; 5:212-216.
9. Kinder et al., 1987. Kinder RB, Osborn DE, Flynn JT, et al: Ureteroscopy and ureteric calculi: How useful? *Br J Urol* 1987; 60:506-508.
10. Vaughan and Gillenwater, 1971. Vaughan Jr ED, Gillenwater JY: Recovery following complete chronic unilateral ureteral occlusion: Functional, radiographic and pathologic alterations. *J Urol* 1971; 106:27.
11. Chuang CJ Zhorlg P, Prenunger GM A comparison of stone damage caused by different models shock wave generation J Urol 1992 148 200-205.
12. Z.Kirkali et al effect of E.S.W.L on the morphology and contractility of rabbit ureter.J.Urology.1995;154:1939-1943
13. A.F.Bierkens et al –The value of antibiotic prophylaxis during E.S.W.L in the prevension of urinary tract infection.J. Urology.1998;159:614-615
14. Crum LA Cavitation Microjet as a contributory mechanism for renal calculi disintegration is ESWL J Urol 1988 140 1587-1590

15. Mostafa MR, Ernst RD, Saltzman B Accurate determination of chemical composition of urinary calculi by spinal CT J urol 1998 159 673-675.
16. PETER JOSEPH et al .Computerized Tomography Attenuation Value of Renal Calculus: Can It Predict Successful Fragmentation of the Calculus by ExtracorporealShockWaveLithotripsy? .J.Urology.2002;167:1968-1971
17. Mitcheson HD Zamestof RG, Bankoff MS et al Determination of Chemical composition of urinary calculi by CT J Urol 1983; 130: 814-819.
18. Segal AJ Spataro RF Linke CA Fronk IN, Robinowitz R. Diagnosis of Non Opaque Calculi by CT Radiology 1978 : 129 447-450
19. Fielding JR, Steele G, Fox A, Heller H, Loughlin KR. Spiral computerized tomography in the evaluation of acute flank pain: a replacement for excretory urography. J –Urol 1997; 157: 2071-3.
20. Evaluation of disintegration in prevesical calculi by 3 dimensional endo ultrasound with surface rendering.J.Urology.2002; 168:450-453.
21. Gyan Pareek et al .H.U on C.T predict stone free rate after ESWL.J.Urology.2003;169:1679-1681

22. Job Chacko et al Does a Slower Treatment Rate Impact the Efficacy of Extracorporeal Shock Wave Lithotripsy for Solitary Kidney or Ureteral Stones?.J.Urology.2006;175:1370-1374

23. DENIS H et al Ureteroscopy with Intravenous Sedation for Treatment of Distal Ureteral Calculi: A Safe and Effective Alternative to Shock Wave Lithotripsy.J.Urology.1996; 156:899-902.

24. Dretler SP, Polykoff G. Calcium oxalate stone morphology; Fine tuning our therapeutic distinctions. J Urol 1996; 155: 828 –33.

25. Hillman BT Drach GW, Tracay P, Gaires JA CT analysis of renal calculus AJR 1984 142: 549 – 552

26. Federle MP MC Anich JW Kaisa JA Goodm8N PC Robert J and Male JC CT of Urinary Calculi AJJ 1981; 136: 255-258.

27. Kuwahara M, Kagiyam S, Kurusus Orikara S CT and Compoisiton of renal calculi URol Res 1984 12(2) 111 – 113.Michael Marberger ,John M.Fitzpatrick .Stone surgery.1991.U.S

28. Chaussy C, Schmiedt E, Jocham D et al First Clinical Experience with Extracerporeally induced destruction on kidney stone by shock waves J.urol 1938; 127: 417-420.

29. Guang –Qiao ZENG and Wei-De ZHONG et al Extracorporeal shock wave lithotripsy versus pneumatic ureteroscopic lithotripsy in

treatment of lower ureteric calculi.Asian.J.Andrology. 2002;4:303-305

30. Andankar M.G,Maheshwar P.N et al.Symptomatic small non obstructing lower ureteric calculi: Comparison of uretroscopy and extracorporeal shock wave lithotripsy.J.P.G.M. 2001;47:177-180
31. Mostafa M.Elhilaili et al Effectiveness and Safety of the Dornier Compact Lithotriptor.Journalof Urology.1996;155(3):834-838
32. Salah Rashed El-Faqih et al. Small bowel perforation after extracorporeal shockwave lithotripsy for ureteric stone: A case report and review of the literature.saudi J.Gastroenterology 2002;8;59-61
33. Rudiger Andressen ,Michael Fedel ,Frank Sudhaoff ,Rainer Friedrichs,Stefan A.Loening .Quality of Semen After Extracorporeal Shock Wave Lithotripsy for Lower Ureteral Stones. Journal of Urology.1996;155(4):1281-1283
34. AUA Guideline for the Management of Ureteral Calculi 2007
35. Peschel et al., 1999. Peschel R, Janetschek G, Bartsch G: Extracorporeal shock wave lithotripsy versus ureteroscopy for distal ureteral calculi: A prospective randomized study. *J Urol* 1999; 162:1909-1912.

36. Pearle MS, Nadler R, Bercowsky E, et al: Prospective randomized trial comparing shock wave lithotripsy and ureteroscopy for management of distal ureteral calculi. *J Urol* 2001; 166:1255-1260.

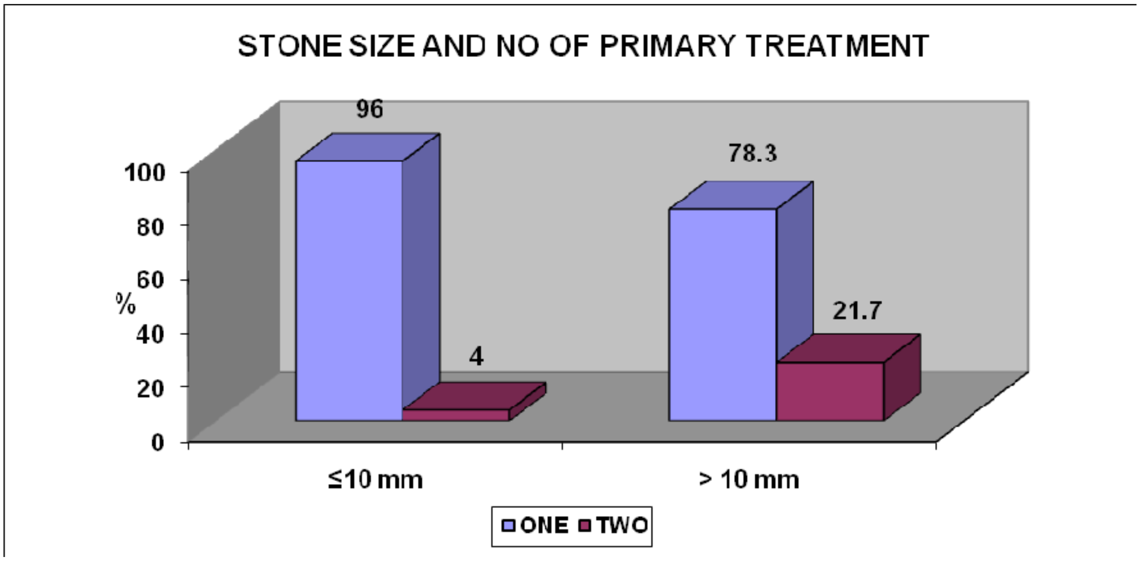
37. Joseph P. Mandar AK, Singh SK, Mandai P. Sankhwar SN and Sharma SK, CT attenuation value of renal calculus can it predict successful fragmentation of the calculus by ESWL? A Preliminary Study J Urol 2002; 167: 1968 – 1971.

38. KH Yip, PC Tam, CWF Lee, YL Leung. The efficacy of extracorporeal shock wave lithotripsy in the treatment of ureteric stones. *HKMJ 1995:1:110-114*

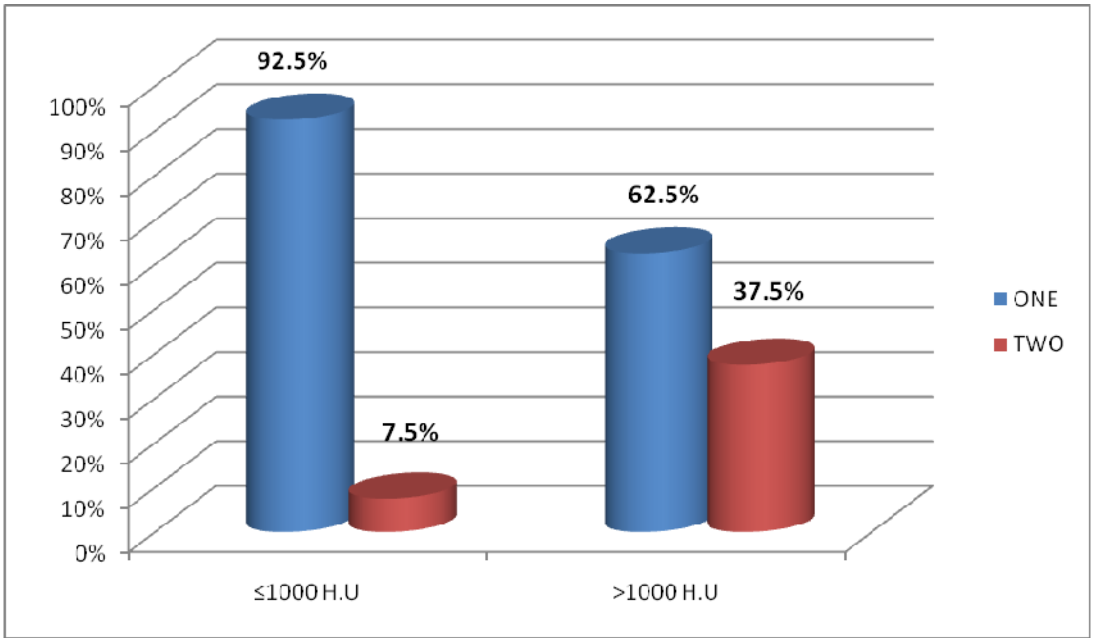
39. V.J. Gnanapragasam, P.D.R. Ramsden, L.S.N. Murthy* and D.J. Thomas. Primary in situ extracorporeal shock wave lithotripsy in the management of ureteric calculi: results with a third-generation lithotripter. B.J.U .1999;84:770-774

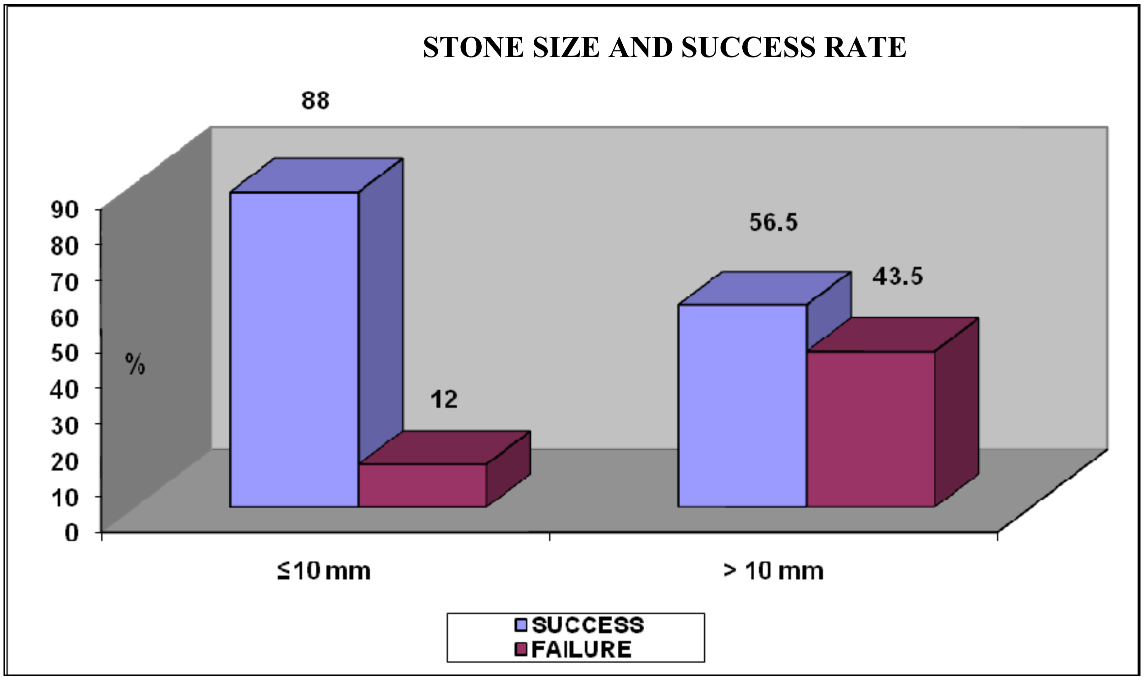
40. .Mohammad Ghafoor ,Anwer Halim et al . Extracorporeal shock wave lithotripsy in the treatment of ureteric stones: Experience from Tawam hospital,UAE .Ann. of Saudi medicine. 2002; 22:18-21.

CHARTS

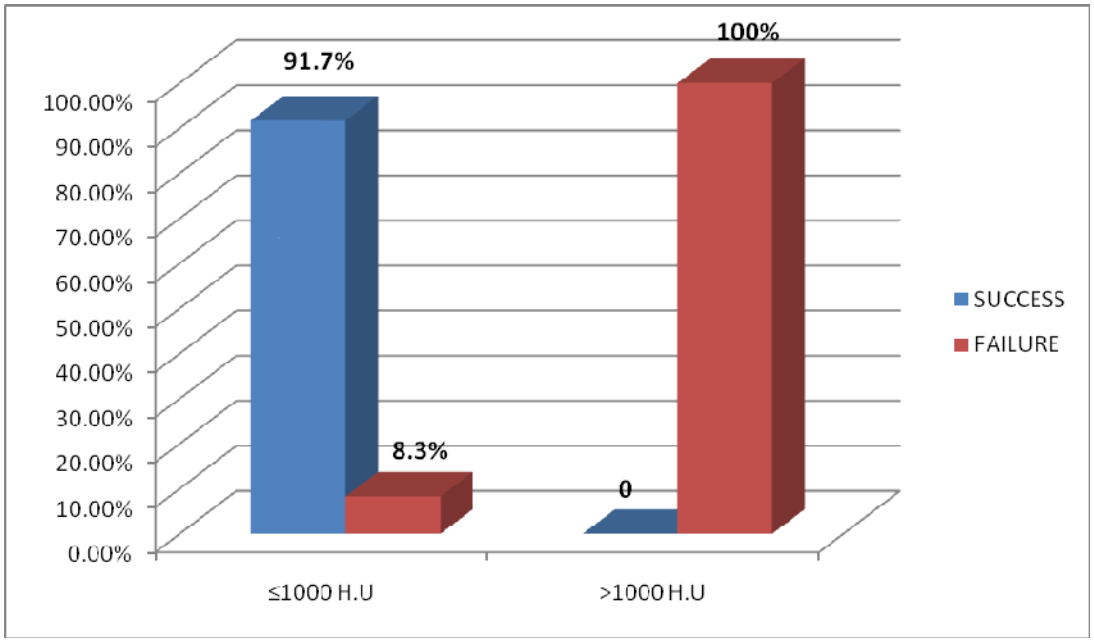


NO OF PRIMARY IN ≤ 1000 H.U & >1000 H.U

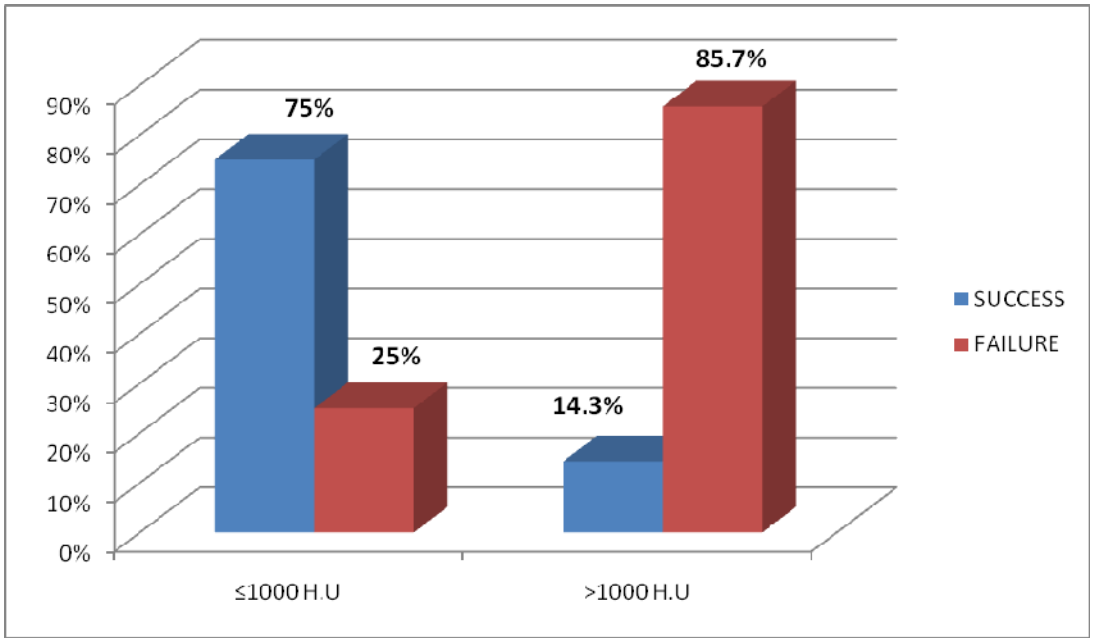



STONE SIZE AND SUCCESS RATE
%
0
10
20
30
40
50
60
70
80
90
88
12
56.5
43.5
≤10 mm
> 10 mm
SUCCESS
FAILURE

STONE FREE RATE IN ≤ 10 MM GROUP



STONE FREE RATE IN >10 MM GROUP



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

Telephone: 044-2530 5000
Fax : 044 – 25305115

L.Dis.No.1459~~8~~7/P & D3/Ethies/Dean/GGH/09 Dated:12.06.2009

Title of the work "Analysis of efficacy of extra corpored Shock wave lithotripsy in the management of lower ureteric calculus"

Principal Investigator Dr. T. Gnanasekaran, MCh., PG

Department : Urology, MMC, Ch.3.

The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting which is held on 23rd June 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.12.6

EFFICACY OF ESWL IN LOWER URETERIC CALCULUS

PROFORMA

NAME: AGE & SEX

ADDRESS:

PHONE NO: MRD NO:

HISTORY:

PAIN – SITE, CHARACTER, DURATION.

HEMATURIA DYSURIA

FEVER VOMITING

OTHER LUTS;

DM/HT/PT H/O DRUG INTAKE

PREVIOUS INTERVENTION/ SURGERY

G/E:

L/E:

GENITALIA:
P.R:
PV:

INVESTIGATIONS:

H.B%
PCV% URINE: ALB
SUG
DEP
URINE :C/S :

R.F.T: Bl. UREA
Sr.CREATININE
Sr.ELECTROLYTES
BLOOD SUGAR

X RAY KUB: RT/LT SIZE-

U/S KUB: HUN -

SIZE-

C.T KUB

CONSENT

BOWEL PREPARATION

ESWL

FOLLOW UP:

15 DAYS: FRAGMENTATION SATISFACTORY/ UNSATISFACTORY

SECOND SITTING- YES/NO

FIRST MONTH: SYMPTOMS
X RAY KUB:
U/S KUB:

SECOND MONTH: SYMPTOMS

X RAY KUB:

U/S KUB:

THIRD MONTH: SYMPTOMS

X RAY KUB:

U/S KUB:

RESULT: SUCCESSFUL / FAILURE

MASTER CHART

NO	AGE/SEX	SIDE	SIZE (cms)	HU	COMORBID	NO OF PRIMARY	SEC PROCEDURE	COMPLICATIONS
1	24/M	LT	1.4x1.2	890		1		PAIN
2	36/M	LT	1.1x1	997		1		
3	43/M	RT	1.1x1	782		1		
4	29/M	RT	1.5x1.3	>1230		2	URS/ICL&DJ	DYSURIA
5	18/M	LT	0.9x0.8	862		1		
6	47/F	RT	1.2x1	972	ASTHMA	1		
7	52/M	LT	1X0.8	855		2	URS/ICL &DJ	DYSURIA
8	35/M	RT	1X0.9	755		1		
9	30/M	LT	1.1x1	693		1		
10	21/F	LT	1.1X0.9	844		1		DYSURIA
11	24/M	RT	0.7X0.6	993		1		
12	43/M	LT	1X0.9	911		1		
13	22/M	RT	1.2X1.1	>1050		1	URS/ICL&DJ	
14	49/M	RT	0.8X0.6	884	HT&DM	1		HEMATURIA
15	17/M	LT	0.9X0.8	795		1		
16	28/M	RT	1X0.9	779		1		HEMATURIA
17	18/F	RT	1X0.8	692	ASTHMA	1		PAIN,DYSURIA
18	29/F	LT	0.8X0.7	592		1		
19	39/M	LT	0.6X0.6	783		1		
20	28/F	LT	1.1X0.8	880		1		
21	52/M	RT	1.5X1	788	HT	2	URS/ICL&DJ	HEMATURIA
22	31/M	LT	0.8X0.7	893		1		
23	70/M	LT	1.1X1	904		1	URS/ICL&DJ	
24	28/M	LT	1X0.9	864		1	URS/ICL&DJ	
25	45/F	RT	1.3X1	>1200	HT	2		DYSURIA
26	29/M	LT	1.1X1	764		1		
27	42/M	RT	1.1X1	658		1	URS/ICL&DJ	
28	19/M	LT	1X0.9	596		1		
29	28/M	LT	1.1X0.9	638		1		
30	31/F	RT	0.8X0.6	643		1		DYSURIA
31	52/M	LT	1X0.9	851	DM&H.T	1		HEMATURIA, DYSURIA
32	28/M	RT	1.4x1.2	>1100		2	URS/ICL&DJ	DYSURIA
33	19/M	LT	1.1X1	869		1		PAIN
34	49/F	RT	1X0.9	866		1		DYSURIA
35	23/F	LT	1.2X1.1	>1270		1	URS/ICL&DJ	
36	43/M	RT	1.1X1	778		1		DYSURIA
37	24/M	RT	1X0.8	879		1		
38	21/F	LT	1.2XX1	>1410		1	URS/ICL&DJ	
39	30/M	RT	1X1	987		1		

NO	AGE/SEX	SIDE	SIZE (cms)	HU	COMORBID	NO OF PRIMARY	SEC PROCEDURE	COMPLICATIONS
40	35/M	LT	1X0.9	908		1		
41	52/M	RT	1.1X1	869	H.T	1		PAIN,DYSURIA
42	45/F	LT	1.5X1.1	756		2	URS/ICL&DJ	UTI,DYSURIA
43	18/M	RT	1.2X0.9	>1090		1	URS/ICL&DJ	
44	27/M	LT	1X0.9	789		1		HEMATURIA
45	42/M	RT	0.9X0.8	908		1		
46	36/F	LT	1X1	698		1		
47	25/M	LT	1X0.9	>1110		1	URS/ICL&DJ	
48	35/F	LT	0.9X0.9	940		1		