

# **FACTORS INFLUENCING THE OUTCOME OF ESWL IN UPPER URINARY TRACT STONES.**

Dissertation submitted in partial fulfillment of the requirements of

*M.Ch degree examination*

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

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# CERTIFICATE

This is to certify that this dissertation entitled **FACTORS INFLUENCING THE OUTCOME OF ESWL IN UPPER URINARY TRACT STONES** submitted by **Dr.P.PRABAKARAN** appearing for **M.Ch ( Urology )** degree examination in August 2014 is a original bonafide record of work done by him for the academic period August 2011- July 2014 under direct supervision and guidance in partial fulfillment of requirement of the Tamil Nadu Dr.M.G.R. Medical University, Chennai.

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I, **Dr. P.PRABAKARAN** , solemnly declare that this dissertation titled **FACTORS INFLUENCING THE OUTCOME OF ESWL IN UPPER URINARY TRACT STONES** as done by me at the Kilpauk Medical College Hospital and Government Royapettah Hospital , Chennai under the guidance and supervision of **Dr.K.THIYAGARAJAN M.S.,M.Ch.DNB.**, Professor of Urology, Govt.Kilpauk medical college.Chennai. This dissertation is submitted to the Tamil Nadu Dr.M.G.R. Medical University, Chennai-600032 in partial fulfilment of the University requirements for the award of the degree of M.Ch., Urology.

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## **ABBREVIATION**

ESWL - Extracorporeal shock waves lithotripsy

SWL –Shockwave lithotripsy

KUB - Kidney ,Ureter , Bladder

USG - Ultrasonogram

IVU – Intravenous Urogram

CT –Computed Tomography

HU – Hounsefield Unit

RFT – Renal function test

C/S – Culture & sensitivity

UPJ – Ureteropelvic junction

PCNL – Percutaneous Nephrolithotomy

BMI – Body Mass Index

F1 – Focal point 1

F2 – Focal point 2

SSD – Skin to stone density

EM -Electromagnetic

EL –Electrohydraulic

EMSE - Electromagnetic shock wave Emitter

COM - Calcium oxalate monohydrate

CA -Carboxyapatite

SFR – Stone free rate

MAP - Magnesium ammonium phosphate

NIH –National Institute of Health

AUA – American Urological Association

ROC – ReceiverOperating characteristic curve

AUC – Area under curve

SPSS –Service product for statistical solution

MEDCALC - Medical Calculator

# INTRODUCTION

Stone disease of the urinary tract is common, and many forms of treatment has been in vogue. Until early eighties open surgery and other endoscopic techniques were the treatment modalities available for urolithiasis<sup>1</sup>. Extracorporeal shock waves lithotripsy (ESWL) was introduced by Christian Chaussay in 1980. Since the mid 1980's ESWL has been established as a minimally invasive procedure for a wide indications of urinary stones . This revolutionized the management of the stone disease throughout the world .

ESWL is a safe, effective method to treat urinary lithiasis. ESWL is usually an outpatient procedure. The success rate in ESWL depends on stone location, size, number, and fragility as well as calyceal anatomy and patency of the urinary tract .

ESWL as a modality was recommended for stones less than 2 cm in size. This limit was set in view of high treatment failures and steinstrasse for bigger calculi<sup>2</sup>. Comparing with surgical techniques ESWL only fragments the stone and does not completely remove them from the urinary tract. These fragments should then be passed out spontaneously<sup>3</sup>. The duration for this spontaneous passage varies and the fragments may cause obstruction to the ureter, leading to complications such as hydronephrosis, renal colic and renal failure . The use of Double -J stents has

contributed to successful stone passage and reduced post ESWL morbidity . Hence the double–J–ureteric stent may be used in those patients having stones larger than 2.5cm<sup>4</sup>.

## **AIMS AND OBJECTIVES**

To study the success rate of **ESWL** in treatment of upper urinary tract stones measuring less than 2cm.

To study the various factors influencing the outcome of **ESWL** in upper urinary tract stones

# 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%. It varies by age, sex and race. For men, incidence begins to rise after age 20, peaks between 40 and 60 years and then begin to decline. For women incidence rates seem to be higher in late 20s and then decreasing to 1/1000/year at the age of 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.

Calcium is the most common component of urinary stones comprising about 75% of all stones. Calcium oxalate forms approximately 60%, mixed calcium oxalate and hydroxyapatite form 20% and brushite stones form 2%. Uric acid and Magnesium Ammonium Phosphate (Struvite) stones occur in 10%. Cystine stones are rare comprising around 1%.

Stone disease can be easily diagnosed using imaging studies like X-ray KUB, USG KUB, IVU 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.

IVU provides both anatomical and functional details. IVU helps in assessing the Infundibulo- pelvic angle and Infundibular width in lower pole stones. Disadvantage being the risk of contrast allergy and contrast induced nephropathy.

Non contrast CT KUB is a simple method to detect renal and ureteric calculi, it helps to assess stone burden , stone density and dilatation of pelvicalyceal system, particularly during an episode of acute colic.

### **Course of Untreated stones**

#### **Stones in the calyces<sup>9</sup>**

In the past due to high complications associated with open surgery, urologists were hesitant to remove asymptomatic stones or stones with minimum symptoms.

Traditionally considered indications for the management of a calculus in the renal collecting system include obstruction, pain and infection. This holds true even in today's modern set up. Pin hole surgeries with minimal morbidity to the patients has allowed to expand the indication for treatment to patients with asymptomatic large stones. To decide for intervention a thorough understanding of the natural course of untreated calyceal stones is necessary.



Hubner and Porpaczy (1990) in their study analyzed the natural history of stones in the calyx and followed the patients for an average period of 7.4 years. In 45% of patients the stone size increased, 68% patients developed infection and pain was experienced by 51% of the patients<sup>10</sup>.

Inci and associates (2007) in their study found that in patients with lower pole calculi that are asymptomatic, 1/3<sup>rd</sup> of the stones progressively increased in size and 11% finally underwent a surgical procedure. Most calyceal stones if left alone without any treatment increase in size and develop symptoms of infection and pain<sup>11</sup>.

Reviewing the literature, evidence for treating small (<5mm) stones that are asymptomatic and non obstructive is still lacking. If asymptomatic stones are not treated, advice must be given regarding the necessity for regular follow-up visits because a large fraction of these calculi finally become symptomatic requiring treatment. Decisions regarding management in such conditions should consider the patient's individual risk factors and the preference of the patient.

In pediatric patients, high-risk professionals like pilots, solitary kidney status and women in the reproductive age group contemplating pregnancy, asymptomatic calyceal stones may be considered for treatment.

## **Factors related to the stone**

Stone size, number, volume of stone, composition of the stone and location of the stone within the kidney influence the indications for treatment.

## **Stone Burden influencing treatment<sup>9</sup>**

Size and number of the stone form the most important factor in influencing the decision for the various treatment modalities in patients with renal calculi. Various criteria for size of the stone that would decide the treatment modality whether ESWL or other surgical procedures have been used in previous studies and guidelines. At present renal stones are classified into nonstaghorn and staghorn stones. Controversies regarding surgical treatment mainly arise while managing nonstaghorn stones.

Clayman and associates (1989) <sup>12</sup>in their study concluded that while comparing the results of various treatment modalities like ESWL and PCNL, or while comparing the lithotripsy methods, parameters such as stone-free rate, number of auxiliary procedures and re-treatment rate should be combined to form an effectiveness quotient. This quotient express treatment results better and allow comparison of different modalities of treatment.

The present principle of ESWL is that as stone burden has an inverse relationship with stone free rate, the need for re-treatment and ancillary procedures increases with stone size. Stone burden is not based only on the basis of the largest stone size

but also the total number of stones present. PCNL is more invasive and is associated with increased morbidity. But stone-free rates following PCNL are better than ESWL and are not influenced by the size of the stone (Lingeman et al, 1987)<sup>13</sup>. Ureteroscopy is another treatment modality with limitations of its use being the stone size and overall burden. The stone fragments are either fragmented and removed or vaporized using laser. With a large stone burden, PCNL has a better efficiency in clearing stones when compared to both ESWL or ureteroscopy. Nearly 50% to 60% of renal stones that are single are less than 10 mm in diameter (Cass, 1995<sup>14</sup>; Renner and Rassweiler<sup>15</sup>, 1999; Logarakis et al<sup>16</sup>, 2000). ESWL in these patients is overall satisfactory and is not dependent on stone location or composition.

Patients with stones ranging between 10 and 20 mm are treated oftenly with ESWL as the first-line management. The location and composition of the stone influence the results of ESWL in patients with stones within this size range. The results for ESWL in patients with 10- 20 mm stones in the lower pole are far less (55%) than those in the upper and middle pole calyces (71.8% and 76.5%, respectively) (Saw and Lingeman<sup>17</sup>, 1999).

Composition of the stone is an important factor while deciding the various alternatives for treatment in patients with stones >10 mm, as calculi containing Cystine or Brushite respond less to ESWL treatment. This effect is significant for

stones larger than 15 to 20 mm. Patients with kidney stones between 10- 20 mm with risk factors predicting poor outcome of treatment with ESWL should be counselled regarding other therapeutic modalities. Both PCNL and ureteroscopy are less significantly influenced by location of the stone and composition and satisfactory results can be obtained with these procedures in patients with stones measuring 10-20 mm.

Poor outcomes following ESWL as monotherapy are seen in patients with renal stones >2 cm. This was recognized nearly 20 years back in an NIH Consensus Conference. The 2 cm cut-off for ESWL first mentioned in this conference still holds good in present day scenarios (Consensus Conference, 1988).

Ureteroscopy, as an alternative to ESWL for large stone burden emerged in the 1990s as a considerable treatment option. Grasso and associates<sup>18</sup> (1998) first published in their series, patients with large (>2 cm) upper urinary tract stones treated by ureteroscopy. 1/3rd of patients with stones in the kidney required a re-look endoscopy; and three patients were converted to PCNL. The overall success rate was defined as fragmentation of the stone to size smaller than 2 mm and in this study it was 91% after the second ureteroscopy procedure, which was comparable to PCNL results. 6-month follow-up data was recorded in 25 patients and demonstrated only 60% stone free rates. In 24% residual lower pole fragments was

seen and in 16% patients there was growth of new stones. With improvements in surgical techniques and innovative technologies, ureteroscopy has been used to treat patients with larger stone burdens with acceptable outcome results and morbidity. But these treatment approaches have often resorted to a staged approach to achieve a successful outcome.

### **Stone Composition determining treatment modality<sup>9</sup>**

Stone fragility was first described by Dretler<sup>19</sup> in 1988. It was defined as the readiness with which a stone is fragmented by SWL and varies with stones of different composition.

When adjusted for size, cystine and brushite calculi were the most resistant to SWL followed by calcium oxalate monohydrate as reported by Saw and Lingeman<sup>17</sup> in 1999. Other stones in descending order of resistance to fragmentation are struvite > calcium oxalate dehydrate > uric acid stones.

The type of fragments produced is also influenced by the stone composition. Cystine and calcium oxalate monohydrate result in large pieces that are difficult to clear from the collecting system ( Rutchik and Resnick<sup>20</sup>, 1998). Patients with stones like brushite, cystine or calcium oxalate monohydrate should be treated by ESWL only if the stone size is <1.5 cm. Patients with bigger stones should

preferentially undergo PCNL or ureteroscopy. The outcome of various modalities of intracorporeal lithotripsy is also affected by the stone composition.

Non-contrast-enhanced spiral CT is the most commonly utilized method of investigating patients with suspected renal colic at present. It is also useful to identify the stone composition utilizing the Hounsfield units of the stone. Several reports have been published using this investigative technology.

Mostafavi and associates<sup>21</sup> (1998) were the first to conduct an in-vitro study which utilized the attenuation levels calculated by CT to predict the chemical composition of the urinary tract calculi.

Saw and associates<sup>22</sup> in 2000 also reported that CT was useful to differentiate between stone groups (with each stone containing a minimum of 60% of a single stone composition) on the basis of absolute attenuation values.

Joseph and associates<sup>23</sup> in 2002 reported that outcome of ESWL was significantly lower for those calculi with attenuation values  $> 1000$  Hounsfield units (HU) when compared with those stones with attenuation values  $< 1000$  HU.

### **Renal Anatomic Factors**

Anatomic factors whether congenital or acquired have been shown to influence the rate of stone clearance following ESWL. Congenital anomalies are relatively common in the upper urinary tract and the majority of defects affecting the

drainage of the collecting system are associated with an increased incidence of stone disease. Examples of congenital abnormalities include ureteropelvic junction (UPJ) obstruction, horseshoe kidney, calyceal diverticula and other ectopic or fusion anomalies. Hydronephrosis due to distal obstruction leads to a failure to clear stone fragments after SWL. The lower pole calyces have a dependent position and hence this affects the stone clearance rate after SWL. Hence any patient with distal obstruction should not undergo ESWL treatment. In the presence of concurrent obstruction and infection, ESWL results in life-threatening urosepsis. Patient is very unlikely to clear fragments of the stone unless the distal obstruction is relieved.

### **Calculi in lower pole of kidney**

Considerable controversy exists regarding the treatment of patients with renal calculi in the lower pole. Lingeman and associates<sup>24</sup> (1994) in a meta analytical study first reported the drawbacks of ESWL for treatment of patients with lower pole stones. The study reported that the stone-free outcome achieved with PCNL was superior to that of ESWL (90% and 60% respectively). Since the 1980s, a considerable change in the distribution of renal stones has been noted. There has been an increase in the percentage of ESWL being used to treat patients with lower calyceal stones (2% in 1984 to 48% in 1991) (Lingeman et al<sup>24</sup>, 1994).

Carr et al<sup>25</sup>, 1996 concluded that change in stone distribution can be explained on the aspect of minute radiographically undetectable fragments to gravitate to more dependent calyces after SWL therapy and to act as a nidus for new stone growth . But the factors resulting in an unsuccessful clearance of fragments from the lower pole after SWL are unclear. This gravity-dependent position of the lower pole calyx can impede the passage of stone fragments (Elbahnasy et al<sup>26</sup>, 1998b).

Sampaio and Aragao<sup>27</sup> (1992 ) first described the anatomic factors.

They concluded that a lower pole having multiple infundibula will have poor drainage .This will result in a lesser chance of the clearance of residual stone fragments than that of an inferior pole drained by a single infundibulum receiving fused calyces. Also they concluded that the small diameter of the lower pole infundibulum might hinder passage of stone fragments. They studied the angle formed between the lower infundibulum and the renal pelvis and hypothesized that an obtuse angle ( greater than 90 degrees ) will facilitate better drainage of fragments from the lower pole.

Even with a poorer outcome of SWL treatment for lower pole calculi , a number of urologists advocate this therapy. A survey among urologists performed by Gerber in 2003 found that 65% of urologists would prefer SWL for lower pole stones 1 to 2 cm in size . 2% of urologists will advice SWL to treat stones



greater than 2 cm . But the success rates are generally poorer for SWL of lower pole calculi.

Albala and associates<sup>28</sup> in 2001 performed a multicenter, randomized, prospective study that compared PCNL or SWL as the treatment options for patients with lower pole calculi.. The stone-free rate at 3 months after treatment, as calculated by nephrotomograms, was 37% for those undergoing SWL and 95% for those undergoing PCNL. Significantly , stone clearance from the lower pole after SWL was especially poor as stone size increased above 10 mm. The main advantage was the lower morbidity associated with SWL.

The Lower Pole Stone Study Group which compared ureteroscopy and PCNL for patients with 10- to 25-mm lower pole stones (Kuo et al, 2003a<sup>59</sup>) concluded that the results of the study favored PNL, which had a 100% stone-free rate,as compared to 80% stone free rate for ureteroscopy.

The optimal approach for treatment of lower pole stones continues to evolve even today. SWL is a good option for lower pole stones of 1 cm or less in aggregate size since there is a considerable chance of achieving a stone-free state with minimal morbidity. Patients with lower pole stones of 2 cm or more are best served with PCNL because this offers them the ideal chance for stone clearance as a single procedure. The real controversy lies in treatment of lower pole calculi 10 to 20 mm in diameter. PCNL, SWL and ureteroscopy are all acceptable options.

Factors to be considered before recommending a treatment modality for these patients includes Stone composition and lower pole anatomy. Patients whose SWL treatment has failed, patients known to have stones resistant to SWL and Patients with an acute lower pole infundibulopelvic angle (with or without other unfavorable anatomic features) should be treated with PCNL or ureteroscopy.

### **Clinical Factors**

All coexisting clinical factors which may affect the safety and the efficacy of the selected treatment must be considered.

### **Urinary Tract Infection**

Urinary tract infection associated with renal calculi, will be difficult to eradicate until the offending stones are completely removed. Instead of SWL, for these patients, PCNL or ureteroscopy, both of which permit the complete removal of stone fragments, may be preferable. Though the reported incidence of sepsis after SWL is less than 1%, a staghorn calculus increases this rate substantially to 2.7% to 56% (Lam et al<sup>60</sup>, 1992a). The risk of sepsis increases if the urine culture demonstrates bacterial growth before SWL (Zink<sup>61</sup>, 1988). Furthermore, presence of obstruction increases the risk of sepsis. Therefore, SWL should be advised and performed only if there is no distal obstruction and urine is sterile.

## **Morbid Obesity**

Morbid obesity is defined as body mass index more than 40 or above 100 pounds or body weight more than 200%. In these cases success depends on the physiologic and technical challenges. (Giblin et al, 1995<sup>62</sup>).

SWL is very difficult for morbid obesity patients because of weight limitations on the lithotripter table or gantry, failure to target the stone radiographically, or the skin to stone distance will be more. If the distance more between skin and stone which obstructs the focus of the shockwaves on the stone. A point located beyond F2 may be needed a blast path method which depends on high pressure (Whelan et al, 1988<sup>63</sup>; Locke et al, 1990<sup>64</sup>).

BMI is an inverse relation and important factor for stone clearance after ESWL (Ackermann et al, 1994<sup>65</sup>; Portis et al<sup>66</sup>, 2003).

Stone-to-skin distance (SSD), on CT, has been popularized. It was reported by Perks<sup>39</sup> (2008) that for SSD below or more than 9 cm, the success rates were 79% versus 57% respectively.

Pareek<sup>38</sup> (2005) study showed 20% of success rate and 80% failure rate for SSD more than 10 cm. SSD was a better predictor of failure of treatment than the BMI.

In morbidly obese patients who have a complex renal calculus , PNL is the treatment of choice. For long SSD we can use extralong working sheath and rigid and flexy nephroscope which will help to overcome this problem.

Ureteroscopic approach is usually used for morbidly obese patients with low stone burden (Dash et al, 2002; Natalin et al, 2009). In morbid obese patients ureteroscopy does not have any extra morbidity. (Preminger et al, 2007).

### **Spinal Deformity or Limb Contractures**

Using lithotripter it becomes very cumbersome to position patients with spinal problems and having contractures of limbs.

In such patients we can go for PCNL and ureteroscopy with flexible instruments.

### **Uncorrected Coagulopathy**

After correcting bleeding diathesis in uncorrected coagulopathy patients PCNL or SWL as a treatment is followed.

### **Other Groups**

The adverse effects of shockwaves will be increased when SWL is used for elderly, children, hypertensive and renal failure patients. to overcome this problem we have to reduce the energy and number of shockwaves. (Janetschek et al<sup>67</sup>, 1997; Evan et al<sup>68</sup>, 1998; Lifshitz et al<sup>69</sup>, 1998).

## **Assessment and Fate of Residual Fragments**

In open surgery any size of the stone considered as failure but in ESWL clinically insignificant stones are considered as successful outcome which is best treatment for upper urinary tract calculi . (Newman et al<sup>70</sup>, 1988).

After ESWL the stone clearance will take several days . 85% of the patients didn't have immediate clearance of stone fragments after SWL .The stone clearance is evidenced by residual of stone fragments caused by shockwaves (Drach et al<sup>71</sup>, 1986).

Eventhough there will be spontaneous passage of stone fragments in the initial 3 months there will be a possibility of spontaneous passing of stones even after 24 months of treatment. (Chaussy and Schmiedt<sup>72</sup>, 1984; Graff et al<sup>73</sup>, 1988; Kohrmann et al<sup>74</sup>, 1993). Stone free rate and success rate have been used to define the outcome of ESWL treatment since it was introduced as a treatment for upper urinary tract calculi. Stone free rate means without any residual stone fragments but the success rate means a combination of both clinically insignificant residual stone as well as stone free state. With the use of CT, ultrasound,KUB ,nephrotomography we can find out clinically insignificant residual stones and stone free status make the comparison difficult between the outcome of ESWL and endourological stone removal methods .

Stone size or diameter equal or less than 4 mm is considered as a successful outcome with other factors like sterile urine without any symptoms. (Newman et al<sup>70</sup>, 1988). Complete stone free state will reduce the risk of regrowth and stone recurrence (Singh et al<sup>75</sup>, 1975; Patterson et al<sup>76</sup>, 1987; Newman et al<sup>70</sup>, 1988). After ESWL if there are residual fragments, then the recurrence rate is 17% to 80% but if stone free, the recurrence rate is only 6% to 15%. (Graff et al<sup>77</sup>, 1988; Zanetti et al<sup>78</sup>, 1991; Nakamoto et al<sup>79</sup>, 1993).

### **Extra Corporeal Shockwave Lithotripsy (ESWL)**

Open surgeries for stone diseases are rarely done nowadays as they are replaced by minimally invasive and non-invasive various treatment procedures. Non-invasive procedure like ESWL will produce minimal morbidity.

Lithotripter is a Greek word. In Greek litho means stone and tripter means crusher. Lithotriptors have been evolved after many years of research in the physics of aviation. When a supersonic aircraft flies, the raindrops strike and create shockwaves that disintegrate solid materials. Lithotripter was thus invented by making certain refinements from physics of flight, which will be useful for the treatment of urinary calculi.

Dr. Christian Chaussay<sup>72</sup>, University of Munich first used electrically generated focused shockwaves in February 1980 to fragment the calculus inside the human kidney.

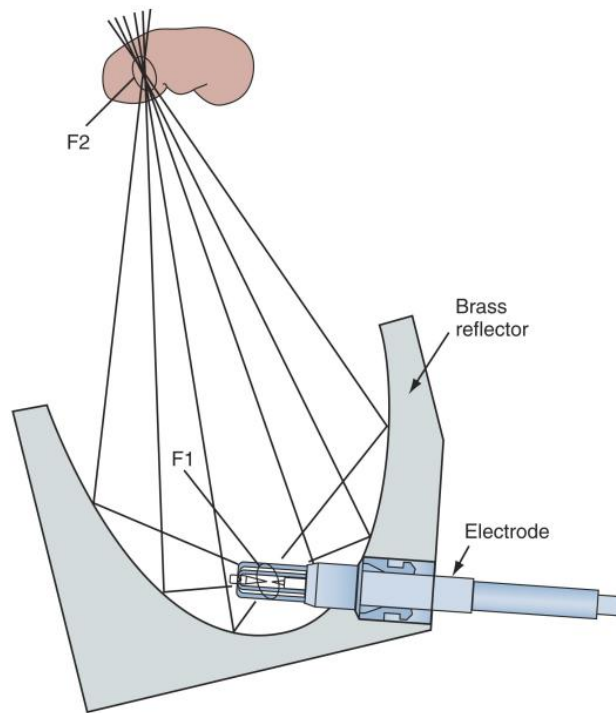
The earliest Lithotripter model HM 1 was soon replaced by HM2 (1982) and by HM 3( 1984)<sup>14</sup>. Each such new generation attempts a progression of technology and a growing sophistication. Also further innovation of the generation is the amalgamation of the lithotripsy control and fluoroscopic screens into an efficient ,convenient, and user friendly console. Lithotripsy technology has made great advances in terms of focusing, patient coupling , shock wave generation and stone localization making it the ideal and most widely used treatment for renal calculi<sup>14</sup>.

## **VARIOUS METHODS OF SHOCK WAVE GENERATION**

Lithotripter Instruments are differentiated by the types of shockwave generators they employ. Modern day Commercially available lithotriptors use Electromagnetic (EM) Electrohydraulic (EH), and Piezoelectric generators<sup>12</sup>.

## ELECTRO HYDRAULIC (SPARK GAP) GENERATORS

The mechanism involves a spherically expanding shockwave generated by an underwater spark discharge (15000-25000V) Electrode at F1 and focused by hemi ellipsoid reflector on to the calculus at F2<sup>12</sup>. Though it is very effective in breaking kidney stones, substantial pressure fluctuations from shock to shock results in a relatively short electrode life.

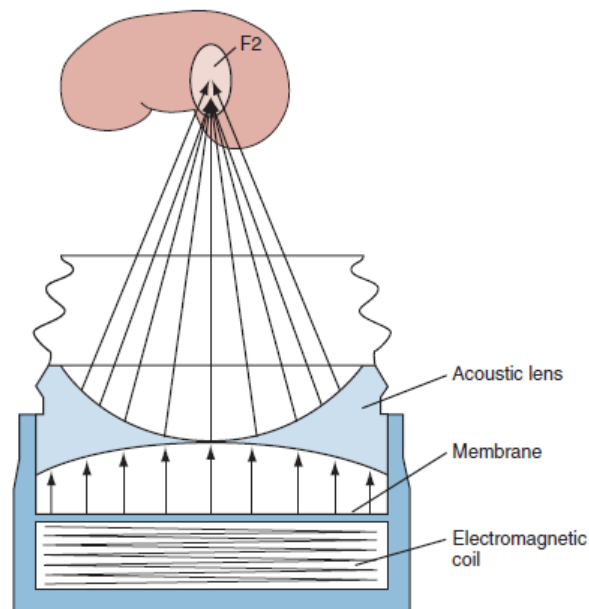




## ELECTROMAGNETIC GENERATORS

EMSE - Electromagnetic shock wave Emitter. The components includes a disk coil which is charged with high voltage pulses (5000-20000V), by which, the membrane lying directly on the coil is thrust outwards<sup>12</sup>. An acoustic lens on the stone helps to focus the shock wave generated.

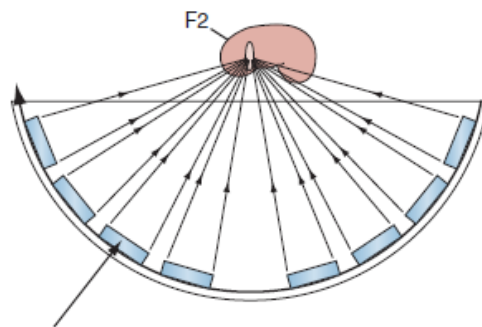
The advantages<sup>66</sup> of electromagnetic generator includes a better controllability and reproducibility. It causes less pain because of the introduction of energy into patients body over a large skin area. The small focussing with high energy densities increases its effectiveness in breaking stones. Disadvantage is also due to the small focal concentration of high energy, resulting in increased rate of subcapsular hematoma formation.



## PIEZOELECTRIC GENERATOR

Piezoelectric energy source uses piezoelectric crystals in a spherical array excited by an electric impulse of 2000-6000V which results in simultaneous sudden expansion and shockwave generation<sup>12</sup>. The resultant waves are focused on to the stone. The advantages are precise focusing , anaesthesia free treatment and a long instrument life .

But the major disadvantage is the insufficient power it delivers, which hampers its ability to effectively break renal stones<sup>66</sup>.



## MECHANISMS OF VARYING STONE FRAGILITY

Stone fragility is the main factor predicting the response of a renal calculus to SWL. This in turn varies with size ,composition and structural features of stone<sup>14</sup>.

Stones with homogenous architecture are less fragile than stones with heterogenous structure. Hardness determines a stone's resistance to cavitation,

microjet impact and fracture. Toughness determines a stone's resistance to spalling damage and crack propagation. Elastic module determines the stone's resistance to shock wave induced deformation. 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 harder, stiffer and more resistant to fracture<sup>66</sup>.

## **MECHANISMS OF STONE FRAGMENTATION**

Stone fragmentation mechanisms 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 are composed of both positive compressive waves and negative tensile waves. Shock waves create bubbles 100-200  $\mu\text{m}$  size that collapse rapidly near the stone surface, producing high speed microjet (770 m/s) which impinges towards the stone surface to cause damage<sup>12</sup>. Numerous minute pits are formed on the anterior surface of stone which is the specific characteristic of cavitation induced surface erosion.

Spalling damage separates the spherical cap from posterior surface of stone. This mechanism 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<sup>66</sup>. Multiple micro

fractures grow and propagate creating large crack lines leading to stone disintegration.

Calculi maintain their form because of innate comprehensive forces.

When tensile strength of a calculus is overcome by opposing force created by shockwaves, Fragmentation occurs. Stone fragmentation occurs by several mechanisms.

The ultimate aim of ESWL is to fragment renal and ureteric calculi as much effectively as possible while minimizing the potential injury to surrounding tissues. Stone fragmentation varies according to stone composition. Cystine stones are most resistant to ESWL<sup>66</sup>. Next in line are Brushite, and Calcium Oxalate Monohydrate.

### **Bioeffects of ESWL**

Shock wave lithotripsy is associated with both acute renal injury and chronic renal changes.

Tables 1 and 2 highlight the Histologic features of acute and chronic changes, Risk factors and aggravating factors for acute renal injury and the mitigating factors for renal injury<sup>68</sup>. Animal models have shown that ESWL can effect both acute and chronic histologic changes in kidney. Acute changes include cellular disruption and necrosis, venous thrombi, tubular necrosis, parenchymal hemorrhage, rupture

of small veins and arteries, rupture of glomerular and periglomerular capillaries<sup>68</sup>. Chronic histologic changes include dilated veins, fibrosis, nephron loss, calcium and hemosiderin deposits and hyalinised scars<sup>68</sup>.

**Table-1 - Acute Renal Side Effects: Risk Factors for Shockwave Lithotripsy**

Age

Obesity

Diabetes mellitus

Preexisting hypertension

Coronary heart disease

Bleeding disorders

Thrombocytopenia

**Table-2 Associated with Shockwave Lithotripsy**

Aggravating Factors

Number of shocks

Duration of shockwave administration—shorter period increases damage

Accelerating voltage—higher the voltage more the damage

Type of shockwave generator—first- vs. second/third-generation devices

Kidney size—juvenile vs. adult

Preexisting renal impairment

Mitigating Factors

Pretreatment with 100 to 500 shocks at low energy level to reduce

lesion size Treatment at a slow rate of shockwave delivery (60 shocks/min)

# **MATERIALS AND METHODS**

## **STUDY DESIGN**

This is a Prospective study of 100 Patients with upper tract stones treated with ESWL at Kilpauk Medical College Hospital, Chennai and Government Royapettah Hospital, Chennai from September 2012 to February 2014

## **INCLUSION CRITERIA**

Upper urinary tract stones  $\leq$  2cms

## **EXCLUSION CRITERIA**

Upper urinary tract stones  $>$  2cms

Pregnant women

Bleeding diathesis

Distal obstruction

In all patients history and physical examination were done. Baseline investigations included Complete Haemogram, RFT, urine C/S, X-ray KUB, USG KUB, IVU and CT KUB. Stone location, stone size, calyceal anatomy and Hounsefield unit of the stone , presence of obstruction and hydronephrosis will be noted.

Bleeding profile (Platelet count, Bleeding time, Clotting time and Prothrombin time), Body mass index (BMI) will also be recorded for each patient .

Patients were explained about the study, ESWL procedure and informed consent were obtained. ESWL was done as outpatient procedure at Rajiv Gandhi Government General Hospital, Chennai. ESWL was done using Dornier Compact Delta II (Electromagnetic Generator) Machine. Patients were administered sedation IV Fortwin (20mg), 30 minutes before procedure.

Patients were followed up after 2 weeks and at 4 weeks, Xray KUB and USG KUB were done to look for residual fragment. Absence of calculi or calculi <4mm will be considered as clearance.



# RESULTS

**Table 1: Descriptive Statistics**

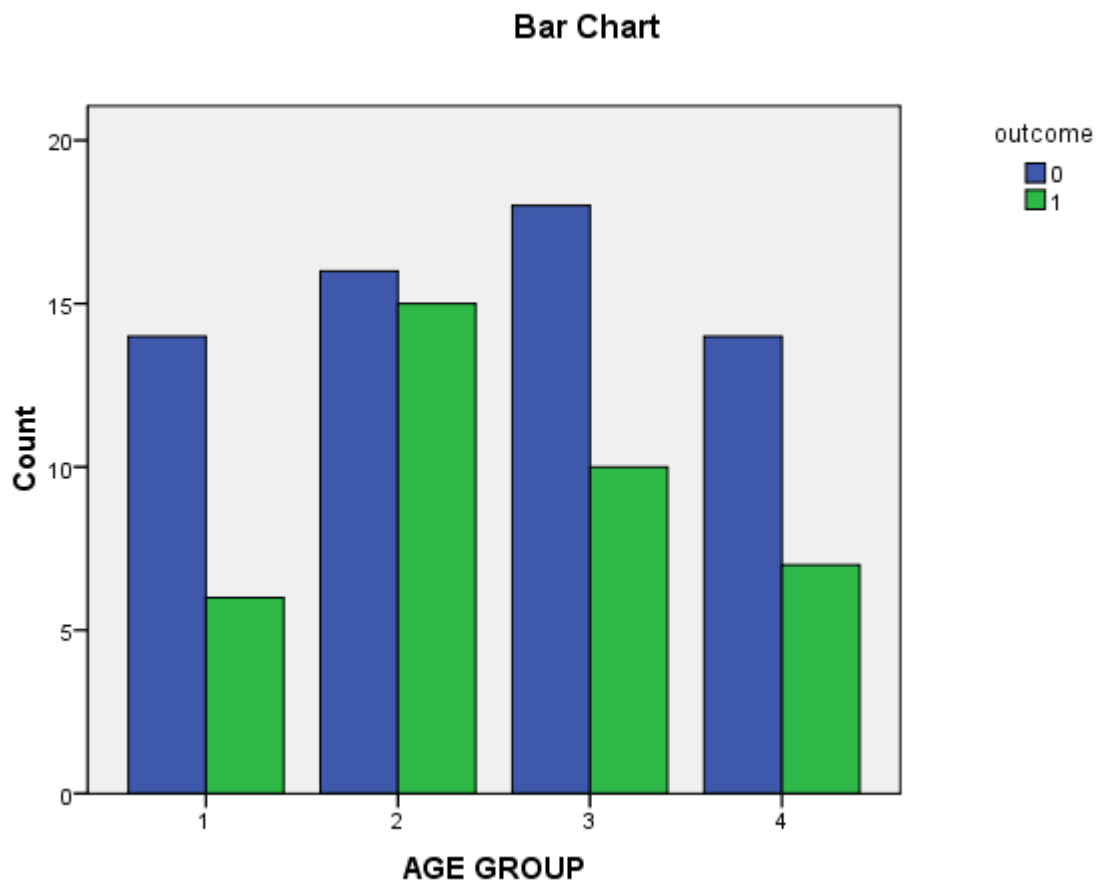
		SEX	STONE SIZE	HU	LOCATION	BMI
N	Valid	100	100	100	100	100
	Missing	0	0	0	0	0
Mean			1.539	769.68		23.86
Median			1.600	760.00		23.50
Std. Deviation			.3856	183.421		3.065
Minimum			.7	400		18
Maximum			2.0	1300		31

**Table 2: Age Group\*Stone Clearance Crosstab**

			outcome		Total
			0	1	
AGE GROUP	<=30	Count	14	6	20
		% within outcome	22.6%	15.8%	20.0%
		% of Total	14.0%	6.0%	20.0%
	31-40	Count	16	15	31
		% within outcome	25.8%	39.5%	31.0%
		% of Total	16.0%	15.0%	31.0%
	41-50	Count	18	10	28
		% within outcome	29.0%	26.3%	28.0%
		% of Total	18.0%	10.0%	28.0%
>50	Count	14	7	21	
	% within outcome	22.6%	18.4%	21.0%	
	% of Total	14.0%	7.0%	21.0%	
Total	Count	62	38	100	
	% within outcome	100.0%	100.0%	100.0%	
	% of Total	62.0%	38.0%	100.0%	

Chi-Square P Value 0.528

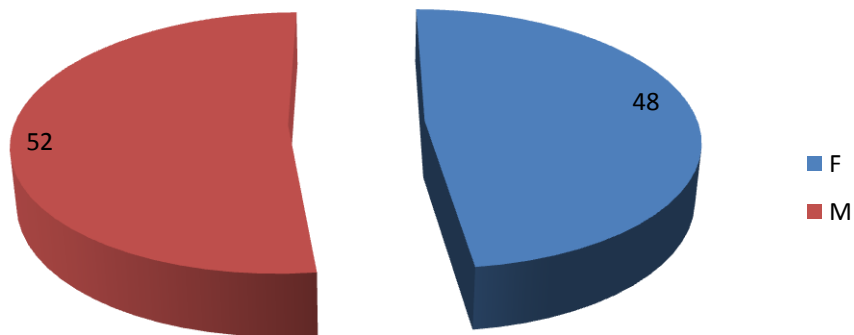
**Chart 1: Age Group\*Outcome**



**Table 3: Sex Distribution**

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid F	48	48.0	48.0	48.0
M	52	52.0	52.0	100.0
Total	100	100.0	100.0	

**Chart 2: Sex Distribution**



**Table 4: Sex\*Outcome Crosstab**

		outcome		Total	
		0	1		
SEX	F	Count	27	21	48
		% within SEX	56.2%	43.8%	100.0%
		% within outcome	43.5%	55.3%	48.0%
		% of Total	27.0%	21.0%	48.0%
SEX	M	Count	35	17	52
		% within SEX	67.3%	32.7%	100.0%
		% within outcome	56.5%	44.7%	52.0%
		% of Total	35.0%	17.0%	52.0%
Total		Count	62	38	100
		% within SEX	62.0%	38.0%	100.0%
		% within outcome	100.0%	100.0%	100.0%
		% of Total	62.0%	38.0%	100.0%

**Chi-Square P value 0.255.**

**Table 5: BMI\*Outcome Crosstab**

			outcome		Total
			0	1	
BMI	<25	Count	44	17	61
		% within outcome	71.0%	44.7%	61.0%
		% of Total	44.0%	17.0%	61.0%
	25-30	Count	18	16	34
		% within outcome	29.0%	42.1%	34.0%
		% of Total	18.0%	16.0%	34.0%
	>30	Count	0	5	5
		% within outcome	.0%	13.2%	5.0%
		% of Total	.0%	5.0%	5.0%
Total	Count	62	38	100	
	% within outcome	100.0%	100.0%	100.0%	
	% of Total	62.0%	38.0%	100.0%	

Chi-Square P value 0.002

Chart 3: BMI\*Outcome

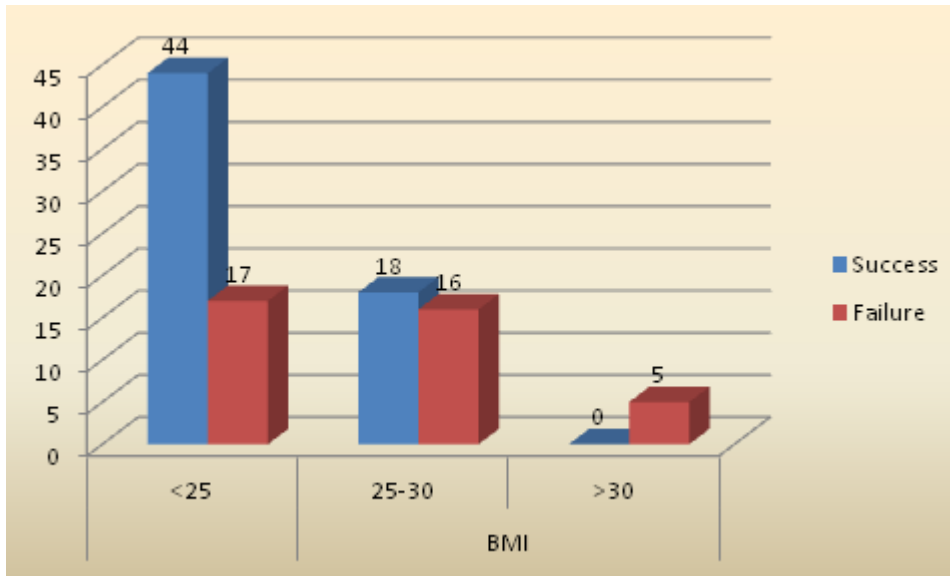


Table 6: Stone Size\*Outcome

		outcome		Total
		0	1	
Sizestone	Count	27	11	38
	<1.5			
	% within Sizestone	71.1%	28.9%	100.0%
	% within outcome	43.5%	28.9%	38.0%
	% of Total	27.0%	11.0%	38.0%
	Count	35	27	62
	>=1.5			
	% within Sizestone	56.5%	43.5%	100.0%
	% within outcome	56.5%	71.1%	62.0%
% of Total	35.0%	27.0%	62.0%	
Total	Count	62	38	100
	% within Sizestone	62.0%	38.0%	100.0%
	% within outcome	100.0%	100.0%	100.0%
	% of Total	62.0%	38.0%	100.0%

Student T test P Value 0.020

Chart 4: Stone Size\*outcome

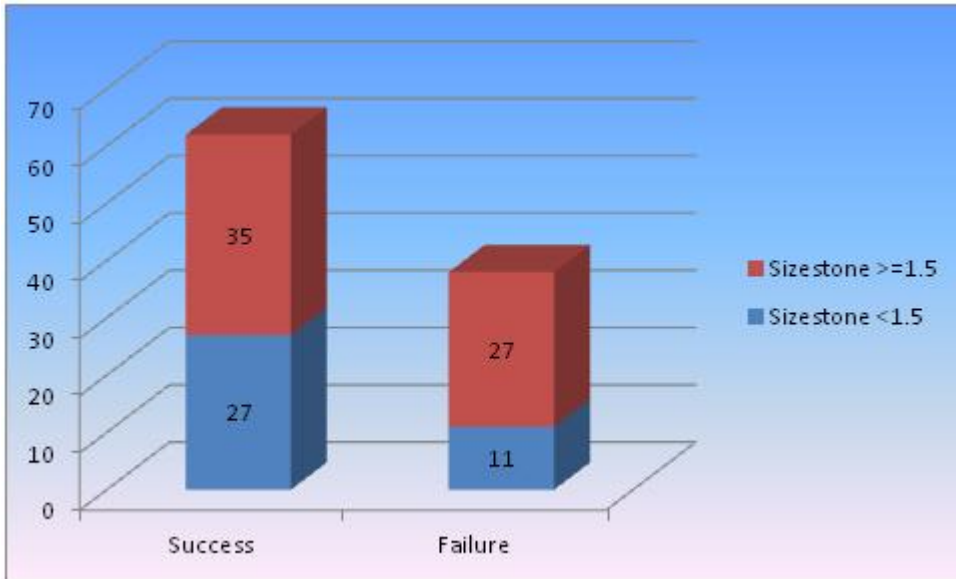
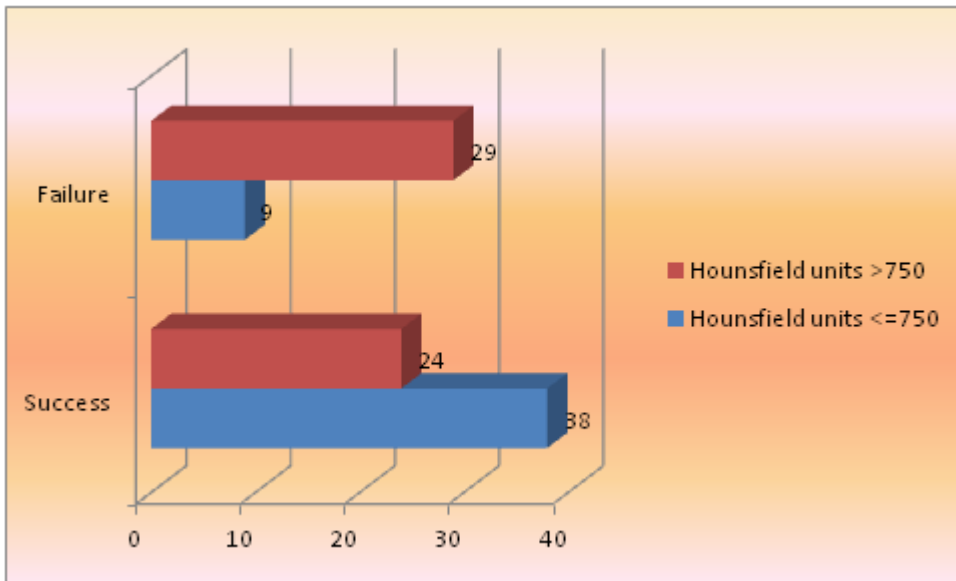


Table 7: HU\*Outcome Crosstab

		Outcome		Total
		0	1	
Hounsfeldunits	Count	38	9	47
	<=750 % within Hounsfeldunits	80.9%	19.1%	100.0%
	% within outcome	61.3%	23.7%	47.0%
	% of Total	38.0%	9.0%	47.0%
	Count	24	29	53
	>750 % within Hounsfeldunits	45.3%	54.7%	100.0%
	% within outcome	38.7%	76.3%	53.0%
	% of Total	24.0%	29.0%	53.0%
	Total	62	38	100
% within Hounsfeldunits	62.0%	38.0%	100.0%	
% within outcome	100.0%	100.0%	100.0%	
% of Total	62.0%	38.0%	100.0%	

Student T test P Value 0.000.

Chart 5: HU\*Outcome



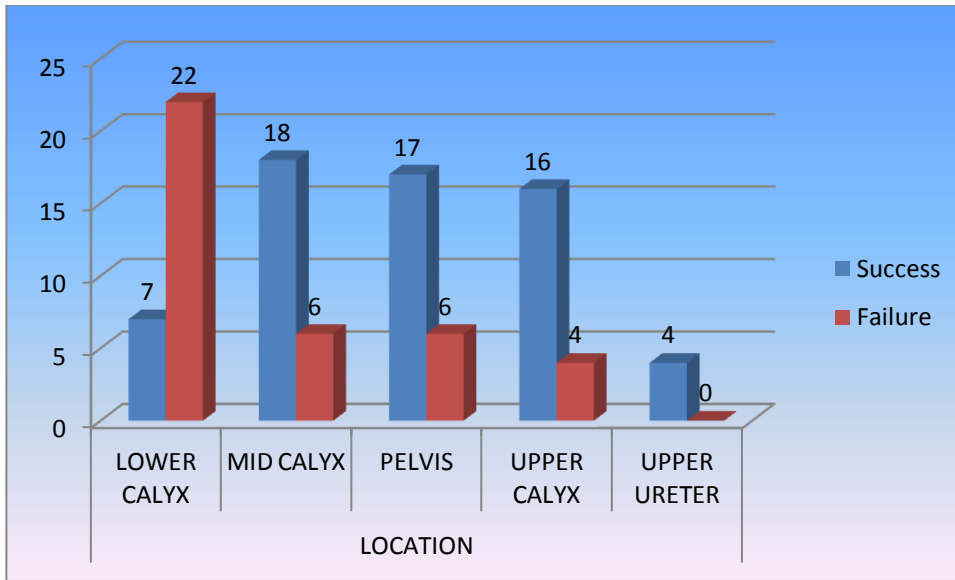
**Table 8: Location\*Outcome Crosstab**

		outcome		Total	
		0	1		
LOCATION	LOWER CALYX	Count	7	22	29
		% within LOCATION	24.1%	75.9%	100.0%
		% within outcome	11.3%	57.9%	29.0%
	MID CALYX	% of Total	7.0%	22.0%	29.0%
		Count	18	6	24
		% within LOCATION	75.0%	25.0%	100.0%
	PELVIS	% within outcome	29.0%	15.8%	24.0%
		% of Total	18.0%	6.0%	24.0%
		Count	17	6	23
	UPPER CALYX	% within LOCATION	73.9%	26.1%	100.0%
		% within outcome	27.4%	15.8%	23.0%
		% of Total	17.0%	6.0%	23.0%
UPPER URETER	Count	16	4	20	
	% within LOCATION	80.0%	20.0%	100.0%	
	% within outcome	25.8%	10.5%	20.0%	
Total	% of Total	16.0%	4.0%	20.0%	
	Count	4	0	4	
	% within LOCATION	100.0%	0.0%	100.0%	
	% within outcome	6.5%	0.0%	4.0%	
	% of Total	4.0%	0.0%	4.0%	
	Count	62	38	100	
	% within LOCATION	62.0%	38.0%	100.0%	
	% within outcome	100.0%	100.0%	100.0%	
	% of Total	62.0%	38.0%	100.0%	

Chi-Square P Value 0.000



Chart 6: Location\*Outcome



## LOGISTIC REGRESSION

### Coefficients and Standard Errors

Variable	Coefficient	Std. Error	P
BMI	0.21417	0.099675	0.0317
LOCATION	3.14933	0.70954	<0.0001
HU	0.0082171	0.0024829	0.0009
Constant	-13.1626		

### Odds Ratios and 95% Confidence Intervals

Variable	Odds ratio	95% CI
BMI	1.2388	1.0190 to 1.5061
LOCATION	23.3205	5.8045 to 93.6936
HU	1.0083	1.0034 to 1.0132

### Hosmer & Lemeshow test

Chi-square	5.6900
DF	8
Significance level	P = 0.6819

**Contingency table for Hosmer & Lemeshow test** [\[Hide\]](#)

Group	Y=0		Y=1		Total
	Observed	Expected	Observed	Expected	
1	10	9.882	0	0.118	10
2	11	10.547	0	0.453	11
3	9	9.325	1	0.675	10
4	8	8.751	2	1.249	10
5	8	7.916	2	2.084	10
6	8	6.746	2	3.254	10
7	2	4.435	8	5.565	10
8	4	2.847	6	7.153	10
9	2	1.321	8	8.679	10
10	0	0.230	9	8.770	9

**ROC curve analysis**

Area under the ROC curve (AUC)	0.901
Standard Error	0.0307
95% Confidence interval	0.825 to 0.952

[Save predicted probabilities](#) - [Save residuals](#)

## ROC curve

Variable	LOGREGR_Pred1
Classification variable	outcome

Sample size		100
Positive group :	outcome = 1	38
Negative group :	outcome = 0	62

Disease prevalence (%)	unknown
------------------------	---------

## Area under the ROC curve (AUC)

Area under the ROC curve (AUC)	0.900891
Standard Error <sup>a</sup>	0.0308
95% Confidence interval <sup>b</sup>	0.824862 to 0.951629
z statistic	13.033
Significance level P (Area=0.5)	<0.0001

<sup>a</sup> DeLong et al., 1988

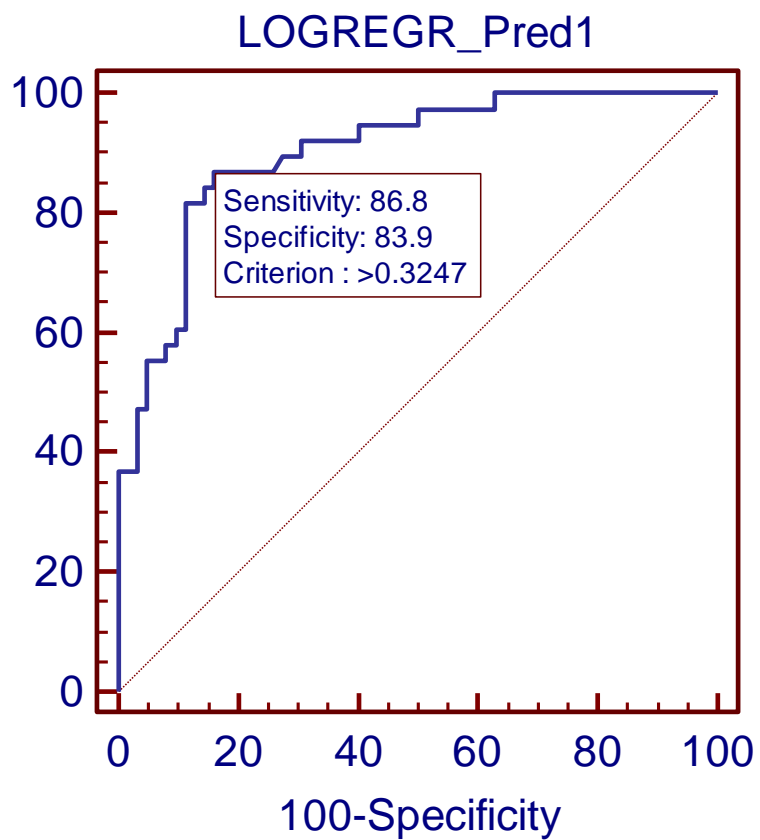
<sup>b</sup> Binomial exact

## Youden index

Youden index J	0.7071
Associated criterion	>0.3247

**Criterion values and coordinates of the ROC curve** [\[Hide\]](#)

Criterion	Sensitivity	95% CI	Specificity	95% CI	+LR	-LR
>0.3247	86.84	71.9 - 95.6	83.87	72.3 - 92.0	5.38	0.16



## SUMMARY OF RESULTS

- 100 patients were included in this analytical study
- Statistical analysis was done using SPSS software version 20 and MEDCALC.
- Univariate analysis for various risk factors influencing the outcome of ESWL was done.
- Logistic regression model using multiple variable was done to calculate ROC curve.
- This study included 100 patients, falling in the age group of 19 to 74 years with a mean age of 40.74 years.
- Age as an independent factor did not significantly correlate to the outcome of ESWL (p value 0.528).
- The next factor considered was the sex of the patient in relation to the outcome of ESWL. In this study there were 52 male patients and 48 female patients.
- Sex of the patient as a univariate factor also did not correlate significantly to the success of ESWL (p value 0.255).
- BMI of the study group was classified into three groups { < 25(61 patients), 25-30(34 patients) and > 30(5 patients)}. The rate of successful ESWL in

these groups were 72%, 52.9% and 0% respectively. The P value according to the Chi square test was 0.002 which showed a significant correlation of BMI with regard to the outcome of ESWL.

- The fourth factor studied was the size of the stone in predicting the outcome of ESWL. The patients were divided into two groups based on the stone size ( $< 1.5\text{cm}$  and  $\geq 1.5$ ).
- 38 patients had stone size  $< 1.5$  cm. This particular group showed a successful outcome of 71%. 62 patients had stone size  $\geq 1.5$  cm with a success rate of 56% which correlated significantly to the outcome of ESWL (p value using T-test 0.020).
- The fifth factor analysed was the density of the stone as assessed by the Hounsefield Units.
- Patients were classified under two categories based on HU value of less or greater than 750 HU. 47 patients had stones with HU less than 750. 80.9% of these patients had a successful outcome of ESWL. The remaining 53 patients had HU more than 750. They had a significantly reduced success rate of 45.3% (p value using T-test- 0.000).
- The next factor considered in the study was the location of the stone in relation to the outcome of ESWL.
- Patients were divided into five groups based on whether the stone was

situated in the upper, middle, lower calyx, renal pelvis or upper ureter.

- 29 patients had lower calyceal stone and 24.1% had a successful outcome in this group following ESWL.
- 23 patients had a stone in renal pelvis and 73.9% had a successful outcome.
- 24 patients had stone in middle calyx with a 75% successful outcome.
- 20 patients had a stone in the upper calyx and 80% of these patients had a successful outcome.
- 4 patients had a stone in the upper ureter and all had a successful outcome.
- This proved conclusively that the location of the stone as an independent factor can significantly predict the positive negative outcome of ESWL, the upper ureteric stones having the best prognosis and the lower calyceal stones having the least successful outcome ( P value using chi-square tests – 0.000).
- Model for multivariate analysis was done using logistic regression analysis to create an ROC curve.
- The factors included in this model were BMI, location and Stone density to predict the outcome following ESWL in upper urinary tract stones < 2 cms. Location of the stone was the most significant factor in this model (p value <0.0001). The model derived has a sensitivity and specificity of 86.8% and 83.9% respectively in predicting the success rate following ESWL.



## DISCUSSION

The ultimate goal of any modality of treatment of upper urinary tract stones is to achieve a 100% stone clearance without causing any morbidity to the patient. The current treatment modalities include percutaneous nephrolithotomy (PCNL), extracorporeal shock wave lithotripsy (ESWL), retrograde intrarenal surgery (RIRS) and in rare cases laparoscopic or open stone surgery. ESWL being a non-invasive technique has added an important dimension to the treatment of stone disease wherein the vast majority of small calculi within the renal system (80 - 85%) can be managed satisfactorily.

ESWL is the preferred modality of treatment for renal stones less than 2cm. However stone free rate (SFR) after treatment has never been near 100% and has been in the range of 65-75%. But its non invasive nature along with high efficacy has resulted in outstanding patient and surgeon acceptance.

Factors affecting stone clearance can be classified into stone factors (size, composition, number, location), renal factors pertaining to anatomy and factors related to the patient.

BMI >30 is a significant factor affecting the success of treatment of upper tract stones. The utility of BMI in predicting successful ESWL is variable.

**Pareek et al**<sup>38</sup> studied the effect of BMI on stone clearance rates. An increased BMI was associated with poor outcomes, which was comparable to this study.

**Thomas & Cass** <sup>29</sup> also reported an overall stone free rate of 68% in obese patients compared to 80 - 85% in non-obese patients. In the contrary, **Hammad Ather et al** <sup>30</sup> did not find BMI to be a predictor for ESWL outcome.

Size of the stone was one of the most important factors determining success of ESWL. Stone size was a significant predictor of a favourable outcome in this study with 71% success reported for stones <1.5cms and 56% for stones >1.5cms.

**Khalil et al** <sup>34</sup> in their analysis of stone free rates after ESWL based on stone location and stone size reported stone free rates for stones less than 1 cm, 1-2 cm, and more than 2 cm at 50.2, 39.6, and 10.2% (P < .05) respectively.

**Abdel-Khalek et al** <sup>35</sup> reported stone free rate as 89.7% for stones <15 mm and 78% for stones >15 mm (p<0.0001).

**Lalak et al** <sup>32</sup> in their series reported an overall stone-free rate of 76%, 66% and 47% for stones of size less than 10 mm, 10 to 20 mm and more than 20 mm respectively. **Newman D et al** <sup>33</sup> in their study found that success rate was 80% with 0-10 mm stones whereas it declined to 60% with size of the stone greater than 30 mm.

All the above studies concluded that size of the stone was one of the most important predictive factor for successful outcome of ESWL.

Stone density has an inverse relation with the ESWL success rate, and CT stone density has a positive correlation with the number of shockwaves needed for fragmentation as concluded from various studies.

**Gupta et al**<sup>37</sup> showed that the worst outcome of ESWL was in patients with calculus densities of more than 750 Hounsfield units and diameters of more than 1.1 cms, and their clearance rate was only 60% while it was 90% for densities below 750 .

**Ouzaid et al**<sup>40</sup> in a prospective study concluded that patients who became stone free or had clinically insignificant stone fragments had a lower density compared with stones in patients with residual fragments [mean (SD) 715 (260) vs. 1196 (171) HU,  $P < 0.001$ ].

**Perks et al**<sup>39</sup> in his study on the role of ESWL for a solitary renal stone of 5–20 mm found the stone attenuation of the successfully treated patients (stone free and complete fragmentation groups) was 837 +/- 277 versus 1092 +/-254 HU for those with treatment failure (incomplete fragmentation;  $P < 0.01$ ).

**Pareek et al**<sup>38</sup> in another prospective study found the difference in the mean HU values for the stone-free patients was 577.8 +/- 182.5 and residual stones groups were statistically significant (910.4 +/-190.2).

**Joseph et al**<sup>36</sup> reported a 95% success rate for calculi  $< 1,000$  HU vs. 55% for stones  $> 1,000$  HU ( $p < 0.01$ ).

The rate of disintegration for stones in the lower calyx treated by ESWL is comparable with stones in other locations within the urinary tract. But the spatial anatomy of the lower calyx is unfavourable for the complete clearance of the fragments.

**Obek et al<sup>44</sup>** in their study about patients with isolated lower pole calculi treated with ESWL reported a stone-free rate of 63%.

**Chen and Stroom<sup>45</sup>** reported a stone-free rate at 1 month following ESWL was 48% and a longer-term stone-free rate after ESWL was 54.3% with isolated lower pole calculi .

In a study by **Lingeman et al<sup>46</sup>** the limitations of ESWL for lower pole stones are highlighted. Patients who underwent ESWL were reviewed and the result was a poor overall stone clearance rate of 60% against 90% for PCNL. Furthermore, higher re-treatment rate was observed when comparing the lower calyx with other intrarenal locations. Successful outcomes for stones measuring less than 10 mm, 10-20 mm and more than 20 mm were 74%, 56%, and 33%, respectively.

**Netto and coworkers<sup>47</sup>** in their study had an overall success rate of 79% for lower calyceal stones. The success rates were 78% for stones <10 mm, 85% for stones measuring 11-20 mm and 50% for stones measuring >20 mm.

**Talic and El Faqih**<sup>43</sup> had a 56% stone free rate for all lower calyceal calculi 3 months following ESWL.

However , **Psihramis and colleagues**<sup>48</sup> reported a higher success rate for lower-caliceal (53%) than for middle- (43%) and upper- (45%) caliceal stones.

**Öbek and associates**<sup>44</sup> in their study reported stone-free rate of 71% for upper, 73% for middle and 63% for lower caliceal stones.

**Graff and colleagues**<sup>49</sup> had similar results, with stone-free rates of 78%, 76%, and 58% for upper pole, Middle and lower pole calculi.

stones residing in upper pole calyces, as well as the renal pelvis and ureteropelvic junction, are associated with the best stone-free rates when treated by SWL.

An analysis was done considering 9 different published series on the management of 8000 stones with ESWL. The stone-free rates for renal pelvic stones varied from 80% for stones measuring less than 10 mm to 56% for larger stones.

**Pace et al**<sup>51</sup> reported a significantly better response to shock wave application in Proximal and midureteric stones than to those in the distal ureter.

**Park et al**<sup>52</sup> managed 301 patients with upper ureteral stones with ESWL. The success rate achieved was 84.3% for stones < 10 mm after a single session. The results for stones measuring > 20 mm were not comparable. The average stone size

in the group treated successfully was 12 mm in comparison to 17 mm in the group that required ancillary treatment.

ESWL was successful for upper ureteral stones < 10 mm in various series. The 1997 AUA Ureteral Stone Clinical Guidelines<sup>53</sup> recommend ESWL as the first line of management for stones <1cm in the proximal ureter, while the ideal treatment for stones > 1 cm still is debatable with both ESWL and ureteroscopy being acceptable options.

The results of treatment for proximal ureteral calculi either in situ or after stent placement range from 57 to 96% with a high re-treatment rate of 5 to 60% .

All these authors were of common opinion that location of the stone was one of the most important predictive factor for successful outcome of ESWL. In this study lower pole calyceal stone clearance was significantly less than that of stones in other locations and is comparable to the above studies.

## CONCLUSION

ESWL is a useful, non invasive modality of treating certain types of upper urinary tract calculi.

The overall success rate of ESWL in this study was 62 % in treating upper urinary tract calculi.

The prognostication of the success of ESWL is possible by identifying certain factors which enable us to easily select the patient group for whom this treatment can be given.

Age and sex of the patient have no role in predicting the successful outcome of ESWL.

BMI of the patient had a significant inverse correlation with successful outcome of ESWL.

Calculi with lesser density(  $HU < 750$ ) and smaller size( $< 1.5\text{cm}$ ) have a better success rates with ESWL.

Calculi of the upper ureter, upper, middle calyces and renal pelvis had a good response rate to ESWL when compared to lower pole calculi.

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## ANNEXURE - 1

**INSTITUTIONAL ETHICAL COMMITTEE**  
**GOVT.KILPAUK MEDICAL COLLEGE,**  
**CHENNAI-10**

**Ref.No.8139/ME-1/Ethics/2012 Dt:06.09.2012.**  
**CERTIFICATE OF APPROVAL**

The Institutional Ethical Committee of Govt. Kilpauk Medical College, Chennai reviewed and discussed the application for approval "A Study on factors influencing the outcome of ESWL in upper urinary tract stones"- For Dissertation purpose submitted by Dr.P.Prabakaran, M.Ch Genito Urinary Surgery, PG Student, KMC, Chennai-10.

The Proposal is APPROVED.

The Institutional Ethical Committee expects to be informed about the progress of the study any Adverse Drug Reaction Occurring in the Course of the study any change in the protocol and patient information /informed consent and asks to be provided a copy of the final report.



  
CHAIRMAN,  
Ethical Committee

Govt.Kilpauk Medical College, Chennai



**Investigations:**

**Hb:**

**TC:**

**DC:**

**RBS:**

**Urea:**

**Creatinine:**

**Urine: Alb**

**Sugar**

**Deposits**

**Urine C/S:**

**X-Ray KUB:**

**USG:**

**IVU:**

**CT-KUB:**

**ESWL:**

**Shockwave frequency:**

**Fragmentation:**

**Residual Calculus:**

## ANNEXURE - 3

NAME	AGE	SEX	LP.NO	DATE	STONE SIZE	NUMBER	HU	LOCATION	BMI	OBST	HN	outcome
KRISHNAN	47	M	1333	12/9/2012	1.6	1	780	MID CALX	26	NO	NO	0
ANSARI	32	M	3213	22/11/2012	1.5	1	890	UPPER CALYX	23	NO	NO	0
ARAYEE	55	F	2040	14/5/2013	1.3	1	560	LOWER CALYX	19	NO	NO	1
ARUMUGAM	43	M	113311	3/12/2012	2	1	650	PELVIS	23	NO	NO	0
BABU	28	M	121123	8/1/2013	1.7	1	780	LOWER CALYX	24	NO	NO	1
VIJAYALAKSHMI	23	F	540	17/1/2013	0.9	1	740	MID CALYX	25	NO	NO	0
PUGHAZHMANI	57	M	130066	21/3/2013	1.2	1	800	PELVIS	21	NO	NO	0
SUBRAMANI	44	M	1322769	20/8/2013	1.3	1	880	LOWER CALYX	24	NO	NO	1
VAMANAN	38	M	114288	17/12/2012	2	1	820	PELVIS	31	NO	NO	1
BABY	32	F	1038	1/10/2012	1.8	1	650	UPPER CALYX	23	no	no	0
HARIBUNISHA	52	F	112849	26/11/2012	1.3	1	780	UPPER CALYX	25	no	no	0
SURESH KUMAR	31	M	725	23/10/2012	2	1	760	PELVIS	23	NO	NO	0
KALAISELVI	34	F	25737	5/9/2012	2	1	460	LOWER CALYX	21	NO	NO	1
KRISHNAKUTTY	47	M	1326	14/10/2012	0.9	1	780	LOWER CALYX	19	NO	NO	1
VASUKI	32	F	1495	18/11/2012	1.5	1	870	UPPER CALYX	24	no	no	0
ARUNACHALAM	43	M	113890	23/09/2012	1.6	1	560	upper ureter	21	NO	NO	0
MUTHU	53	M	2145	14/09/2012	1.5	1	650	UPPER CALYX	23	NO	NO	0
SANDHANAM	25	M	734	23/07/2013	0.7	1	810	MID CALX	25	NO	NO	0
VASANTHA	42	F	115367	31/10/2013	1	1	490	PELVIS	18	NO	NO	0
VADIVEL	38	M	7256	24/9/1012	2	1	1200	LOWER CALYX	19	NO	NO	1
JANAKI	29	F	114987	7/12/2012	1.9	1	780	MID CALX	21	NO	NO	0
VARSHA	19	F	5426	5/6/2013	1.2	1	560	UPPER CALYX	21	NO	NO	0
ERANIAPPAN	48	M	8734	26/05/2013	0.9	1	470	MID CALX	23	NO	NO	0
IMTHIAZ	56	M	940	31/12/2013	1.4	1	1200	LOWER CALYX	24	NO	NO	1
SUBHA	27	F	116762	24/11/2012	1.9	1	470	PELVIS	25	NO	NO	0
DAVID	36	M	129676	24/10/2012	0.9	1	590	MID CALX	24	NO	NO	0
KAVITHA	27	F	940	20/12/2013	2	1	530	LOWER CALYX	23	NO	NO	0
ANITHA	19	F	8345	21/12/2013	1.3	1	620	LOWER CALYX	25	NO	NO	1



JEREMIAH	28 M	9283	19/03/2013	1.4	1	420	UPPER ureter	18	NO	NO	0
SULTHAN	38 M	8362	18/04/2013	0.8	1	720	PELVIS	22	NO	NO	0
KALEESWARI	45 F	119873	23/10/2012	1.8	1	920	MID CALX	31	NO	NO	1
SELVI	35 F	834902	10/8/2013	1.9	1	980	MID CALX	23	NO	NO	1
REVATHI	36 F	832982	17/08/2013	2	1	760	PELVIS	26	NO	NO	0
ABDUL KHADER	26 M	1873	26/07/2013	1.9	1	710	LOWER CALYX	23	NO	NO	0
DEVI	57 F	2932	17/12/2012	0.9	1	740	MID CALX	19	no	no	0
TYSON	35 M	9387	13/05/2013	1.8	1	810	UPPER CALYX	20	NO	NO	1
SINGARAVELAN	25 M	82739	18/05/2013	1.6	1	720	LOWER CALYX	27	NO	NO	0
PARVEEN	36 F	9282	13/02/2013	2	1	840	MID CALX	25	NO	NO	0
AADHAVAN	47 M	3832	17/9/2012	1.4	1	920	MID CALX	30	NO	NO	0
HAKKIM	48 M	282	18/05/2013	1.7	1	980	LOWER CALYX	25	NO	NO	1
JENNIFER	28 F	8263	20/09/2013	1.9	1	560	PELVIS	27	no	no	1
VASANTHI	19 F	9282	20/01/2014	1.4	1	810	LOWER CALYX	21	NO	NO	0
HARRIS	38 M	9281	31/01/2014	2	1	910	UPPER CALYX	31	NO	NO	1
VAMSI	35 M	92872	4/2/2014	0.8	1	920	MID CALX	23	NO	NO	1
VANITHA	26 F	2982	31/05/2013	1.7	1	1200	PELVIS	26	no	no	1
SELVANAYAGI	36 F	9382	14/10/2012	1.9	1	830	UPPER CALYX	23	NO	NO	0
KOTTESHWARI	27 F	2982	12/8/2013	2	1	920	MID CALX	28	NO	NO	1
UDHAY	37 M	9282	16/09/2013	1.9	1	710	PELVIS	23	NO	NO	0
MOHAMMED	36 M	2892	19/03/2013	1.5	1	400	PELVIS	21	NO	NO	0
SENTHIL KUMAR	45 M	5764	08/05/2013	1.6	1	820	UPPER CALYX	27	NO	NO	0
KALIMUTHU	32 M	3124	05/12/2012	1.5	1	910	MID CALYX	22	NO	NO	0
KUPPAMMAL	57 F	5434	09/02/2013	1.3	1	600	LOWER CALYX	26	NO	NO	1
MURUGESHAN	65 M	6494	12/9/2012	1.4	1	560	upper ureter	25	NO	NO	0
SELVANAYAGI	43 F	4943	9/6/2013	1.7	1	740	LOWER CALYX	22	NO	NO	1
JODEESHWARI	48 F	8976	12/8/2013	0.9	1	718	UPPER CALYX	21	NO	NO	0
RAJENDRAN	36 M	6794	21/12/2013	1.2	1	680	PELVIS	19	NO	NO	0
PALANIAMMAL	74 F	34619	23/04/2013	1.3	1	900	LOWER CALYX	24	NO	NO	1
SRIDHAR	28 M	31629	07/05/2013	2	1	840	PELVIS	31	NO	NO	1

RAJITHAM	52	F	645	23/11/2012	1.8	1	730	MID CALYX	22	no	no	0
VASANTHAPRIYA	35	F	34918	27/02/2013	1.3	1	860	MID CALYX	25	no	no	0
BASKAR	48	M	9764	29/12/2012	2	1	760	PELVIS	19	NO	NO	0
UMA MAHESHWARI	36	F	3458	16/04/2013	1.9	1	645	LOWER CALYX	25	NO	NO	1
VENKATESH	46	M	7846	12/09/2012	0.9	1	730	LOWER CALYX	29	NO	NO	1
LEELAVATHI	42	F	7824	23/12/2013	1.5	1	810	UPPER CALYX	21	no	no	0
KRISHNAN	39	M	6597	28/11/2012	1.6	1	580	upper ureter	24	NO	NO	0
SURESH	28	M	3254	04/11/2012	1.5	1	720	MID CALYX	23	NO	NO	0
GANAPATHY	41	M	68975	20/03/2013	0.7	1	743	UPPER CALYX	25	NO	NO	0
SUBBUTHAI	48	F	32784	01/09/2012	1.1	1	590	PELVIS	20	NO	NO	0
GAJARANI	37	F	63248	06/04/2013	2	1	1140	LOWER CALYX	19	NO	NO	1
HARITHA	46	F	96784	20/07/2013	1.9	1	760	UPPER CALYX	24	NO	NO	0
LAKSHMI	51	F	31245	14/11/2013	1.2	1	680	UPPER CALYX	21	NO	NO	0
GANESAN	42	M	65328	31/10/2012	0.9	1	520	MID CALYX	23	NO	NO	0
KESAVAN	35	M	78943	02/02/2013	1.5	1	1260	LOWER CALYX	27	NO	NO	1
GIRIJA	41	F	6784	14/09/2013	1.8	1	540	PELVIS	22	NO	NO	0
CHRISTOPHER	24	M	346187	15/08/2013	1	1	630	UPPER CALYX	24	NO	NO	0
VASANTHAMMAL	43	F	34618	21/09/2013	1.9	1	590	LOWER CALYX	23	NO	NO	0
KUPPAMMAL	68	F	9764	18/09/2012	1.4	1	700	LOWER CALYX	25	NO	NO	1
SHEIKH AHAMED	24	M	3782	31/10/2012	1.3	1	670	MID CALYX	21	NO	NO	0
JANSIRANI	52	F	7391	31/01/2013	1	1	700	PELVIS	22	NO	NO	0
HELEN AMUDHA	44	F	8279	21/03/2013	1.6	1	936	MID CALX	31	NO	NO	1
MARY	31	F	9371	23/03/2013	1.8	1	920	LOWER CALYX	23	NO	NO	1
FAHRID	64	M	8237	04/09/2013	2	1	745	PELVIS	26	NO	NO	0
JEEVA	37	M	9764	12/08/2013	1.7	1	810	LOWER CALYX	23	NO	NO	1
SINDHOORI	43	F	64373	25/12/2013	1	1	640	MID CALX	24	no	no	0
AYEESHA	63	F	9999	16/03/2013	2	1	810	UPPER CALYX	25	NO	NO	1
INIYAN	46	M	87645	20/06/2013	1.5	1	710	LOWER CALYX	27	NO	NO	0
KALAVATHI	61	F	54976	11/12/2012	1.9	1	915	MID CALX	25	NO	NO	0
DEVAN	29	M	3467	23/10/2013	1.4	1	886	MID CALX	30	NO	NO	0

SATHISH	32	M	3917	10/09/2012	1.7	1	1020	LOWER CALYX	25	NO	NO	1
REVATHY	41	F	3461	26/06/2013	1.8	1	1056	PELVIS	27	no	no	1
SELVI	55	F	4389	28/06/2013	1.2	1	780	LOWER CALYX	21	NO	NO	0
ABDUL KHADER	34	M	67894	24/04/2012	2	1	849	UPPER CALYX	28	NO	NO	1
SANKARAN	63	M	316457	29/04/2013	1	1	930	MID CALX	23	NO	NO	1
BENITHA	45	F	3467	18/08/2013	1.8	1	1300	PELVIS	26	no	no	1
PARTHASARATHY	33	M	97846	17/07/2013	1.7	1	850	UPPER CALYX	23	NO	NO	0
MEERJAHAN	41	F	34215	12/12/2013	1.9	1	945	LOWER CALYX	28	NO	NO	1
AROCKIARAJ	52	M	978463	11/09/2012	1.9	1	760	PELVIS	23	NO	NO	0
EZHILARASAN	57	M	64978	25/12/2013	1.5	1	430	UPPER CALYX	21	NO	NO	0
DEVI	34	F	6457	13/09/2012	2	1	960	LOWER CALYX	24	NO	NO	1
WASIM	68	M	6481	23/04/2013	1.8	1	680	PELVIS	27	NO	NO	0

**Key to master chart:**

OBST:           Obstruction  
 HN:             Hydronephrosis  
 HU:             Hounsfield Unit  
 Out come:      0 = Success  
                   1 = Failure

## Annexure-4

The screenshot displays a Turnitin document viewer interface. The main document is titled "The Tamil Nadu Dr. M.G.R. Medical University - Medical - DUE 31-Mar-2014". The document content is as follows:

**INTRODUCTION**

Stone disease of the urinary tract is common, and many forms of treatment have been in vogue. Until early eighties open surgery and other endoscopic techniques were the treatment modalities available for urolithiasis. Extracorporeal shock wave lithotripsy (ESWL) was introduced by Christian Chaussay in 1980. In the mid 1980's ESWL has been established as a minimally invasive procedure with a wide indications of urinary stones. This revolutionized the management of stone disease throughout the world.

ESWL is a safe, effective method to treat urinary lithiasis. ESWL is usually an outpatient procedure. The success rate in ESWL depends on stone location, number, and fragility as well as calyceal anatomy and patency of the

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