COMPARATIVE STUDY OF EXTRACORPOREAL SHOCKWAVE LITHOTRIPSY OUTCOMES FOR RENAL STONES WITH AND WITHOUT STENTING

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CERTIFICATE

This is to certify that this dissertation entitled **"Comparative study of extracorporeal shockwave lithotripsy outcomes for renal stones with and without stenting"** submitted by **Dr. A. ANAND** appearing for **M.Ch (Urology)** degree examination in August 2013 is a original bonafide record of work done by him 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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This is to certify that this dissertation entitled **"Comparative study of extracorporeal shockwave lithotripsy outcomes for renal stones with and without stenting"** is a original bonafide record of work done by **Dr.A. ANAND,** Post Graduate in M.Ch (Urology) under my direct supervision and guidance in partial fulfillment of requirement of the Tamil Nadu Dr.M.G.R. Medical University, Chennai.

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DECLARATION BY THE CANDIDATE

I, **Dr. A. ANAND ,** solemnly declare that this dissertation titled **"Comparative study of extracorporeal shockwave lithotripsy outcomes for renal stones with and without stenting"** was done by me at the Kilpauk Medical College Hospital and Government Royapettah Hospital , Chennai under the guidance and supervision of **Dr.C.Ilamparuthi, M.S.,M.Ch.,DNB.,** Professor of Urology, Govt.Royapettah Hospital.

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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INTRODUCTION

Urolithiasis has afflicted mankind since antiquity. 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.[1] 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 usually an outpatient procedure. ESWL is a safe, effective method to treat urinary lithiasis. 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 was recommended for stone size <2 cm. This size limit was recommended because of problems with high treatment failure rates and steinstrasse for larger calculi. [2] In contrast to traditional methods, however, ESWL does not remove the stone completely but rather fragments it into pieces of various sizes. These must then be passed out of the urinary tract spontaneously .[3] The duration of this passage varies enormously and fragments may obstruct the ureter, thus leading to post-ESWL complications such as renal colic, hydronephrosis, and renal failure . In particular, after the ESWL treatment of larger calculi, a number of fragments may become impacted in the ureter and form a steinstrasse (a part or the whole of ureter is filled with stone fragments). Hence the double–J–ureteric stent may be used in those patients having stones larger than 2.5cm .[4]

Double - J stents are commonly placed in patients before ESWL .[5] The use of Double -J stents has contributed to successful stone passage and reduced post ESWL morbidity but there also have been reports of complications caused by these indwelling ureteral stents .[6] It may causes frequency, dysuria, pain, haematuria, urinary tract infection, fever, [7] and encrustations. Insertion of double-j-stent in patients is still an unresolved issue. [8]

AIMS AND OBJECTIVE

- To compare the outcomes of ESWL with and without stenting for Renal stones measuring 10mm to20 mm.

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.

The most common component of urinary calculi is calcium, which is a major constituent of nearly 75% of stones. Calcium oxalate makes up about 60% of all stones; mixed calcium oxalate and hydroxyapatite, 20%; and brushite stones, 2%. Both uric acid and struvite (magnesium ammonium phosphate) stones occur approximately 10% of the time, whereas cystine stones are rare (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.

Natural History

Calyceal Stones[9]

Hubner et al (1990) in their review on calyceal stones followed up for 7.4 years. Observed that , 45% of the stones increased in size, 68% experienced symptoms of infection, and 51% experienced pain. [10]

Factors to be considered in the treatment of renal stones

Factors to be considered include stone burden, stone location, stone composition, anatomical abnormality, morbid obesity, UTI and uncorrected coagulopathy

Stone factors

Stone size is one of the important determinants of ESWL. Renal stones measuring <10mm have excellent success with ESWL regardless of their location. For stones measuring 10mm – 20 mm the success rate depends on stone location and composition. For stones measuring more than 20 mm monotherapy with ESWL carries poor outcome

Stone composition

when adjusted for size, cystine and brushite calculi are the most resistant to SWL, followed by calcium oxalate monohydrate, struvite, calcium oxalate dihydrate, and uric acid stones.[11]

CT scan has been used to predict the success of ESWL for renal stones based on their Hounsfield unit.

SWL success rates were significantly lower for those calculi with attenuation values greater than 1000 Hounsfield units (HU) than for those calculi with attenuation values less than 1000 HU.[12]

Renal Anatomic Factors[9]

Stone-free rates after ESWL for patients with hydronephrosis or obstruction are poor .Ureteropelvic junction obstruction, horseshoe kidney, ectopic or fusion anomalies as well as calyceal diverticula can hinder stone clearance following ESWL.

Lower Pole Calculi[9]

For stones measuring more than 10 mm stone clearance following ESWL depends on favaroble anatomical factors such as Infundibular width less more than 5mm, Infundibular length less than 3 cm and Infundibulopelvic angle more than 90 degrees.

Extra Corporeal Shockwave Lithotripsy (ESWL)

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

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

In February 1980 Dr. Christian Chaussay, University of Munich first used electrically generated focused shockwaves to fragment stones within a human kidney.

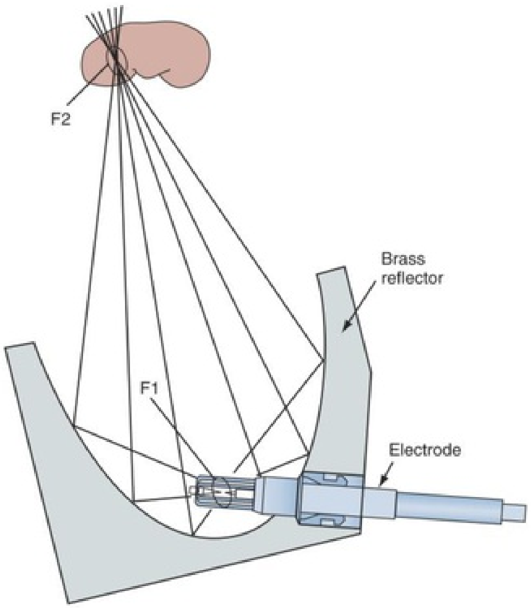
The first Lithotriptor model HM 1 soon replaced by HM 2 in 1982 and in 1984 by Model HM 3. Each new generation reflects progression of technology and a growing sophistication. Further modification of the generation is the consolidation of fluoroscopic screens and the lithotripsy control into a convenient, efficient and user friendly console. Shockwave lithotripsy technology has advanced rapidly in terms of shock wave generation, focusing, patient coupling and stone localization making it the most widely used treatment for renal calculi.

METHODS OF SHOCK WAVE GENERATION

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

ELECTRO HYDRAULIC (SPARK GAP) GENERATORS

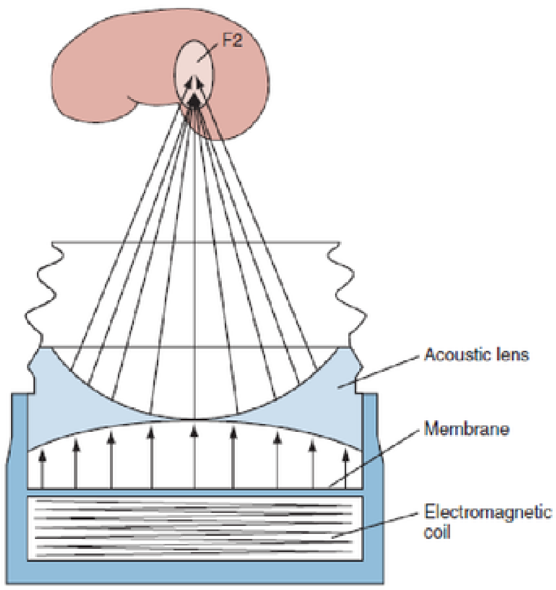
A spherically expanding shockwave is generated by an underwater spark discharge (15000-25000V) Electrode at F1 and focused by hemi ellipsoid reflector on to the calculus at F2. The advantage of this generator is its effectiveness in breaking kidney stones. Disadvantages are substantial pressure fluctuations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



ELECTROMAGNETIC GENERATORS

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

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

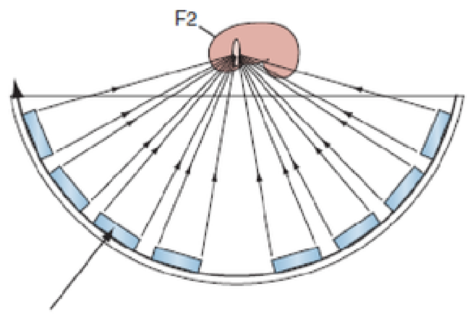


PIEZOELECTRIC GENERATOR

Piezoelectric energy source uses a spherical array of piezoelectric crystals excited by an electric impulse of 2000-6000V. This results in simultaneous sudden expansion and shockwave generation. These waves are focused on to the stone.

The advantages are the focusing accuracy, a long service life, and anaesthesia free treatment.

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



MECHANISMS OF VARYING STONE FRAGILITY

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

MECHANISMS OF STONE FRAGMENTATION

Damage methods are surface erosion at the anterior surface of stone, spalling damage at the posterior surface of stone and layer separation at the interface of adjacent stone laminar surface. Shock Waves composed of positive compressive waves and negative tensile waves. Shock waves produce bubbles 100-200 ms size which collapse rapidly near the stone surface, producing high speed microjet (770 m/s) that impinge towards the stone surface to cause damage. On the anterior surface of stone numerous minute pits are formed. It is the specific characteristic of cavitation induced surface erosion.

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

Calculi maintain their form because of innate comprehensive forces.

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

The ultimate goal of ESWL is to fragment renal and ureteric calculi as effectively as possible with minimizing the potential injury to surrounding tissues.
Stone fragmentation varies according to stone composition cystine stones are most ESWL resistant. Next are Brushite, and Calcium Oxalate Monohydrate.

Bioeffects of ESWL

ESWL is associated with both acute renal injury and chronic renal changes. Histologic features of acute and chronic changes, Risk factors and aggravating factors for acute renal injury and the mitigating factors for renal injury are shown in the tables 1 and 2. Animal models has shown that ESWL can effect both acute and chronic histologic changes in kidney. Acute changes include venous thromi, cellular disruption and necrosis, tubular necrosi, parenchymal hemorrhage, rupture os small veins and arteries, rupture of glomerular and periglomerular capillaries. Chronic histologic changes include nephron loss, dilated veins, fibrosis, calcium and hemosidirin deposits and hyalinised scars.

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

Age
Obesity
Coagulopathies
Thrombocytopenia
Diabetes mellitus
Coronary heart disease
Preexisting hypertension

Table -2 Associated with Shockwave Lithotripsy

Aggravating Factors
Number of shocks
Period of shockwave administration—shorter period increases damage
Accelerating voltage—higher voltage increases 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 or less)

DJ Stents

Ureteral stents are fundamental to many urological procedures. While stents serve many functions, including relief of renal obstruction, they are most commonly used after diagnostic and therapeutic endoscopic procedures. A number of significant improvements in stent design and materials have been made, although infection and encrustation remain significant problems when chronic stent use is required. In addition, long-term indwelling ureteral stents may cause serious complications. Urologists should have a clear understanding of stent materials and design as well as of the appropriate indications for stent placement, etiology of stent related complications and methods to address and manage these problems.

STENT USE FOLLOWING SWL

At a number of facilities stents are routinely placed before SWL to prevent renal obstruction from stone fragments. It remains controversial whether steinstrasse following SWL can be prevented by pre-SWL stent placement. Studies have shown that stenting before SWL does not affect the rate of steinstrasse, while other investigations suggest that pre-SWL stenting prevents fragment obstruction following SWL.[13] Definitive recommendations have not been made by the American Urological Association guidelines committee but a number of studies support in situ SWL without stent placement before the procedure, citing equivalent or better clearance rates in the nonstented cohort without known stent related morbidities.[14-17] While no statistical difference in stone passage was demonstrated, 1 study showed that patients stented before SWL had more stent related symptoms (urgency, frequency and dysuria) but fewer hospital readmissions and emergency room visits following treatment.[18] Overall stenting for routine SWL is not indicated based on the body of literature to date.

Glenn Preminger et al [19](2007) stated that stenting is not mandatory after uncomplicated simple ureteroscopy and shock wave lithotripsy, though it remains a common practice. Patients with stents seem to have significantly more bladder and lower urinary tract symptoms than those in whom stents are not placed. However, there is a subgroup of patients who likely benefit from stenting following a procedure because of the increased risk of complications.

COMPLICATIONS OF STENTS

Although stents have proven benefits for stone management, often they are associated with significant patient discomfort. In a number of contemporary studies up to 85% to 90% of stented patients reported irritative voiding symptoms, including frequency, urgency, dysuria, flank pain, suprapubic pain and hematuria.[20] Stent migration has been described in a proximal or distal direction and if the stent migrates through the urinary sphincter, it may cause urinary incontinence.[21] Patient noncompliance or poor administration of a stent registry may lead to retained ureteral stents and their attendant complications. Removal of retained stents may be complicated by severe encrustation, large stone formation, recurrent urinary tract infection and hematuria.[22,23] Severe encrustation and resultant stone formation may lead to obstruction, which may eventually threaten the renal unit and may even lead to death.[23,24] Retained stents producing hydronephrosis have been reported by several groups.[23-25]

Stent fragmentation is a relatively rare complication with a reported prevalence of 0.3% to 10%.[25,26] The clinical presentation of a fragmented ureteral stent may be sepsis, hemorrhage or pain. Rapid disintegration associated with urinary tract infections and spontaneous excretion of fragments have also been reported.[27]

MATERIALS AND METHODS

STUDY DESIGN

This is a Prospective study of 150 Patients with renal stones treated with ESWL at Kilpauk Medical College Hospital, Chennai and Government Royapettah Hospital, Chennai during January 2011 to December 2012

INCLUSION CRITERIA

- All patients with Renal stones measuring 1- 2 cms in size are included in the study

EXCLUSION CRITERIA

- Stones < 1 cm or > 2 cm
- Renal anomaly – Horse shoe kidney, Malrotated kidney
- Calyceal diverticulum
- Distal obstruction
- Uncontrolled infection
- Coagulation disorder
- Pregnancy
- Previous renal surgery

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, favorable/unfavorable lower pole calyceal anatomy and Hounsefield unit of the stone were recorded.

Patients were explained about the study, ESWL procedure and informed consent were obtained. Patients were randomly allotted to stented and Insitu group.

Stenting was done under regional anaethesia using a rigid cystoscope, in difficult cases stenting was done using rigid Ureteroscope .

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. Presence of residual fragments (>4mm) after 2 sittings of ESWL is taken as treatment failure.

RESULTS

- 150 patients were included in this study
- They were randomized into two groups of 75 patients each
- Group A was stented before ESWL
- Group B was treated with ESWL without stenting.

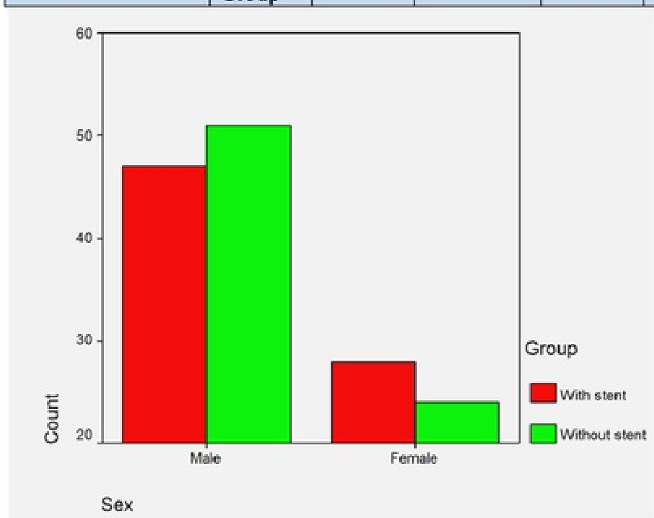
Age Distribution

	Group	N	Mean	Std. Deviation	Std. Error Mean	P-value (T-Test)
Age	With stent	75	40.91	12.660	1.462	0.239
	Without stent	75	43.43	13.453	1.553	

Age distribution table shows that both the groups are comparable statistically.

Sex

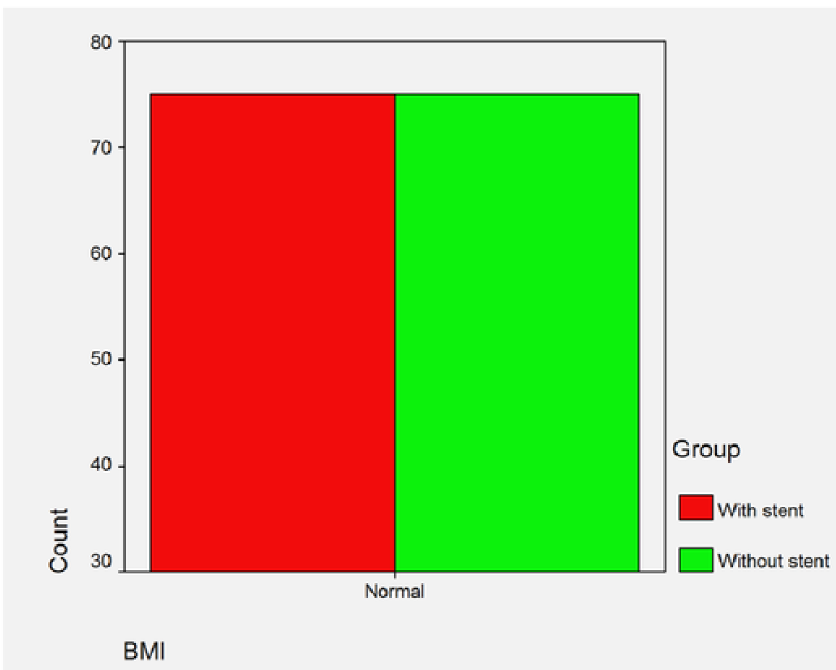
			Group		Total	p-value (Chi-Square Tests)
			With stent	Without stent		
Sex	Male	Count	47	51	98	0.493
		% within Sex	48.0%	52.0%	100.0%	
		% within Group	62.7%	68.0%	65.3%	
	Female	Count	28	24	52	
		% within Sex	53.8%	46.2%	100.0%	
		% within Group	37.3%	32.0%	34.7%	
Total		Count	75	75	150	
		% within Sex	50.0%	50.0%	100.0%	
		% within Group	100.0%	100.0%	100.0%	



Sex distribution table/Bar chart shows that both the groups are comparable statistically.

BMI

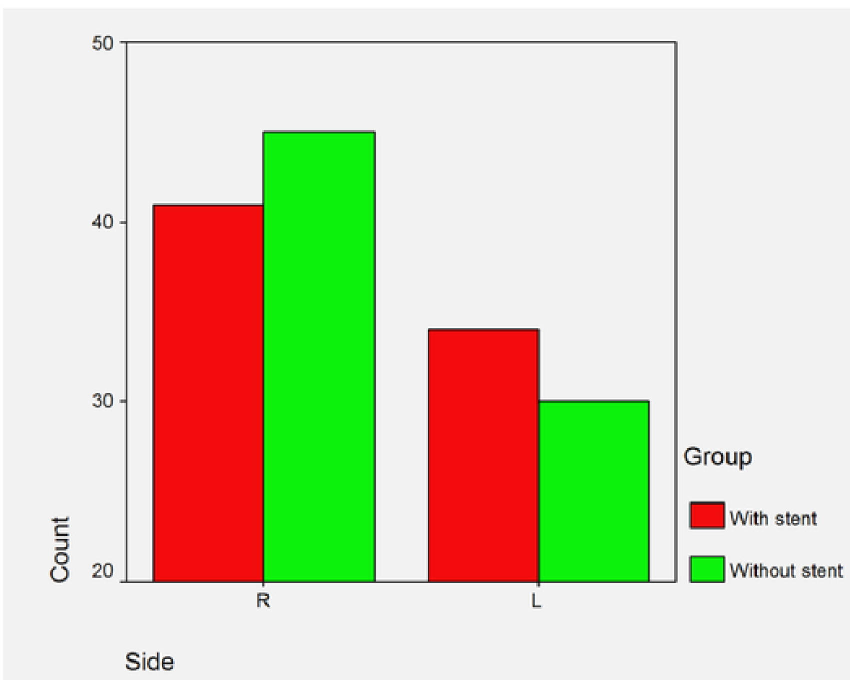
			Group		Total
			With stent	Without stent	
BMI	Normal	Count	75	75	150
		% within BMI	50.0%	50.0%	100.0%
		% within Group	100.0%	100.0%	100.0%
Total		Count	75	75	150
		% within BMI	50.0%	50.0%	100.0%
		% within Group	100.0%	100.0%	100.0%



BMI distribution table/Bar chart shows that both the groups are comparable statistically

SIDE

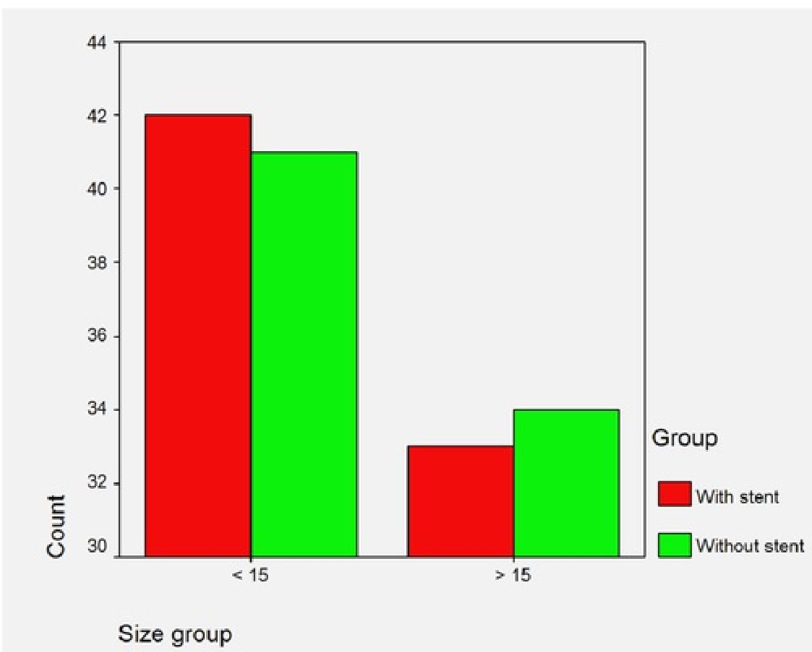
			Group		Total	P-value (Chi-square test)
			With stent	Without stent		
Side	Right	Count	41	45	86	0.509
		% within Side	47.7%	52.3%	100.0%	
		% within Group	54.7%	60.0%	57.3%	
	Left	Count	34	30	64	
		% within Side	53.1%	46.9%	100.0%	
		% within Group	45.3%	40.0%	42.7%	
Total		Count	75	75	150	
		% within Side	50.0%	50.0%	100.0%	
		% within Group	100.0%	100.0%	100.0%	



Side distribution table/Bar chart shows that both the groups are comparable statistically

Size

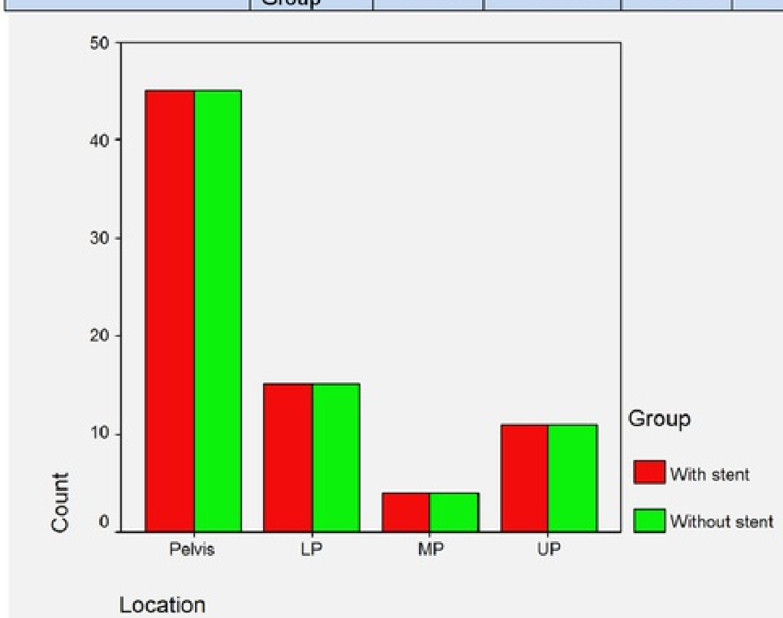
			Group		Total	P-value (Chi-square test)
			With stent	Without stent		
Size group	< 15	Count	42	41	83	0.87
		% within Size group	50.6%	49.4%	100.0%	
		% within Group	56.0%	54.7%	55.3%	
	> 15	Count	33	34	67	
		% within Size group	49.3%	50.7%	100.0%	
		% within Group	44.0%	45.3%	44.7%	
Total		Count	75	75	150	
		% within Size group	50.0%	50.0%	100.0%	
		% within Group	100.0%	100.0%	100.0%	



Size distribution table/Bar chart shows that both the groups are comparable statistically

Location

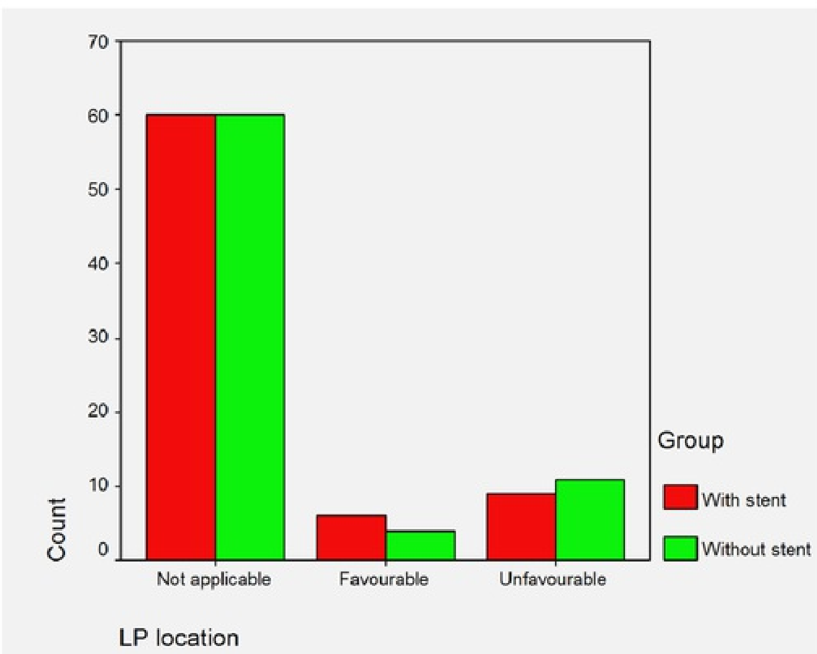
			Group		Total	P-value (Chi-square test)
			With stent	Without stent		
Location	Pelvis	Count	45	45	90	1.0
		% within Location	50.0%	50.0%	100.0%	
		% within Group	60.0%	60.0%	60.0%	
	LP	Count	15	15	30	
		% within Location	50.0%	50.0%	100.0%	
		% within Group	20.0%	20.0%	20.0%	
	MP	Count	4	4	8	
		% within Location	50.0%	50.0%	100.0%	
		% within Group	5.3%	5.3%	5.3%	
	UP	Count	11	11	22	
		% within Location	50.0%	50.0%	100.0%	
		% within Group	14.7%	14.7%	14.7%	
Total		Count	75	75	150	
		% within Location	50.0%	50.0%	100.0%	
		% within Group	100.0%	100.0%	100.0%	



Stone location distribution table/Bar chart shows that both the groups are comparable statistically

Lower pole (LP) location

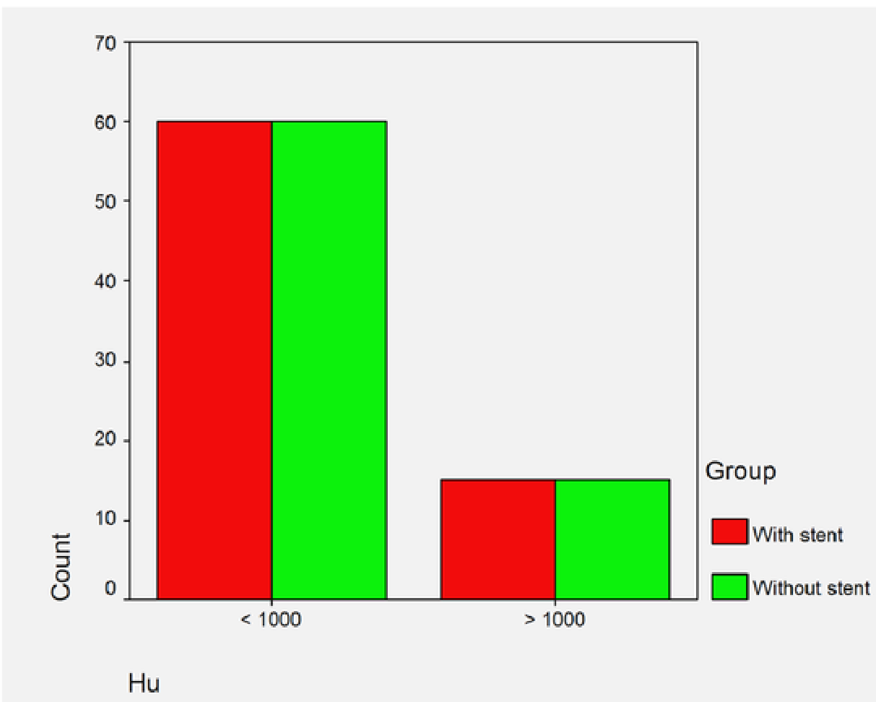
			Group		Total	P-value (Chi-square test)
			With stent	Without stent		
LP location	Not applicable	Count	60	60	120	0.741
		% within LP location	50.0%	50.0%	100.0%	
		% within Group	80.0%	80.0%	80.0%	
	Favourable	Count	6	4	10	
		% within LP location	60.0%	40.0%	100.0%	
		% within Group	8.0%	5.3%	6.7%	
	Unfavourable	Count	9	11	20	
		% within LP location	45.0%	55.0%	100.0%	
		% within Group	12.0%	14.7%	13.3%	
Total		Count	75	75	150	
		% within LP location	50.0%	50.0%	100.0%	
		% within Group	100.0%	100.0%	100.0%	



Lower pole stone location table/Bar chart shows that both the groups are comparable statistically

Hounsefield units (Hu)

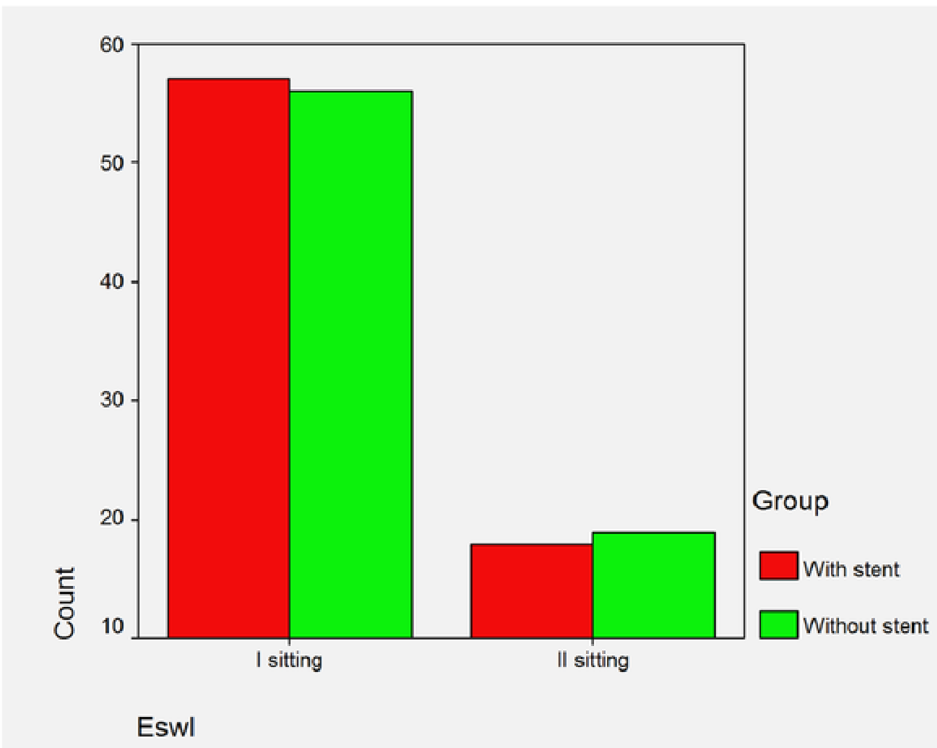
			Group		Total	P-value (Chi-square test)
			With stent	Without stent		
Hu	< 1000	Count	60	60	120	1.0
		% within Hu	50.0%	50.0%	100.0%	
		% within Group	80.0%	80.0%	80.0%	
	> 1000	Count	15	15	30	
		% within Hu	50.0%	50.0%	100.0%	
		% within Group	20.0%	20.0%	20.0%	
Total		Count	75	75	150	
		% within Hu	50.0%	50.0%	100.0%	
		% within Group	100.0%	100.0%	100.0%	



Hounsefield units for stones distribution table/Bar chart shows that both the groups are comparable statistically

Eswl – Number of sittings

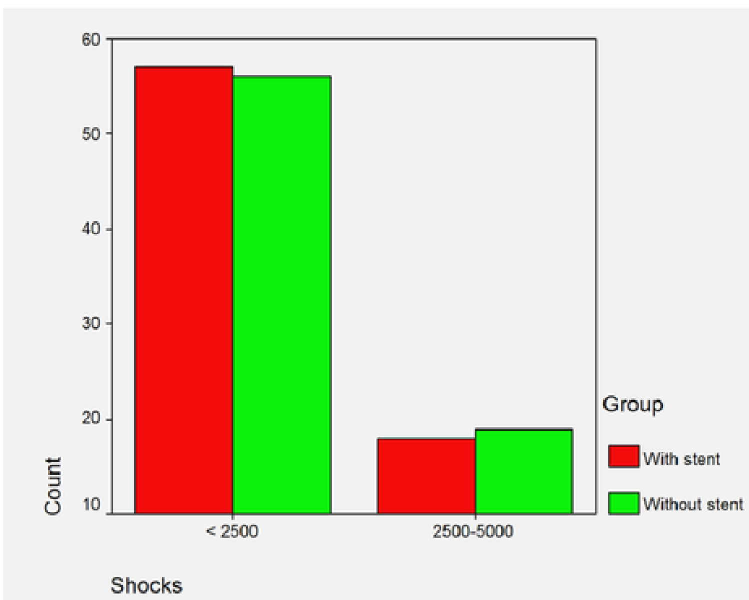
			Group		Total	P-value (Chi-square test)
			With stent	Without stent		
Eswl	I sitting	Count	57	56	113	0.85
		% within Eswl	50.4%	49.6%	100.0%	
		% within Group	76.0%	74.7%	75.3%	
	II sitting	Count	18	19	37	
		% within Eswl	48.6%	51.4%	100.0%	
		% within Group	24.0%	25.3%	24.7%	
Total		Count	75	75	150	
		% within Eswl	50.0%	50.0%	100.0%	
		% within Group	100.0%	100.0%	100.0%	



Number of ESWL sittings distribution table/Bar chart shows that there is no statistical significant difference observed between the two groups.

Number of Shocks

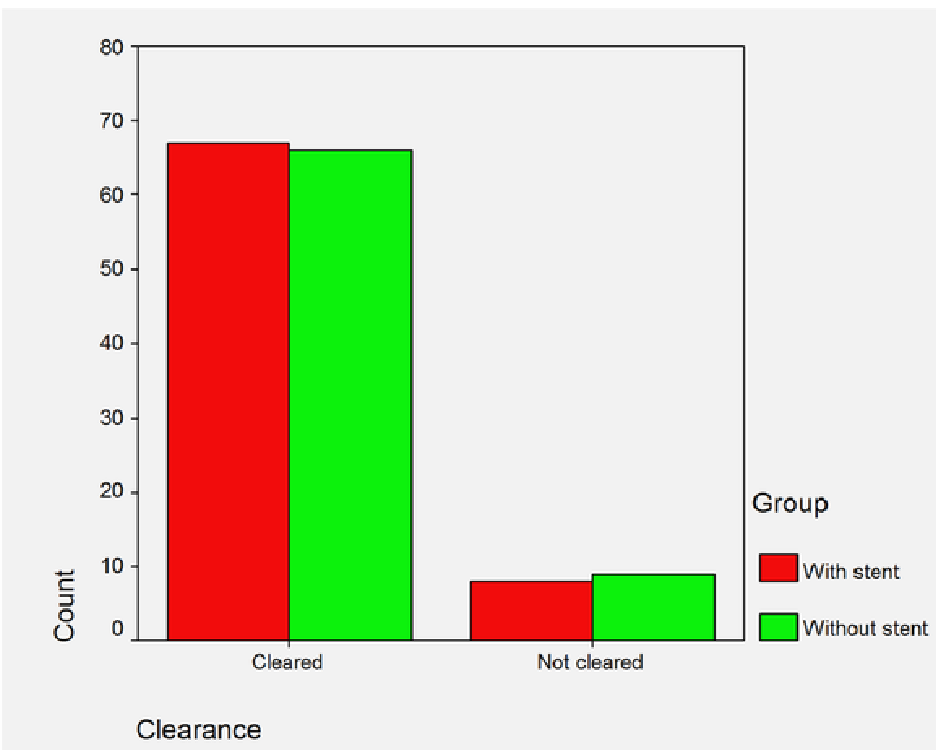
			Group		Total	P-value (Chi-square test)
			With stent	Without stent		
Shocks	< 2500	Count	57	56	113	0.85
		% within Shocks	50.4%	49.6%	100.0%	
		% within Group	76.0%	74.7%	75.3%	
	2500-5000	Count	18	19	37	
		% within Shocks	48.6%	51.4%	100.0%	
		% within Group	24.0%	25.3%	24.7%	
Total		Count	75	75	150	
		% within Shocks	50.0%	50.0%	100.0%	
		% within Group	100.0%	100.0%	100.0%	



Number of shock waves distribution table/Bar chart shows that there is no statistically significant difference observed between the two groups.

Clearance

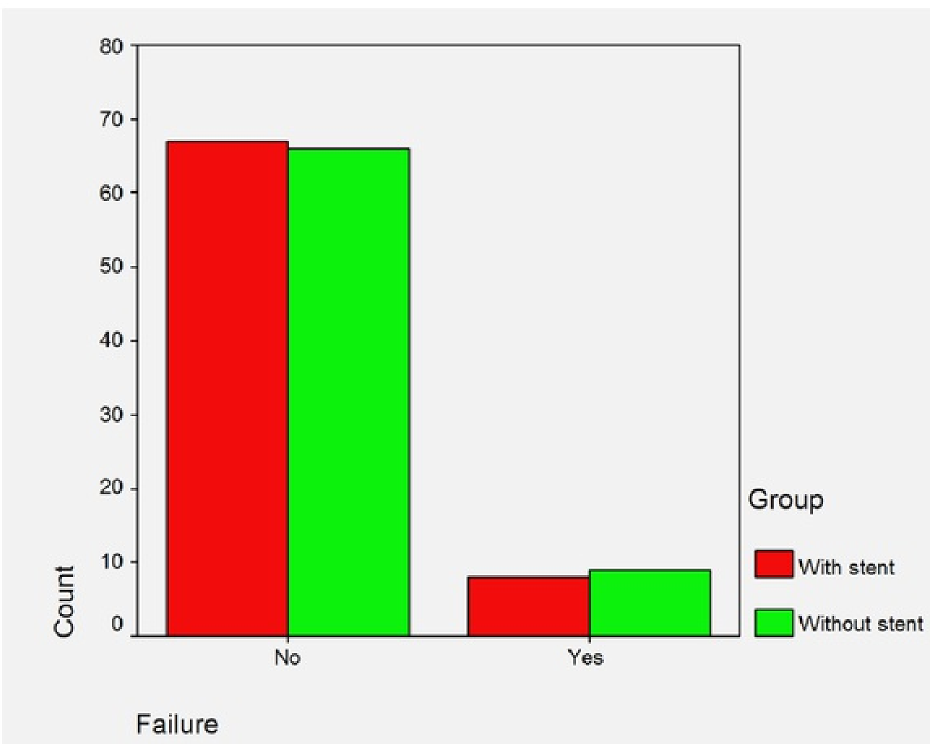
			Group		Total	P-value (Chi-square test)
			With stent	Without stent		
Clearance	Cleared	Count	67	66	133	0.797
		% within Clearance	50.4%	49.6%	100.0%	
		% within Group	89.3%	88.0%	88.7%	
	Not cleared	Count	8	9	17	
		% within Clearance	47.1%	52.9%	100.0%	
		% within Group	10.7%	12.0%	11.3%	
Total		Count	75	75	150	
		% within Clearance	50.0%	50.0%	100.0%	
		% within Group	100.0%	100.0%	100.0%	



Stone clearance distribution table/Bar chart shows that there is no statistically significant difference observed between the two groups.

ESWL Failure

			Group		Total	P-value (Chi-square test)
			With stent	Without stent		
Failure	No	Count	67	66	133	0.797
		% within Failure	50.4%	49.6%	100.0%	
		% within Group	89.3%	88.0%	88.7%	
	Yes	Count	8	9	17	
		% within Failure	47.1%	52.9%	100.0%	
		% within Group	10.7%	12.0%	11.3%	
Total		Count	75	75	150	
		% within Failure	50.0%	50.0%	100.0%	
		% within Group	100.0%	100.0%	100.0%	



ESWL failure distribution table/Bar chart shows that there is no statistically significant difference observed between the two groups.

Steinstrasse

			Group		Total	P-value (Chi-square test)
			With stent	Without stent		
Steinstrasse	No	Count	73	72	145	0.649
		% within Steinstrasse	50.3%	49.7%	100.0%	
		% within Group	97.3%	96.0%	96.7%	
	Yes	Count	2	3	5	
		% within Steinstrasse	40.0%	60.0%	100.0%	
		% within Group	2.7%	4.0%	3.3%	
Total		Count	75	75	150	
		% within Steinstrasse	50.0%	50.0%	100.0%	
		% within Group	100.0%	100.0%	100.0%	

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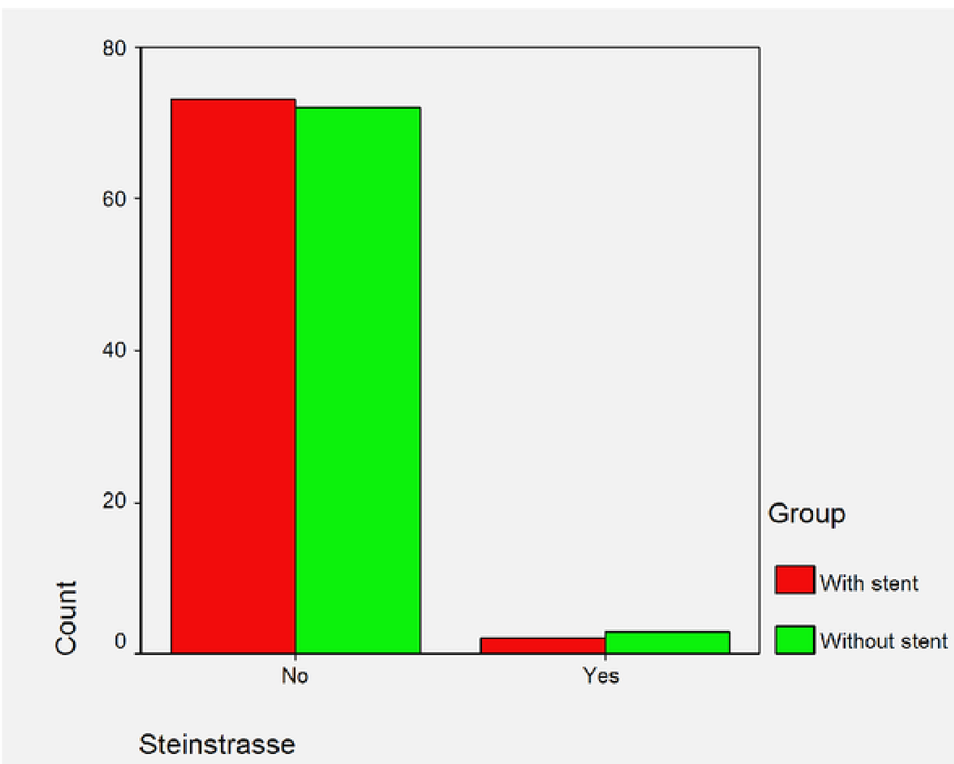
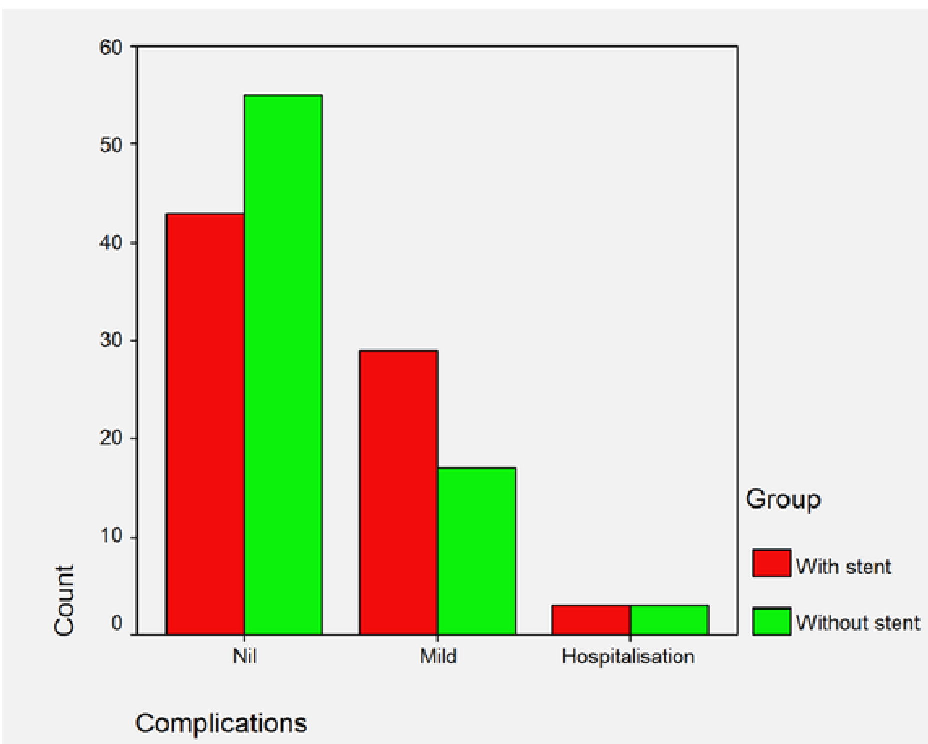


Incidence of Steinstrasse distribution table/Bar chart shows that there is no statistically significant difference observed between the two groups.

Complications

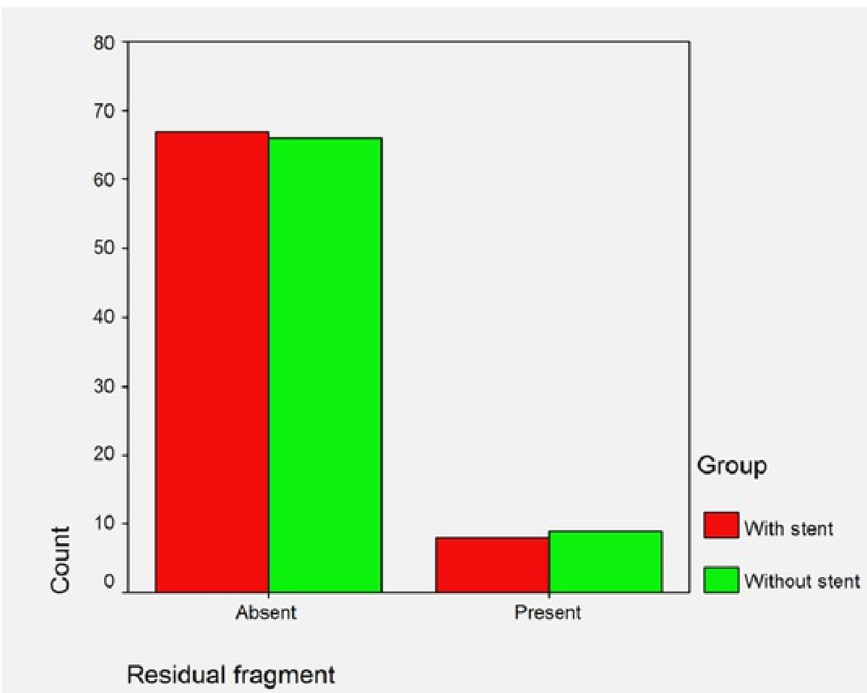
			Group		Total	P-value (Chi-square test)
			With stent	Without stent		
Complications	Nil	Count	43	55	98	0.1
		% within Complications	43.9%	56.1%	100.0%	
		% within Group	57.3%	73.3%	65.3%	
	Mild	Count	29	17	46	
		% within Complications	63.0%	37.0%	100.0%	
		% within Group	38.7%	22.7%	30.7%	
	Hospitalisation	Count	3	3	6	
		% within Complications	50.0%	50.0%	100.0%	
		% within Group	4.0%	4.0%	4.0%	
Total		Count	75	75	150	
		% within Complications	50.0%	50.0%	100.0%	
		% within Group	100.0%	100.0%	100.0%	



Incidence of complications distribution table/Bar chart shows that there is no statistically significant difference observed between the two groups.

Residual fragment

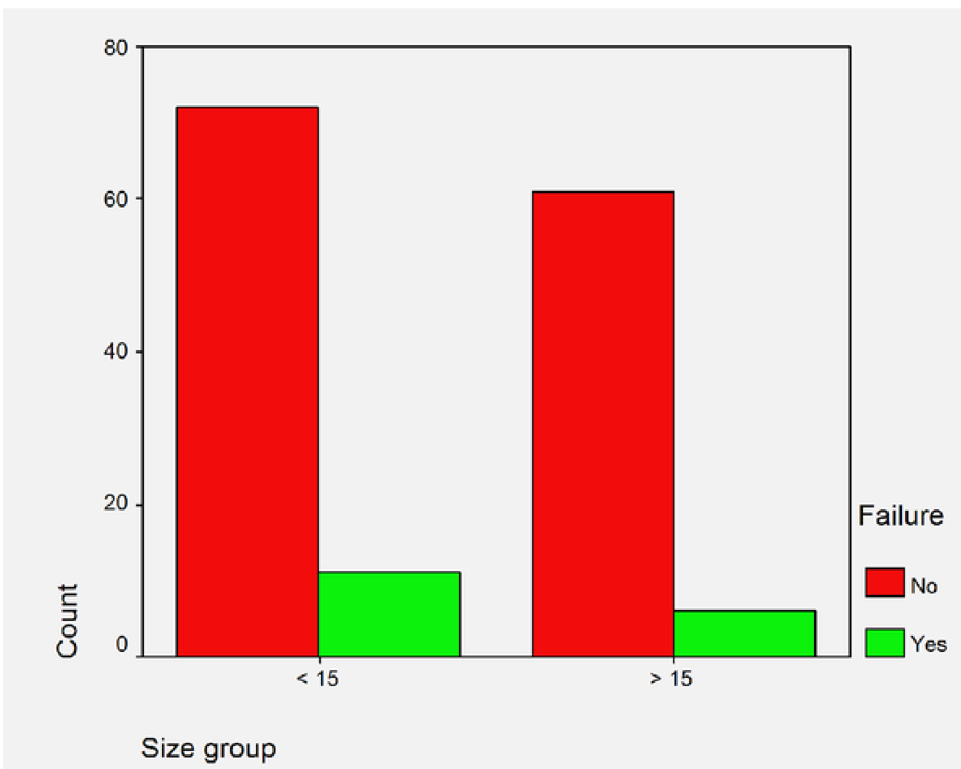
			Group		Total	P-value (Chi-square test)
			With stent	Without stent		
Residual fragment	Absent	Count	67	66	133	0.797
		% within Residual fragment	50.4%	49.6%	100.0%	
		% within Group	89.3%	88.0%	88.7%	
	Present	Count	8	9	17	
		% within Residual fragment	47.1%	52.9%	100.0%	
		% within Group	10.7%	12.0%	11.3%	
Total		Count	75	75	150	
		% within Residual fragment	50.0%	50.0%	100.0%	
		% within Group	100.0%	100.0%	100.0%	



Residual fragments distribution table/Bar chart shows that there is no statistically significant difference observed between the two groups.

Comparison of Size group vs ESWL Failure

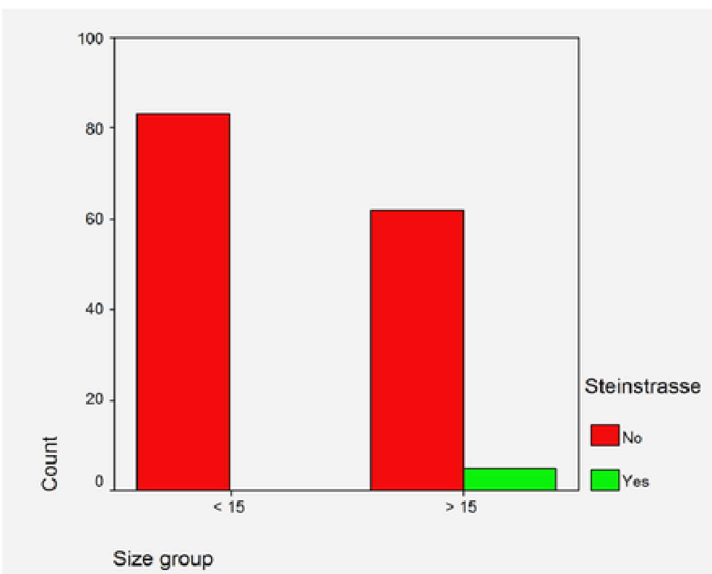
			Failure		Total	P-value (Chi-square test)
			No	Yes		
Size group	< 15	Count	72	11	83	0.409
		% within Size group	86.7%	13.3%	100.0%	
		% within Failure	54.1%	64.7%	55.3%	
	> 15	Count	61	6	67	
		% within Size group	91.0%	9.0%	100.0%	
		% within Failure	45.9%	35.3%	44.7%	
Total		Count	133	17	150	
		% within Size group	88.7%	11.3%	100.0%	
		% within Failure	100.0%	100.0%	100.0%	



Comparison of stone size with failure shows that there is no statistically significant difference is observed.

Comparison of Size group vs Steinstrasse

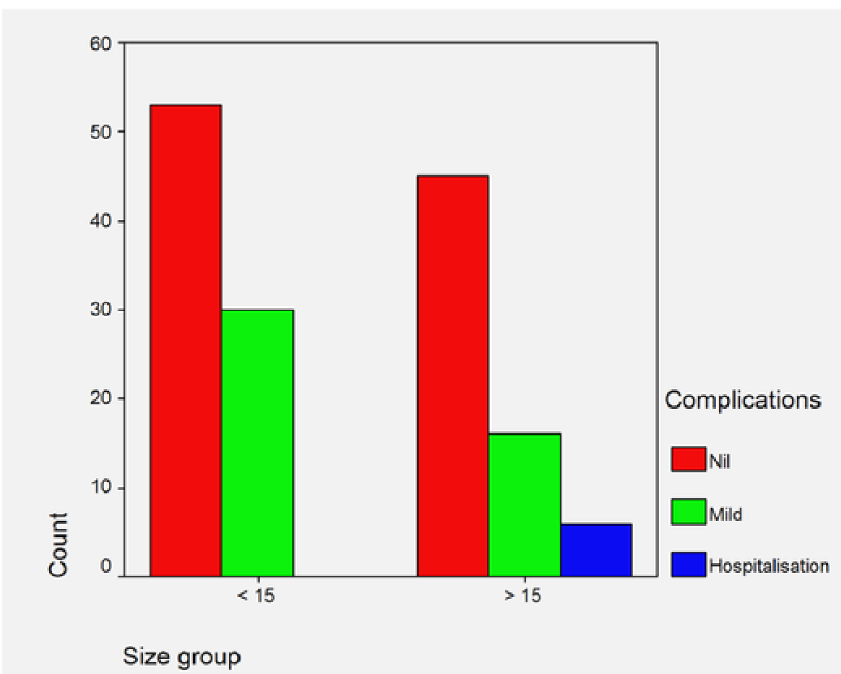
			Steinstrasse		Total	P-value (Chi-square test)
			No	Yes		
Size group	< 15	Count	83	0	83	0.011
		% within Size group	100.0%	.0%	100.0%	
		% within Steinstrasse	57.2%	.0%	55.3%	
	> 15	Count	62	5	67	
		% within Size group	92.5%	7.5%	100.0%	
		% within Steinstrasse	42.8%	100.0%	44.7%	
Total		Count	145	5	150	
		% within Size group	96.7%	3.3%	100.0%	
		% within Steinstrasse	100.0%	100.0%	100.0%	



Comparison of stone size with steinstrasse shows that there is statistically significant difference is observed (p <0.011).

Comparison of Size group vs Complications

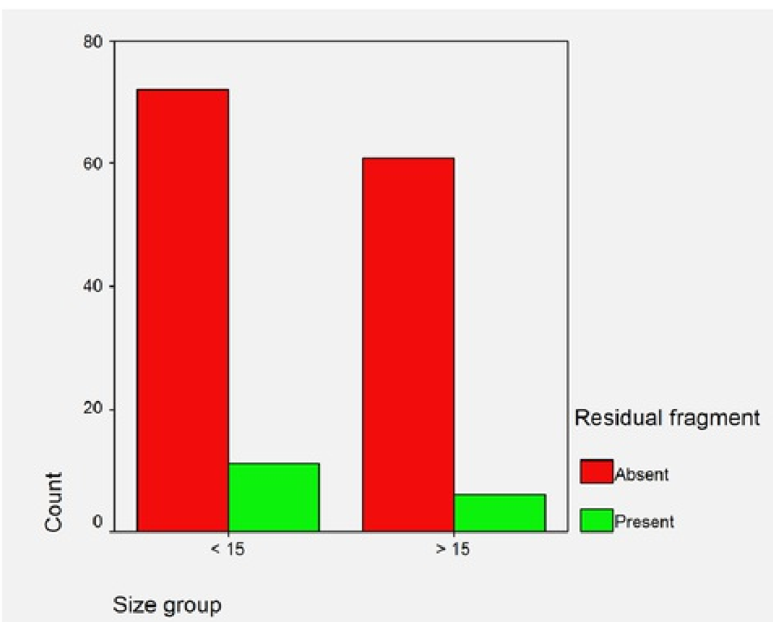
			Complications			Total	P-value (Chi-square test)
			Nil	Mild	Hospitalisation		
Size group	< 15	Count	53	30	0	83	0.09
		% within Size group	63.9%	36.1%	.0%	100.0%	
		% within Complications	54.1%	65.2%	.0%	55.3%	
	> 15	Count	45	16	6	67	
		% within Size group	67.2%	23.9%	9.0%	100.0%	
		% within Complications	45.9%	34.8%	100.0%	44.7%	
Total		Count	98	46	6	150	
		% within Size group	65.3%	30.7%	4.0%	100.0%	
		% within Complications	100.0%	100.0%	100.0%	100.0%	



Comparison of stone size with complications shows that there is no statistically significant difference is observed

Comparison of Size group vs Residual fragment

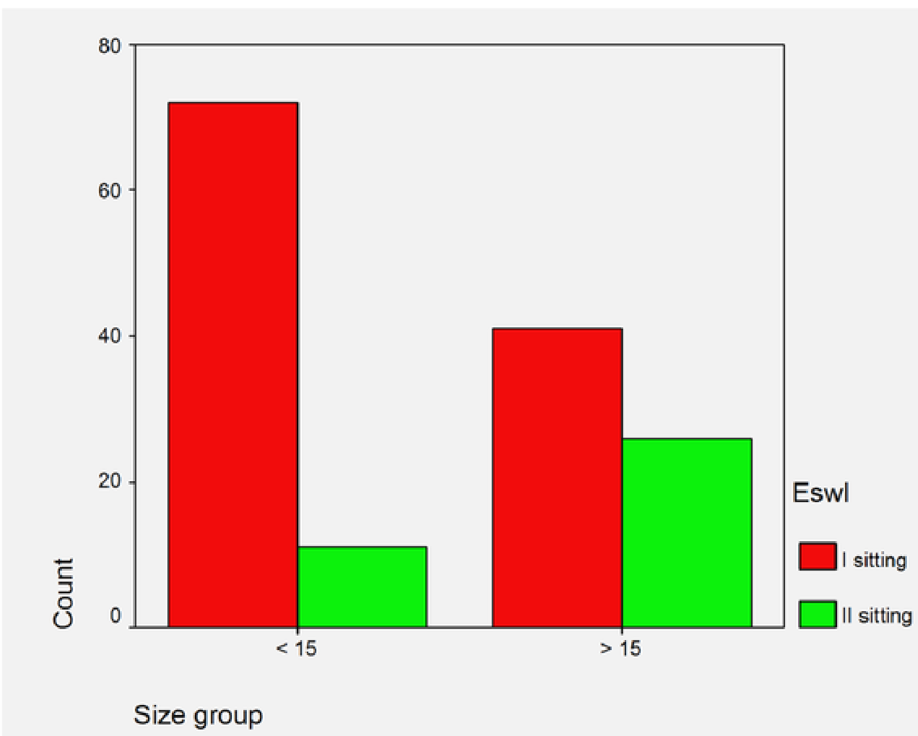
			Residual fragment		Total	P-value (Chi-square test)
			Absent	Present		
Size group	< 15	Count	72	11	83	0.409
		% within Size group	86.7%	13.3%	100.0%	
		% within Residual fragment	54.1%	64.7%	55.3%	
	> 15	Count	61	6	67	
		% within Size group	91.0%	9.0%	100.0%	
		% within Residual fragment	45.9%	35.3%	44.7%	
Total		Count	133	17	150	
		% within Size group	88.7%	11.3%	100.0%	
		% within Residual fragment	100.0%	100.0%	100.0%	



Comparison of stone size with Residual fragments shows that there is no statistically significant difference is observed.

Comparison of Size group vs Number of Eswl sittings

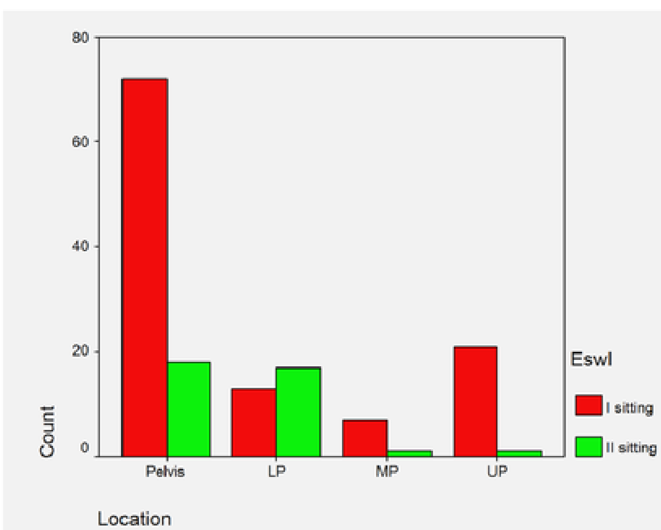
			Eswl		Total	P-value (Chi-square test)
			I sitting	II sitting		
Size group	< 15	Count	72	11	83	0.001
		% within Size group	86.7%	13.3%	100.0%	
		% within Eswl	63.7%	29.7%	55.3%	
	> 15	Count	41	26	67	
		% within Size group	61.2%	38.8%	100.0%	
		% within Eswl	36.3%	70.3%	44.7%	
Total		Count	113	37	150	
		% within Size group	75.3%	24.7%	100.0%	
		% within Eswl	100.0%	100.0%	100.0%	



Comparison of stone size with number of ESWL sittings shows that there is statistically significant difference is observed (p <0.001)

Comparison of stone location vs Number of Eswl sittings

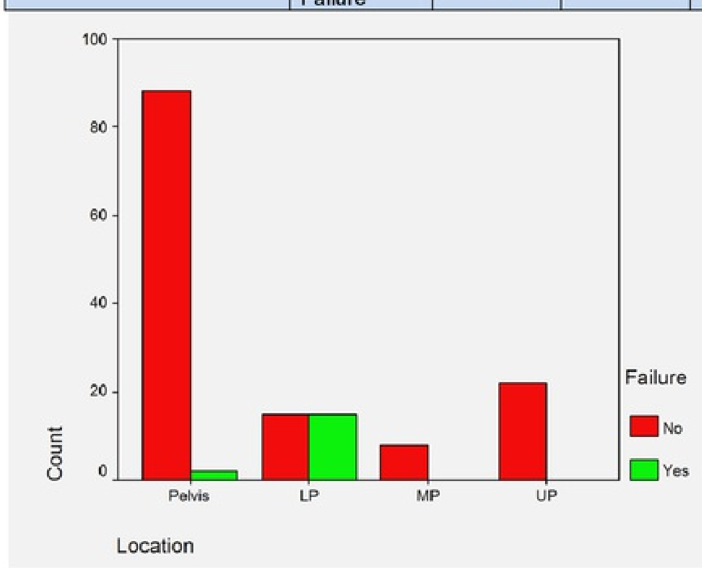
			Eswl		Total	P-value (Chi-square test)
			I sitting	II sitting		
Location	Pelvis	Count	72	18	90	0.001
		% within Location	80.0%	20.0%	100.0%	
		% within Eswl	63.7%	48.6%	60.0%	
	LP	Count	13	17	30	
		% within Location	43.3%	56.7%	100.0%	
		% within Eswl	11.5%	45.9%	20.0%	
	MP	Count	7	1	8	
		% within Location	87.5%	12.5%	100.0%	
		% within Eswl	6.2%	2.7%	5.3%	
	UP	Count	21	1	22	
		% within Location	95.5%	4.5%	100.0%	
		% within Eswl	18.6%	2.7%	14.7%	
Total		Count	113	37	150	
		% within Location	75.3%	24.7%	100.0%	
		% within Eswl	100.0%	100.0%	100.0%	



Comparison of stone location with number of ESWL sittings shows that there is statistically significant difference is observed ($p < 0.001$).

Comparison of stone location vs ESWL Failure

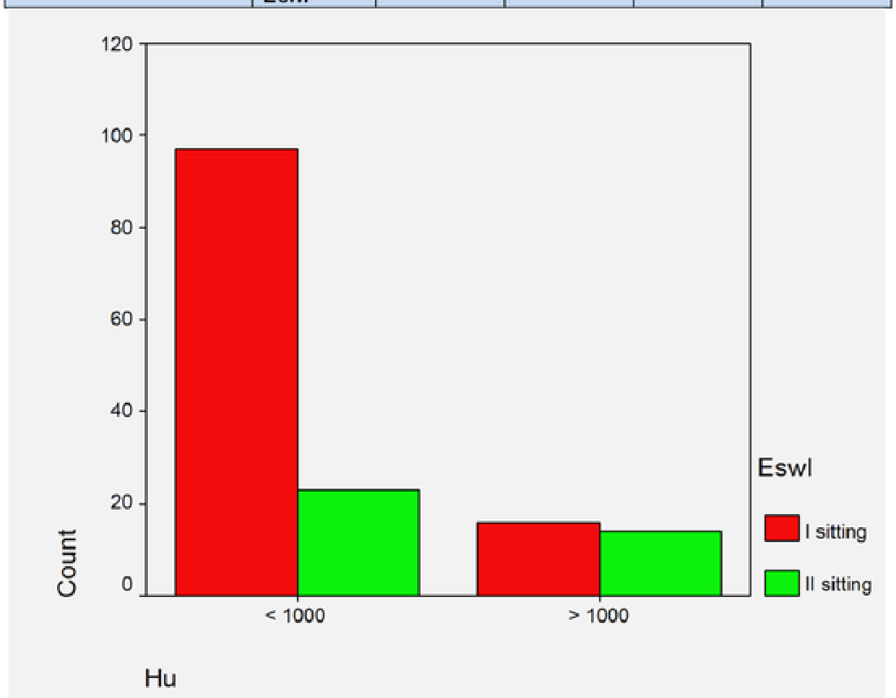
			Failure		Total	P-value (Chi-square test)
			No	Yes		
Location	Pelvis	Count	88	2	90	0.001
		% within Location	97.8%	2.2%	100.0%	
		% within Failure	66.2%	11.8%	60.0%	
	LP	Count	15	15	30	
		% within Location	50.0%	50.0%	100.0%	
		% within Failure	11.3%	88.2%	20.0%	
	MP	Count	8	0	8	
		% within Location	100.0%	.0%	100.0%	
		% within Failure	6.0%	.0%	5.3%	
	UP	Count	22	0	22	
		% within Location	100.0%	.0%	100.0%	
		% within Failure	16.5%	.0%	14.7%	
Total		Count	133	17	150	
		% within Location	88.7%	11.3%	100.0%	
		% within Failure	100.0%	100.0%	100.0%	



Comparison of stone location with ESWL failure shows that there is statistically significant difference is observed (p <0.001).

Comparison of Hounsefied units(Hu) vs Number of Eswl sittings

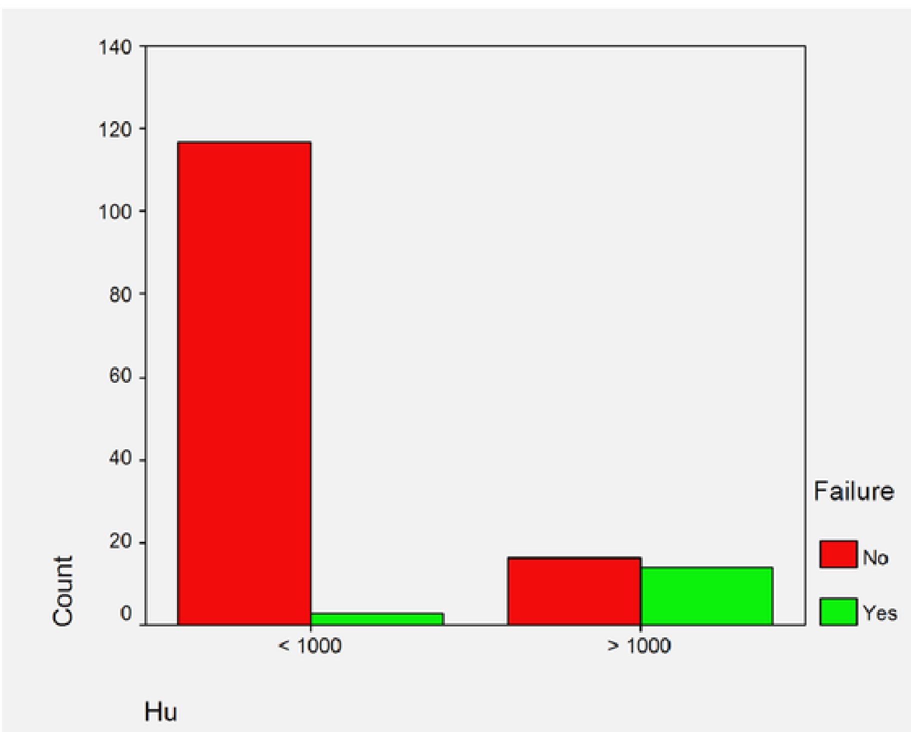
			Eswl		Total	P-value (Chi-square test)
			I sitting	II sitting		
Hu	< 1000	Count	97	23	120	0.002
		% within Hu	80.8%	19.2%	100.0%	
		% within Eswl	85.8%	62.2%	80.0%	
	> 1000	Count	16	14	30	
		% within Hu	53.3%	46.7%	100.0%	
		% within Eswl	14.2%	37.8%	20.0%	
Total		Count	113	37	150	
		% within Hu	75.3%	24.7%	100.0%	
		% within Eswl	100.0%	100.0%	100.0%	



Comparison of stone Hounsefield units of stone with number of ESWL sittings shows that there is statistically significant difference is observed ($p < 0.002$).

Comparison of Hounsefield units (Hu) vs ESWL Failure

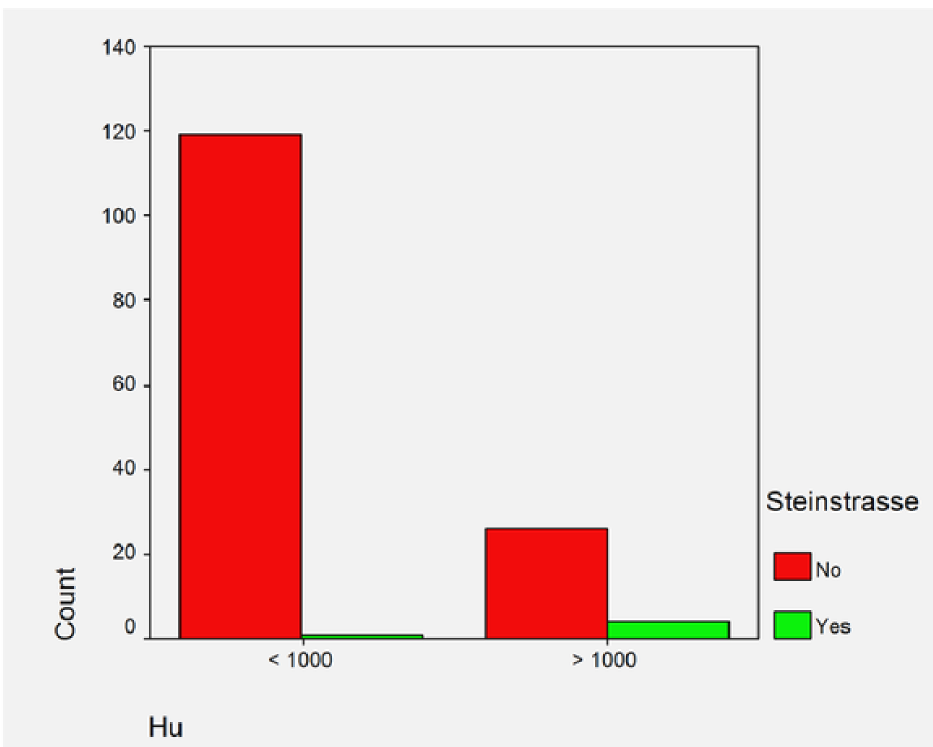
			Failure		Total	P-value (Chi-square test)
			No	Yes		
Hu	< 1000	Count	117	3	120	0.001
		% within Hu	97.5%	2.5%	100.0%	
		% within Failure	88.0%	17.6%	80.0%	
	> 1000	Count	16	14	30	
		% within Hu	53.3%	46.7%	100.0%	
		% within Failure	12.0%	82.4%	20.0%	
Total		Count	133	17	150	
		% within Hu	88.7%	11.3%	100.0%	
		% within Failure	100.0%	100.0%	100.0%	



Comparison of stone Hounsefield units of stone with ESWL failure shows that there is statistically significant difference is observed (p <0.001).

Comparison of Hounsefiend units (Hu) vs Steinstrasse

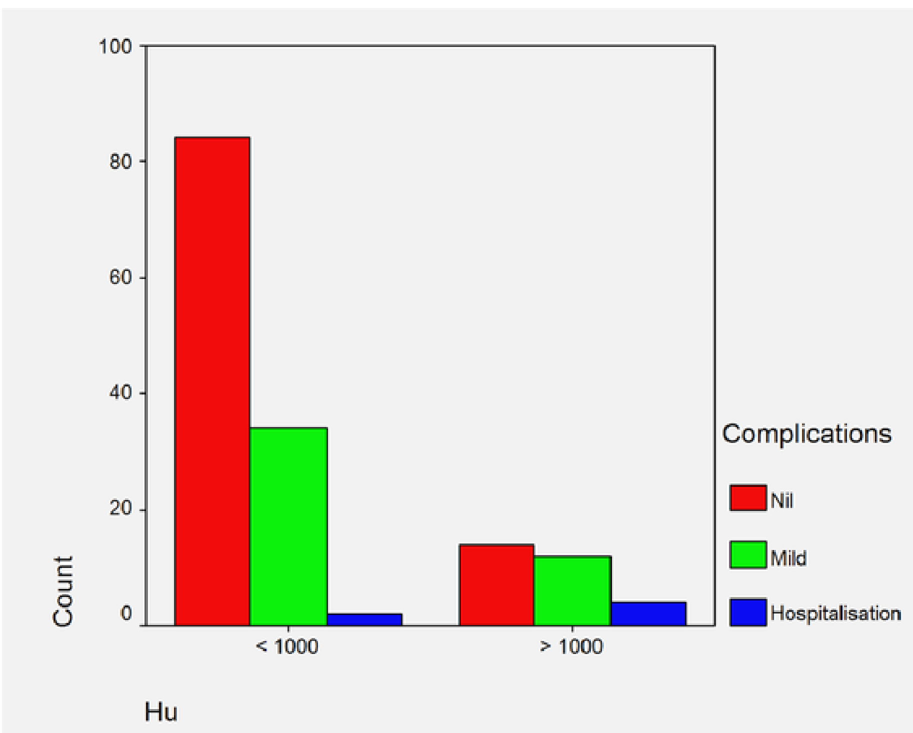
			Steinstrasse		Total	P-value (Chi-square test)
			No	Yes		
Hu	< 1000	Count	119	1	120	0.001
		% within Hu	99.2%	.8%	100.0%	
		% within Steinstrasse	82.1%	20.0%	80.0%	
	> 1000	Count	26	4	30	
		% within Hu	86.7%	13.3%	100.0%	
		% within Steinstrasse	17.9%	80.0%	20.0%	
Total		Count	145	5	150	
		% within Hu	96.7%	3.3%	100.0%	
		% within Steinstrasse	100.0%	100.0%	100.0%	



Comparison of stone Hounsefield units of stone with Steinstrasse shows that there is statistically significant difference is observed ($p < 0.001$).

Comparison of Hounsefield units (Hu) vs Complications

			Complications			Total	P-value (Chi-square test)
			Nil	Mild	Hospitalisation		
Hu	< 1000	Count	84	34	2	120	0.004
		% within Hu	70.0%	28.3%	1.7%	100.0%	
		% within Complications	85.7%	73.9%	33.3%	80.0%	
	> 1000	Count	14	12	4	30	
		% within Hu	46.7%	40.0%	13.3%	100.0%	
		% within Complications	14.3%	26.1%	66.7%	20.0%	
Total		Count	98	46	6	150	
		% within Hu	65.3%	30.7%	4.0%	100.0%	
		% within Complications	100.0%	100.0%	100.0%	100.0%	



Comparison of stone Hounsefield units of stone with complication shows that there is statistically significant difference is observed (p <0.004).

DISCUSSION

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

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

The success rate of ESWL is determined by factors such as stone size, composition, location, presence of obstructive changes and anatomical anomalies. The number of shocks required for fragmentation is related not only to the size of the stone but also to its hardeness or brittleness which largely depends on its chemical composition.

In contrast to traditional methods, however, ESWL does not remove the stone completely but rather fragments it into pieces of various sizes. These must then passed out of the urinary tract spontaneously. The duration of this passage varies

enormously and fragments may obstruct the ureter, thus leading to post-ESWL complications such as renal colic, hydronephrosis, and renal failure . In particular, after the ESWL treatment of larger calculi, a number of fragments
may become impacted in the ureter and form a steinstrasse.

To prevent steinstrasse and other post-ESWL complications, ureteral stenting has been widely used. However, its efficacy has been controversial. Although stents have proven benefits for stone management, often they are associated with significant patient discomfort. In a number of contemporary studies up to 85% to 90% of stented patients reported irritative voiding symptoms,Including frequency, urgency, dysuria, flank pain, suprapubic pain and Hematuria.

Sulaiman et al found that the incidence of steinstrasse was 6.3%.[28] When the stone is less than 10 mm stents are used only occasionally. For stones between 10 mm and 20 mm there appears to be no general consensus about the usefulness of stenting.[29] It decreases significantly with the use of a double-J stent once the stone has surpassed 20 mm in diameter. Furthermore, in patients with stones >20 mm, a stent greatly reduces the risk of acute symptoms in the event of a Steinstrasse and will also permit the continuation of stone treatment in the majority of cases.

Manoj Monga et al[30] in their review on stent related complications noted that Irriatative LUTS are commonly seen with usage of stents, Frequency(50-60%), Urgency(57-60%), Dysuria(40%), Incomplete emptying (76%), Flank pain (19-32%), suprapubic pain (30%) and Hematuria(25%).They concluded that the best way of reducing the stent realated morbidity is by preventive measure with conscious use of stents in only absolutely indicated cases with evidence based criteria.

Glenn Preminger et al [19] in their review on role of stenting concluded that Stenting is not mandatory after uncomplicated simple ureteroscopy and shock wave lithotripsy. Patients with stents seem to have significantly more bladder and lower urinary tract symptoms than those in whom stents are not placed. However, there is a subgroup of patients who likely benefit from stenting following a procedure because of the increased risk of complications.

Joseph et al[12] reported overall success rate of 80% for calculus upto 2cm. When they assessed the susceptibility of stone fragmentation by ESWL according to HU, they found that the success rate for stone with attenuation value < 1000 HU was significantly higher than that for stone with value >1000 HU. In their study they found a significant correlation between number of shocks required for stone fragmentation and the attenuation value of the stone.

Chandoke et al[18] concluded that ureteral stents are associated with more irritative voiding symptoms, their use seems to result in fewer hospital readmissions and emergency room visits compared to when no stent is used to treat solitary kidney stones 10 to 20 mm or solitary proximal ureteral stones less than 20 mm. Stents do not influence stone-free rates and they result in higher irritative voiding symptoms after shock wave lithotripsy.

Abdulla Musa et al[31] in a prospective, randomized study reported that there was no difference in stone clearance between stented and non stented group of patients who were treated with ESWL for renal stones of less than 2cm and they concluded that stenting was not beneficial in such patients and it increased the stent related complications and increased the overall cost of treatment.

In our study, we have noted that stenting does not influence the stone free rate post ESWL, which was similar to that reported by Glenn Preminger et al[19], Chandoke et al[18] and Abdulla Musa et al[31]. The success rate in our study was 88.7%

Most of the stented patients did experience mild stent related complications which did not require any hospitalization.

Incidence of steinstrasse was not statistically significant in both groups in our study population which could be due to the small stone size of 10mm-20mm were only included in this study, this was similar to the observations reported by sulaiman et a.[28]

With regard to stone location only 50% success rate could be achieved for lower pole calculus measuring 10mm- 20mm,whereas success rate with other location was good, which is statistically significant.

With regard to stone size there was no statistically significant difference with success rate, complications and residual fragments.

With regard to the Hounsfield units of the stones, when HU is more than 1000 HU, the incidence of ESWL failure, Number of ESWL sittings required for stone clearance, steinstrasse and complications were more which is statistically significant. This observation is comparable to that made by Joseph et al.

CONCLUSION

1. **There is no statistically significant difference in stone clearance rate between ESWL with stenting and without stenting for renal stones measuring less than 20mm.**
2. **There is no statistically significant difference between stenting and without stenting with regard to steinstrasse for renal stones measuring less than 20mm.**
3. **Lower pole location significantly reduced the success rate of ESWL for stones measuring between 10mm -20mm.**
4. **Renal stones with Hounsfield unit of more than 1000 HU had significantly reduced success rate of ESWL and increased number of ESWL sittings.**
5. **Stones with Hounsfield unit of more than 1000 HU had significantly increased incidence of steinstrasse and complications following ESWL.**
6. **Stenting before ESWL in uncomplicated cases of renal stones measuring less than 20mm increases the stent related complications and overall treatment cost.**
7. **Stenting before ESWL is not beneficial in uncomplicated cases of renal stones measuring less than 20mm.**