



EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY;

EXPLORATION OF INFUNDIBULOPELVIC ANGLE AS PREDICTIVE FACTOR FOR STONE CLEARANCE IN LOWER CALYCEAL CALCULI TREATMENT

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ABSTRACT... Background: Urolithiasis is a common ailment that costs billions of Dollars every year. Recurrent urinary tract obstruction or urolithiasis may stimulate the fibrogenic flow, which is responsible for the definite functional loss of renal parenchyma. In the few past years, the management of urinary calculi undertook a remarkable modification. Open surgery for stones is nearly replaced by minimal or non-invasive operative procedures like ureterorenoscopy, percutaneous nephrolitholapaxy and extracorporeal shock wave lithotripsy (ESWL). **Study Design:** Randomized Controlled Trial. **Setting:** Department of Urology Services Hospital Lahore. **Duration of Study:** 1st January -30th December 2016. **Material and methods:** The comparative study of 60 cases through Non probability convenient sampling was conducted to evaluate the outcome of ESWL in patients with single lithiasis of lower pole calyx with different infundibulopelvic angles as measured on pre-treatment IVU. **Results:** The mean age of all the patients was 33.70 ± 10.72 years. Out of 60 Patients 32(53.3%) were males while 28(46.7%) were females with 1.14 male to female ratio. In group A, the mean LIPA was $78.83 \pm 4.71^\circ$ and in group B, was $100.53 \pm 5.73^\circ$. The overall mean LIPA of the patients was $89.68 \pm 12.11^\circ$. Stone clearance was noted in 39 (65%) patients. 15 patients (38.46%) and 24 patients (61.53%) in group A and B respectively. p -value=0.015. After ESWL stone clearance was more in patients having $IPA \geq 90^\circ$ as compared to $IPA 70-90^\circ$. **Conclusion:** Stone clearance is significantly higher with $IPA > 90^\circ$ as compared to $IPA 70-90^\circ$. In future now we are able to implement the use of $IPA \geq 90^\circ$ instead of using $< 90^\circ$ that is more successful in achieving stone clearance.

Key words: Renal Stone, Extracorporeal Shock Wave Lithotripsy ESWL, Stone Clearance, Infundibulopelvic Angle (IPA).

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INTRODUCTION

Urinary tract calculi are of great concern for human beings since the earliest records of civilization.¹ Urinary tract stone development usually occurs in about 1-14% of the broad population according to socio-economic conditions and different ecological areas. Urinary grits are the 3rd most common disease of urinary area.

In addition to the reported incidence and occurrence of renal stone calculated from patient data, there is occurrence of 3% silent stones that may only be exposed incidentally or by screening.² Another study reported that in Pakistan, the occurrence of renal stones in patients with urinary infections was 18.98%.³

The management of renal stones has remarkable modification. Before the 1980s, open surgery was considered to be the main method to remove kidney stones. For now among these numerous choices of stone clearance, ESWL is recognized as the model treatment for renal and Ureteric stones as it is a non-invasive in nature and maximum success in terms of stone clearance.⁴ Usually, ESWL has minimum complication and only has few contra indications e.g., pregnancy or aortic aneurysms.⁴

It is generally established that ESWL is the method of choice for removal of kidney stones with a maximum size of ≤ 2 cm.⁵ The stone clearance rate of renal calculi varies, ranging from 45% to 95%. The stone clearance after ESWL is strongly associated to stone fragmentation and their clearance.⁶

Stone fragmentation is influenced by several factors, stone factors (burden, number, and composition), patient factors (obesity, body habits), operator experience, and machine factor (type of lithotripter, shock wave number, shock wave energy). Furthermore, the approval rate of stone fragments is affected by location of stone and patterns of intrarenal collecting system drainage and urinary transport.⁷

Lower Calyceal stones represent 22%-44% of all stone which require proper treatment. At this site, clearance rate is lower due to some contentious features that effects the efficiency of ESWL. It has been recommended that this phenomenon could be revealed by an anti-gravitational site of the lower renal calyx.⁸

On contrary, after ESWL, remaining fragments can originate complications like chronic pain, obstruction, sepsis and regrowth, which sometimes necessitate an intervention.⁹

It is a technique, in which stone is focused externally and used shochwaves to fragment the stone in small pieces that can easily be excreted in urine. ESWL depends on stone size, location and anatomy of collecting system. ESWL is stone effective in < 2 cm diameter, less effective in >2 cm, cystine or calcium oxalate monohydrate stones. (NH3). In case of lower polar stone the factors effecting the excretion of stone fragments are (1) Infundibulo-pelvic angle (2) Infundibular length (3) Infundibular width etc present study was planned to evaluate the outcome of ESWL in patients with single lithiasis of lower pole calyx with different infundibulopelvic angles as measured on pre-treatment IVU. (lower pole calculi treated with ESWL, IPA >90° compared with IPA ≤ 90°).

MATERIALS AND METHODS

Ethical Approval

Study protocols were approved from institutional ethical board.

Conflict of Interest

Authors declare no conflict of interest

Study Design

Randomized Controlled Trial.

Setting

Department of Urology Services Hospital Lahore.

Duration of Study

1st January -30th December 2016

Sample Size

The sample size was calculated by the following formula keeping the power of study equal to 99% and level of significance equal to 5%. The sample size was 29 in each group.

$$n = \frac{(Z_{1-\alpha/2} \sqrt{2p(1-p)} + Z_{1-\beta} \sqrt{p_1(1-p_1)p_2(1-p_2)})^2}{(p_1 - p_2)^2}$$

The sample size according to the formula was 29. For the sake of simplicity, the sample was taken of 30 patients in each group.

Sampling Technique

Non probability convenient sampling

Inclusion Criteria

Patients of both genders with a solitary lower calyceal stone ≤ 20 mm in size.

Exclusion Criteria

Grade III obesity BMI ≥ 40Kg/ m². (2) Patients ≤ 14 years of age, (3) Previous ipsilateral renal surgery, (4) Infundibular length > 3cm, (5) Infundibular width <5mm, (6) Infundibulopelvic angle <70°.

METHODOLOGY

Patients with solitary lower calyceal stone 20mm or less were selected and divided into two groups (30 each) depending upon infundibulopelvic angle on IVU. Group-A was include IPA 70°-90° and Group-B was include IPA ≥ 90°. Exclusion criteria were horseshoe kidney, severe hydronephrosis, multiple stone location, multiple or branched calyx, stone size larger than 2 cm, acute urinary tract infection, coagulopathy or H/O anticoagulants usage, and pregnancy. In addition, all patients had pretreatment IVU done

and were evaluated by medical history, physical examination, and ultrasonography of the urinary tract. The BMI in kg/m² was also be recorded. The stone size and location were reviewed and determined on anteroposterior abdominal plain X-ray of IVU series. Stone size was defined as the largest diameter of the stone under bi-dimensional film and measured with computer software (Digital Imaging and Communication in Medicine, DICOM). Also, the spatial anatomic factors of the lower pole of the kidney, such as infundibular length (IL), infundibular width (IW) and infundibulopelvic angle (IPA), was measured in pretreatment IVU with DICOM. All patients received treatment with ESWL using a StorzModulith SLX lithotripter under intravenous analgesic sedation. The maximal number of shock waves was estimated to be no more than 3,000. The maximum number of sessions was six in three months. The targeted stone was noted to be disintegrated into fragments by the operator under fluoroscopic imaging during treatment. The treatment outcome of stone clearance were determined and evaluated with plain abdominal X-ray films and ultrasonography within 3 months after ESWL. Residual stone status was defined as persistent stone fragments larger than 2 mm on plain abdominal X-ray films. All the data was recorded in the proforma.

Statistical Analysis

The statistical analysis was done with help of SPSS version 16.0 Statistical significance of all the factors like stone size and anatomical factors were compared between two groups using Chi-square test.p-value of ≤ 0.05 will be considered significant.

RESULTS

Among total study subjects (n=60) 53.3% (n=32) were males while 46.7% (n=28) were females with 1.14 male to female ratio. Study participants were divided into two groups (a=IPA 70-90°& b= IPA> 90°) with the frequency of 50% (n=30) in each group. The mean ages of group A and B patients were noted as 34.33±9.57 and 33.06±11.89 years, the overall mean age was 33.70±10.72 years. Among group A, Out of 30 Patients 50% (n=15) were males and 15% (n=15)

were females, whereas in group B 56.7% (n=17) were males and 43.3% (n=13) were females.

Out of total (n=60) patients, 63.3% (n=38) were presented with pain, 18.3% (n= 11) with complaint of vomiting and 18.3% (n=11) with history of Hematuria. Figure-1

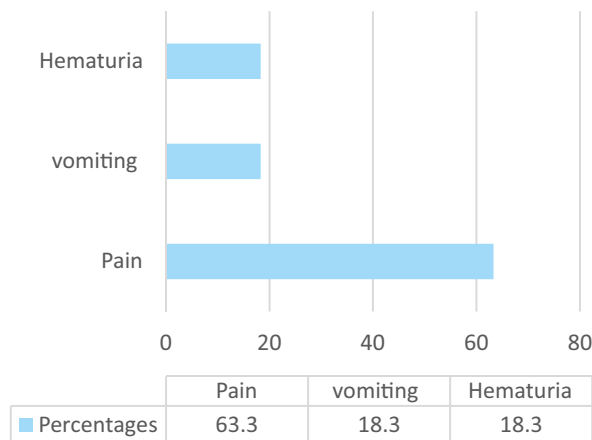


Figure -1. Distribution of symptoms

Among group A patients mean BMI was 21.2 ±4.9Kg/m², andin group B patients it was noted as 17.4 ±5.0 Kg/m². The overall mean BMI was 19.3 ±5.3 Kg/m².

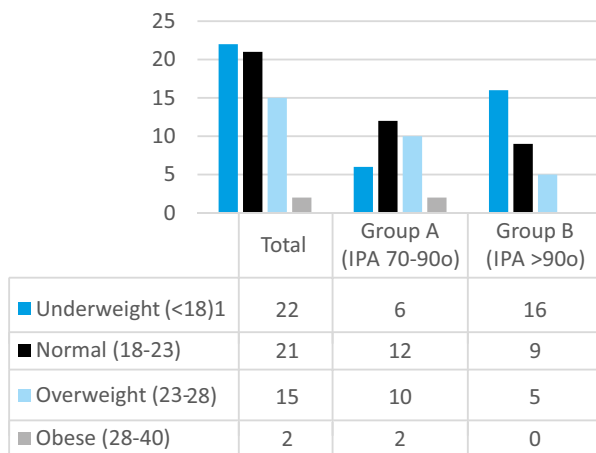


Figure-2. Frequency distribution of BMI stratified by weight

Out of 60 patients 36.7% (n=22) appeared with lower weight in which 20% (n=6) were from group A and 53.3% (n=16) were from group B, similarly 35% (n=21)patients belong to normal weight in which 40% (n=12) were from group A

and 30% (n=9) were from group B, 25% (n=15) were overweight in which 33.3% (n=10) were from group A and 16.7% (n=5) were from group B. Only 3.3% (n=2) patients appeared with obese status in which all 6.7% (n=2) patients belong to group A. there was insignificant association between group A and group B (p-value =0.07). The mean blood urea level of group A and B patients was 30.2 ±4.9 and 25.9±6.1. The overall mean Blood urea level was 28.0±5.6 (p-value = 0.009). The mean Serum Creatinine value of group A and B patients was noted as 0.8 ±0.2 & 0.6±0.3. The overall mean Serum Creatinine was 0.7±0.3. (p-value =0.009).

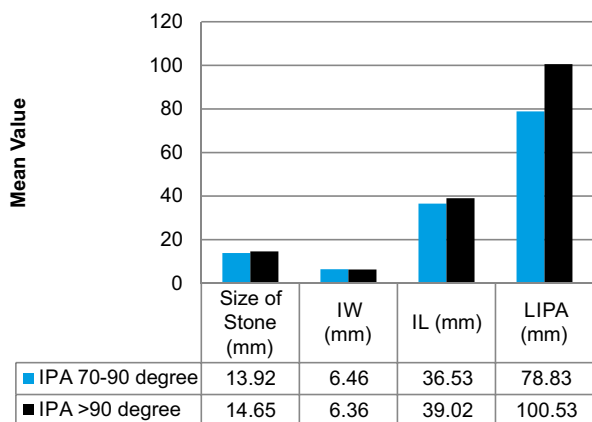


Figure-3. Mean value with respect to study group

The mean Stone size of group A patients was 13.9± 4.6 mm and group B patients was noted as 14.6±2.6mm. The overall mean stone size was 14.2±3.7mm. (p-value = 0.03).

In this study 43.3% (n=26) patients had laterality of stone on right side in which 46.7% (n=14) were from group A and 40% (n=12) were from group B, whereas 56.7% (n=34) appeared with left laterality of stone in which 53.3% (n=26) were from group A and 60.0% (n=18) were from group B.

Stone clearance	Study Group		Total	Chi Square	P-Value
	IPA 70-90°	IPA > 90°			
Yes	15 (50%)	24 (80%)	39 (65%)	5.93	0.015
No	15 (50%)	6 (20%)	21 (35%)		
Total	30 (100%)	30 (100%)	60 (100%)		

Distribution of stone clearance with respect to study groups

The mean IW value of group A patients was 6.4±1.0mm & in group B was 6.3±0.9 mm. The overall mean IW value was 6.4±1.0mm. (P-value = 0.35).

In this study the mean IL value of group A patients was noted as 36.53±5.48 mm and the mean IL value of group B patients was noted as 39.03±3.70 mm. The overall mean IL value of the patients was 37.78±4.80 mm with minimum and maximum IL value of 27 & 48 mm respectively. (P-value = 0.01).

In this study the mean LIPA value of group A patients was noted as 78.8±4.7 degree and the mean LIPA value of group B patients was noted as 100.5±5.7 degree. The overall mean LIPA value of the patients was 89.6±12.1 degree. (P-value = 0.33).

In group A, there were 23.3% (n=7) patients who required 2000 shock waves, 6.7% (n=2) patients who required 2500 shock waves and 70% (n=21) patients who required 3000 shock waves. In group B, there were 16.7% (n=5) patients who required 2000 shock waves, 3.3% (n=1) patients who required 2500 shock waves and 80% (n=24) patients who required 3000 shock waves.

Among group A the 3.3% (n=1) patients attended two sessions, 33.3% (n=10) attended third session, 33.3% (n=10) attended fourth session, 16.7% (n=5) attended fifth session and 13.3% (n=4) appeared at sixth session. Similarly in group B the 16.7% (n=5) patients attended two sessions, 20.0% (n=6) attended the third session, 36.7% (n=11) attended the fourth session, 16.7% (n=5) at fifth session and 13.3% (n=4) attended sixth session.

Out of total (n=60) patients 65% (n=39) appeared with stone clearance in which 38.4% (n=15) were from group A and 61.5% (n=24) were from group B patients. Similarly the 35% (n=21) appeared with no stone clearance in which 71.4% (n=15) were from group A and 28.5% (n=6) were from group B. Statistically there is significant difference between both study groups i.e. (p -value=0.015.)

DISCUSSION

ESWL is the treatment of choice in most of the ureteric and renal stones because it is least invasive and has lower side effects.^{10,11} ESWL is one of the most commonly used procedures to re-move renal calculi from the upper urinary tract.^{12,13}

Since the invention of ESWL in the early 1980s, a reduced success in the management of lower-polar stones when compared to the treatment results of stones in the higher and center calyces, this reduced success being linked to the poor authorization of fragments rather than a reduced fragmentation.¹⁴

Clearance of stone from the inferior pole depends upon the structure of lower pole after the fragmentation with ESWL.¹⁵ Thus it is hypothesized that this randomized controlled trial compare the IPA 70-90° and IPA ≥90° to see the stone clearance with both methods to investigate about the best method which can be adopted without compromising the health of the patient.

Thus in this randomized trial, we included 60 patients who presented in urology ward with the mean age of 33.70±10.72 years. Patients were casually divided in two equal groups. The mean age of the patients randomized to IPA 70-90° was noted as 34.33±9.57 years while the mean age of patients randomized in to IPA >90° was noted as 33.06±11.89 years.

In our trial, there were 32 (53.3%) male and 28 (46.7%) female patients with male-to-female ratio of 1:1.14. Hence there were more females involved in our study with lower calyceal renal stone. Most common presentation of patient was with pain (63.33%) on the effected side.

Small number of patients was also present with complaint of vomiting (18.33%) and Hematuria (18.33%).

In our trial, out of 60 patients, 22 (36.7%) patients were underweight, 21 (35%) were of normal weight, 15 (25%) were overweight and only 2 (3.3%) patients were obese with mean BMI of 19.36±5.32 Kg/m². Current literature has reported that there is no effect of BMI on stone clearance.¹²

In our study, we calculated the mean Stone size value of the patients was 14.28±3.76mm. A study has reported that the mean stone size was 0.87±0.22 cm (i.e. 87±22mm) which is far high than our study.¹²

In our trial, in IPA 70-90°, the mean infundibular width (IW) was noted as 6.46±1.07 mm, the mean infundibular length (IL) was noted as 636.53±5.48 mm and the mean LIPA was noted as 78.83±4.71°. While in IPA ≥90°, the mean IW was noted as 6.36±0.99 mm, the mean IL was noted as 39.03±3.70 mm and the mean LIPA was noted as 100.53±5.73°.

In our study, out of 60 patients, stone free kidney was attained in 39 (65%) patients. Another study demonstrated the total stone-free rate was 84.5%.(16) Another study reported almost same rate of stone clearance (86.5%) after 3 months of ESWL.¹⁷ But Sahinkanat et al,¹⁸ reported the stone-free rate in 62% patients.

Out of these 39 patients who had stone clearance, 15 (38.46%) were from group IPA 70-90° and 24 (61.53%) were from group IPA >90°. Statistically there was significant difference between both study groups i.e. p -value=0.015 and it was found that the rate of stone clearance is higher with IPA >90° as compared to IPA 70-90°. A study has demonstrated that 74% kidneys had a measured angle >90° and these anatomic pyelocalyceal features play an important role in stone clearance rate. Sampaio et al., found that 72% people developed stone-free when the lower LIPA was >90° while only 23% people were stone-free when the angle was <90°.¹⁹

Srivastava et al, has reported that with IPA <90°, the stone clearance rate was 0% while with >90°, the stone clearance rate was 90%.²⁰

Sabnis et al.²⁰ stated remaining stones in 64% of the patients with a LIPA of <90° and just 12% in those with a LIPA >90°. Keeley et al.²¹, presented that if the LIPA was <100°, the stone approval rate was 34%, but 66% in when ≥100°.

Elbahnasy et al.,²² presented that an LIPA of ≥90° was institute just in 12% of his patients. Mad-bouly et al. reported a LIPA of >90° in just one patient.

Another study stated that with LIPA 70-90° stone clearance was observed in 83.9% cases clinically and 78.5% radiologically while with IPA ≥90°, stone clearance was observed in 94.7% clinically and 84.2% radiologically.

However, another study¹² tried to remove ureteric stone with setting angle at <40° and ≥40° and found that with IPA <40° stone free rate was 44.1% and with ≥40° stone free rate was 43.4% and he concluded that that IPA is not a statistically significant predictor of the outcome of stone clearance.

Thus this can also be accomplished that greater angle can have more success rate as compared to small angle.

CONCLUSION

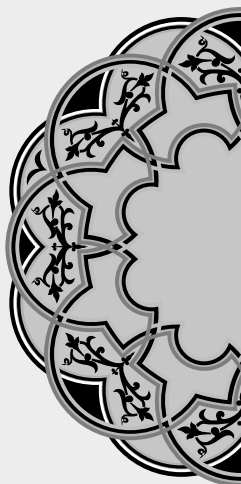
Through this study, it was found that the rate of stone clearance is significantly higher with IPA >90° as compared to IPA 70-90°. Thus the hypothesis we stated has been proved through results of our study. In future now we are able to implement the use of IPA ≥90° instead of using <90° that is more successful in achieving stone clearance.

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*“Common sense is a flower
that doesn't grow in everyone's garden.”*

Unknown

AUTHORSHIP AND CONTRIBUTION DECLARATION

Sr. #	Author-s Full Name	Contribution to the paper	Author=s Signature
1	Iftekhar Ahmed	Study Design	
2	Muhammad Farooq	Principle investigator	
3	Abdul Mannan Qureshi	Supervise the work	
4	Muhammad Saeed	Manuscript writing	
5	Sami Ur Rehman	Literature search	