Predictive Factors for Successful Extracorporeal Shock Wave Lithotripsy in Lower pole stone

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Abstract: Objective: To study the predicting factors for successful Extracorporeal Shock Wave Lithotripsy (ESWL) in lower caliceal calculi. **Subjects and Methods:** We included (150 renal units) in 150 patients with lower calyceal stones in this prospective study. Patient's Body Mass Index (BMI) measured. From Non Contrast Computerized Tomography (low-dose NCCT) and or Intravenous Urography (IVU); infundibular length (IL), infundibular width (IW), Infundibulo –pelvic angle (IPA), stone size, Hounsfield Unit (HU) and skin to stone distance (SSD). Patients treated with ESWL using Dornier SII lithotripter. Patients undergone four sessions. Patients followed after two weeks before the next session by plain X-ray for radio opaque stone or ultrasound for radiolucent stone. A "successful outcome" is defined as complete stone clearance. Absence of stone disintegration or presence of surgical fragment >4 mm after four sessions was considered failure of ESWL treatment. Then, patients followed three months later plain X-ray for radio opaque stone or ultrasound for radiolucent stone. **Results**: ESWL had clearance rate of 64.60% in this research. Average stone HU: 750, IPA: 86̊, IL: 17mm, IW= 8mm, stone size: ≤10mm, SSD: 72mm and BMI: 28. A statistically significant relationship was found between values in which; HU was less than 975 (P = 0.00), SSD was less than 86 mm (P = 0.004), IPA was more than 70̊ (P = 0.00), IL was less than 30mm (P= 0.00), IW was more than 5mm (P = 0.00) and stone size was ≤10mm (P = 0.00). **Conclusion:** The use of low-dose NCCT and or IVP will allow predicting ESWL clearance through values of HU, SSD, stone size, IPA, IL and IW in lower calyceal calculi.

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1. Introduction:

Extracorporeal shock wave lithotripsy (ESWL) has become the first-line of treatment for most of urinary calculi, especially those smaller than 2 cm in size **[1].**

There is much variability about treatment results of ESWL with success rates from published series varying from 60% to 90 % **[2]**. The success depends on many stone factors (stone size, site, composition, degree of obstruction), technical factors (available equipment, cost) **[3]**. One important cause that predicts the success of ESWL in lower pole stones is the calyceal anatomy**[4]**. The lower pole infundibular length (IL), infundibular width (IW) and the infundibulopelvic (IPA) angle on intravenous urography (IVU) have been shown to impact stone clearance. Also SSD and the HU for measuring the density of the stone on NCCT are predictive factors **[5].**

In this study, we aimed to evaluate the factors that predict ESWL outcome in lower calyceal calculi.

2. Subjects and methods:

From January 2015 to May 2016, we prospectively evaluated (150 renal units) in 150 patients with lower calyceal stones undergoing ESWL treatment at Alazhar lithotripsy center. Exclusion criteria uncontrolled coagulopathy, Patients with addition stones in another calyx or pelvis, Patients with serum creatinine > 2mg /dl and pregnancy. The protocol of this study has approved by hospital ethical committee and informed consent obtained from all patients. All patients evaluated by history, physical examination, BMI measurement and laboratory investigations which included urinalysis, complete blood picture, serum creatinine, and coagulation profile.

Before the procedure, urine cultures obtained, and, if positive, appropriate antibiotics prescribed for one week. Urine cultures repeated to document sterile urine. Before ESWL all patients had low-dose NCCT and or IVU. The largest diameter and the mean density of the stone in HU calculated. Also the distance between skin and stone SSD measured by measuring three distances from the stone to the skin at 0̊, 45̊, and 90̊. By using radiographic dimensions values calculated to represent SSD for each stone. The lower pole infundibular length (IL) measured from the most distal point at the bottom of the infundibulum to a midpoint at the lower lip of the renal pelvis also infundibular width (IW) measured at the narrowest point along the infundibular axis. About the infundibulopelvic (IPA) angle a line drawn connecting the central point of the pelvis opposite the margins of the superior & inferior renal sinus to the central point of the ureter opposite the lower kidney pole (ureteropelvic axis). Using an antero-posterior radiograph from the IVP, the inner angle between this line and the central axis of the lower pole infundibulum measured. As shown in (**Figure 1**).

The ESWL procedure performed under intravenous sedation on an outpatient basis with a Dornier lithotripter S II (Dornier, Medtech, and Munich, Germany). Patients delivered 3000 shocks at 80 shocks / min to each stone. After the procedure, patients prescribed analgesics (50 mg diclofenac sodium, twice/day for 1 week if needed).

An interval of 14 days maintained between ESWL sessions. A plain film taken after each ESWL session for radio opaque stone and abdominopelvic ultrasound for radiolucent stones to document fragmentation and before the next session to find out position and clearance. The results of stone fragmentation & clearance reviewed with infundibular length, infundibular width, Infundibulopelvic angle, body mass index, stone size, stone number, radio-opacity, Hounsfield density and skin to stone distance. Clearance defined as complete disappearance of the renal calculus; fragments of 4 mm or less {clinically insignificant residual fragments (CISRF)}. Treatment failure considered if there no fragmentation or there residual fragments larger than 4 mm {clinically significant residual fragments (CSRF)} after four sessions.

Data analyzed by using the Chi-square test for categorical variables and T-test for continuous variables. Differences resulting in p<0.005 were considered statistically significant.

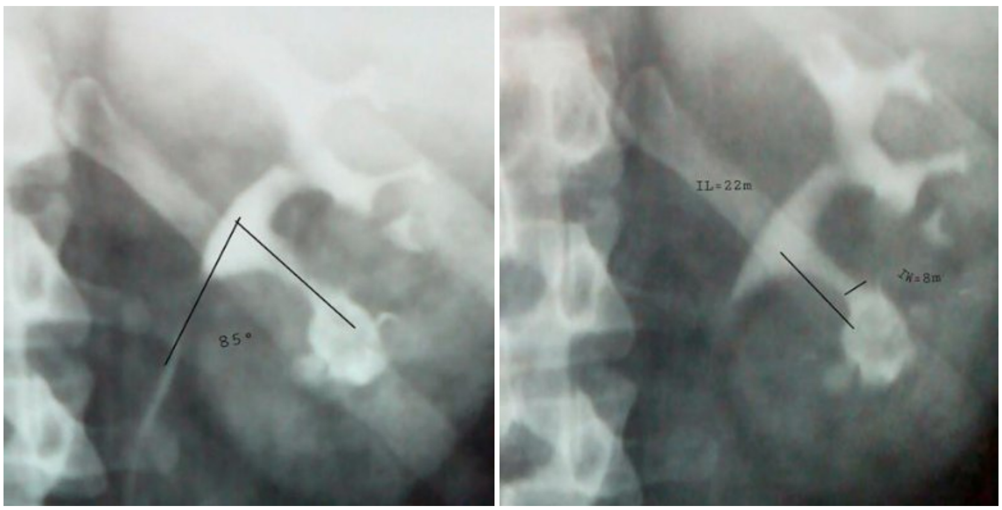


Figure 1. Measurement of the lower-pole calyceal anatomy. IVU show that IL is 22mm, IW is 8 mm and IPA is 85°.

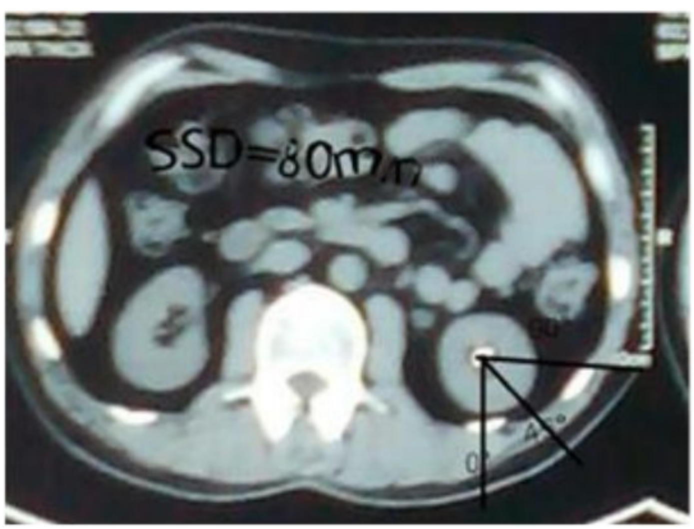


Figure 2. Shows mean SSD is 80 mm and it calculated by measuring SSD at 0°, 45° and 90° using radiologic caliper then calculating their mean value.

3, Results

This study included 150 patients with lower calyceal renal stones, 97 (64.6%) were stone-free and 53 (35.4%) had residual fragments after a follow-up of 3 months.

The mean values of succeeded ESWL are; HU= 823 with Standard Deviation (SD) was 246.51, IPA=86° with SD was 12.63, IL=17mm with SD was 4.94, IW= 8mm with SD was 1.64, stone size≤10mm with SD was 5.58 (Table 1), SSD=72mm with SD was 18.54 9 (**Figure 2**), B.M.I=28 with SD was 5.67 and stone residual=2.5mm with SD was 0.50 mm. The values considered significant ($p < 0.05$).

As for the effect of B.M.I on stone clearance, 98/150 patients (65.3%) with a B.M.I≤ 28 kg/m2 were stone-free, compared to 52/150 patients (34.7%) with a B.M.I > 28 kg/m2.

Table 1: Association and agreement of different parameters for success

			Clearance		Total	X^2	P-value	Kappa agreement
			Failure	Success				
HU	> 750	No.	**37**	**23**	**60**	**36.27**	**0.00****	**0.57**
		%	**61.66%**	**38.34%**	**40%**			
	≤ 750	No.	**6**	**84**	**90**			
		%	**6.66%**	**93.34%**	**60%**			
SSD	> 86	No.	**21**	**19**	**40**	**8.12**	**0.004***	**0.31**
		%	**52.5%**	**47.5%**	**26.7%**			
	≤ 86	No.	**23**	**87**	**110**			
		%	**20.9%**	**79.1%**	**73.3%**			
IPA	< 70	No.	**26**	**11**	**37**	**38.33**	**0.00****	**0.53**
		%	**70.2%**	**29.8%**	**24.6%**			
	≥ 70	No.	**16**	**99**	**113**			
		%	**14.1%**	**87.6%**	**75.4%**			
IL	> 30	No.	**12**	**0**	**12**	**31.11**	**0.00****	**0.37**
		%	**100%**	**0.0%**	**8%**			
	≤ 30	No.	**29**	**109**	**128**			
		%	**21.1%**	**78.9%**	**92%**			
SIZE	> 10mm	No.	**26**	**7**	**33**	**51.27**	**0.00****	**0.609**
		%	**78.8%**	**21.2%**	**22%**			
	≤10mm	No.	**16**	**101**	**117**			
		%	**13.7%**	**86.3 %**	**78%**			
IW	< 5	No.	**21**	**2**	**23**	**44.87**	**0.00****	**0.54**
		%	**91.3%**	**8.7%**	**15.3%**			
	≥ 5	No.	**22**	**105**	**127**			
		%	**17.3%**	**82.7%**	**84.7%**			

Table 1 show that success predicted when; HU is less than 750, SSD is less than 86 mm, IPA is more than ≥ 70°, IL is less than ≤ 30mm, IW is more than ≥ 5 mm and stone size is ≤10mm ($p <$ **0.05).**

Table 2: Validity of limits for detection of success.

	Sensitivity	**Specificity**	**+VE predictive**	**-VE predictive**	**Accuracy**
HU	**78.4%**	**86.2%**	**93.5%**	**60.9%**	**80.5%**
SSD	**82.0%**	**48.0%**	**79.3%**	**52.1%**	**72.09%**
IPA	**89.6%**	**62.2%**	**86.0%**	**69.6%**	**81.9%**
IL	**100.0%**	**29.7%**	**78.6%**	**100.0%**	**80.4%**
Size	**93.8%**	**63.2%**	**86.7%**	**80.0%**	**85.1%**
IW	**97.9%**	**48.6%**	**83.03%**	**90.0%**	**84.09%**

Table 2 shows that HU and stone size parameters have independent good predictive ability, however; predictive ability of SSD, IPA, IL and IW do not have independent good predictive ability.

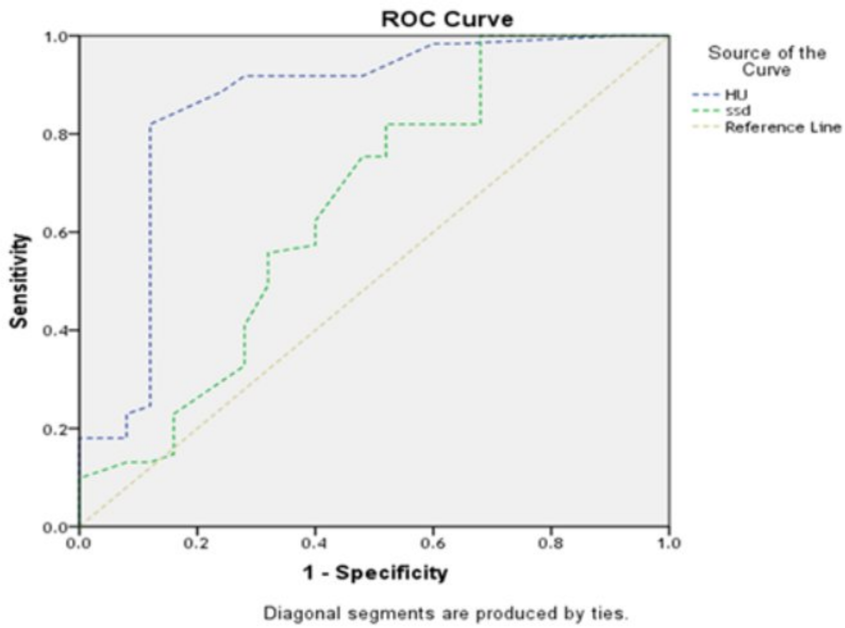
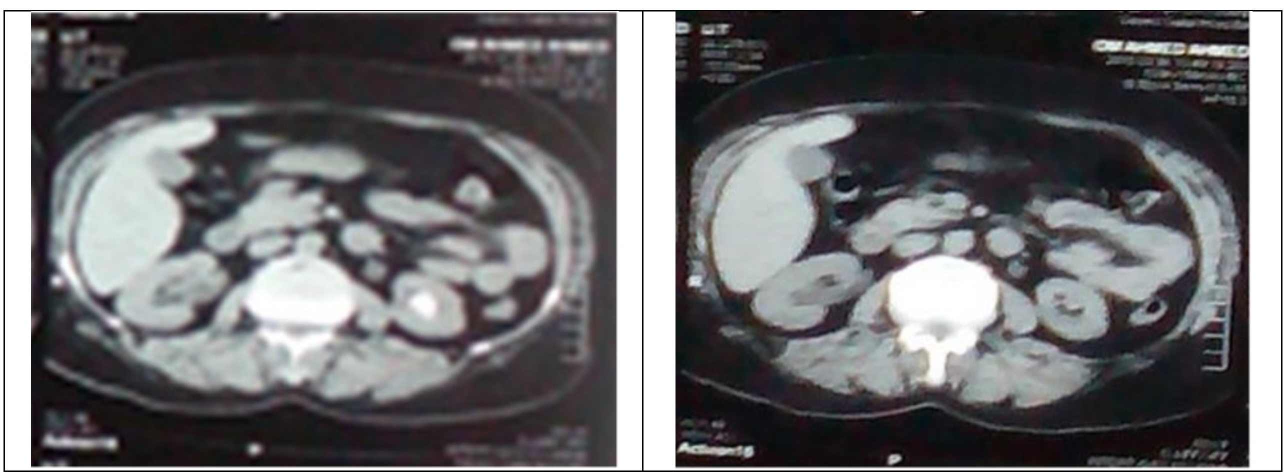


Figure 3. ROC Curve for detection of HU and SSD cut off for success.

ROC curve shows best cutoff value for HU <750 and for SSD <86 with AUC 0.85 & 0.65 respectively (**Figure 3**).

The most common complication was post ESWL hematuria (16%). Only one patient needed ureteroscopy for post ESWL impacted ureteric stone. Four patients underwent ureteroscopy for post ESWL stein-strass stones (3% needed ureteroscopy). Other patients with complications treated medically.



A B

Figure 4 A & B:- NCCT axial cut pre and post ESWL for the same patient showing left lower calyceal stone 12mm, 80mm SSD with HU 720. (Predictive Score 69.12%) (The patient became stone free after 3 ESWL sessions) Ninety two renal units (61.3%) had undergone one or two sessions of ESWL, 27 (18%) three, while 31 (20.7%) had four sessions, with a mean of 2.1 sessions.

4. Discussion

Extracorporeal Shock Wave Lithotripsy is non-invasive nature; low morbidity has become a useful method of treatment, and as such as a first method of choice for treat kidney stones with 80% to 90% treatment success **[6].** We here review our experience of the efficacy of ESWL in one hundred and fifty patients With solitary, lower pole renal stones.

We found in our study that lower calyceal stone clearance was only 64.6% and this supported by another study **[7]** that reported that the lower pole has got lesser rates of clearance due to the unfavorable spatial anatomy of the lower pole collecting system. So according to their results the site of stone may affect clearance but not the disintegration.

Data about relationship between stone free rate and calyceal anatomy. Our study supported by the study of **Rachid et al. [8]** who also demonstrated that an acute pelvic lower pole infundibular angle hinders the spontaneous discharge of fragments after ESWL. We found that acute angle less than 70̊ failure rate was (69.7%).

Our results match with **Arpali et al. [9]** who found that; The presence of a LIP angle greater than 70̊, an IL less than 30 mm and an IW greater than 5 mm is strongly related to a high success rate for ESWL; however, a negative result achieved in a large percentage of cases if these values are, respectively, less than 70̊, greater than 30 mm and less than 5 mm.

PCNL considered for stones ＞10 mm in the largest dimension since ESWL is generally recommended for stones ≤10mm, **[10]**. **Lingeman et al. [11]** reported a post-ESWL stone-free rate of 74%, 56% and 33% for lower pole stones less than 1.0, 1.0 to 2.0 and greater than 2.0 cm, respectively. In a multicenter prospective study by **Albala et al. [12]** confirmed this negative correlation. They found that lower pole kidney stones greater than 10 mm associated with only a 21% stone-free rate. In our study the stone size mean success value was also ≤10mm mm with 65% success rate (P = 0.00).

In our study, we found positive correlation between stone size and stone clearance with 86.7% success rate in stones ≤10mm in size while 80% failure in stones >10mm in size (P = 0.00). This is comparable to **Wilaiwan et al. [13]** who found in his study that stone size had significant impact on the success of ESWL. For stones <15 mm the stone-free rate ranged from 89.7% to 91.5% and for stones >10mm mm the success rate ranged from 55% to 78%.

There is no doubt that endoscopic procedures can do better stone-free outcomes for lower-pole stones with a diameter exceeding 10 mm as compared to ESWL. Accordingly, the EAU guideline recommends endoscopic procedures as a primary treatment for lower-pole stones with a diameter greater than 10 mm **[14]**. However, choosing RIRS or PCNL for 10–20 mm sized lower-pole renal stones are still controversial. Traditionally, RIRS has superiority in terms of less morbidity and a shorter convalescence, but PCNL has shown better stone-free rates.

The average number of treatment sessions was 2.1 in this series. Fifty-nine percent of patients required one to two sessions while the remaining 41% >2 sessions. **JiWoong.** et al. **[20]** in their series reported one to two sessions in 72.9% patients, remaining 27.1% required >2 sessions with mean of 1.93 sessions **[20].** Stone sizes were smaller (mean 9mm) in above series justifying more treatment sessions in our patients.

On multivariate analysis; by **Al-Hakary et al. [14]** found that B.M.I (greater than 30 kg/m2) and stone density (greater than 900 HU) impacted stone fragmentation while stone size (greater than 10 mm) and density impacted stone clearance; Infundibular length (greater than 25 mm) was the only anatomical factor that significantly affected the stone-free rate.

Our study is supported by **Foda et al. [15]** study who demonstrated that stone disintegration failed if the stone density was > 934 HU; therefore, they did not recommend ESWL in this group of patients. **Ouzaid et al. [16]** revealed a 970 H.U threshold for predicting ESWL outcome.

A god correlation exists between S.S.D and B.M.I when examining all upper tract stones. B.M.I and S.S.D are certainly interrelated **[17].** Take advantage of B.M.I in predicting successful ESWL is variable. **Pareek et al**. **[18]** found B.M.I to be a significant predictor of success.

Conversely, in our study, BMI failed to predict successful ESWL outcomes, since S.S.D remained a significant predictor and this agree with **Ng et al. [19]** study. **Ji Woong [20]** found that B.M.I was not a significant predictor of failure of ESWL. He suggests that the effect of BMI is probably related to the distance of the stone from the skin. Our study results about SSD showing that mean success value of SSD is 72 mm while cutoff vale of SSD was 86 mm, so <86 mm SSD predicted ESWL success (p = 0.004).

In our study, we found that all radiolucent stones succeeded to fragmented and cleared. On the other hand; only 61.9% of radio-opaque stones cleared. Success predicted when; Hounsfield unit is less than 750 and skin to stone distance is less than 86 mm (P = 0.04). Our mean value of BMI success is 28 (P = 0.011) but we could not find significant cut off to B.M.I success prediction.

Nazar et al. [21] described a formula to predict ESWL outcome by a score of Stone size in centimeters (cms) multiplied by SSD in cms and HU then divided by 100. Pre ESWL score less than 100 have probability of stone free rate more than 98 percent.

Score to predict outcome = $\frac{?????\ ????\ ?\ ????\ ?\ ?\ ??}{???}$

That was matching in our study mean values of success as H.U= 520, S.S.D=80mm and size=2cm. So, our score is 83.2 (**Figure 4 A & B**).

Conclusion:

We found that success predicted when; Hounsfield unit is less than 750, skin to stone distance is less than 86 mm, Infundibulo-pelvic angel is more than 70̊, Infundibular length is less than 30mm, infundibular width is more than 5 mm and stone size is less than 2 cm. There was an inverse relationship among HU and stone size with the success rate. They are independent factors of ESWL success prediction.

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