

## The impact of changing the focus size of piezoelectric lithotripsy on renal stone disintegration: A prospective randomized study

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### Abstract

The purpose of this study is to evaluate the efficacy of different focus sizes used in shock wave lithotripsy (SWL) in breaking up renal stones. Methods One hundred patients with radio-opaque renal stones up to 20 mm were included in this prospective trial from the urology department at Benha University Hospital. Patients were divided into two groups at random. Group A was overseen by F1 and Group B by F2.KUB determined the percentage of patients who were stone-free after two weeks. There were no statistically significant differences between groups with respect to loin pain ( $P = 0.121$ ), loin pain duration ( $P = 0.963$ ), stone size ( $P = 0.443$ ), stone density ( $P = 0.6$ ), stone number ( $P = 0.897$ ), stone location, or hydronephrosis ( $P = 1.01$ ).Stones were most often found in the left lower calyx (28%) of patients in group A, and the left mid-calyx (38% of patients in group B). Two-week residual ( $P = 0.024$ ), residual size ( $P = 0.049$ ), and stone-free rate ( $P = 0.033$ ) all differed significantly across the groups. In terms of adverse effects, group B had a substantially greater incidence of both colic (22% vs. 10%,  $P = 0.027$ ) and fever (20% vs. 6%,  $P = 0.034$ ). In terms of hematuria, no significant changes were found ( $P = 0.239$ ). A high stone-free rate can be achieved with a small focus size and a constant force and rate in SWL, but these findings need to be validated in the presence of other variables, such as breathing or stone movement, which can influence effectiveness.

**Keywords:** impact of, changing, the focus size, piezoelectric, lithotripsy

### 1. Introduction

Surgical removal of urinary stones or mechanical disintegration of bladder stones through the urethra were the two active methods of stone removal prior to the introduction of shock wave lithotripsy (SWL) in 1982. The minimally invasive aspect of SWL presented a safe option with compelling effectiveness, and as its usage extended to other medical specialties, it became widely accepted by patients and urologists. [1].

In the years that followed, more and more effective alternatives for treating urolithiasis emerged, such as percutaneous lithotripsy (PNL) and ureteroscopy (URS). Compared to SWL, URS and PNL have greater stone-free rates with fewer treatment sessions as a result of technological developments and miniaturisation of surgical equipment, the introduction and development of laser technology, and the development of digital imaging. [2].

However, unlike with first-generation lithotripters like URS or PNL, the stone-free rate did not increase as a result of technological advancements in SWL, such as the replacement of the water bath with gel cushions and the provision of a more stable energy output. [3].

While the physical principle of the shock wave and its disintegrative effect has been studied in previous publications, little is known about how the interaction of different

lithotripter settings and energy sources affects the shock wave's capacity to disintegrate. [4].

Thanks to recent developments in lithotripter technology, treatment parameters including shockwave frequency and focus size may now be adjusted. Numerous studies focused on the latter, and thanks to a meta-analysis by Li et al., we know what works best. The relative significance of focus size and shockwave intensity, however, remains unknown. Using an in vitro stone model, Vesper et al. (2020) examined the efficacy of several lithotripter settings, including intensity and focus size, in causing stone fragmentation. We perform a research to investigate the effects of various lithotripter focus diameters on the fragmentation of an in vivo stone [7, 8].

### 2. Methods and Patients

One hundred patients seeking ESWL at the urology department of Benha University Hospital with radio-opaque renal stones up to 20 mm in size were included in this prospective study. Controlled experiments...

Estimating the Number of Samples

Based on an estimated stone-free rate of 50% in the F1 group and 40% in the F2 group, the sample size was determined using G\*Power software version 3.1.9.2. To account for potential dropouts, the sample size will be expanded from 143 to 150 patients (75 in each group). There was a 5 percent change in alpha and an 80 percent increase in power.

Patients are eligible if they have had no previous treatment for radiopaque renal stones up to 20 mm in size. Other conditions that exclude participation include: being pregnant; having untreated urosepsis or urinary tract infection; having a kidney anomaly (such as ectopic, duplex, horseshoe, etc.); having decompensated coagulopathy; having uncontrolled arrhythmia; being morbidly obese; and having an abdominal aortic aneurysm greater than 4.0 cm.

Patients were divided into two groups at random (double-blind randomization using computer software to generate random numbers). Groups A and B used F1 focus = 2mm, 126 MPa, while Group C used F2 focus = 4mm, 119 MPa.

Patients performed imaging tests such multi-slice spiral CT and plain abdominal radiography of the kidneys, ureters, and bladder (KUB) to determine the size and density of the stones.

Method: A piezoelectric lithotripter (Wolf PiezoLith3000 Richard Wolf GmbH,

Knittlingen, Germany) is used in this investigation to help detect the kidney stone with the use of a computerised x-ray system. This is carried out in the supine posture after the administration of an IV analgesic (pethidine). We use shockwaves that are 90 hertz in frequency and 20 kilovolts in strength. All patients received the equivalent of four thousand shockwaves in a single treatment session. The manufacturer specifies the following Pmax values for maximum shockwave emission at various focal lengths: F2 = 4 mm, 119 MPa; F1 = 2 mm, 126 MPa. The focusing zone has a 6 dB lateral diameter. (Figure 1 shows)

Follow-Up: The patient was treated with oral antibiotics for seven days, and then two weeks later, SFR was evaluated using a digital KUB. The absence of any stones measuring 4 millimetres or more in diameter at the time of inspection is considered stone-free.

Abbreviations: Kilovolts = kV Megapascals = MPa



Fig.(1) ESWL using piezoelectric lithotripter with two different focus sizes.

### 3. Results

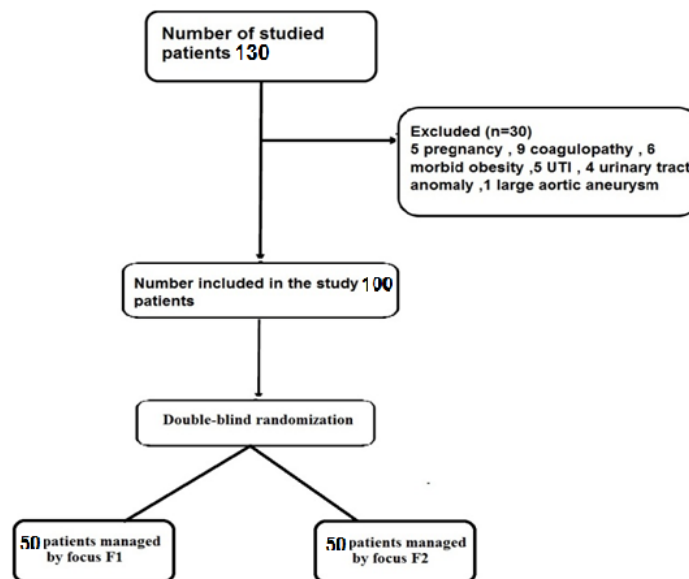


Figure 2: Flowchart of the study

A total of 130 patients met the inclusion criteria for this research, however 30 were disqualified because they did not meet the exclusion criteria, leaving 100 patients. Please refer to Figure 2.

□ **Universal features**

Age (P = 0.07), sex (P = 0.874), body mass index (BMI) (P = 0.888), chronic illness (P = 0.087), and surgical history (P = 0.335) showed no significant differences between the groups.

**Table (1)** General characteristics of the studied groups

	<b>Group A (n = 50)</b>	<b>Group B (n = 50)</b>	<b>P-value</b>
<b>Age (years)</b>	40 ±14	43 ±15	0.07
<b>Sex</b>			
Males	32 (64)	31 (62)	0.874
Females	18 (36)	19 (38)	
<b>BMI</b>	26 ±4	26 ±4	0.888
<b>Chronic disease</b>	12 (24)	14 (28)	0.087
<b>Surgical history</b>	20 (40)	23 (46)	0.335

Data were presented as mean ±SD or number (percentage)

**Psychological and Behavioural Traits**

Stone size (P = 0.443), stone density (P = 0.6), stone number (P = 0.897), stone location (P = 1.01), or duration of loin discomfort (P = 0.963) were not significantly different amongst the groups tested (Table 2).

**Table (2)** Clinical characteristics of the studied groups

	<b>Group A (n = 50)</b>	<b>Group B (n = 50)</b>	<b>P-value</b>
<b>Loin pain</b>	49 (98)	45 (90)	0.123
<b>Loin pain duration (months)</b>	4.5 (1 - 6)	3.2 (1 - 6)	0.961
<b>Stones size</b>	12 ±4	13 ±4	0.443
<b>Stone density (H.U.)</b>	983 ±271	1026 ±243	0.51
<b>Number of stones</b>			
One	40 (80)	39 (78)	0.887
Two	6 (12)	8 (16)	
Three	4 (8)	3 (6)	
<b>Site of stones</b>			-
Lt lower calyx	14 (28)	2 (4)	
Lt mid calyx	1 (2)	19 (38)	
Lt renal pelvis	6 (12)	5 (10)	
Lt upper calyx	4 (8)	2 (4)	
Rt lower calyx	2 (4)	1 (2)	
Rt mid calyx	0 (0)	9 (18)	
Rt renal pelvis	4 (8)	6 (12)	
Rt renal pelvis & mid calyx	6 (12)	0 (0)	
Rt upper & lower calyx	3 (6)	2 (4)	
Rt upper & middle calyx	1 (0)	3 (6)	
Rt upper calyx	5 (10)	0 (0)	
Rt upper calyx & renal pelvis	4 (8)	1 (2)	
<b>Hydronephrosis</b>	12 (24)	12 (24)	1.0

\* Significant; Data were presented as mean ±SD, median (min-max), or number (percentage)

❖ **Outcome**

There is significant differences were observed between the studied groups regarding residual after two weeks (P = 0.024), size of residual (P = 0.049), and stone-free rate (P = 0.033) (Table 3, Figure 3).

**Table (3)** Outcome of the studied groups

	<b>Group A (n = 50)</b>	<b>Group B (n = 50)</b>	<b>P-value</b>
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<b>Residual after two weeks</b>	18 (36)	35 (70)	0.024*
<b>Size of residual</b>	4 (1 - 9)	8 (3 - 15)	0.049*
<b>Stone free rate</b>	32 (64)	15 (30)	0.033*

Data were presented as number (percentage) or median (min-max)

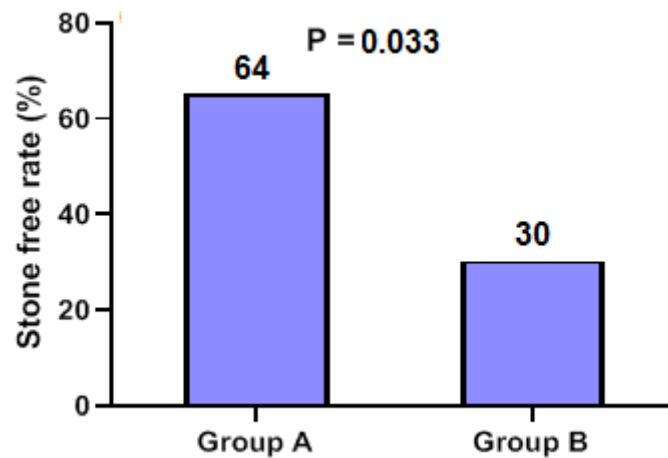


Fig.(3) Stone free rate in the studied groups

#### ❖ Complications

Group B demonstrated significantly higher colic (22% VS. 10%,  $P = 0.027$ ) and fever (20% VS. 6%,  $P = 0.034$ ). No significant differences were observed regarding hematuria ( $P = 0.239$ ) (Table 4, Figure 4).

Table (4) Complications in the studied groups

	Group A (n = 50)	Group B (n = 50)	P-value
<b>Fever</b>	3 (6)	10 (20)	0.034*
<b>Colic</b>	5 (10)	11 (22)	0.027*
<b>Hematuria</b>	4 (8)	3 (6)	0.239

\* Significant; Data were presented as number (percentage)

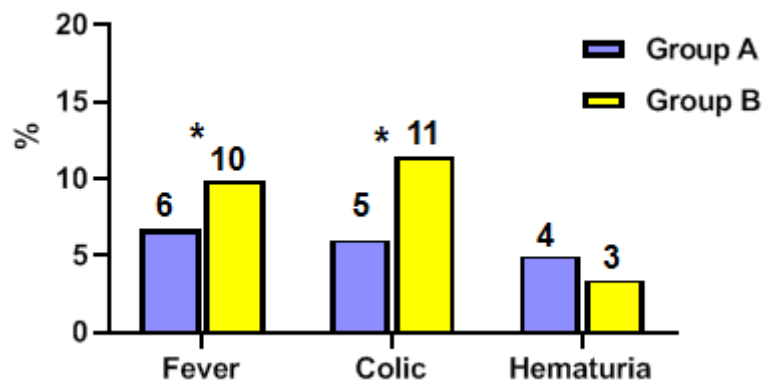


Fig.(4) Complications in the studied groups

#### ❖ Association of stone size and stone density with stone free rate in group A

A significant association was reported between stone density and stone free rate ( $P = 0.009$ ). Those with stone free demonstrated significantly higher percentage of density  $< 1000$  HU (78.1%) than in those with no stone free (61.1%). No significant association was reported between stone size and stone free rate ( $P = 0.134$ ) (Table 5, Figure 5).

Table (5) Association of stone size and stone density with stone free rate in group A

	Stone free		P-value
	Yes (32)	No (n = 18)	
<b>Stone size</b>			
5 - 10 mm	8 (25)	2 (11.1)	0.134
11 - 15 mm	15 (46.8)	10 (55.5)	
16 - 20 mm	9 (28.1)	6 (33.3)	
<b>Stone density (HU)</b>			
<1000	25 (78.1)	11 (61.1)	0.009
>1000	7 (21.8)	7 (38.8)	

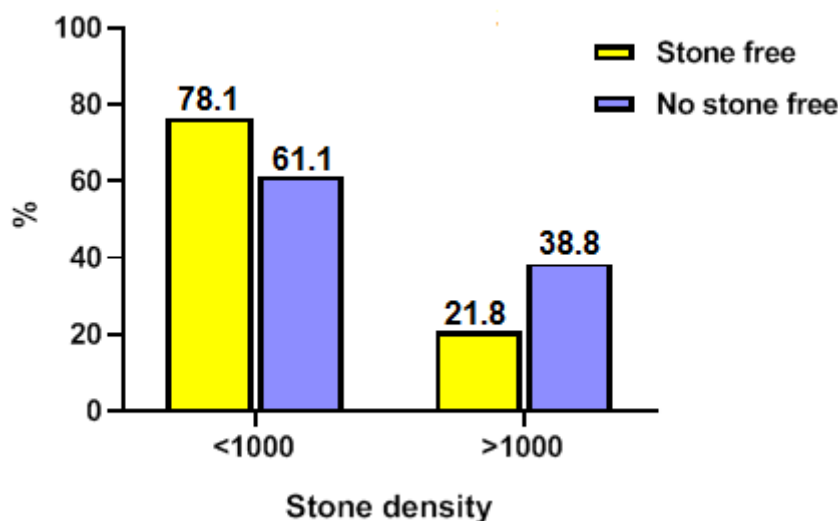


Fig.(5) Association of stone density with stone free rate in group A

Group B's Stone Free Rate is correlated with Stone Size and Stone Density

Stone free rates were significantly correlated with stone sizes (P = 0.019). Those who were stone-free were less likely to have stones between 5 and 10 millimetres in diameter (40%) than those who were not (25.7%), while those who were not were more likely to have stones between 16 and 20 millimetres in diameter (31.4%) than those who were stone-free (6.6%).

Furthermore, it was shown that there is a statistically significant correlation (P 0.005) between stone density and stone free rate. Table 6 and Figure 6 show that the proportion of stone-free individuals with densities below 1000 HU is much greater than the percentage of non-stone-free individuals with densities below 1000 HU (51.4%).

Table (6) Association of stone size and stone density with stone free rate in group B

	Stone free rate		P-value
	Yes (n = 15)	No (n = 35)	
<b>Stone size</b>			
5 - 10 mm	6 (40)	9 (25.7)	0.019
11 - 15 mm	8 (53.3)	15 (42.8)	
16 - 20 mm	1 (6.6)	11 (31.4)	
<b>Stone density (HU)</b>			
<1000	11 (73.3)	18 (51.4)	0.005
>1000	4 (26.6)	17 (48.5)	

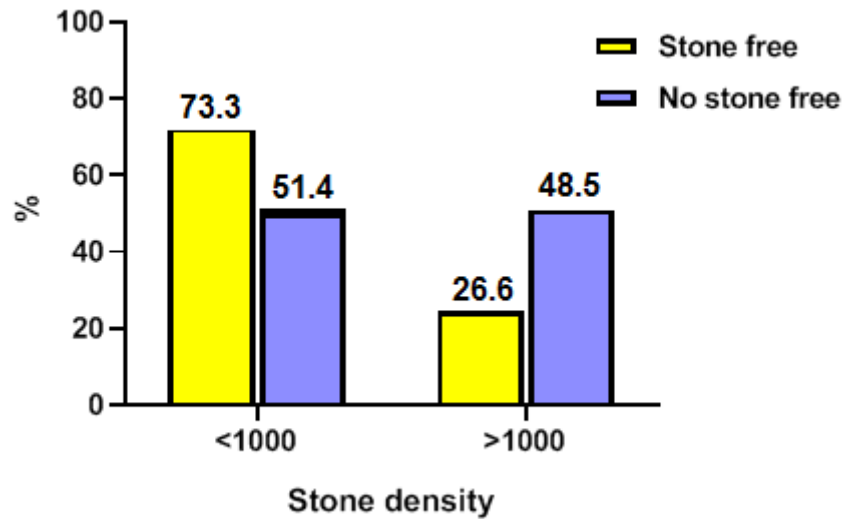


Fig.(6) Association of stone density with stone free rate in group B

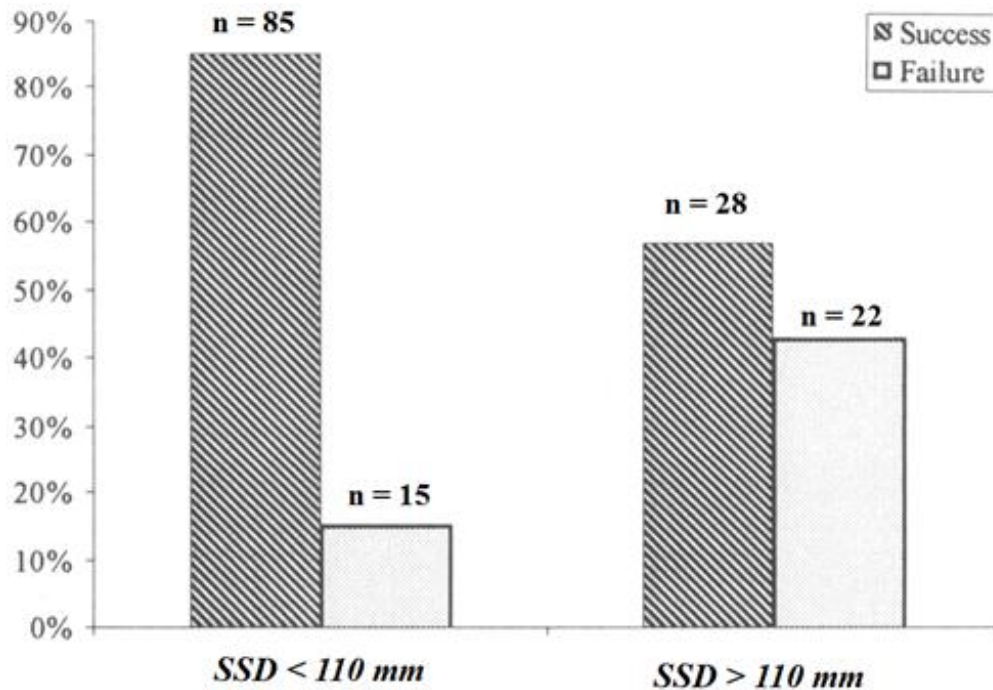


Fig.(7) relation between stone to skin distance (SSD) & Stone free rate (SFR)

**Statistics As Used**

For this study, we used IBM's SPSS 28 (Armonk, NY, USA) for statistical analysis and data administration. The Kolmogorov-Smirnov test and other methods of directly visualising the data demonstrated that the quantitative information was regularly distributed. Means, standard deviations, medians, and ranges were shown for the numerical data on the assumption of normality. The classified data was summarised using

percentages and raw numbers. The Mann-Whitney U-test and t-test The U test, which was designed for use with both normally and non-normally distributed variables, may be used to compare quantitative data across groups. To compare discrete categories, researchers utilised the Chi-square or Fisher's exact test. To determine whether there was a correlation between stone size, density, and stone-free %, we used the Chi-square test. Each statistical test yielded a paired set of

findings. The p-value has to be lower than 0.05 to be considered significant.

#### 4. Discussion

The optimum treatment for certain kinds of stones is still debatable, but ESWL is now a standard option for the majority of renal and ureteral calculi. Therefore, endourological treatments are a very successful alternative to ESWL for patients with large renal, lower calyceal, or lower ureteral calculi. [10, 12]

For the purpose of better patient selection and counselling, several studies and investigations have focused on the parameters impacting treatment success after ESWL. In addition to statistically detecting these characteristics, multivariate analysis often provides an insightful differentiation of their relative importance. [13, 14]

Both the ureteral and renal stone success rates are affected by the amount, size, and fragility of the stones. However, it is often suggested to take into account other factors, such as the placement of the stone, the severity of the blockage, and the patient's body mass index. The focus size, shock wave strength, and frequency of the lithotripter all have a role in the final result. Unless the stone's location or chemical composition makes ESWL impossible, most renal calculi less than 20 mm in diameter should be treated with this method initially. [14, 15]

Particle retention in the collecting system due to gravity or anatomical factors accounts for the vast majority of post-ESWL failure rates. When compared to other calyceal or renal pelvic calculi, the success rate of treating lower calyceal stones is consistently lower. Controlled inversion treatment with or without diuresis, as well as percussion and directed jet irrigation in the lower calyx using a cobra catheter, are just a few of the methods that have been tried and shown to be effective in the elimination of stone pieces. The anatomy of the lower calyx has been more popular as of late. This study establishes the prognostic relevance of the length and breadth of the lower pole infundibulum, as well as the infundibulo-pelvic angle, in the management of lower calyceal calculi. [16]

There is noticeable variation in stone fragility, and clinical experience with ESWL has revealed that this trait strongly correlates with radiologic density (apart from cystine calculi). Beyond questions about the chemical composition and structural properties of the stones, basic research into their acoustic and mechanical capabilities has provided scientific reasons for this phenomenon. In the lack of a defined mechanism for predicting stone

physicochemical properties, clinical application, especially patient selection and foreseeing possible repercussions, is difficult. [12]

The predictive value of dilation of the upper urethra is still up for debate. However, it is generally accepted that the effectiveness of in situ ESWL therapy for urinary stones is diminished by severe hydronephrosis. The lack of water-stone interactions that sustain cavitation and the alteration in peristalsis are thought to be the major reasons of the ESWL failure rate in these instances of severe blockage. Furthermore, it is likely that stone impaction in the urothelium does not promote fragment migration. [14, 15]

Extremely tough for those with obesity, it is now generally accepted that those with extreme (morbid) obesity are not candidates for ESWL. In addition, the patient may be too heavy for the lithotripter gantry, or the stone may be too far below the surface for the shockwaves to reach. Older machines' less-reliable fluoroscopic and sonographic technologies made it more difficult to precisely localise stones. In order to increase the stone-free rate, modern lithotripters contain adjustable focus diameters that can be fine-tuned to the stone's specific dimensions. [11, 12]

Piezoelectric lithotripters employ piezoceramic components arranged on a spherical cylinder to generate a pressure wave by rapid dilatation. These acoustic waves produce a high-energy shockwave by being precisely focused on a target according to their geometric alignment on the concave carrier. However, when the shockwaves enter the body across a vast region of skin, the patient's pain threshold is lowered, allowing SWL to be performed without anaesthesia. When compared to electrohydraulic and electromagnetic lithotripters, piezoelectric lithotripters have a lower average compressive pressure (p +) (avg), however the Wolf Piezolith 3000 employs a double layer of piezoceramic components to equal its power. The focus breadth of the piezoelectric lithotripter may be adjusted to one of three different settings thanks to the shock wave synchronisation of the double-layer piezoelements. The Piezolith 3000 has an output pressure range of 48 MPa (Focus 3) to 148 MPa (Focus 1), with Focus 1 being the highest. [13, 14]

It is now normal practise to do statistical analysis of the effect of different focus sizes on the outcomes of ESWL for renal stones. Radiopaque renal calculi up to 2 centimetres in size were treated in 100 patients using a

piezoelectric lithotripter (Wolf PiezoLith3000 Richard Wolf GmbH, Knittlingen, Germany). We examine two focus sizes (F1 and F2) to evaluate the efficacy of different focus sizes during shock wave lithotripsy (SWL) with respect to renal stone fragmentation. No significant differences were observed between the studied groups regarding age ( $P = 0.07$ ), sex ( $P = 0.874$ ), BMI ( $P = 0.888$ ), chronic disease ( $P = 0.087$ ), and surgical history ( $P = 0.335$ ), loin pain ( $P = 0.121$ ), loin pain duration ( $P = 0.963$ ), stone size ( $P = 0.443$ ), stone density ( $P = 0.6$ ), number of stones ( $P = 0.897$ ), site of stones, and hydronephrosis ( $P = 1.01$ ). According to the findings, 32 patients with SFR had F1 focus, whereas 15 patients with SFR experienced F2 focus. Two-week residual ( $P = 0.024$ ), residual size ( $P = 0.049$ ), and stone-free rate ( $P = 0.033$ ) all differed significantly across the groups.

These findings contrast with those of a study conducted with an electrohydraulic lithotripter (HM-3 Lithotripter) by (Qin et al., 2010), which found that the disintegration of stones is enhanced by a lithotripter field with low peak pressure and a broad beam focus size. Another research utilising piezoelectric lithotripsy (Veser et al. 2020) found that in vitro stone disintegration is enhanced by a smaller focus size of 2-4 mm lateral diameter at -6 dB and a greater peak pressure.

There was a statistically significant correlation between stone density and stone free rate in subgroup A (F1) ( $P = 0.009$ ). The proportion of stone-free teeth was substantially greater in those with a stone density of less than 1000 HU (78.1%) compared to those with a stone density of more than 1000 HU (61.9%). Stone size was not shown to be correlated with stone-free rates ( $P = 0.132$ ) [16].

There was a statistically significant correlation between stone density and stone free rate in subgroup B (F2) ( $P = 0.005$ ). Those with a stone density of less than 1000 HU had a considerably larger proportion of stone-free teeth (73.3% vs. 51.4%). In addition, there was a correlation between stone size and stone-free rate that was statistically significant ( $P = 0.019$ ). Those who were stone-free were less likely to have stones between 5 and 10 millimetres in diameter (40%) than those who were not (25.7%), while those who were not were more likely to have stones between 16 and 20 millimetres in diameter (31.4%) than those who were stone-free (6.6%).

These findings on the effect of stone size and density on stone fragmentation by ESWL may be compared to other research showing the prognostic variables which influence the

success rate after ESWL in (2954) individuals with renal stones (Abdel-Khalek et al., 2004). Stone-free rates were found to be 89.7% for stones 15 mm and 78% for stones >15 mm ( $p < 0.001$ ), suggesting that stone size has a major role in determining success. In another research, Joseph et al. looked at how well CT attenuation value predicted fragmentation effectiveness with ESWL in 30 patients with renal calculi. Stones with an attenuation value of more than 1000 HF units had a far lower success rate than those with a value of less than 1000 HF units [18].

Colic was more common in Group B than in Group A (22% vs. 10%,  $P = 0.027$ ) and fever was more common in Group B than in Group A (20% vs. 6%,  $P = 0.034$ ) following ESWL. This might be because the ureter is being passed bigger pieces of the crumbling stone. But further research may be needed to determine the precise reason. In terms of hematuria, no significant changes were found ( $P = 0.239$ ). Therapeutic tolerance during ESWL depends heavily on shock wave strength and density, particularly at the degree of epidermal penetration of the shockwaves, yet the pathophysiology of pain during ESWL is still poorly understood. Distance from the point of focus to the cutaneous plane determines the size of the entrance region. As piezoelectric SWL progresses from the kidney to the ureter, less and less analgesic is needed. In addition, we've mentioned before that female patients tend to have a lesser tolerance than male patients. Variations in stone depth may account for these differences in discomfort [19, 20].

## 5. Conclusion

In SWL, a tiny focus size with steady power and pace produces a substantially high stone free rate. These results, however, need to be confirmed in the presence of other factors that may alter effectiveness, such as breathing or stone movement.

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