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Original article

The Effect of Piezoelectric Shock Wave Lithotripsy Focus Size on Renal Stones Fragmentation: a Prospective Randomized Study

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Abstract:

Background: In patients presenting with urolithiasis, shock wave lithotripsy (SWL) is an option in management.

Aim of the work: The objective is to evaluate the efficacy of two different focal sizes of a piezoelectric extracorporeal lithotripter on renal stone fragmentation. **Methods:** The study was carried out on 150 patients with radio-opaque renal stones up to 20 mm seeking treatment by SWL. Patients were divided randomly into two equal groups. F1 focus = 2 mm, 126 MPa (Megapascal) was used for group A, and F2 focus = 4 mm, 119 MPa, was used for group B. After 3 months, KUB is done to determine the success of stone disintegration. **Results:** There were insignificant variations between the studied groups regarding loin pain, loin pain duration, stone size, stone sites, density, numbers, and hydronephrosis (p value > 0.05). The most frequent site of stones in group A and B was the mid calyx (29.5% and 33.3%, respectively). There were insignificant variations between the studied groups regarding residual after 3 months, size of residual, and successful stone disintegration rate (p value > 0.05). Regarding complications, colic was significantly higher in group B (22.7% vs. 9.3%, p = 0.026). Fever and hematuria were insignificantly different between the studied groups (p value > 0.05). **Conclusion:** Different focus sizes with fixed intensity and frequency result in non-significant differences concerning stone fragmentation. However, a combination of both F1 and F2 is recommended to achieve better results.

Keywords: Shock Wave Lithotripsy; Focus Size; Renal Stone; Fragmentation; Extracorporeal Lithotripter; Urolithiasis Management.

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Introduction

Prior to the introduction of shock wave lithotripsy (SWL) in 1982, active stone extraction was through either the surgical removal of urinary stones or the mechanical annihilation of UB stones via the urethra. SWL is minimally invasive and provides a safe alternative with convincing efficacy, resulting in its broad acceptance among patients and urologists as its use extended to other medical sectors [1].

Ureteroscopy (URS) and percutaneous lithotripsy (PCNL) eventually replaced it as the preferred therapy for urolithiasis. URS and PCNL have greater stone-free rates in fewer treatment sessions than SWL because of technological advances, including the reduction of surgical instruments, the advent of laser technology, and digital imaging [2, 3].

The advancement of lithotripter technology allows for more precise adjustment of treatment parameters such as focal size and frequency of shockwaves. Li et al. conducted a meta-analysis to determine the optimal frequency of shock waves, the topic of several research studies [4]. The relevance of focus size, however, remains uncertain. Veser et al. investigated the influence of lithotripter settings with varying intensities and focus sizes on the disintegration of an in vitro stone model [5]. We compared lithotripter settings with two different focus sizes to determine their influence on stone breakdown.

Patients and Methods

This prospective randomized study was carried out on 150 patients with radio-opaque renal stones up to 20 mm who attended the urology department at Benha University Hospital from June 2022 to March 2023.

Ethics approval: The Research Ethics Committee at Faculty of Medicine, Benha University (REC-FOMBU) has met and reviewed the research from the ethical point of view and approved it. The study number: MS: 29-2022.

Sample size calculation:

The sample size was calculated using G*Power software version 3.1.9.2 based on an expected stone-free rate of 50% and 40% in the F1 and F2 groups, respectively (F1 focus = 2 mm, 126 MPa (Megapascal) and F2 focus = 4 mm, 119 MPa). The total sample size will be 143 patients, and the sample size will be increased to 150 patients (75 per group) to compensate for possible loss of follow-up. Alpha (type I error) and power were adjusted at 5% and 80%, respectively.

Inclusion criteria are patients with radio-opaque renal stones up to 20 mm with no history of renal stone treatment. While the exclusion criteria are pregnancy, untreated urinary tract infection/urosepsis, kidney anomalies (ectopic, duplex system, horseshoe, etc.), decompensated coagulopathy, uncontrolled arrhythmia, morbid obesity and abdominal aortic aneurysm > 4.0 cm.

Patients were divided randomly (double-blind randomization using computer random number generator software) into two equal groups. F1 focus was used for group A, and F2 was used for group B.

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

Technique:

In this study, using a piezoelectric lithotripter (Wolf PiezoLith3000 Richard Wolf GmbH, Knittlingen, Germany), after IV analgesic (pethidine) administration in the supine position, a computerized x-ray machine is used to pinpoint the location of the stone within the kidney. We use a frequency of 90 shockwaves per minute and an intensity of 20 kV. All patients received 4000 shockwaves during only one session. The lateral diameter of the focal zone is 6 dB, and the maximum shockwave output pressure (Pmax) according to manufacturer information for each focus setting is: $F1 = 2$ mm, 126 MPa; $F2 = 4$ mm, 119 MPa.

Follow-Up: Each patient was given oral antibiotics for 7 days, and a digital KUB was done after 3 months for SFR evaluation. At the time of evaluation, stone-free status is defined as the absence of pieces 4 mm or larger.

Abbreviations: kV = kilovolts MPa = Megapascal

Statistical methods

SPSS 28 was used for data management and statistical analysis (IBM, Armonk, New York, United States). The Kolmogorov–Smirnov test and direct visualization methods proved that quantitative data were normally distributed. The quantitative data were presented as means, standard deviations, medians, and ranges based on the assumption of normality. To summarize category data, we utilized percentages and numbers. Mann-Whitney both the U and t tests The U test was created for evaluating quantitative data across groups for normally and non-normally distributed variables. To compare categorical data, Chi-square or Fisher's exact test was utilized. The Chi-square test was used to investigate the correlations between stone size, density, and stone-free rate. Each statistical test produced two outcomes. P values less than 0.05 were statistically significant.

Results

Hundred and eighty patients were eligible for this study; 30 patients were excluded according to the exclusion criteria, and the remaining 150 patients were divided into two groups. (Figure 1).

Demographic characteristics were shown in table 1. Clinical characteristics showed no statistically significant difference between both studied groups (Table 1).

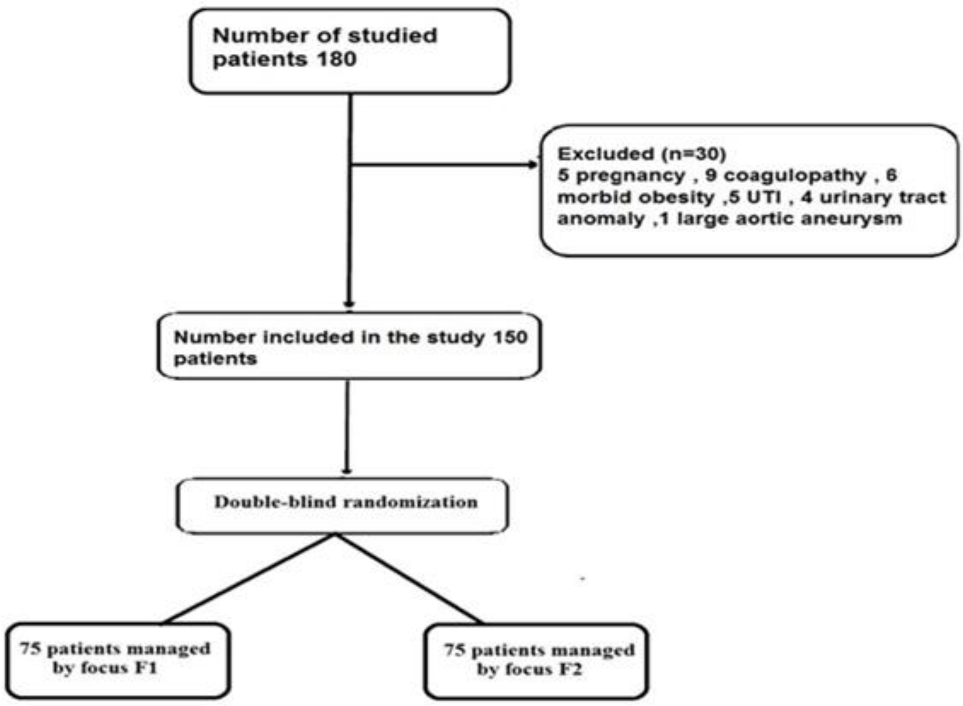

Figure 1: Flowchart of the study.

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Table 1: Demographic characteristics of the studied groups.

	Group A (n = 75)	Group B (n = 75)	*p* value
Age (years)	45 ±14	40 ±15	0.06
Sex			
Males	48 (64)	47 (62.7)	0.865
Females	27 (36)	28 (37.3)	
BMI	27 ±4	27 ±4	0.899
Medical history	37 (49.3)	27 (36)	0.099
Surgical history	37 (49.3)	31 (41.3)	0.325
Clinical characteristics			
Loin pain	75 (100)	71 (94.7)	0.120
Loin pain duration (months)	4 (1 - 6)	3 (1 - 6)	0.962
Stone size (mm)	13 ±4	13 ±4	0.444
Stone density (H.U.)	993 ±272	1022 ±253	0.50
Number of stones			
One	65 (86.7)	65 (86.7)	0.896
Two	7 (9.3)	6 (8)	
Three	3 (4.0)	4 (5.3)	
Site of stones			-
lower calyx	10 (13.3)	8 (10)	
renal pelvis	20 (26.6)	18 (24)	
mid calyx	17 (22.6)	20 (26.6)	
upper calyx	7 (9.3)	8 (10)	
renal pelvis &mid calyx	5 (6.6)	4 (5)	
upper & lower calyx	6 (8)	6 (8)	
upper & middle calyx	5 (6.6)	6 (8)	
upper calyx & renal pelvis	5 (6.6)	5 (6.6)	
Hydronephrosis	17 (22.7)	17 (22.7)	1.0
Minimal	7	8	
Mild	5	6	
Moderate	3	3	
Sever	2	0	

Data were expressed as mean ±SD, median, or number (%);.* Significant as *p value* < 0.05;t- test, or U Mann-Whitney, Chi-square test, Fisher's exact test.

Regarding complications: Group B demonstrated significantly higher colic than group A (22.7% VS. 9.3%, *p* = 0.026). Fever and hematuria were insignificantly different between the studied groups (*p value* > 0.05) (Table 2).

* Significant: *p*<0.05; Data were presented as number (%): Chi-square test or Fisher's exact test.

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 = 0.008). Those who have become successfully treated demonstrated a significantly higher percentage of low density (< 1000 HU) (79.1%) than in those who have not become successfully treated (50%) (Table 3).

Association of stone size and stone density with stone free rate in group B: A significant association was reported between stone size and stone free rate (*p* = 0.009). Stones with a size of 5–10 mm were more common in those who have become successfully treated (56.4%) than in those who have not become successfully treated (25%), while stones with a size of 16–20 mm were more common in those who have not become successfully treated (27.8%) than in those who have become successfully treated (7.7%). Additionally, a significant association was reported between stone density and stone free rate (p= 0.004). Those who have become successfully treated demonstrated a significantly higher percentage of low density (< 1000 HU) (79.5%) than those who have not become successfully treated (47.2%) (Table 3).

Table 2: Complications in the studied groups.

	Group A (n = 75) (%)	Group B (n = 75) (%)	p-value
Fever	5 (6.7)	8 (10.7)	0.384
Colic	7 (9.3)	17 (22.7)	0.026*
Hematuria	8 (10.7)	4 (5.3)	0.229

Table 3: Association of stone size and stone density with stone free rate (SFR) in both groups.

	Group A **(SFR)**		p-value	Group B **(SFR)**		p-value
	Yes (43)	**No (n = 32)**		**Yes (n = 39)**	**No (n = 36)**	
Stone size						
5 - 10 mm	12 (27.9)	3 (9.4)	0.132	22 (56.4)	9 (25)	0.009
11 - 15 mm	19 (44.2)	19 (59.4)		14 (35.9)	17 (47.2)	
16 - 20 mm	12 (27.9)	10 (31.3)		3 (7.7)	10 (27.8)	
Stone density (HU)						
<1000	34 (79.1)	16 (50)	0.008	31 (79.5)	17 (47.2)	0.004
>1000	9 (20.9)	16 (50)		8 (20.5)	19 (52.8)	

unpaired Student's t- test, Chi-square test or Fisher's exact test

Regarding the number of SWL sessions that was needed in each group, group A showed that 43 patients were successfully treated after one SWL session, 20 patients after 2 sessions, 5 patients after 3 sessions, and 7 patients showed no response. On the other hand, group B showed that 39 patients were successfully treated after one SWL session, 18 patients after 2 sessions, 7 patients after 3 sessions, and 11 patients showed no response.

In both groups, patients with SSD < 110 mm showed a higher success rate (85%) compared to patients with SSD > 110 mm (success rate: 56%). (Figure, 2)

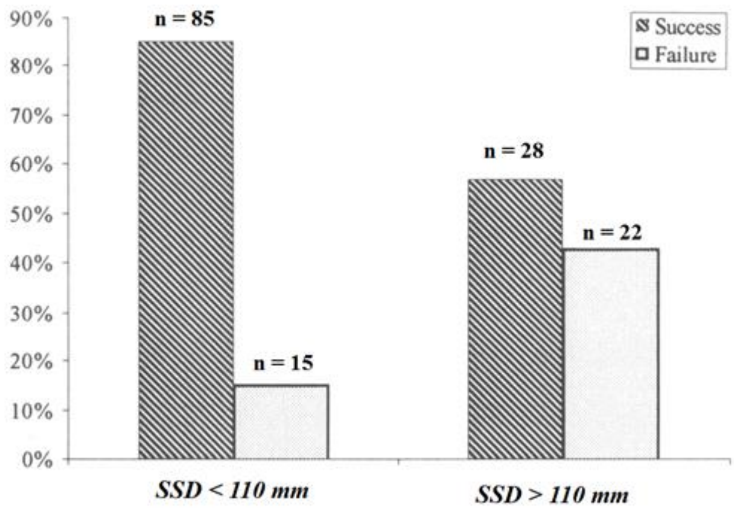

Figure 2: relation between stone to skin distance (SSD) & Stone free rate (SFR).

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Discussion

The impact of varying focal sizes on the efficacy of SWL for renal stones is now often evaluated statistically. 150 patients were treated with a piezoelectric lithotripter for radiopaque renal calculi up to 2 centimeters in size (Wolf PiezoLith3000 Richard Wolf GmBH, Knittlingen, Germany). We assessed two focus sizes (F1 and F2) to examine the efficacy of different focus sizes for renal stone fragmentation during SWL. The acoustic waves are directly focused on an area of interest through their geometrical alignment on the concave carrier, resulting in a high-energy shockwave at the focus point [6, 7]. Regarding age, sex, BMI, chronic condition, surgical history, loin pain, loin pain duration, stone size, stone density, number of stones, location of stones, and hydronephrosis, there was no significant difference between the two investigated groups. According to the findings, 43 patients exhibited SFR when exposed to F1 focus, and 39 patients experienced SFR when exposed to F2 focus. However, there were no significant differences between the groups for residual after 3 months, residual size, or stone-free rate [8, 9].

By rapidly expanding piezoceramic components atop a spherical cylinder, piezoelectric lithotripters generate pressure waves. At the focus point, these acoustic waves form a high-energy shockwave due to their geometry on the concave carrier. When the shockwaves penetrate further into the body, the patient's pain threshold decreases, enabling SWL to be delivered without anesthetic. Even though piezoelectric lithotripters have a lower average compressive pressure than electrohydraulic or electromagnetic lithotripters, the Wolf PiezoLith 3000 employs a double layer of piezoceramic components to match its power. By synchronizing the double-layer piezoelements with shock waves, the focal breadth of the piezoelectric lithotripter may be tuned to one of three positions. Similarly, the PiezoLith 3000's maximum output pressure (MPa) varies from 48 MPa (Focus 3) to 148 MPa (Focus 1) [8, 10].

Several studies and investigations have focused on the variables that influence the outcome of therapy following SWL to improve patient selection and counselling. In addition to finding these traits analytically, multivariate analysis often provides an interesting evaluation of their relative significance [11, 12].

The volume, size, and fragility of the stones have a significant influence on the success rate of ureteral and renal stone removal. However, the influence of other characteristics, such as the position of the stone, the degree of obstruction, and the patient's BMI, is often contested. In addition, the focal size, intensity, and frequency of the lithotripter's shock waves influence the outcome. Therefore, SWL is the treatment of choice for the majority of renal calculi ≤ 20 mm in diameter, while endourological procedures are used when the location or chemical composition of the stone is unfavorable [9, 13].

Using an electrohydraulic lithotripter (HM-3 Lithotripter), Qin et al. found that a lithotripter field with low peak pressure and a broad beam focus size resulted in much better stone disintegration than one with high peak pressure and a restricted beam focus size. Using piezoelectric lithotripsy, Veser et al. demonstrated that a smaller focus size of 2–4 mm lateral diameter at 6 dB and a greater peak pressure result in more efficient in vitro stone disintegration [10, 14].

In group A (F1), a significant association was reported between stone density and stone-free rate. Those with stone density < 1000 HU demonstrated a significantly higher percentage of stone free (79.1%) than in those with stone density > 1000 HU (50%). No significant association was reported between stone size and stone-free rate.

A significant relationship was found between stone density and stone free rate in group B (F2). Those with stone density

< 1000 HU demonstrated a significantly higher percentage of stone free (79.5%) than in those with stone density > 1000 HU (47.2%). Additionally, a significant association was reported between stone size and stone-free rate. In the small stone size group of 5–10 mm, the stone-free rate was higher (56.4%) than the no-stone-free rate (25%), while in the large stone size group of 16–20 mm, those who have not become successfully treated (27.8%) were more than those who have become successfully treated (7.7%).

In 2954 patients with renal stones, Abdel-Khalek et al. discovered the predicted parameters that impact the success rate of SWL. The stone-free rate was 89.7% for stones < 15 mm and 78.2% for stones >15 mm ($p = 0.001$), indicating that the size of the stone considerably influenced success. Joseph et al., examined the CT attenuation value of renal calculi in 30 patients as a predictor of effective fragmentation with SWL. Stones with an attenuation value of more than one thousand HF units had a much lower success rate than those with an attenuation value of less than one thousand HF units [15, 16].

Obesity may make SWL very challenging, and it is now generally recognized that substantially obese individuals are not candidates for SWL. In addition, the obese patient may be too huge for the lithotripter gantry, or the targeted stone may be too deep relative to the shock waves' focus zone. Stone localization difficulties were more prevalent in machines of the first generation, when fluoroscopic and ultrasonic equipment were less effective. Thus, technical advances in the most current lithotripter have simplified stone focusing and enabled the alteration of various stone-targeted focus sizes to increase the stone-free rate [17, 18].

Regarding complications after SWL, group B (F2) demonstrated significantly higher colic (22.7% vs. 9.3%). This may be due to larger fragments of the disintegrating stone passing through the ureter. However, more studies may be needed to know the exact cause. Fever and hematuria were insignificantly different between both study groups. The pathophysiology of pain during SWL is currently poorly understood, and treatment tolerance is strongly dependent on shock wave strength and density, especially shockwave penetration depth into the epidermis. Depending on the distance between the focus point and the cutaneous plane, this entry zone varies. The demand for analgesics diminishes significantly from the kidney to the ureter during piezoelectric SWL. We have also observed that female patients have a lesser tolerance than their male counterparts. Variations in stone depth may help explain these disparities in discomfort [7, 19].

The limitations of the current study are represented by the need to confirm these results with a larger sample size, follow up the patients for longer periods, calibrate the lithotripter machine several times during the period of the study, use more advanced imaging facilities, and fine sponsors to help with financial issues.

Conclusion

Different focus sizes with fixed intensity and frequency result in no significant differences concerning stone fragmentation. However, a combination of both F1 and F2 is recommended to achieve better results. These results need to be confirmed with multiple parameters interfering with the efficacy, like respiration or stone migration.

Declarations

Funding: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Conflict of interest: The authors of this research have no conflicts of interest to declare that are relevant to the content of this research.

Consent to participate: An informed consent was obtained from all individuals included in this study.

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Consent for publication: patients signed informed consent regarding publishing their data and photographs.
Availability of data and material: The data generated during the current study are available from the corresponding author and are included in this published article.
Code availability: Not applicable.
Authors contributions: The authors confirm contribution to the paper as follows: Study conception and design: Dr.Tarek M. EL Karamany, Data collection: Dr.Mostafa A. EL Saadany and Dr.Hosam Abu EL-Nasr , Analysis and interpretation of the results: Dr.Salah A. EL Hamshary, Draft manuscript preparation: Dr.Shabib A. Mohamed , All authors reviewed the results and approved the final version of the manuscript.

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