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Clinical Experience of Extracorporeal Shock Wave Lithotripsy in Treatment of Renal Stones Employing the Recent [Richard Wolf, PiezoLith 3000Plus] at [Al-Azhar University Hospital, Assiut Branch]

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Abstract

Background: Urolithiasis has an important role in the structure of the urological pathology, due to its high incidence, frequency of recurrence and complications.

The aim of the work: To evaluate the efficacy of shock wave lithotripsy [SWL] as a therapeutic for renal stones, using recent Richard Wolf, PiezoLith 3000Plus device at Al-Azher university hospital Assiut branch.

Patients and Methods: A prospective study included 50 patients was conducted between September 2022 and April 2023. They were selected from Al-Azher University Hospital, Assiut branch. The procedure was considered to be successful in patients with no stone fragments or with any stone fragments smaller than 4 mm in size at 2 and 6 weeks after the first, second or third session

Results: The overall success rate is 84%, with 16% of cases failing. The PiezoLith 3000Plus device, developed by Richard Wolf, is highly effective in treating renal stones. Considerable variance existed among SF status, stone size, stone density, BMI, and SSD. There was no significant relation between SF status stone laterality, height of the patient or degree of HN.

Conclusion: The success of SWL in renal stones may be recognized through identifying elements like patient BMI, SSD, & calculus density. The PiezoLith 3000Plus device, developed by Richard Wolf, is highly effective in treating renal stones.

Keywords: Renal stones; Calculi; Extracorporeal Shock Wave Lithotripsy; Richard Wolf PiezoLith.

INTRODUCTION

Nephrolithiasis is one of the oldest diseases known to medicine. It is estimated that 1-15% individuals suffer from kidney stone formation at some point during their lifetime, and the prevalence and incidence of kidney stone is reported to be increasing worldwide. Without proper treatment, kidney stones can cause the obstruction of the ureter, hematuria, frequent urinary tract infections, vomiting or painful urination, culminating in the permanent functional damage of the kidneys [1].

Urolithiasis has an important role in the structure of the urological pathology, due to its high incidence, frequency of recurrence and complications. It reduces the medium life span from 5% to 20% of the patients, the recurrences being detected in 50 :67% of the cases] [2].

The treatment options of kidney stones include open surgery, extracorporeal shock wave lithotripsy, retrograde intrarenal surgery [RIRS], percutaneous nephrolithotomy [PCNL], laparoscopy and ureterorenoscopy [rigid or flexible] [3].

European Association of Urology [EAU] guidelines offer shock wave lithotripsy [SWL] treatment algorithm for renal stones based on size and location. For stones in the upper or middle pole or renal pelvis, SWL is the first-line method for stones of <20 mm. Stones located in the lower pole can be treated by SWL, which has satisfactory results for stone sizes of <15 mm, but for larger stones URS or PCNL are the methods of choice [4].

All lithotripsy machines consist of 4 main components. They are shock wave generator, focusing system, coupling mechanism, and imaging or localization unit .There are three primary shockwave generator designs in use. The first utilizes electrode tips as a point source and is known as an electro-hydraulic generator. Shockwaves are produced when an electrical spark occurs between the tips. These occurrences are linked to the evaporation of water at the tips. Shockwaves are produced by passing an electromagnetic coil in one direction and a metal membrane in the other. The last one relies on the piezoelectric effect; the sphere's surface is covered with piezoelectric crystals. The piezoelectric crystals generate shockwaves by contracting in response to the external energy that powers the lithotripter [5]

The outcome of ESWL in treatment of renal stones is affected by stone size, location, composition, density, multiplicity and skin-stone distance [SSD]. Based on clinical experience and on studies: frequency, power, focus size, power ramping are technical factors that affect the stone free status [6].

THE AIM OF THE WORK

This study aimed to evaluate the efficacy of shock wave lithotripsy [SWL] as a therapeutic for renal stones, using recent Richard Wolf, PiezoLith 3000Plus device at Al-Azher university hospital Assiut branch.

PATIENTS AND METHODS

This prospective study was conducted in the department of Urology, Al-Azher University Hospitals [Assiut] from September 2022 to April 2023. 50 patients with renal stones were included of patients attending outpatients' clinics. All patient sample were treated by PiezoLith 3000 plus at Al Azhar University Hospital. A full history was taken and complete physical examination was done to all patients. They were investigated by urine analysis, coagulation profile, KUB x-ray film, pelvi-abdominal US and non-contrast CT.

Inclusion Criteria included Male and female patients between 20 and 60 years of age, average body built had a single renal stone sized less than or equal 20 mm as measured by CT operator and Hounsfield unit less than 1200. While patients with contraindications of ESWL, congenital abnormalities on the same side and patients with musculoskeletal malformations were excluded.

Technique: The day before the session the patients start fasting 12 hours before the session and they are is given adsorbent agent the minimize the gas collection in abdomen and improve stone visualization. All patients were given medications to control pain as morphine and NSAID in order to decrease undesired patient movement. Patient was asked to lie on the SWL table in supine position and come in contact with generator membrane, ultrasound gel was applied on the patient flank in area with contact with the membrane insurance that there was no air between the membrane and patient body was done. As a basic principle treatment in supine position. Stone localization done by ultrasound in radiolucent stones and X-ray fluoroscopy for detection of radio-opaque stones. The localization approach starts within the 0° projection .The goal is to position the stone in the center of the focus by adjusting all three dimensions, x axis [left-right], y-axis [head-feet] and z-axis [height-depth].

Focus size is important for successful SWL so it is adjust at the start of the session at small focus then it was changed in some cases to lager focus according to the stone disintegration advancement . Treatment starts at lower energy levels, from 8 to 10 degree on the scale of power followed by progressive augmentation [ramping] up to 18, rather than applying maximum energy levels right at the beginning. Shock waves was applied at a frequency rate of 60 Hz at the start of the session then increased to 90 HZ. The maximum amount of shock waves depends on energy levels, and on stone localization other stone and patient factors as stone size, density or SSD, it ranged from 2000- 4000 shock waves.

Follow up: The procedure was considered to be successful in patients with no stone fragments or with any stone fragments smaller than 4 mm in size at 2 and 6 weeks after the first, second or third session. Stones smaller than 4 mm were considered clinically insignificant stone fragments. Patients who had a significant residual stone [>4 mm] or stones not fragmented 2 weeks after 1st SWL session were scheduled for another session one month after the 1st session. If they had significant residual 2 weeks post the 2nd session they were scheduled for the 3rd and last session [maximum number of sessions] one month after the second one with total treatment period of 3 months. If there was significant residual 2 weeks after the third session were considered Failed ESWL and were treated with alternative treatment methods.

Statistical analysis: The gathered information was systematically arranged, categorized, & subjected to statistical analysis utilizing version 25 of the Statistical Package for the Social Sciences [SPSS] software [SPSS Inc., USA]. In addition to conducting descriptive statistics on all research variables, a normality test was also applied to all quantitative variables. The normality of the information was examined using the Kolmogorov-Smirnov & Shapiro-Wilk tests.

In lieu of means & standard deviations, medians, ranges, & interquartile ranges [IQR] were employed to summarize numerical data. A synthesis of categorical data was performed using percentages. Disparities among categorical variables were examined using the chi-square test. As applicable, the results of the information analysis were displayed in the text or figures. Significant variations are those in which the probability [p] value is less than 0.05.

RESULTS

The patient age ranged between 20 and 60 years, the majority of them were in their forties. Males represented 76.0% of all study population and no obese subjects were recorded. The renal pelvis was the commonest site of stone location [46.0%] followed by the upper and middle calyces. The majority of stone had a density from 350 to 1000 [66.0%]. The number of session was one, two and three in 54%, 26.0% and 20%, respectively [Table 1].

Stone clearance was achieved for 54% after the first session and increased to 84% after the third session. Thus, the overall success [overall stone free rate was 84.0%]. The failure was recorded for 16% after the third session [Table 2].

The success was significantly associated with lower body mass index, lower SSD, lower stone density and locations other than lower calyx [Table 3].

Table [1]: Demographics and Characteristics of stones among study patients

Variable		Values
Age	Mean±SD	38.0±15.8
	Min. – Max.	20-60
Sex [n,%]	Male	38 [76.0%]
	Female	12[24.0%]
BMI [kd/m^2]	Mean±SD	26.3/ 2.1
	Min. – Max.	17.6 – 29.1
Stone location [n,%]	Upper calyx	10[20.0%]
	Middle calyx	10[20.0%]
	Pelvis	23[46.0%]
	Lower calyx	7 [14.0%]
Stone density [n, %; Mean±SD]	From 350-1000	33 [66.0%]; 790±190
	From 1001-1200	17 [34.0%]; 1135±50
No of session	Once	27 [54.0%]
	Twice	13 [26.0%]
	Thrice	10 [20.0%]

Table [2]: Stone free rate after the first, second and third session.

Variable		Values
Stone free status [n,%]	After first session	27[54.0%]
	After second session	13[26.0%]
	After third session	2 [4.0%]
	Overall stone free rate	42[84.0%]
	Failure	8 [16.0%]

Table [3]: Factors associated with success among study population

Variable		Success [n=42]	Failure [n=8]	Test	P
BMI		26.6±1.9	28.6±1.3	3.21	0.004*
SSD		9.2±0.8	11.1±0.9	2.36	0.022*
Stone density	350-1000 HU	32 [76.20%]	1 [12.5%]	12.14	<0.001*
	1001-1200 HU	10 [23.80%]	7 [87.5%]		
Stone location	Upper calyx	9 [21.4%]	1 [12.5%]	18.86	<0.001*
	Middle calyx	9 [21.4%]	1 [12.5%]		
	Pelvis	22 [52.4%]	1 [12.5%]		
	Lower calyx	2 [4.8%]	5 [62.5%]		

DISCUSSION

Urolithiasis is the third most prevalent urological disorder on a global scale, resulting in substantial morbidity & mortality in ten percent to fifteen percent of the population. Dietary & lifestyle modifications are anticipated to contribute to an increase of almost two million lives by 2050, accompanied by a 25 percent surge in healthcare expenditures [7].

In our research, it was determined that BMI & SSD values were significant predictors of SWL efficacy in the therapy of renal stones. Where the mean BMI and SSD in SF group were 26.3 and 9.2 cm respectively and were 28.6 and 11.1 in failed group. This indicate that low BMI and less SSD may affect positively the success outcome.

Consistent with the majority of previous research, the findings of the present research indicate that there are no significant correlations among the age & gender of the patient, side effects, or treatment effects [8].

Our study showed a significant relationship between the stone size and stone free rate, P value <0.05 which is a statistically significant. There were 12 patient with stone size <10mm with stone free rate 22% and 2% failed. While there were 38 patient with stone size 10-20 mm, 62% case of them ware free and 14% cases failed. In a prospective study data were collected on total of 1230 patients with kidney stones in the study showed that, stone size is a statistically significant factor for predicting SWL success [9].

As regard to the stone density and stone free status :There is a strong relationship between type of stone density and stone free rate. These results may reflect that stone density is an important predictor factor of success rate and reflect the high efficacy of our device to achieve a very good result against hard stones.

As regarding to the stone site and stone free status: In our study the location of stones in the stone free group [84%] the majority was in the renal pelvis 44% patient, 4% lower calyx, 18% both middle and lower calyx, however the failed group [16%] was 10% in the lower calyx and 2% in each upper & middle calyx and renal pelvis. That coincides with a prospective study included 714 renal units in 687 patients with isolated caliceal stones using a Lithostar lithotriptor [Siemens Medical Systems, Erlangen, Germany]. The stones were localized in the lower, mid and upper calices in 455, 104 and 128 patients, respectively. The effectiveness quotient of extracorporeal shock wave lithotripsy was 36%, 46% and 41% for lower, middle and upper pole stone disease, respectively [p = 0.4]. There was a highly significant correlation between stone-free and stone location. The overall stone-free rate was 66%, and 63%, 73% and 71% for lower, middle and upper calyceal stones, respectively [p = 0.1] [4].

Overall, the results of current work agree with **Oliveira et al.** [10] who reported an overall success rate of 85%. They added that the stone size and location are significantly associated with the treatment success. However, the stone to skin distance [SSD] did not correlated with outcome [different than the current work]. This may be explained by the used device, as we used the recent with multimodal device. In addition, the retrospective nature of their study and variation in the number of patients may be responsible.

In agreement with the current work, where stone lower calyx was associated with higher rate of failure, **Alić et al.** [11] reported that, stones located in the lower renal calyx, tend to leave fragments after treatment. These fragments remain in the calyx and lead to recurrent formation of the stone.

Conclusion: The success of SWL in renal stones can be determined by identifying elements like patient BMI, age, SSD, and calculus density. The overall success rate is 84%, with 16% of cases failing. Richard Wolf created the PiezoLith 3000Plus device, which is very effective in treating proximal ureteral stones. However, the small sample size is a major limiting step against globalization of results. Future studies are recommended.

Disclosure:

None to be disclosed.

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