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Case-controlled Study

The effect of stone and patient characteristics in predicting extra-corporal shock wave lithotripsy success rate: A cross sectional study

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ABSTRACT

Introduction: We determine the effect of patient characteristics (age, sex, and body mass index BMI) and stone characteristics (density, location, and size) by non-contrast computed tomography of the kidneys, ureters, and bladder (CT-KUB) in predicting the success of extracorporeal shock wave lithotripsy (ESWL) in the treatment of kidney and ureteric stones. We present this study to further enrich the knowledge of physicians towards the effect of different patient characteristics upon predicting extra-corporal shock wave lithotripsy success rates.
Methods: We evaluated 155 patients who received ESWL for renal and ureteric stone measuring 3–20 mm (mm), over a 3-month period. The stone size in millimeters, density in Hounsfield units (HU) and its location was determined on pre-treatment CT-KUB. ESWL was successful if post-treatment residual renal stone fragments were ≤3 mm and for ureteric stones should be totally cleared.
Results: The overall success of ESWL treatment was observed in 65.8% of the 155 patients. There was no significant difference seen when the effect of patients age, sex and BMI were studied with ESWL outcome with P values were 0.155, 0.101 and 0.415 respectively. Also, stone location either in the kidney or ureter has no statistically significant effect on ESWL response rate. while stone density and size determined on CT KUB have statistically significant effect on the success rate of ESWL with a P-value of 0.002 and 0.000 respectively.
Conclusions: This study shows that determination of stone density and stone size on CT KUB pre ESWL can help to predict the outcome of ESWL. We propose that stone density <500 HU and stone size < 5 mm are highly likely to result in successful ESWL.

1. Introduction

Urinary stones are common pathology, affecting 12% of men and 5% of women in their lifetime and the recurrence occur in two thirds of patients within 20 years. Kidney and ureteral stones are the third most common pathologies in urology after urinary infections and diseases of the prostate. The incidence of urinary stones is reported to be increasing in both developed and developing countries over the past few years [1,2]. Increasingly, the diagnostic radiological modality used for urinary tract lithiasis is computed tomography of the kidneys, ureters and bladder without contrast (CT-KUB) [3]. Unlike ureteric stones, most renal stones are asymptomatic, but can become symptomatic when they migrate to the ureteropelvic junction or ureter and can lead to complications such as hematuria, flank pain, urinary tract infection and also renal failure [4]. In order to prevent these complications, there are various treatment options such as Extracorporeal Shock Wave Lithotripsy (ESWL), ureteroscopy (URS), Retrograde Intra-Renal Surgery (RIRC), Percutaneous Nephrolithotomy (PNL), and open surgery [1,5]. Of these methods ESWL which was introduced in 1980 is a safe, non-invasive, effective and have become the most commonly used

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method for treating nephrolithiasis. Despite that, patients should be selected carefully to avoid unnecessary complications such as hemorrhage, infection and flank pain [6,7]. The success rate of ESWL is dependent on a number of factors, which include stone density, size, shape and location, and patient characteristics like Body Mass Index (BMI) [6]. We evaluate the role of stone (density in Hounsfield Units (HU), location and size) and patient (sex, age and BMI) characteristics in predicting the success of ESWL treatment, though some studies investigate the factors affecting ESWL outcome, our study investigates many factors (related to patient and the stone) together to see which can predict ESWL outcome.

2. Materials and methods

2.1. Study design

This is a cross sectional study conducted from February 2021 to April 2021 affiliated with the Faculty of Medicine, Yarmouk University, an ethical approval number (IRB/2021/19) was provided by our institution. Research was registered in ResearchRegistry.com, Registration number (researchregistry7035). https://www.researchregistry.com/register-now#home/registrationdetails/610d8ab6cd7ff9001eb7065c/

2.2. Population

The study included patients with renal or ureteric stones, aged between 18 and 82, who attended the Extracorporeal Shock Wave Lithotripsy unit.

2.3. Inclusion and exclusion criteria

Inclusion criteria were kidney and ureteric stone measuring between 3 and 20 mm in patients who had undergone a pre-treatment CT-KUB and who were also radio-opaque on pre-treatment KUB (kidney, ureter and bladder) x-ray film. Patients who did not have a pre-treatment CT-KUB, had radiolucent stone or had a ureteric stent or nephrostomy tube before ESWL were excluded. Also, patients with elevated kidney function test, severe pain not relieved by analgesia or pyelonephritis due to obstructed ureteric stone were also excluded from the study. In addition to that patient who didn't attend after ESWL session to do follow up KUB x-ray were also excluded from the study.

3. Methods

About 155 patients fulfilled our criteria, informed written consents were obtained from all participants after explaining the objectives and benefits of the research. Participants had the right to refuse participation or withdraw from the study at any point without any detriment to their health care. Patient age, sex and BMI were recorded during the treatment session. All patients had a CT-KUB with a helical CT scanner. Determination of stone characteristics (location in kidney or ureter, size in mm and density in HU) was carried out at the CT workstation by the radiologist using axial planes. All patients received around 3500 shock waves from Lithotripter. Stones were fragmented using fluoroscopic/ultrasound guidance. Post-treatment KUB x-ray scan was used to assess fragmentation of ureteric and renal stone in the first 2 weeks after fragmentation, if residual renal stone fragments were $\leq$3 mm and for ureteric stones should be totally cleared, then patients were considered to have clinically successful ESWL outcomes [8].

Data entry and analysis were performed using the SPSS statistical package (version 20). Categorical data were analyzed using the chi-square test. A p-value of $<$0.05 was considered statistically significant. This work has been reported in line with the STROCSS criteria [9].

4. Results

Of the 155 patients who underwent ESWL for renal and ureteric stone in our unit between February 2021 and April 2021 and fulfill our study criteria, about 78.1% of the patients were male, with age range from 18 to 82 years old (mean 44.83 year) (Table 2). Patients BMI were also calculated and classified into 4 groups Underweight, normal, Overweight and obese (which is also sub classified into further three classes) [10]. About 39.4% of the patients were overweight, 31.6% obese, 27.7% normal BMI and only 1.3% underweight (Table 2), the mean value for BMI was 28.04 kg/m^2.

Stone size varies between 0.3 and 20 mm, with two-thirds of the stones were in the ureter (Table 2). For stone density patient stones were classified into three groups less than 500 HU, 500 HU to 800 HU and more than 800 HU, with about half of the stones were with HU between 500 and 800 (Table 2) and the mean value for stone density was 726.7. The overall success of ESWL treatment was observed in 65.8% of the 155 patients (Table 1). There was no statistically significant effect seen when the effect of patients age, sex and BMI were studied with ESWL outcome with P values were 0.155, 0.101 and 0.415 respectively (Table 2).

On the other hand, as stone density measured in HU decreases, the success rate of ESWL improves, as in our study patients with stone density less than 500 HU has 90.3% ESWL success rate, compared to 64.9% and 51.1% for stones with density between 500 and 800 HU and more than 800 HU respectively, with a P-value of 0.002 (statistically significant).

There is also statistically significant effect seen when the effect of stone size and ESWL outcome was studied (P-value = 0.000). patients who underwent ESWL with stone size less than 5 mm have 73% ESWL success rate compared to 68.4% for stones between 5 mm–10 mm and 32% for stones more than 10 mm.

Unlike stone density and size, stone location either in the kidney or ureter has no statistically significant effect on ESWL response rate with P value of 1.000.

5. Discussion

Since its introduction in 1980 by Chaussy et al., ESWL has gained an increasing popularity in the treatment of urinary stones and has become the treatment modality of choice for uncomplicated renal and ureteral stones <20 mm in diameter due to its safe and non-invasive nature [1,11,12]. Previous studies have reported a wide variation of ESWL success rate ranging from 46% to 91% [4,12] (in our study, success rate was 65.8%). Different definitions of successful and failure outcomes were used by different authors, one study defined failure outcome of ESWL as the presence of significant residual fragments larger than 4 mm after 3 months from ESWL [13]. Another study considered ESWL failure If stone

Table 2
Variables and their classifications to be studied with ESWL outcome and P value for each variable.

Variables to be studied with ESWL outcome	P value
Age (from 18 to 82)	0.155
Gender: Male (78.1%)	0.101
Female (21.9%)	
BMI: Underweight (1.3%)	0.415
Normal (27.7%)	
Overweight (39.4%)	
Obese (31.6%)	
Stone location: Kidney (31.6%)	1
Ureter (68.4%)	
Stone density: Less than 500 HU (20%)	0.002
500 HU -800 HU (49.7%)	
More than 800 HU (30.3%)	
Stone size: Less than 5 mm (71.6%)	0.000
From 5 mm to 10 mm (12.3%)	
More than 10 mm (16.1%)	

Table 1
Total number of patients, with the number of patients who had successful stone fragmentation and those who failed.

		Gender		Total
		Male	Female	
ESWL outcome	Failure	37	16	53
	Success	84	18	102
Stone size(mm)	Less than 5	89	22	111
	5–10	17	2	19
	More than 10	15	10	25
Stone density (HU)	Less than 500	27	4	31
	500–800	53	24	77
	More than 800	41	6	47
Age groups	Less than 20	0	1	1
	20–39.9	42	14	56
	40–59.9	59	10	69
	60–79.9	17	9	26
	More than 80	3	0	3
BMI groups	Normal	37	7	44
	Overweight	46	16	62
	Obese (class I)	32	9	41
	Obese (class II)	6	1	7
	Obese (class III)	0	1	1

was not fragmented at all, or if there were residual fragments measuring 5 mms or more after four sessions [14].

Failure of ESWL results in unnecessary exposure of renal parenchyma to shock waves and complications like renal hematoma [15].

Increasing Efforts have been made to determine factors that predict ESWL outcome and improve patients' selection. Many factors have been studied and reported to affect ESWL outcome. These factors can be classified into patient related-factors such as age, gender, BMI, anatomy of urinary tract, and stone related factors obtained from imaging studies such as stone size, location, density, Skin-to-Stone Distance (SSD), and the type and properties of the used lithotripter [1,2,4,12,16].

5.1. Age

Few studies have found that age has a significant effect on ESWL outcome, in a study of 3023 patients with renal and ureteric stones the author revealed that the younger the patient, the higher the stone-free rate [17]. Other studies showed that age was not a significant factor affecting the ESWL outcome [12,16]. as we found in our study.

5.2. Gender

As in our study, gender was not found to be a statistically significant predictor of ESWL outcome in many previous studies [16,18]. However, in other studies gender was a statistically significant factor that affect ESWL outcome, in a study of 235 patients with urinary stones, success rate of ESWL was higher in males [12].

5.3. BMI

Although skin-to-stone distance (SSD) have a positive correlation with BMI, in some studies there were a significant relationship between SSD and ESWL success but not between BMI and ESWL success, the reason behind this is probably that, in contrast to SSD, BMI does not truly reflect central body fat distribution [19] however, in other studies BMI was a predictive factor for ESWL success, Waqas M et al. found that patients with BMI <30 kg/m2 have a higher ESWL success rate than patients with BMI >30 kg/m2 (P- value = 0.001) [20].

5.4. Stone size

Stone size which can be measured by the largest diameter of stone on CT KUB scan, was of statistical significance to affect the outcome of ESWL in multiple previous studies. In a study conducted on 427 patients with renal stones, the success rate for stones $\leq$10 mm was 90% and 70% for stones $>$10 mm (p-value $<$ 0.050) [18]. in another study of 203 patients with renal stones the median stone diameter in the success group was 9.39 mm and 13.41 mm in the failure group (p -value $<$0.001) [2]. In a study of 130 patients with ureteral stones, stone size was also a significant predictor of ESWL outcome [21]. However, other studies found that there is no significant correlation between stone size and ESWL success such as a study of 43 patients with urinary stones, stone size has no significant difference between the two groups neither in the univariate nor the multivariate analysis [22].

5.5. Stone density

Stone fragility depends on stone composition and its mineral content [5,23]. Many studies have investigated the relationship between stone density on radiological imaging and its composition and reported that it is possible to predict stone composition from its density [24,25]. Moreover, the role of stone density in influencing ESWL outcome was the subject of study in many researches and was demonstrated as a predictor for success rate of ESWL [5,23,26].

Stone density can be obtained from CT KUB and expressed as Stone Attenuation Value (SAV) in Hounsfield Units (HU) or as seemed to be more accurate HU density in HU/mm(2, 25) and less commonly radio-density of stone on KUB as compared to that of 12th rib [5].

Different studies have recommended different densities, Gupta et al. have found that the best ESWL outcome was found when mean stone density $\leq$750 HU [27]. In another prospective study on 50 patients with urinary stones, the author determined that a 970 HU threshold of stone density is a very specific and sensitive for prediction of ESWL outcome [28]. El-Nahas et al. have found that stone density $>$1000 HU is a significant predictor for the failure of ESWL [29].

5.6. Stone location

Stone location affects ESWL success rate; Abdel-Khalek et al. found that renal pelvis and upper calyceal stones have ESWL success rate that is 2.37 and 1.81 times greater than lower calyceal stones, respectively [30].

5.7. SSD

Park et al. found in his study of 43 patients with renal stones that SSD was the only factor that influences ESWL success in the multivariate logistic regression analysis(22), this is probably because as SSD became longer, the shockwave force would be attenuated [31]. However, studies on Asian populations discussed that, SSD is not a significant predictor for ESWL success because they have thin body volumes compared to Western populations. Moreover, the effect of SSD on ESWL success for ureteral stones was controversial [31].

6. Conclusions

Our study was limited by the number of centers and participants. a wider range of participants would have been better for reaching more efficient results. We conclude that the determination of stone density and stone size on pre-treatment CT-KUB can predict the success of ESWL for both ureteric and renal stone. The value of using these variables may aid in better selecting patients for ESWL and thus improving the efficacy of ESWL. Further studies on a larger scale are needed to validate these results.

Conflicting interests

The authors declare that there was no conflict of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amsu.2021.102829.

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Author contribution

All authors read and approved the content of the submitted study.

Consent

Consent was obtained from all the volunteers.

Registration of research studies

In accordance with the Declaration of Helsinki 2013, all research involving human participants has to be registered in a publicly accessible database. Please enter the name of the registry and the unique identifying number (UIN) of your study.

You can register any type of research at http://www.researchregistry.com to obtain your UIN if you have not already registered. This is mandatory for human studies only. Trials and certain observational research can also be registered elsewhere such as: Clinicaltrials.gov or ISRCTN or numerous other registries.

Not Applicable.

Guarantor

The Guarantor is the one or more people who accept full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

Mohammad Al- zubi

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