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ORIGINAL ARTICLE

Different Modalities of Localization of Radiolucent Renal Stones during Extracorporeal Shock Wave Lithotripsy

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ABSTRACT

Background: Nephrolithiasis is a common disease. It affects quality of life. Urinary calculi may be radiopaque or radiolucent on conventional radiography according to its composition. However, only radiopaque stones can be detected by fluoroscopy. Radiolucent stones can be localized by ultrasound (U/S) or using contrast media.

Aim: To evaluate different modalities localization of radiolucent stones during extracorporeal shock wave lithotripsy (ESWL) regarding efficacy, safety and cost-benefit.

Methods: This prospective randomized clinical trial study included 48 patients presented to urology department by renal stones were treated by ESWL using electromagnetic Dornier lithotripter at Zagazig university hospital. Patients were divided into: Group(A) underwent ESWL on radiolucent renal stones, localized by U/S guidance and group (B) underwent ESWL on radiolucent renal stones, localized by fluoroscopy guidance by application of contrast media infused intravenously or through a ureteric catheter.

Results: There were no statistically significant differences ($p>0.05$) betweenU/S guided group and contrast guided group as regards stone free rate (SFR) after one ESWL session. There were no significant differences between the two treatment modalities regarding occurrence of complication ($p>0.05$). U/S guidance is more cost effective than contrast use.

Conclusions: U/S guidance has similar results to fluoroscopy with application of contrast media in localization of radiolucent renal stones during ESWL regarding SFR and complications. However, U/S has slightly better results and more cost effective than contrast fluoroscopy, U/S guidance is preferred due to the absence of radiation exposure.

Keywords: Radiolucent Renal Stones; Extracorporeal Shock Wave Lithotripsy; Ultrasound.

INTRODUCTION

Urinary tract stones are a common disease affecting of 5–10% of the population **[1]** with clinical manifestations such as loin pain, nausea, vomiting, hematuria, and in severe cases, hydronephrosis and renal function impairment **[2].**Urolithiasis is a global disease affecting all geographical regions in the world. The annual prevalence is between 3–5%. Most patients with renal calculi tend to have repeated episodes of urolithiasis. Renal stone recurrence rates are roughly 10% annually, 50% over a period of 5–10 years, and 75% over a period of 20 years **[3].**Although calcium oxalate stones are the most frequent type, uric acid stones account for 10% of all urinary calculi. Uric acid stones tend to be recurrent**[4].** Low urine PH, radiolucency on conventional radiography, and low density on NCCT are indicative of the presence of uric acid stones mostly. **[5].**After its introduction in 1980, ESWL has significantly altered the treatment of urinary calculi because it is an outpatient, minimally invasive procedure and doesn't require anesthesia **[6].**Small and medium-sized kidney stones respond well to ESWL treatment, with varying published success rates as high as 90%. Since the ESWL is noninvasive, less expensive, has fewer adverse effects, and quicker recovery, it has become the most popular procedure for treating renal stones with a diameter of less than 20 mm **[7].**

Stone site, size, location, composition, stone attenuation values on Non contrast computed tomography (NCCT), skin-to-stone distance [SSD], pelvicalyceal anatomy, patient body mass index [BMI], and shockwave delivery frequency are some of the established factors influencing the SFR when ESWL has been used for management **[8, 9].**ESWL is assisted by imaging tools to detect the location of urinary stones and help focusing shock waves towards the stone. To maximize the accuracy of the shock waves, precise and real-time imaging of the stone's location is necessary **[10].**Urinary stones can be localized by using fluoroscopy or U/S. Since ESWL was introduced in the 1980s, fluoroscopy has been utilized extensively to detect the stones during ESWL and is compatible with all lithotripter devices. However, fluoroscopy can only detect stones that are radiopaque. In the meanwhile, radiolucent stones can be visualized using U/S. Additionally, using U/S guidance during ESWL has the advantage of preventing exposure to radiation. Radiolucent stones can also be visualized under fluoroscopy by using contrast media **[11, 12].**U/S usage in localization of renal stones during ESWL may be difficult in obese patients and needs more experience **[13].**

METHODS

This Prospective randomized clinical trial (closed envelope) included 48 patients presented to urology department by renal stones were treated by ESWL using electromagnetic Dornier lithotripter at Zagazig university hospitalin a period between May 2023 to January 2024.

Patients more than 18 years old with radiolucent renal stones (upper, middle calyceal, pelvic less than 2 cm or lower calyceal more than 1 cm and less than 2 cm) were included in the study. Radiopaque stones, any contraindication to ESWL

(Bleeding diathesis, Pregnancy, Pyonephrosis, uncontrolled hypertension, cardiac pacemaker, distal obstruction), Uncontrolled DM, renal impairment, renal or ureteric anomalies and Morbid obesity BMI >35 were excluded in the study.

All patients were subjected to History taking, physical examination, lab. Investigation (CBC, PT, PTT, INR, KFT, LFT, RBS, Urinalysis & urine culture.) & pelvi-Abdominal ultrasound which can detect radiolucent stones in addition to radio-opaque stones and helps in assessment of the result of ESWL on renal stones.NCCT was performed before each ESWL session. Stone criteria are identified as regard to size, side, location, skin to stone distance, stone density and associated hydronephrosis.

Assuming that all cases met the inclusion and exclusion criteria will be included. During the study period (6 months), 8 cases /month, 48 cases will be included as a comprehensive sample.

Patients fulfilling the study criteria were randomly allocated to one of two groups (24 patients in each): Group(A) underwent ESWL on radiolucent renal stones, localized by U/S guidance (Sonoscape) and group (B) underwent ESWL on radiolucent renal stones, localized by fluoroscopy guidance by application of contrast media infused intravenously or through a ureteric catheter. There were 2 cases difficult to be localized by US due to obesity, so shifted to contrast group and there was 1 case of previously known contrast allergy in contrast guided group, so, shifted to U/S group.

all the patients signed an informative written consent. The patients in the fluoroscopy group been informed about the hazards of radiation exposure and contrast injection.

ESWL was performed by using the electromagnetic Dornier Delta III lithotripter (Med Tech, Germany). The patients received analgesia before starting ESWL session in form of (nalbuphine 20mg) intravenous diluted in 10cc normal saline 0.9%, and (ketorolac tromethamine 30mg) intramuscular. Anesthesia was used in localization of migrated radiolucent stones to kidney during ureteroscopy operation in same setting while patient was anaesthetized, could not afford flexible ureteroscopy and accepted ESWL with contrast guidance, in this case, a ureteric catheter fixed and patient transported from operating room (OR) to ESWL machine room which is near to OR and Localization was done through application of contrast through a ureteric catheter. Analgesia or Anesthesia was used to minimize pain to increase ESWL efficacy.

In patients with migrated radiolucent renal stones to kidney during ureteroscopy, the size of previously ureteric stone was detected through preoperative NCCT and stone site was localized by application of contrast though a ureteric catheter.Intravenous fluid administration was given to all patients throughout the procedure and all patients were treated in supine position with water cushion adjusted below the flank. Each patient took off his cloths and placed in supine position on the ESWL table.

In Group (I): Use of U/S in Localization of radiolucent stones during ESWL (U/S ESWL), (included 23 patients): localization of stone is done by inserting the U/S probe, then the table is moved in medio-lateral, cephalo-caudal and up-down directions, first we localize the kidney shadow then the stone with its hypoechoic shadow appears, then we move the probe up and down until the stone become in the center of the cross mark to start the lithotripsy.In Group (II): radiolucent renal stones localized by fluoroscopy guidance by application of contrast media infused intravenously or through a ureteric catheter (Contrast FLURO ESWL), (included 25 patients): Dose of IV injected contrast: 1 ml / kg. Contrast injected through ureteric catheter is diluted with saline in a ratio of 1:2 and taken as needed. When the stone is localized, the lithotripsy started.

The lithotripsy is started with low power, increasing gradually until reaching the maximum allowed power (18) Jules, the frequency used was 65 shock / second for all patients, all patients received a total of 3000 shocks at maximum for each session.

When the patient completes the session, he remained in a side room for 30 to 60 minutes for checking of his vital signs giving information and advisement regarding the post lithotripsy course and time of next visit, then all patients discharged on (oral analgesia and alpha-blocker). Throughout the ESWL session, the patient's position was changed to improve stone localization and shock waves accuracy. Every 600 shocks or when the patient moved, the location was evaluated and modified in the contrast FLURO ESWL group. The patient's position wasn't altered if their stone was still in the focal zone. While in the U/S ESWL group, positioning was modified based on the real time imaging of the stone's location throughout the session.

Follow up:Patient were followed up by Pelvi-abdominal U/S 2w post ESWL to detect results of ESWL on radiolucent renal stones and detect complications such as perinephric hematoma & NCCT of the abdomen and pelvis used in patients with backpressure changes and when U/S is unable to conclusively identify the presence of stones or residual stones that are 4 mm or less and to validate the stone-free rate or successful ESWL. Another ESWL session—which is regarded as a supplementary treatment—needed for residual stones more than 4 mm. urinalysis was done to detect complications as hematuria and urinary tract infection.

STATISTICAL ANALYSIS

Using IBM SPSS Statistics for Windows, Version 23.0 (Armonk, NY: IBM Corp. 2015), all data were gathered, tabulated, and statistically analyzed. Qualitative data were presented as percentages and figures, while quantitative data were given as the mean ± SD & median (range). The non-normally distributed variables of the two groups were compared using the Mann Whitney U test. The normally distributed variables of the two groups were compared using the t test. The Chi-square test or the Fisher Exact test, when suitable, was used to compare the percentage of categorical variables. All tests were two sided. P-value < 0.05 was considered statistically significant and p-value ≥ 0.05 was considered statistically non-significant.

RESULTS

There were no statistically significant differences ($p>0.05$) betweenU/S guided group and contrast guided group as regards demographic characters and BMI, Less response to ESWL with high BMI. (Table 1).

There were no statistically significant differences ($p>0.05$) betweenU/S guided group and contrast guided group as regards characters of kidney stones, better results with low stone density and decreased skin to stone distance. (Table 2).

All patients inU/S guided group received analgesia versus 88% on Contrast FLURO guided group, the difference was statistically non-significant (p>0.05). The other 12% of contrast FLURO guided group received anesthesia while performing ESWL on migrated radiolucent stone to kidney during ureteroscopy. (Table 3)

All patients received a total of 3000 shocks for each ESWL session, maximum allowed power (18) Jules. In U/S guided group: three patients needed to adjust probe position. In Contrast FLURO guided group: contrast instillation through Intravenous route was used for 22 patients (88%) and 3 patients (12%) through a ureteric catheter. Radiation dose during ESWL was measured by thermoluminescent dosimeter (TLD). To evaluate the entrance surface dose (ESD), each TLD chip placed on back of patient at the entrance surfaces of the X-ray beam. Mean value of Exposure to radiation was 60.08±21 mGy with range from 39 to 125 mGy. Mean Fluoroscopy time was 169.8±16.39 with range 42 to 212 second. (Table 4).

There were no statistically significant differences (p>0.05) betweenU/S guided group and contrast guided group as regards SFR after one ESWL session and number of needed additional sessions. There were 3 patients needed 1 auxiliary session in U/S guided group compared to 4 patients in contrast guided group. There was 1 patient in contrast guided group needed a complementary third session (Table 5).

U/S guided ESWL has more success rate (87%) compared to contrast FLURO guided ESWL (80%) in localization of radiolucent renal stone, but there were no statistically significant differences (p>0.05) betweenU/S guided group and contrast FLURO guided group as regards incidence of success rate (Table 6).

There were no statistically significant differences (p>0.05) betweenU/S guided group and contrast FLURO guided group as regards size of stone residual and occurrence of complication (p>0.05). These complications (including Steinstrasse) were managed conservatively and no intervention was needed. One patient in contrast guided group suffered from only mild symptoms of contrast allergy (itching – nausea) and occurred after stone localization, so not shifted to other group, and managed successfully with IV corticosteroids. (Table 7).

Table (1): Relation between outcome of U/S and contrast FLURO guided ESWL on radiolucent renal stone and patient characters (age-gender-BMI)

Patient characters			**U/S guided ESWL outcome (after 1st session of ESWL)**		**t-test**	**P value**	**Contrast FLURO guided ESWL outcome (after 1 session of ESWL)**		**t-test**	**P value**
			success n.20	failed n.3			Success n.20	Failed n.5		
Age	Mean ±SD		50.65±11.77	44 ±6.25	0.946	0.355	49.85±9.84	52±9.24	0.44	0.663
gender	Females	N	10	2			12	2		

Patient characters			U/S guided ESWL outcome (after 1st session of ESWL)		t-test	P value	Contrast FLURO guided ESWL outcome (after 1 session of ESWL)		t-test	P value
			success n.20	failed n.3			Success n.20	Failed n.5		
		%	50.0%	66.7%			60.0%	40.0%		
	males	N	10	1	f	0.99	8	3	f	0.62
		%	50.0%	33.3%			40.0%	60.0%		
Body mass index (BMI)	Over-weight	N	13	0			13	0		
		%	65.0%	0.0%	f	0.068	65.0%	0.0%	f	0.01*
	obese	N	7	3			7	5		
		%	35.0%	100.0%			35.0%	100.0%		

Table (2): Relation between outcome of U/S and contrast FLURO guided ESWL on radiolucent renal stone and stone characters

Stone characters			U/S guided ESWL outcome (after 1 session of ESWL)		t-test	P value	Contrast FLURO guided ESWL outcome (after 1 session of ESWL)		t-test	P value
			Success n.20	Failed n.3			Success n.20	Failed n.5		
site of stone	upper calyceal	N	4	1			5	0		
		%	20.0%	33.3%	1.33^{c}	0.72	25.0%	0.0%	1.66^{c}	0.64
	middle calyceal	N	4	1			3	1		
		%	20.0%	33.3%			15.0%	20.0%		
	Lower calyceal	N	6	1			5	2		
		%	30.0%	33.3%			25.0%	40.0%		
	pelvic	N	6	0			7	2		
		%	30.0%	0.0%			35.0%	40.0%		
side	left	N	11	1			11	3		
		%	55.0%	33.3%			55.0%	60.0%		
	right	N	9	2	f	0.59	9	2	f	0.99
		%	45.0%	66.7%			45.0%	40.0%		
Stone size (mm)	Mean ±SD		12.8 ±1.67	16 ±1	3.18	0.004*	12.6±1.69	16.2±1.3	4.40	0.0001 *
Stone density (HU)	Mean ±SD		291.9±70.73	396.33 ±8.32	6.31	0.0001*	300.55±54.9	360.8±66.59	2.11	0.046*
Skin to stone distance (mm)	Mean ±SD		100.35 ±4	109.33 ±3.06	3.710	0.001*	101.55±5.32	108±3.54	2.54	0.018*

Table (3): Analgesia or Anesthesia use during treatment among studied groups.

Analgesia or Anesthesia	U/S localized group n.23	Contrast FLURO guided group n.25	p-value
○ Analgesia ○ Anesthesia	23(100.0) 0(0.0)	22(88.0) 3(12.0)	0.235

Table (4): ESWL parameters and radiation exposure distribution among studied groups.

ESWL parameters & radiation exposure	U/S guided group n.23	Contrast FLURO guided group n.25
Maximum Number of shocks per session	3000	3000
Maximum power (Jules)	18	18
Need to adjust probe position	3(13.0)	-
Method of contrast instillation ○ Intravenous route ○ Through ureteric catheter	-	22(88.0) 3(12.0)
Exposure to radiation mean ± SD Range	-	60.08±21 39-125
Fluoroscopy time(second) mean ± SD Range	-	169.8±16.39 140-212

Table (5): SFR & Number of needed additional sessions among studied groups.

SFR & Number of needed additional sessions	U/S guided group n.23 n (%)	Contrast FLURO guided group n.25 n (%)	p-value
SFR after one ESWL session: <4 mm >4mm	20(87.0) 3(13.0)	20(80.0) 5(20.0)	0.703
Additional sessions: yes no	3(13.0) 20(87.0)	5(20.0) 20(80.0)	0.703
Number of additional sessions - one session - two sessions	3(13.0%) 0	4(16.0) 1(4.0)	0.99

Table (6): Outcome distribution among studied groups.

	U/S guided group n.23	Contrast FLURO guided group n.25	p-value
Outcome Success Failed	20(87.0) 3(13.0)	20(80.0) 5(20.0)	0.703

Table (7): Size of stone residual distribution and complications among studied groups.

	U/S guided group n.3	Contrast FLURO guided group n. 5	p-value
Size of stone residual mean ± SD Range	10±2 8-12	9.6±1.5 8-12	0.757
Gross Hematuria: <24 h. >24 h.	19(82.0) 4(17.0)	21(84.0) 4(16.0)	0.99
Pyelonephritis(fever)	1(4.3)	3(12.0)	0.61
Per nephric collection	0.0	0.0	
Stein Strasse	1(4.3)	1(4.0)	0.99
Dysuria	4(17.4)	4(16.0)	0.99
Frequency	1(4.3)	3(12.0)	0.61
Urgency	1(4.3)	3(12.0)	0.61
Contrast Allergy	-	1(4.0): mild symptoms (Itching - nausea)	-

DISCUSSION

In this Study, we performed ESWL in our study on patients with radiolucent renal stone using U/S or fluoroscopy with contrast guidance, included 48 patients were divided into two groups, one group: Localization of the radiolucent renal stones by using U/S, and another group in which Localization done by Fluoroscopy using contrast application either through intravenous route or through a ureteric catheter.

The contrast injected through a ureteric catheter, in localization of radiolucent renal stones, can be used in cases of migrated ureteric stone to kidney during ureteroscopy, obesity and contrast allergy. We found that localization with application of contrast through a ureteric catheter has better results than IV contrast, the cause may be that retrograde contrast injection helps dissolution of radiolucent renal stones due to its low density and also the anesthesia controls pain and movement of patient more than analgesia, thus increases the ESWL efficacy, but there is a risk of anesthesia.

Among multiple reports that performed comparing use of U/S and fluoroscopy in localization of renal stones during ESWL, only **Goren et al.[11]** found a significant difference between U/S and fluoroscopy outcomes. The other studies found no significant differences. However, all studies showing similar results regarding SFR between two groups, use of U/S guidance had better results compared to fluoroscopy group. Furthermore, the majority of studies found that, in order to protect patients from radiation exposure, U/S was preferred over fluoroscopy **[14].**

In agreement with our study, A single center retrospective cohort study by **Smith et al.**, aimed to compare SFR using fluoroscopy or U/S. The study enrolled 95 patients with renal calculi undergoing first ESWL treatment with localization using U/S (48 patients) and fluoroscopy (47 patients). There was no significant difference between the demographic data of both groups **[15]**, which is consistent with our study, in which we relieved that using U/S in localization of radiolucent renal stones with higher SFR (87%) compared to using Fluoroscopy with contrast guidance (80%), but there was no statistically significant difference (p>0.05) between two groups.

As well, the current study supported by **Van Besien et al.**, who reported that in the U/S guided group, the favorable success rate (stone-free or asymptomatic residual fragments) was 79% (45/57) while in the fluoroscopy guided group, it was 70% (40/57). There was no significant difference in the success rate between the two groups. When comparing the U/S guided group to the fluoroscopy guided group, the estimated success rate for the former was 9% higher **[10].** In our study, there was no significant difference in positive outcome in both groups, but the success rate was 7% higher in U/S guided group.

However, **Ozkaya**, reported that the success rate was 90.5% in fluoroscopic guided group, it was 92.3% in U/S guided group and no statistically significant difference was observed between the groups **[12].** As well, in our study, success rate in U/S guided group slightly better than fluoroscopy guided group, but also there was no statistically significant difference (p>0.05) between two groups.

Regarding complication rate, **Ozkaya** reported that there was no statistically significant difference between U/S guided group and fluoroscopy guided group respectively, and there was no statistically significant difference between the groups **[12]** which is consistent to our study.

Hassanpour et al. [16] reported that mean fluoroscopy time 106.24 second and radiation entrance surface dose ranges from 30.1 to 162 mGy while using fluoroscopy guidance in localization if renal stones. In our study, mean fluoroscopy time 169.8 second (range from 42-212 second) and radiation entrance surface dose ranges from 39 to 125 mGy in Contrast FLURO ESWL but radiation free in U/S guided ESWL.As well, the current study by **Chang et al. [13]** reported that Significant lower retreatment (U/S guided ESWL 14.8% vs. fluoroscopy guided ESWL 35.6%), which is inconsistent to our study in which There was no statistically significant difference (p>0.05) betweenU/S guided group and contrast FLURO guided group as regards number of additional sessions but more sessions needed in contrast FLURO guided group (20%) compared to U/S guided group (13%).Furthermore, **Waqas et al. [17]** found that patients with BMI <30 kg/m2 have a higher ESWL success rate than patients with BMI >30 kg/m2, which is consistent with our study in which less ESWL success rate in obese patients.Also, **Elbaset et al. [18]** reported that more success rate in ESWL on renal stones less than 1 cm, which is consistent with our study in which more success rate for renal stones less than 12.6±1.6 regardless U/S or fluoroscopy used in guidance.

Regarding effect of stone density on outcome, **Muter et al. [19]**, reported that there was a significant statistical difference between the mean stone density in the responders to ESWL (661±139 HU) and the non-responders to ESWL (1001±98 HU), which consistent to our density, in which less response to ESWL in higher stone density. Mutar et al., was studying effect of ESWL on radiopaque renal stones but in our study, on radiolucent renal stones.In addition, **Duarsa and Pribadi[20]**, found that fluoroscopy guided ESWL is more cost effective than U/S guided ESWL. In contrast, in our study, we relieved that the cost effectiveness ratio in U/S-ESWL is 1245 Egyptian pound with 100% SFR compared to 2222.5 Egyptian pound with 100% SFR. So, in our study, U/S guidance is more cost-effective than fluoroscopy with contrast application.

CONCLUSIONS

U/S guidance has similar results to fluoroscopy with application of contrast media in localization of radiolucent renal stones during ESWL regarding SFR and complications. However, U/S has slightly better results and more cost effective than contras:t fluoroscopy, U/S guidance is preferred due to the absence of radiation exposure.

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