Journal of Complementary Medicine Research, ISSN: 2146-8397 Vol. 14, No. 5, 2023 (pp.490-497)
RESEARCH ARTICLE WWW.JOCMR.COM

Radiation exposure hazard for Management of Renal Stones by using Flexible ureteroscopy and Extracorporeal Shock Wave Lithotripsy: A Prospective Comparativetrial

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Abstract
Background: Flexible ureteroscope (FURS) and Extracorporeal Shock WaveLithotripsy (ESWL) are treatment options in patients with Renal calculi up to 2 cm
Objective:to evaluate whether the two procedures are superior for treatingrenal stones with a low radiation exposure risk.
Patients and Methods:the study included 50 patientscomplaining of Renal stones less than 2 cm. Patients underwent either FURS or ESWL randomly. The procedures were done at Kafr Elsheikh University Hospital. The patients were divided into two groups. Group A: Patients received a Flexible ureteroscope (FURS). Group B: patients underwentExtracorporeal Shock Wave Lithotripsy (ESWL).
Results: No statistically significant difference was found between the two studied groups regarding age, sex, size, and BMI. Also, there was a statistically significant difference regarding hospital stay,stone-free rate, radiation time, and the air kerma-area product. Patients who underwent ESWL were exposed to an ionizing radiation dose with a mean of 2386.49 cGy*cm^2 (SD=760.96 cGy*cm^2). In the URS group, a mean of 4976.5 cGy*cm^2 (SD=1559.83 cGy*cm^2) with (P value <0.001).
Conclusion: FURS is considered highly efficient, with a higher stone-free rate after a single procedure than ESWL.The patients treated by FURS had higher exposure to ionizing radiation doses than patients treated by ESWL.

DOI: 10.5455/jcmr.2023.14.05.49

Introduction

However, kidney stones are mostly asymptomatic in early stages, active intervention is frequently performed in different situations as stone growth, associated infections, renal colic, and de novo obstruction.(1)

Regarding the EAU (European Association of Urology) urolithiasis guideline, PCNL is the first choice for radiopaque renal stones greater than 2 cm while ESWL or FURS is first choice for renal stones less than 1 cm. (2)

FURS has the advantages of direct visualization, fragmentation, and extraction of kidney stones. With the simultaneous advances in F-URS and holmium laser, it has the upper hand and the accepted option for the management of kidney stones, has a higher success rate and lower retreatment rate, but includes disadvantages such as invasiveness, need for anesthesia, high cost, and need of expensive instruments and maintenance, especially during the learning curve .(3)

ESWL has several advantages such as non-invasiveness, low complication rate, no anesthesia requirement, and a high level of patient acceptance. However, the effectiveness could be affected by stone size, density, composition, anatomical factors, body habitus of patients, and obesity. Therefore, it may associate with a lower stone-free rate (SFR) and higher retreatment rate .(4)

Flexible ureteroscopy and ESWL is performed under fluoroscopy, routinely. Fluoroscopy in flexible Ureteroscope is used not only to place access sheath, but also to identify the ureterorenal collecting system and locate the stone. Radiation is a risk for both surgeons and other healthcare professionals and patients.(5)

The aim of this study was to evaluate whether the two procedures, which have superior for

the treatment of renal stones, expose the patient to a substantial radiation and it should be taken into consideration when establishing the therapeutic strategy.

Patients and Methods

This study is a prospective randomized comparative study .the study has been conducted at Urology department at Kafrelsheikh University in Kafrelsheikh,Egypt between April 2023 to October 2023. Patients had been diagnosed at the outpatient clinic and evaluated for their suitability to the study. Patients eligible for study inclusion were informed about the trial ;if they agreed to participate , they signed an informed consent form.

The patients were randomized into two groups, Group A :Flexible ureteroscope (FURS) group underwent holmium laser lithotripsy using flexible ureteroscopy (Boston scientific(lithovue)while, Group B : extracorporeal shock wave lithotripsy (ESWL) group underwent extracorporeal shock wave lithotripsy (STORZ MEDICAL Modulith SLX-F2 FD21, Germany).

Philips BV Pulsera C-Arm (produced in 2015 by Philips, Holland),for ureteroscopy and radiological focusing of stones, and theradiological devices of the lithotripters have similar characteristics, measured the same way.

We evaluated patient exposure to ionizingradiation by using a relevant parameter, the air kerma-area product (P_{KA}; all values in $cGy*cm^2$), calculated from the radiation dose valuesrecorded by the fluoroscopy device. P_{KA} depends on technical parameters that change due toanatomical characteristics of each case examined, such as body mass index (BMI)

All patients were admitted to the hospital as inpatient cases for the treatments. The following preoperative parameters for each patient were recorded: age, gender , and stone size, density and location (upper calyx, lower calyx , middle calyx and renal pelvis).

Only58 patients were randomized to FURS groups and ESWL groups as shown in the CONSORT chart . After excluding patients due to infected hydronephrosis or failure to reach the stone in FURS groups, also, high respiratory rate in ESWL groups,

Outcome measures and data collection: Preoperative demographic data (age, gender and BMI). Preoperative radiological stone data (stone site, side, size and density). Intraoperative data (operative time ,radiation time and air kerma-area product)andPostoperative data (Complications and stone free rate).

Data analysis was performed using the software SPSS (Statistical Package for the Social Sciences) version 26. Categorical variables were described using their absolute frequencies and were compared using chi square test, fisher exact and Monte Carlo tests when appropriate. To compare ordinal data between two groups, chi square for trend test was used. Shapiro-Wilk test was used to verify assumptions for use in parametric tests. Quantitative variables were described using their means and standard deviations. To compare quantitative data between two groups, independents sample t test (for normally distributed data) was used. To assess change in certain variable over two point of time, paired sample t test (for normally distributed quantitative variable) and Wilcoxon signed rank test (for categorical data) were used. The level statistical significance was set at $P<0.05$. Highly significant difference was present if $p\leq0.001$.

The used tests were:

1 - Chi-square test: For categorical variables, to compare between
different groups.

2- Fisher's Exact or Monte Carlo correction

Correction for chi-square when FURS than 20% of the cells have expected count less than 5

3- Student t-test: For normally quantitative variables, to compare between three studied groups.

Results

50 patients randomly assigned interventions, twenty-fourpatients (48%)were randomly selected to undergo FURS and twenty-six(52%) to undergo ESW and underwent final analysis. Fig.1

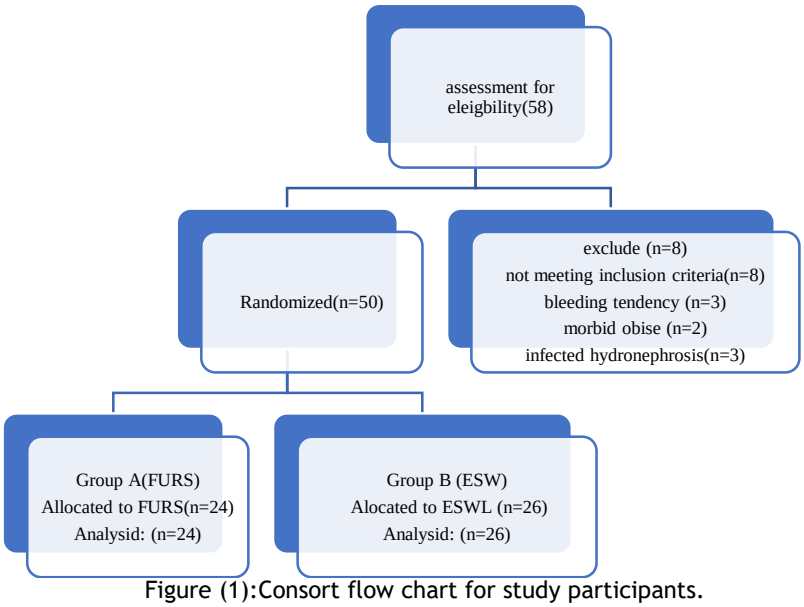

Figure (1):Consort flow chart for study participants.

- **Demographic Data:**

There is statistically non-significant difference between the studied groups regarding gender, age, weight, height or body mass index.(Table 1)

Table (1) Comparison between the studied groups regarding demographic data

	Flexible URS group N=24(%)	ESWL group N=26(%)	x^2/t	p
Gender: Female Male	 9 (37.5%) 15 (62.5%)	 14 (53.8%) 12 (46.2%)	1.342	0.247
	Mean ± SD	**Mean ± SD**	**t**	**p**
Age (year)	41.33 ± 14.06	45.19 ± 12.17	-1.04	0.304
Weight (kg)	78.0 ± 5.49	78.19 ± 7.12	-0.106	0.916
Height (cm)	1.73 ± 0.07	1.71 ± 0.07	0.78	0.439
BMI (kg/m^2)	26.23 ± 2.44	26.76 ± 2.67	-0.73	0.469

x^2Chi square test t independent sample t test

- **Radiological data:**

There is statistically non-significant difference between the studied groups regarding stone site, size, or HU. (Table 2)

Table (2) Comparison between the studied groups regarding stone characteristic data

	Flexible URS group N=24(%)	ESWL group N=26(%)	x^2/t	p
Stone site: Lower calyx Mid calyx Renal pelvis	 7 (29.2%) 2 (8.3%) 15 (62.5%)	 2 (7.7%) 2 (7.7%) 22 (84.6%)	MC	0.2
	Mean ± SD	**Mean ± SD**	**t**	**p**
HU	1139.79 ± 358.39	1042.77 ± 196.29	1.174	0.248
Stone size (ml)	13.68 ± 3.81	13.47 ± 3.34	0.216	0.83

x^2Chi square test t independent sample t test MC Monte Carlo test **p≤0.001 is statistically highly significant

- **Operative Data:**

The operative time was recorded in FURS groups from the start of visualizing cystoscopy till insertion of the ureteric stent while in ESWL groups from the start of the shock waves till its stoppage.

The Operative time in FURS group ranged between (15.0 - 80.0mins), with the meantime was 44.42 ± 12.58mins. While, in ESWL group, the operative time ranged between (30.0-52.0 mins), with the mean timewas 43.38 ± 8.06 mins.(Table 3,figure2)

The Radiation time in FURS group ranged between (40.0 sec - 7.0mins), with the mean time was 3.7 ± 1.41mins. While, in ESWL group, the operative time ranged between (3.0-11.35 mins), with the mean timewas 7.05 ± 3.39 mins.(Table 3)

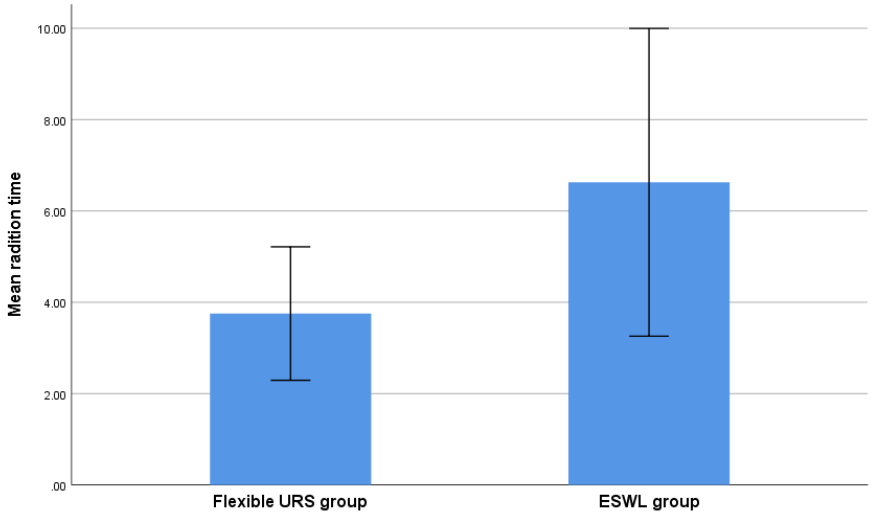

figure (2) Simple bar chart showing comparison between groups regarding radiation time.

There is statistically significant difference between the studied groups regarding radiation time.
There is statistically non-significant difference between the studied groups regarding operative time.

Table (3) Comparison between the studied groups regarding operative data

	Flexible URS group N=24(%)	ESWL group N=26(%)	t	p
	Mean ± SD	**Mean ± SD**		
Radiation time	3.7 ± 1.41	7.05 ± 3.39	-4.622	<0.001**
Operative time	44.42 ± 12.58	43.38 ± 8.06	0.348	0.729

t independent sample t test MC Monte Carlo test **p≤0.001 is statistically highly significant

- **Radiation:**

Patient radiation dose was expressed in terms of total P_{KA} in cGy*cm^2.Patients who underwent ESWL were exposed to an ionizing radiationdose with a meanof 2386.49 cGy*cm^2 (SD=760.96 cGy*cm^2).In the URS group a meanof 4976.5 cGy*cm^2 (SD=1559.83 cGy*cm^2).

There is statistically significant difference between the studied groups regarding radiation time.

By comparing both studied groups in terms of BMI and stone size, it is evident that all the groups withobese and abdominally obese patients received radiationdoses higher than the normal weight group.(Table 4)

There is statistically significant difference between the studied groups regarding.

Theaverage radiation dose was higher in the FURS group (p=0.001).In obese patients the average dose of radiation was higher in FURS group (p=0.001), while in patients with normal weightthe average radiation also higher in The URSgroup (p=0.001).

Table (4) Comparison between the studied groups regarding Influence of body mass index and stone size upon patient radiation.

	Flexible URS group N=24(%)	ESWL group N=26(%)	t	p
	Mean ± SD	**Mean ± SD**		
P_{KA}	4976.5 ± 1559.83	2386.49 ± 760.96	7.366	<0.001**
Stone size< 1cm	3135.3 ±759.12	3390.6±527.90	7.549	<0.001**
Stone size > 1cm	2564.3 ±724.09	5699.1±1128.59	9.476	<0.001**
P (pt)	<0.001**	<0.001**		
BMI <25	2235.2 ±741.53	5116.4±1316.51	8.452	<0.001**
BMI >25	2738.2 ±754.39	5658.13±1241.54	7.247	<0.001**
P (pt)	<0.001**	<0.001**		

t independent sample t test pt paired sample t test **p≤0.001 is statistically highly significant

- **Postoprative Complication rate:**

As regard Postoperative complications , in FURS ,there is one patient complain from sever colic pain , four patients from fever , and one patient suffering from significant hematuria .all cases treated conservative not need intervantion. On other hand in ESWL group,there is three patients complain from sever colic pain , one patient from fever , one patients suffering from significant hematuria and one patient persented with stienstruss. all cases treated conservative except two patients need intervantion.

There is statistically non-significant difference between the studied groups regarding incidence of fever, colic, hematuria, steins truss stone or modified Clavelin score.

Table (5) Comparison between the studied groups regarding post-operative complications:

	Flexible URS group N=24(%)	ESWL group N=26(%)	x^2/t	p
Sever colic pain	1 (4.2%)	3 (11.5%)	Fisher	0.611
fever	4 (16.7%)	1 (3.8%)	Fisher	0.182
Significant Hematuria	1 (4.2%)	1 (3.8%)	Fisher	>0.999
JJ exchange	0 (0%)	1 (3.8%)	Fisher	>0.999
Steins truss	0 (0%)	1 (3.8%)	Fisher	>0.999
Modified Clavien: Grade I Grade IIIa	 5(20.8%) 0 (0%)	 5 (19.2%) 2 (7.7%)	Fisher	0.491

x^2Chi square test t independent sample t test MC Monte Carlo test **p≤0.001 is statistically highly significant

- **Stone free rate:**

The stone free rate (SFR) defined as no stone residual fragments or asymptomatic insignificant residual fragments less than or equal to 4 mm during patients follow up.

As regard Stone free rate, 17 patients (70.8%) in FURS group and 17 patients (65.4%) in ESWL group. (Table 6)

There is statistically **significant** difference between the studied groups regardingstone free ratio postoperatively (stone free rate was in 70.8% within flexible URS group versus 65.4% within ESWL group)

Table (6) Comparison between the studied groups regarding stone free ratio

	Flexible URS group N=24(%)	ESWL group N=26(%)	x^2	p
Failed Free Residual	0 (0%) 17 (70.8%) 7 (29.2%)	5 (19.2%) 17 (65.4%) 4 (15.4%)	4.362	0.037*

x^2Chi square for trend test *p<0.05 is statistically significant. p for McNemar test

Discussion

There is increasing concern about the radiation exposure of urolithiasis patients during diagnosis and treatment.(6)

The treatment options for renal stone disease include surveillance, medical treatment, ESWL, PNL, mini-PNL, F-URS, laparoscopy and open surgery. As a result of the improvements and miniaturization of instruments, only 1–2 % of kidney stones are treated by open surgery (7).

The EAU urolithiasis guidelines state that for stones <1 cm ESWL or F-URS is the first choice

(8). For stones between 1 and 2 cm, there is a gray zone and still controversial, because ESWL, F-URS and PNL are all options depending on favorable and unfavorable anatomical and stone factors.

The aim of this study was to evaluate whether the two procedures, which have superior for the treatment of renal stones, expose the patient to a substantial radiation and it should be taken into consideration when establishing the therapeutic strategy.

On comparison of the Patients' demographics dataincluding age, sex and BMI showed no significant difference between two groupsFURS and ESWL. Cope with **that ElNahas et al., (2012), Singh et al., (2014), Kumar et al., (2015) and Resorlu et al., (201**2) as they showed no significant difference in their studies. The patients were matching in both studied group in these regards.(2,3,9,10)

In our study, Radiologic finding of stone in both groups (size ,site , laterality and location) we have found no significant difference and this cope with other researchers . in our study, we had stones in variable pelvicalyceal system there weren't super selection stone site but most of stones presented in renal pelvis .

Some researchers conducted their studies on renal pelvic stones only like **Cui et al., (2014)** with 42 patients in FURS group and 48 patients in ESWL group and **Bas et al., (2014)** with 47 patients in FURS group and 52 patients in ESWL group. Other researchers conducted their studies on upper and middle calyceal stones like **Cecen et al., (2014).** While others like **ElNahas et al., (2012), Singh et al., (2014)** and **Kumar et al., (2015)** conducted their studies on lower pole stones.(2,3,10–13)

On comparison the operative time which was recorded from the start of visualizing cystoscopy till insertion of the ureteric stent while in ESWL groups from the start of the shock waves till stopping ,The operative time in FURS group (mean 44.4 ± 12.85 mins) was found to be insignificant difference compared to the ESWL group (mean 43.38 ±8.06 mins) Respectively P-value 0.729 .which is in cope with**Kumar et al., (2015)** in their study showed no significant difference with mean 47.5±1.1 and 43.6 ±1.4 for FURS and ESWL groups respectivelyP-value 0.23. Also, **Resorlu et al., (2012)** showed lower operative time in FURS with laser lithotripsy with mean 43.1 ±17. This may be due to their experience and available facilities.

On other hand ,**Singh et al (2014)** showed similar results with mean 78±20.03 and 42 ± 6.3 for FURS and ESWL groups respectively P-value 0.0001.

Other author like ,**ElNahas et al., (2012)** in their study comparing FURS with laser lithotripsy and ESWL for lower pole stone 10-20 mm found that the mean operative time was 73 ± 29 and 92 ± 41 for FURS and ESWL groups respectively P-value 0.018 and this difference is ongoing to calculating the operative time of ESWL in their study as the sum of all ESWL sessions.

On comparison TheRadiation time in FURS group ranged between (40.0 sec - 7.0mins), with the mean time was 3.7 ± 1.41minswithhigh significant difference compared to the ESWL group (3.0-11.35 mins), with the mean timewas 7.05 ± 3.39 mins.Respectively P-value <0.001

Patient exposure to radiation dose varies dependingon many factors: size of the stones, operator experience, radioopacityof the stones, patient's BMI, stone enclavation in the ureteric mucosa, intraoperative difficulties due toanatomical causes, etc. (14)

Comparing FURS and ESWL regarding the X-ray exposureof the patient, we found a high significant difference between these two groups, regardless of difference in BMI or stone size. Which is highly significant in FURS group with p value <0.001.cope withPricop et al.found asignificant difference between these two groups(p=0.014).(14)however,Rebuck et al., found no significant differencebetween the two procedures(15).

According to Preston et al. exposure to ionizing radiationat the age of 30 increases the incidence of cancers ofparenchymal organs till the age of 70 by 35% per Gy for menand by 58% per Gy for women(16).

Younger patients who more frequently undergo surgery under fluoroscopic guidance, they are more susceptible toradiation-inducedlesions than older patients.(17)

In thisstudy, Stone free rate (SFR) was (17/24) patients (70.8%) in FURS group and (17/26) patients (65.4%) in ESWL group, showed no stone residual fragments or asymptomatic insignificant residual fragments less than or equal to 4 ml for one month follow up after 1st session P-value <0.037 Singh P et al., (2014) concluded similar results 29 (82.8%) patients in FURS and 17 (48.5%) patients in ESWL group P-value <0.005.(10)

So , we cope with**ElNahas et al.,** concluded similar results with 32 (86.5%) patients in FURS and 42 (67.7%) patients in ESWL group (P-value <0.038) in spite of comparing FURS with the sum of all ESWL sessions and follow up was after 3 months which concluded that FURS for renal stones is more effective than ESWL for more than one session.(3) Also, **Resorlu et al.** concluded higher SFR with 87.0% and 66.5% in in FURS and ESWL respectively, with (P-value <0.001)(9).**Cecen et al., (2014)** showed non-significant statisticaldifference between both groups, 61 patients (92.42%) and 94 patients(87.4%) for FURS and ESWL groups respectively P-value 0.27(13). Also, **Kumar et al.** noticed similar results 78 (86.6%) patients in FURS and 74 (82.2%) patients in ESWL group P-value < 0.34(2). This may be due to good quality of shockwave lithotripter, low stone density or low BMI. But, still in both studies FURS enjoyed a higher success rate than ESWL,

The explanation of the different result can be explained by the surgeon experience as well as the different ESWL machines used. Also, site of the stone within the kidney may play a role.

Conclusions

However, FURShas a significantly higher success rate compared with ESWL in stone free rate. The dose of radiation patients who have been exposed is higher in FURS. So, it is a challenge for urologists to perform the best treatments which lead to the stone free result, but meanwhile with lower doses of radiation for both the patients and the medical staff .

Study Limitations

small sample size is one of limit of this study. So, further larger patients' sample are required for confirmation of our results. More specifications of stone position will be better looked at in the future.More complex varieties of cases should be included in further studies. A longer follow-up is required to determine the long-term complications.

Financial support and sponsorship: No
Conflict of Interest: NO Conflict of Interest

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Author Contributions Statemen

Khaled Magdy Zeinelabden: collecting data and writing paper.
Elsayed Abdelhalim Elsayed: Statistical analysis of the data.
Mohamed Galal : collecting data.
Tarek Abdelbaky : revision of Statistical analysis of the data and paper.
Hossam Nabeeh: revision of paper.