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Flexible Ureteroscopic Laser Lithotripsy versus Extracorporeal Shock Wave Lithotripsy in Management of Upper Ureteral Calculi up to 2 cm

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Original Research Article

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ABSTRACT

Aims: To compare the outcome after flexible ureteroscopic (FURS) laser lithotripsy and extracorporeal shock wave lithotripsy (ESWL) for management of patients with upper ureteral calculi up to 2 cm.
Study Design: A prospective randomized comparative study.
Place and Duration of Study: Tanta Urology Department, Tanta University in Tanta, Egypt between October 2018 to October 2021.
Methodology: We included 95 patients (62 men, 33 women) with upper ureteral calculi up to 2 cm. 48 patients underwent flexible ureteroscopic laser lithotripsy while 47 patients underwent extracorporeal shock wave lithotripsy. The outcome including the operative time, the success rate, retreatment rate, auxiliary procedures and complication rates was reported.
Results: The complete stone free rate was 95.8% in the FURS group and 72.3% in the ESWL group 1 month postoperatively (P value = <0.002). As regard auxiliary procedures (4.2%) in FURS group and (6.4%) in ESWL group underwent secondary procedures (P value = 0.677). The respective complication rates (evaluated using the Clavien system) were 5.2% in FURS group, and 7.3% in ESWL group (P value = 0.323).

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Conclusion: FURS affords a comparable success rate than ESWL and seems to be a promising alternative to ESWL when higher stones densities are to be treated. Prospective randomized controlled trials are needed to confirm these findings.

Keywords: Flexible ureteroscopy; extracorporeal shock wave lithotripsy; ureteral stones; laser.

1. INTRODUCTION

Ureteric stones usually presented with attacks of acute colicky loin pain associated with nausea and vomiting, occur in at least 50% of patients. Large upper ureteral stones may cause obstruction, infection and deterioration of renal function [1,2].

The management of upper ureteral stones includes extracorporeal shock wave lithotripsy (ESWL), ureteroscopy (URS) with semirigid or flexible instruments, laparoscopy (LAP), and open surgery [3].

The management depends on stone factors like localization, size, density and radiolucency, anatomical factors, obstruction, technical capacity of the department, patient's preference and surgeon's skills [4].

Recently, the widespread expansion in minimally invasive techniques minimizes the role of open surgery. ESWL has been introduced as an alternative technique and fragments stones in the upper ureter through the use of shock waves [5].

Several factors affect the treatment of kidney stones as the size, location, and stone composition. Stones with a maximum diameter of 20 mm, ESWL looks the standard procedure as it is non-invasive, with a low rate of complications, and no need for anaesthesia [5].

The contraindications for ESWL are restricted to pregnancy, severe skeletal deformities, morbid obesity, distal urinary tract obstruction to the stone, and aortic and/or renal artery aneurysms. Also, ESWL relatively contraindicated in patients with bleeding daisies, uncontrolled hypertension or severe urinary tract infection [5].

Unfortunately, ESWL can cause trauma to the kidney, steinstrasse (obstruction due to fragments becoming impacted in the ureter), haematoma, infection, sepsis, hypertension and diabetes mellitus [6,7].

Due to the limitations of the success rate and the complications of ESWL, other minimal invasive modalities for upper ureteral stones from 1 – 2.5 cm such as retrograde intrarenal surgery (RIRS) are growing up [8].

Flexible ureteroscopy has been reported for clinical diagnosis in 1964. The advancements in the URS designs of ureterorenoscopes, stone fragmentation systems and endourologic techniques, ureteroscopic lithotripsy especially flexible ureteroscopy has been widely used [8]. Laser appliance with URS improves the stone clearance in a single session even in the stones more than 10 mm and greatly reduced the complication rates [9].

2. MATERIALS AND METHODS

2.1 Study Design

A prospective randomized comparative study for patients with upper ureteral calculi underwent FURS laser lithotripsy or ESWL between October 2018 to October 2021.

2.2 Study Population

Ninety-five patients with upper ureteral calculi up to 2 cm underwent FURS laser lithotripsy or ESWL in Tanta University Hospital, between October 2018 to October 2021. Patients were divided into two groups. Group A: included 48 patients underwent flexible ureteroscopic laser lithotripsy, Group B: included 47 patients underwent extracorporeal shock wave lithotripsy.

2.3 Study Methods

2.3.1 Preoperative evaluation

Age, gender and body mass index (BMI) of patients were recorded. Stone site, size and hounsfield unit (HU) also were reported according to non-contrast multi-slice computed tomography (CT) scan of urinary tract.

2.3.2 Operative procedures

2.3.2.1 Group A

All patients received preoperative IV broad spectrum antibiotic (third generation

cephalosporin). Under general anesthesia, the patient is positioned in the lithotomy position, C-arm fluoroscopy was available. Visualizing cystoscopy, insertion of a guidewire (0.035 or 0.028 stiff hydrophilic) under fluoroscopy up to the renal pelvis. Ureteral dilation (dilating balloons, sequential hydrophilic ureteral dilators or passage of the semi-rigid ureteroscopy).

Retrograde uretero-pyelography was done. Two guide wires were positioned into the renal pelvis; (working wire and safety wire). A ureteral access sheath (Boston Scientefic 11/13 Fr) was introduced over the wire. Insertion of FURS (OTU WiScope Single-Use Digital FURS) up to the upper ureter under fluoroscopic assistance. A 200-µm holmium laser fiber was used; starting with 0.6 J pulse energy with a rate of 6 to 8 Hz. The pulse energy could be raised up to 0.8 J or 1.0 J for hard stones, and the frequency could be increased up to 20 Hz. The stone basket (Zero Tip Nitinol Stone Basket 1.9 - 2.5 Fr) was used for retrieval of larger stone fragments. The access sheath was removed under vision to allow inspection of the ureteral mucosal perforations or bleeding. Insertion of the ureteric catheter either (DJ or open tip) 6 Fr. Then insertion of the urethral catheter.

2.3.2.2 Group B

On an outpatient basis, using (Dornier Compact Delta II lithotripter). Administration of IV fluids, diuretics mannitol 10% and analgesics. The table is placed in the zero position. The patient was positioned in the supine position with his affected side opposite the machine drum. The stone was localized by fluoroscopy in two plains in anteroposterior and in oblique plain. Topical infiltration anesthesia with 10 cm 2% Lidocaine diluted in 10 cm normal saline was given S.C. in the area of drum contact. A thin layer of K-Y jelly was applied on the machine drum directly after filling the drum with the fluid automatically. Then fine localization of the stone site in the focus was done fluoroscopically both in the anteroposterior and in the oblique plains. The shock waves number used about (2000-4000) waves, at a rate of (60-90) shocks per minute. The power at first was low then the intensity gradually increased till reaching the full power of machine. Observing the stone site in the focus was tested every 5 minutes. The patients were discharged at the same day of treatment.

2.3.3 Outcome measures

Operative time in minutes was recorded in group A from the start of visualizing cystoscopy till insertion of the ureteric stent while in group B from the start of the shock waves till its stoppage. Complication rate according to the Clavien-Dindo Classification of Surgical Complications in to 4 grades.

The stone free rate (SFR) after four weeks from the first session defined as no stone residual fragments or asymptomatic insignificant residual fragments less than or equal to 4 mm.

Retreatment rate was defined as the need for a second session of the same modality.

Auxiliary procedure rate was defined as using a method of treatment other than the primary treatment to render the patient free of stones.

2.4 Statistics

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) [10] Qualitative data were described using number and percent. The Kolmogorov-Smirnov test was used to verify the normality of distribution Quantitative data were described using range (minimum and maximum), mean, standard deviation and median. Significance of the obtained results was judged at the 5% level.

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 more than 20% of the cells have expected count less than 5

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

3. RESULTS

3.1 Patients Demographic Data

Group A included 33 males and 15 females, while group B included 29 males and 18 females. The mean age of the studied patients was 42.6 **±** 8.47 and 39.6 **±** 9.72 years for group A and group B respectively. The mean BMI of the studied patients 25.6 **±** 2.53 and 25.3 **±** 3.52 (kg/m2) for group A and group B respectively. There was no significant difference between both groups as regard patients' demographic data as shown in (Table 1).

Table 1. Comparison between the two groups according to demographic data

Demographic data	Flexible ureteroscopic laser (n = 48)		Extracorporeal shock wave (n = 47)		Test of Sig.	p
	No.	%	No.	%		
Gender					χ^2=0.520	0.471
Male	33	68.8	29	61.7		
Female	15	31.2	18	38.3		
Age (years)					U =890.000	0.076
Min. – Max.	30.0 – 55.0		28.0 – 54.0			
Mean ± SD.	42.6 ± 8.47		39.6 ± 9.72			
Median (IQR)	45.5 (35.0 – 49.0)		36.0 (30.0 – 49.0)			
BMI (Kg/m^2)					U =1015.000	0.397
Min. – Max.	23.0 – 31.0		21.0 – 30.0			
Mean ± SD.	25.6 ± 2.53		25.3 ± 3.52			
Median (IQR)	25.0 (24.0 – 27.0)		25.0 (22.0 – 29.0)			

U: Mann Whitney U test *χ^2: Chi-square test*

Table 2. Stone characteristic in the two groups

Radiological data of the stones	Flexible ureteroscopic laser (n = 48)		Extracorporeal shock wave (n = 47)		Test of Sig.	p
	No.	%	No.	%		
Side					χ^2=0.257	0.612
Right	21	43.8	23	48.9		
Left	27	56.2	24	51.1		
Size (mm)					χ^2=0.100	0.752
<10	23	47.9	21	44.7		
≥10	25	52.1	26	55.3		
Min. – Max.	7.0 – 20.0		6.0 – 19.0		U = 1113.500	0.913
Mean ± SD.	11.9 ± 4.18		11.7 ± 3.89			
Median (IQR)	10.5 (8 – 15.75)		11.0 (9.0 – 15.0)			
Density (HU)					U = 1087.500	0.762
Min. – Max.	690.0 – 1000.0		660.0 – 1000.0			
Mean ± SD.	837.1 ± 104.80		830.6 ± 107.08			
Median (IQR)	840.0 (750.0 – 925.0)		810.0 (750.0 – 910.0)			

U: Mann Whitney U test *χ^2: Chi-square test*

3.2 Stone Characteristics

As regard stone side 21 and 23 patients in group A and group B respectively had their stones in the right ureter. As regard stone size, in group A 25 patients had a stone ≥1.0 cm, while in group B 26 patients had a stone ≥1.0 cm. The stone size in group A ranged between (7.0 - 20.0 mm), the mean was 11.9 **±** 4.18 mm while in group B the size ranged between (6.0 – 19.0 mm), the mean was 11.7 **±** 3.89 mm. The mean HU was 837.1 **±** 104.80 and 830.6 **±** 107.08 for group A and group B respectively. There was no statistically significant difference in both groups as regard the characteristics as shown in (Table 2).

3.3 Operative Time

The mean operative time was 74.9 **±** 10.84 and 40.7 **±** 5.31 mins for group A and group B respectively, which was statistically significant difference in favor of group B as shown in (Table 3).

3.4 Complication Rate

According to the Clavien-Dindo classification 5 patients and 7 patients in group A and group B respectively had postoperative complications, which was statistically insignificant difference as shown in (Table 4).

Table 3. Comparison of procedure time in the two groups

Procedure time (min.)	Flexible ureteroscopic laser (n = 48)	Extracorporeal shock wave (n = 47)	Mann Whitney U	p
Min. – Max.	60.0 – 90.0	35.0 – 55.0	U= 0.000	<0.001*
Mean ± SD.	74.9 ± 10.84	40.7 ± 5.31		
Median (IQR)	75.0 (65.0 – 85.0)	40.0 (35.0 – 45.0)		

*U: Mann Whitney U test, *: Statistically significant at p ≤ 0.05, <0.001 (Highly significant)*

Table 4. Complications in the two groups

Complication rate (The clavien–dindo classification)	Flexible ureteroscopic laser (n = 48)		Extracorporeal shock wave (n = 47)		MC	p
	No.	%	No.	%		
GI: Colic, analgesic	1	2.1	5	10.6	3.765	0.323
GII: Fever, IV antibiotics	3	6.3	1	2.1		
GIII: Fever, JJ insertion	1	2.1	0	0.0		
GIII: colic, semirigid URS	0	0.0	1	2.1		

MC: Monte Carlo Exact test

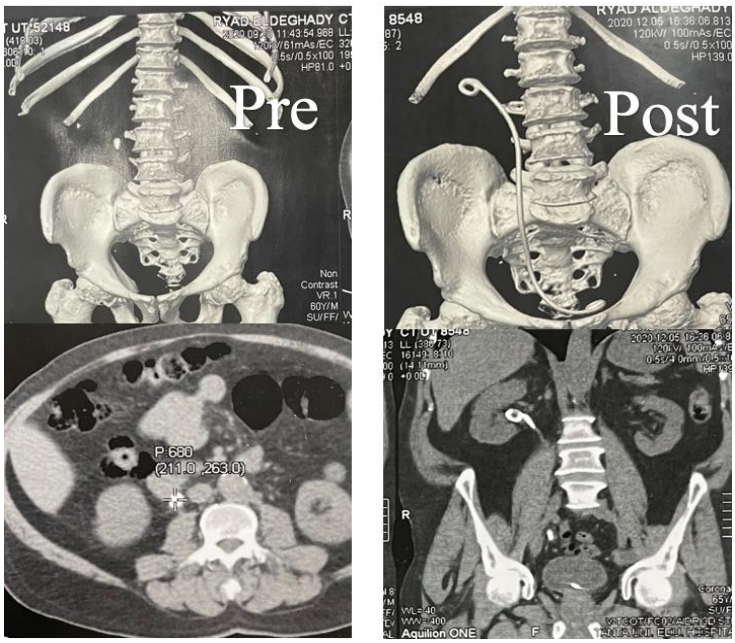

Fig. 1. A stone free case after FURS and laser lithotripsy for upper ureteral stone 18 mm

3.5 Stone Free Rate, Retreatment and Secondary Procedure

As regard Stone free rate, one month follow up after single treatment session, 46 patients (95.8%) and 34 patients (72.3%) in group A and group B respectively, showed no stone residual fragments or asymptomatic insignificant residual fragments less than or equal to 4 ml. which was statistically significant difference in favor of group A. (P value = <0.002) (Table 5, Fig. 1).

As regard retreatment, no patient in group A needed another session. While 10 patients (21.3%) in group B needed a second session of ESWL, which was statistically significant difference in favor of group A as shown in (Table 5). (P value = 0.001).

Table 5. Stone free rate, retreatment rate and auxiliary procedure in the two groups

	Flexible ureteroscopic laser (n = 48)		Extracorporeal shock wave (n = 47)		Test of sig.	p
	No.	%	No.	%		
Stone free rate	46	95.8%	34	72.3%	χ^2=9.857	0.002*
Retreatment rate	0	0.0	10	21.3%	FE = 11.414	0.001*
Auxiliary procedure	2	4.2%	3	6.4%	FE =0.234	0.677qq

FE: Fischer Exact test, χ^2: Chi-square test

**: Statistically significant at p ≤ 0.05, <0.001 (Highly significant)*

As regard usage of auxiliary procedure, 2 patients (4.2%) in group A needed a secondary procedure, the two patients underwent ESWL session. While, in group B 3 patients (6.4%) underwent auxiliary procedures. Two patients underwent FURS and laser lithotripsy and the third one underwent semi rigid URS pneumatic lithotripsy. Which was statistically insignificant difference as shown in (Table 5).

4. DISSCUSSION

Advancements in endoscope technologies and operative techniques have led to a broader application of FURS in the management of urolithiasis to include larger and more complex stones. Continued progression in FURS may increase its clinical applicability and supplant other procedures as the first line treatment option for urolithiasis [11].

Flexible ureteroscopy is an important method for treating ureteral calculi. This relatively new technique is particularly beneficial for patients who are unsuitable for ESWL or percutaneous nephrolithotripsy (PCNL), patients with repetitive ESWL failure, obesity, hemorrhagic disease, lower calyceal calculi, or calyceal diverticular calculi, and patients who require multiple ESWL [12].

Other minimally invasive technique is ESWL. It is an attractive option for patients as it provides a truly minimally invasive approach to achieve overall stone free rates (SFR) approaching 75% [13].

It has been recommended as a first-line treatment for upper ureteric calculi in several studies with a success rate of 80-90% with advances in the shock wave generators; including the Dual-head, the tandem-pulse and wide-focus low pressure lithotripters, till the advances in stone location and imaging [14,15].

This is a prospective randomized comparative study between FURS laser lithotripsy and ESWL in the treatment of upper ureteral stones up to 2 cm. By comparing operative time, post-operative complications, retreatment rate, the stone free rate and auxiliary procedures after 4 weeks follow up.

Operative time was recorded in FURS group from the start of visualizing cystoscopy till insertion of the ureteric stent while in ESWL group from the start of the shock waves till its stoppage. Complication rate via the clavien-dindo classification of surgical complications in to 4 grades. Retreatment was defined as the need for a second session of the same modality. 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 four weeks after the first FURS or ESWL session. Auxiliary procedure rate was defined as using a method of treatment other than the primary treatment to render the patient free of stones.

The patients randomly assigned interventions into 2 groups: Group A (48 patients) underwent holmium laser lithotripsy using flexible ureteroscopy (WiScope Single-Use Digital FURS) while, Group B (47 patients) underwent extracorporeal shock wave lithotripsy (Dornier Compact Delta II lithotripter, Germany).

On comparison of the demographic patients data including age, sex and body mass index, showed no significant difference between both group FURS and ESWL. Also, comparison between radiologic finding of stones in both group including size and site, showed no significant difference. These cope with most of researchers like Kartal I et al. [16], Obaid A et al. [17], Aboutaleb H et al. [18], Cui Y et al. [19] and Kartal I et al. [16] and guarantee the matching in our sample selection.

As regard 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 its stoppage. The operative time in FURS group (mean 74.9 ± 10.84 mins) was found to be significantly longer compared to the ESWL group (mean 40.7 ± 5.31 mins) (P-value <0.001). This copes with Kartal I et al. [16] and Aboutaleb H et al. [18]

Cui Y et al. [19] showed no significantly difference in between FURS and laser lithotripsy an ESWL (mean 40.0± 10.0, 42.5± 11.3, for FURS and ESWL respectively, P-value 0.29). Also, Obaid A et al. [17] showed no significant difference. This may be due to their experience, availability of equipment and ureteric diameter which allows easy introduction of ureteroscope.

In the current study, Stone free rate (SFR) was (46/48) patients (95.8%) in FURS group and (34/47) patients (72.3%) 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. There was statistically significant difference (P-value <0.002).

Similar results found in Kartal I et al. [16] (89.6%, and 41.4% for FURS and ESWL respectively at 2 weeks P-value <0.001) and Aboutaleb H et al. [18] (86.4%, and 59.0% for FURS and ESWL respectively at 3 months P-value <0.002). Also, Manzoor S et al. [20] on 100 patients with 10 -15 mm proximal ureteric stones, showed Success rate similar to our study result with a 49.2% success rate after the first session of ESWL.

Cui Y et al. [19] showed no significantly difference in between FURS and laser lithotripsy an ESWL (97.5%, 87.5% and 92.5% P-value 0.2 and 0.6) for FURS, ESWL second session and ESWL third session respectively. Also, Obaid A et al. [17] showed no significant difference. Also, Elkholy M et al. [21] on 50 patients had proximal ureteral stones and 47 patients had middle ureteral stones, showed a higher success rate than the current study, where the overall success rate was 94%.

The difference is clearly due to the use of more than ESWL session compared to one FURS session as well as the difference in the site and/or size of the stone treated.

The retreatment rate was again defined as the need a second session of the same modality as long as there was a significant residual more than 4 mm during follow up. In the current study (10/47) patients (21.3%) in ESWL group needed a second session of extracorporeal shock wave lithotripsy, with no retreatment rate in FURS group, which was statistically significant difference (P-value 0.001). Kartal I et al. [16] and Aboutaleb H et al. [18] showed similar results with higher ESWL sessions (around 3 ESWL sessions).

The absence of retreatment requirement following FURS when used within the ureter can be explained on the basis of easier localization, better controls during fragmentation and the previous long experience of the operators using semi-rigid URS for ureteral stone treatment.

While, Karadag et al. [22] showed higher retreatment rate (6%) on their study on 61 patients suffered from proximal ureteric stones with FURS and laser lithotripsy. This may attribute to larger residual fragments which were difficult to pass spontaneously or due to distal ureteric edema and inflammation.

As regard secondary auxiliary procedure rate was defined as using a method of treatment other than the primary treatment to render the patient free of stones. (2/48) patients (4.2%) in FURS group underwent ESWL session. While, in ESWL group (3/47) patients (6.4%) underwent secondary procedures. Two patients underwent FURS and laser lithotripsy and the third one underwent semi rigid URS pneumatic lithotripsy. There was no statistically significant difference in both groups (P-value = 0. 677). Aboutaleb H et al. [18] showed similar results with no insignificant difference in auxiliary procedures P-value 0.96.

While Kartal I et al. [16] concluded significant difference (4.5%, 25.9% for FURS and ESWL respectively P-value <0.001) as regard secondary procedures. May be due to more stone hardness, quality of the shockwave generator, distal ureteric obstruction which needed dilatation and stone extraction after ESWL.

Currently, there is no available data on recurrence rates of proximal ureteral stone after FURS in short term follow up. Our study showed a significantly lower recurrence rate following FURS. We explain that stones were fragmented

using a Holmium laser and small fragments were extracted by basket during the FURS procedure. Also, fragments position during FURS procedure may have facilitated spontaneous passage of fragments.

On the other hand, spontaneous passage of fragments after ESWL sessions achieved due to stones position, mobility of the patients and plenty of fluids. Also, cases with failed ESWL underwent auxiliary procedures. Three patients in ESWL group underwent secondary procedures. Two patients underwent FURS and laser lithotripsy and the third one underwent semi rigid URS pneumatic lithotripsy.

Regarding the post-operative complication rate, it is classified by The Clavien-Dindo Classification of Surgical Complications for better evaluation. The current study showed (5/95) patients (5.2%) and (7/95) patients (7.3 %) in FURS and ESWL respectively. With postoperative complications; 6 patients with grade I (a patient in FURS group and 5 patients in ESWL group), 4 patients with grade II (3 patients in FURS group and a patient in ESWL group) and 2 patients with grade III (one patient in FURS group and one patient in ESWL group), with no statistically significant difference (P-value 0.323).

In the current study renal colic, which was treated with strong analgesics found in (1/48) patient (2.1%) and (5/47) patients (10.6%) in FURS and ESWL respectively. Cui Y et al. [19] in their study showed 2 patients (2.5%) and 9 patients colic (11.25%) in FURS and ESWL respectively. Kartal I et al. [16] noticed 11 patients (5.5%) and 9 patients (5.6%) in FURS and ESWL respectively. Also, Aboutaleb H et al. [18] showed 8 patients (9.9%) and 32 patients colic (48.5%) in FURS and ESWL respectively.

In the current study fever, which was treated with IV antibiotics complaint by (3/48) patients (6.3%) and (1/47) patient (2.1%) in FURS and ESWL respectively. Kartal I et al. [16] noticed 8 patients (4.0%) and 4 patients (2.5%) in FURS and ESWL respectively. Karadag et al. [22] on 61 patients suffered from proximal ureteric stones showed post-operative fever (Clavien-Dindo grade GII) in 8 (13.1%) patients in FURS group.

In the current study (1/48) patient (2.1%) in FURS group presented with fever (sepsis), which did not respond to conservative measures and needed urgent intervention (DJ insertion). Kartal I et al. [16] noticed also one patient with urosepsis in FURS group which was treated with urgent nephrostomy.

In the current study (1/47) patient (2.1%) in ESWL group presented with renal colic (due to steinstrasse), which did not respond to conservative measures and needed semirigid URS intervention. Aboutaleb H et al. [18] showed 3 patients (3.7%) and 23 patients colic (34.8%) in FURS and ESWL respectively, Conservative management succeeded in 14 patients (61%) and failed in 9 patients (39%), who were then shifted to URS lithotripsy. These may attribute to patient's negligence of good hydration measures and post ESWL instructions.

All the reviewed studies showed complications between Clavien-Dindo grade GI to GII in form of colic, fever and LUTS, with less degree documented GIII in some cases, with no documented GIV or GV as a post-operative complication. These suggests the improvement in technology, surgeons' experience and less invasive instruments.

5. CONCLUSION

There is a continuous improvement in the field of endourological management of stones over the last decades. Both FURS with laser lithotripsy and ESWL are similar with no statistically significant difference as regard complication rate and auxiliary procedure usage rate in patients with upper ureteral stones less than or equal 2 cm. FURS with laser lithotripsy has a significant result as a lower retreatment rate and higher stone free rate. FURS had a longer procedure time especially in stone more than 1.5 cm, when it is compared with ESWL session. ESWL is considered as a less invasive and outpatient procedure. In our hand and our institution, following these results, we can recommend FURS with laser lithotripsy as the first treatment modality for proximal ureteric stones > 0.5 cm and ≤ 2 cm.

Further studies are needed with larger patients' sample for confirmation of our results.

CONSENT

As per international standard or university standard, patients' written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

After getting institutional review board approval (IRB number: 32662/10/18), the study has been conducted in a single tertiary center at Tanta Urology Department, Tanta University in Tanta, Egypt between October 2018 to October 2021.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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