# Comparison between Flexible Uretero-Renoscope and Shock Wave Lithotripsy in Management of Lower Pole Renal Stones 10-20 mm

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**Abstract:** ***Background**: Lower Pole (LP) renal stones are challenging to manage due to the existence of anatomical features that make stone removal more complex. Eextracorporeal shock wave lithotripsy (ESWL) has historically been the treatment of choice for all stones less than 20 mm in size; however advances in laser lithotripsy are favoring flexible ureteroscopy (FURS) in the treatment of renal stones. Objective: evaluate the outcomes of retrograde intrarenal surgery by FURS and ESWL in the management of Lower pole renal stones 10-20mm. **Patients and methods**: A Prospective two arms clinical interventional study that involved 80 adult patients diagnosed with lower pole renal stones of (10-20 mm) Patients were randomized into two groups, Group FURS consisted of 40 patients (n=40) were offered treatment with FURS for their renal stones. Group ESWL consisted of 40 patients (n=40) were offered treatment by ESWL, both groups were evaluated for stone-free rate at 2 weeks and 3 months interval in addition to other parameters. **Results**: there was a significant difference between both groups regarding procedure time, that procedure time was more in FURS group(p=0.001). SFR In 2 weeks and 3 months were significantly superior in FURS ,75% of patients were Stone free at 2 weeks,87.5% at 3 months in FURS group while only 17.5% were stone free at 2 weeks and 50% at three months in ESWL group (p=0.001).*

**Keywords:** Flexible Uretero-Renoscope, Shock Wave, Lithotripsy, renal stone

## 1. Introduction

Urolithiasis affects 5 to 15 percent of the world's population, has a high recurrence, which after 5 years can reach up to 50 percent, and occurs often in the workforce population, resulting in significant individual and hospital costs; therefore, it is a health issue of great sociosanitary importance. In recent decades, the prevalence of urinary stones has increased significantly, resulting in a rise in health system expenditures [1].

Lower Pole (LP) renal stones are more challenging to manage due to the existence of anatomical features that make stone removal more complex. European Association of Urology recommendations states that Extracorporal shockwave lithotripsy (ESWL) is effective and that treatment outcome is depending on stone size, location, composition, and patient's characteristics. It offers clear recommendations for the first treatment of small (10 mm) LP stones with ESWL or flexible ureterorenoscopy (FURS) and big (>20 mm) LP stones with percutaneous nephrolithotomy (PCNL). Nonetheless, the option for the primary care of medium-sized (10–20 mm) LP stones remains controversial. ESWL is now suggested over FURS and PCNL in the absence of "unfavorable" stone composition and anatomical variables [2].

A fundamental aspect of LP's troublesome nature is The pelvicalyceal system anatomy. Due to the disadvantageous location of the lower pole, spontaneous stone passing is difficult [3]. In addition, the influence of an acute infundibulopelvic angle, a narrow infundibular width, and a long infundibular length on obstructing stone clearance are well-established unfavorable predictors for stone-free rate (SFR) following initial therapy with ESWL [4]. However, there is currently lack of consensus about the thresholds at which these anatomical traits begin to severely impede stone evacuation and the radiological means by which these values may be reliably verified ; That by itself confronts urologists with a problem when establishing a patient's appropriateness for ESWL [5]

ESWL has historically been the treatment of choice for all stones less than 20 mm in size because to its minimal invasiveness, low morbidity, quick procedure duration, and little convalescence [3, 6]. However, in parallel to anatomical considerations, there are other critical aspects that might influence the efficacy of ESWL, such as the type of lithotripter, amount of shockwaves given, and energy level employed [4] Lower pole anatomy, the nature of the stone, and the patient's body habitus all effect the potential of ESWL to produce a stone-free, fragment-free patient in a single session [5].

Renal stone therapy has been enhanced by the development of holmium laser technology and advances in flexible URS, which have enabled smaller diameters, larger working channels, more qualified imaging modalities, and enhanced deflection mechanisms [7] and expanded the retrograde intrarenal surgery (RIRS) indications, which is now regarded as one of the most common endourologic procedures used to treat renal stones with high success rates; it is well-received by patients due to the fact that the affliction is usually mild and does not necessitate a longer hospital stay or extended absence from work. In addition to the reduced risk of blood loss, renal parenchymal injury and renal impairment are also minimized [8-11]. Currently, RIRS is recognized for its safety in stone management, particularly in patients with morbid obesity, musculoskeletal deformity, bleeding diathesis, and ESWL failure. RIRS is suggested for stones of less than 2 cm, particularly lower pole stones or in patients with contraindications for ESWL [12, 13]. While its SFR profile is very variable, ranging from 59 to 94% based on anatomical position and stone volume [14]. In the present clinical analysis, we evaluate and compare the outcomes of retrograde intrarenal surgery by Flexible Ureteroscope (F-URS) and ESWL for the management of Lower pole renal stones 10- 20mm.

## 2. Method

### 2.1 Study design

A Prospective two arms clinical interventional study that involved 80 adult patients diagnosed with lower pole renal stones of (10-20 mm) by urologists in the outpatient clinic and indicated for treatment. Patients were randomized into two groups, Group FURS consisted of 40 patients (n=40) with 24 males (60%) and 16 females (40%) with a mean age of 35.6 ± 10.063 years, patients in this group were offered treatment with FURS for their renal stones. Group ESWL consisted of 40 patients (n=40) with 27 males (67.5%) and 13 females (32.5%) with a mean age of 40.75 ± 15.199 years, patients in this group were offered treatment by ESWL, A total of 3000 shocks were delivered at a frequency of 80 shocks per minute during each session or until the stone was completely fragmented under fluoroscopic control.
All patients underwent history, clinical and urological examinations on presentation, Body Mass Index has been determined. KUB has been done in addition to Abdominal Ultrasound (US) and abdominal CT scan for diagnosis and determining the stone laterality, size, and location. Patients also underwent Urinalysis, Urine culture and sensitivity, CBC, Serum creatinine, PT, PTT, and INR investigation to determine their eligibility for intervention and for the present study, and after March 2020 Patients were required to test for PCR of COVID- 19.

Both groups underwent their assigned procedures and characteristics of therapy were recorded including (hospital stay, procedure duration), patients were monitored for postoperative complications including Clavien 1 set (Colic, ileus, and haematuria), Clavien 2 (Sepsis), and Clavien 3 set (Ureteric injury, and Steinstrass).

Patients were then monitored for their stone-free rate which has been regarded as no residual stone or stones ≤4 mm by plain abdominal radiograph of the kidneys, ureters, and bladder (KUB) and by the abdominal US at 2 weeks, 4 weeks, 6 weeks and 3 months duration. Based on their stone clearance, ESWL patients were determined for a follow-up session if not stone free at 2 weeks, and a maximum of three sessions two weeks apart in total including the initial session was decided to be done, before deciding on an auxiliary therapy. FURS patients were also offered another session if not stone free at 2 weeks follow-up and a maximum of two sessions two weeks apart in total including the initial session was decided to be done, before deciding on an auxiliary therapy. SFR at 2 weeks and 3 months from initial therapy were used in outcome evaluation in this study. The total number of therapy sessions was then recorded as well as the frequency and modalities of auxiliary treatment.

### 2.2 Study settings

The study was conducted between the 1st of August 2021 and the 1st of October 2022 at "Ghazi Al-Hariri surgical specialties hospital" in the urology polyclinic setting, patients who needed hospital stay were referred to the urology ward of the same center. Written and Informed consent has been taken from the patients for both the current mode and auxiliary modes of treatment if needed as well as a written informed consent for participating in this study.

### 2.3 Inclusion criteria

Adult patients (age >18 years) of both sexes diagnosed with Lower pole radiopaque renal stones of 1-2 cm in size.

### 2.4 Exclusion criteria

Patients with congenital anomalies of the renal system (Ectopic kidney, horseshoe kidney, Duplex system), patients with distal obstruction (PUJO, Uretric stricture), patients with active urinary tract infection, pregnancy, Obesity with BMI >29Kg/m$^2$, and patients who refused participation in the study.

### 2.5 ESWL Procedure

Patients underwent the procedure under analgesia by diclofenac sodium 75mg/3ml IM injection (Voltaren 75mg/3ml IM, Novartis AG, Basel, Switzerland). An electromagnetic lithotripter with fluoroscopic control (Modularis™ Siemens Healthineers, Erlangen, Germany) was used in this study. A total of 3000 shocks were delivered at a frequency of 80 shocks per minute during each session or until the stone was completely fragmented. Patients were evaluated 2 weeks after each ESWL session with KUB and abdominal US to assess stone fragmentation and renal obstruction. Repeated treatment was carried out if inadequate fragmentation of the stone was observed for a maximum of three sessions. If there was no breakage of the stone, the patient was moved to another line of treatment as an auxiliary treatment.

### 2.6 FURS Procedure

Ceftriaxone vial 1gm IV (MESPORIN 1gm Vial IV, Acino International AG, Zurich, Switzerland) given 1 hour before the induction of General anasthesia to the patient by the anesthetist. A Single-Use flexible UreteroRenoscope (Pusen PU3033A, Zhuhai PUSEN Medical Technology Co. Ltd., Zhuhai, Guangdong China.) with Laser system using 200 microns laser Fiber (Litho EVO, FDA.report device ID: 08059173390960, Version model no.: PVMS00058, Quanta system SpA™, Samarate, Varese, Italy). Patients were placed in a lithotomy position, prepared, and draped. Before FURS a semi-rigid ureteroscope 8 Fr. (Karl Storz™ uretro-renoscope, Item no.: 27002k, Karl Storz TH., Bangkok, Thailand) was routinely used in all patients, which all were stented by 5 Fr. JJ catheter two weeks before the procedure. Lithotripsy was done at 0.8 J and 6 Hz and we increase the energy of the laser depending on the hardness of the stone, then with the aid of a tipless nitinol basket (Zerotip™, nitinol stone retrieval basket, order no.: M0063901050, Boston Scientific Corporation, Massachusetts, USA), large fragments were extracted through of the protective sheath avoiding the use of tweezers through the FURS that can favor its breakage. At the end of the procedure, the hospital policy was followed with placement of 5-6 Fr JJ stent for 10-14 days together with an indwelling Foley catheter for 12-24 hours. Repeat treatment was carried out if inadequate fragmentation of the stone was observed for a maximum of two sessions. If there was no breakage of the stone, the patient was moved to another line of treatment as auxiliary treatment.

### 2.7 Sample Size Estimation

Convenient sample that involved 80 patients recruited in the study.

### 2.8 Ethical approval

Ethical committee approval was received from the Ethics Committee of Iraqi Board for Medical Specialization (Approval No: A1022 on: May 1st, 2021). Written informed consent taken from all the patients in accordance with Helsinki declaration of human studies.

### 2.9 Statistical analysis

Statistical package for social science version 18 (SPSS18) was used for both data entry and data analysis. Continuous variable presented as mean ± standard deviation (SD) and discrete variable presented as number (%). Intendent T-test used to test the significance between continuous variable and Chi-square test (or fisher exact test when appropriate) for discrete variable. P-value of ≤0.05 were considered Significant.

## 3. Results

A total of 80 patients with lower pole renal stones managed by F-URS or ESWL were included in this study; 40 patients were managed by F-URS and 40 patients were managed by ESWL. No significant difference was observed between both groups regarding their age, BMI, and sex, as illustrated by table 1.

**Table 1:** Assessment of demographical variables

| Parameters | F-URS | ESWL | p-value |
|---|---|---|---|
| Number | 40 | 40 | - |
| Age (year) | 35.60 ± 10.06 | 40.75 ± 15.2 | 0.07 |
| BMI (kg/m$^2$) | 20.63 ± 1.68 | 20.58 ± 1.82 | 0.89 |
| Sex | | | 0.48 |
| Male | 24 (60%) | 27 (67.5%) | |
| Female | 16 (40%) | 13 (32.5%) | |

The Number of sessions and retreatment were significantly more in ESWL group (p=0.001), stone free rate (SFR) in 2 weeks and 3 months were significantly better in F-URS, 75% of patients were Stone free at 2 weeks, 87.5% at 3 months in F-URS group while only 17.5% were stone free at 2 weeks and 50% at three month in ESWL group (p=0.001) and these variables are shown table 2 and figures 1 and 2.

**Table 2:** Distribution of outcome variables according to procedure type

| Parameters | F-URS | ESWL | p-value |
|---|---|---|---|
| Number | 40 | 40 | - |
| Stone size (cm), mean ± SD | 1.495 ± 0.2075 | 1.545 ± 0.2745 | 0.36 |
| Procedure time (min), mean ± SD | 82.03 ± 8.862 | 39.92 ± 5.264 | <0.001 |
| Side, n (%) | | | |
| Right | 17 (42.5%) | 17 (42.5%) | |
| Left | 23 (57.5%) | 23 (57.5%) | |
| No of Sessions, n (%) | | | 0.001 |
| 1 | 35 (87.5%) | 6 (15.0%) | |
| 2 | 5 (12.5%) | 8 (20.0%) | |
| 3 | 0 (0%) | 26 (65.0%) | |
| SFR (2 weeks), n (%) | 30 (75%) | 7 (17.5%) | 0.001 |
| SFR (3 weeks), n (%) | 35 (87.5%) | 20 (50.0%) | 0.001 |
| Retreatment, n (%) | 5 (12.5%) | 35 (87.5%) | 0.001 |
| SFR: stone free rate, n: number, SD: standard deviation | | | |

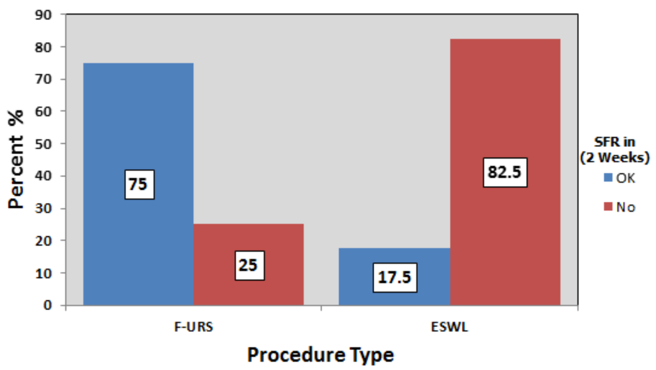

**Figure 1:** Distribution of procedures according to SFR in 2 weeks.

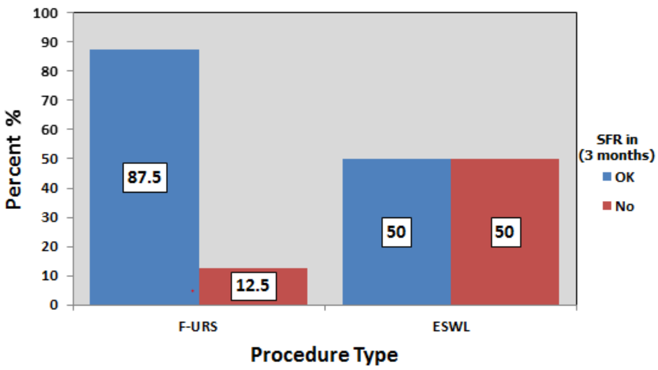

**Figure 2:** Distribution of procedures according to SFR in 3 months.

Apparently, 50% of ESWL group patients need auxiliary treatment while only 12.5 % of F-URS Patients need auxiliary treatment(p=0.001). In ESWL group,20 patients need auxiliary treatment,14 of them treated by F-URS and 6 of them treated by PCNL as auxiliary treatment. In F-URS group, 5 patients need auxiliary treatment, 3 patients treated by PCNL and 2 patients treated by ESWL as auxiliary treatment and these results. Overall complications were comparable in both groups. Regarding these postoperative complications, in F-URS group 14 patients developed

(Clavien1) complication, 8 of them develop renal colic, 1 of them develop lieus, and 5 of them develop haematuria and all of them treated conservatively (p=0.81). Two patients treated by F-URS developed (Clavien2) complication as sepsis and were treated by admission and conservative treatment (p=0.64). Two patients developed Uretric injury (Clavien 3a) and were managed by prolonged stenting for 8 weeks (0.39). In ESWL group,15 patients developed (Clavien 1) complication. 10 of them developed colic, 2 of them with lieus, 3 of patients developed haematuria.and all of them treated conservatively (p=0.81). Three patients developed (Clavien2) complication as sepsis and were treated by admission and conservative treatment (p=0.64). Four patients developed steinstrass (Clavien 3a) (p=0.39), 3 of them were managed by DJ stenting, and one of them treated conservatively, as illustrated in table 3.

**Table 3:** Assessment of auxiliary treatment and patients' willingness to undergo procedures

| Parameters | F-URS | ESWL | p-value |
|---|---|---|---|
| Number | 40 | 40 | - |
| Patients willing to undergo procedure again | 23 (57.5%) | 19 (47.5%) | 0.37 |
| Auxiliary treatment | 5 (12.5%) | 20 (50%) | 0.001 |
| Clavien1 (Colic, ileus, haematuria) | 14 (35%) | 15 (37.5%) | 0.81 |
| Clavien 2 (Sepsis) | 2 (5%) | 3 (7.5%) | 0.64 |
| Clavien 3 (Ureteric inj. Steinstras) | 2 (5%) | 4 (10%) | 0.39 |
| Auxiliary Rx in detail | | | 0.001 |
| PNL | 3 (7.5%) | 6 (15%) | |
| ESWL | 2 (5%) | 0 (0%) | |
| RIRS | 0 (0%) | 14 (35%) | |
| No | 35 (87.5%) | 20 (50%) | |

## 4. Discussion

Lower Pole stones are more challenging to treat because of anatomical reasons that make stone removal more challenging. Our study showed that retreatment and auxiliary treatment were higher in ESWL group (p=0.001),these findings are consistent with Ismail MB et al study [1] and Singh BP et al study [13] which stated that retreatment and auxiliary treatment were higher and significant in Patients with LP stones treated by ESWL.

In a recent meta-analysis review research conducted in the United Kingdom, Donaldson et al. examined the benefits and drawbacks of several urological procedures for the removal of lower pole stones (2cm). Retrograde intrarenal surgery and percutaneous nephrolithotomy were shown to be more successful than ESWL in the treatment of lower pole stones larger than 10 mm. However, for lower pole stones less than 10 mm in size, the ESWL demonstrated more effectiveness and safety than other treatments, particularly for lower pole stones less than 2 cm in size accompanied with percussion, diuresis, and inversion therapy [3] .

According to guidelines issued by the European Association of Urology in 2015, kidney stones of 1-2 cm in diameter may be treated with ESWL or endourological procedures [15]. In affluent nations, the trend of therapeutic choice has turned toward retrograde intrarenal surgery and minimally invasive percutaneous nephrolithotomy, with little interest in ESWL, due to greater SFR rates associated with surgical procedures [16] .

American research by De et al.[17] showed that Patients with lower pole stones (1-2 cm) treated with retrograde intrarenal surgery had a higher SFR, less hemorrhage, and a shorter hospital stay than those treated with minimally invasive percutaneous nephrolithotomy. Another Egyptian study revealed that retrograde intrarenal surgery had a greater SFR than ESWL, but that ESWL has a lower complication rate [18]. In our study SFR was higher in F-URS group, and complications were comparable in both groups.

However, Chaussy et al [19] research conducted in Germany, ESWL is the treatment of choice for lower renal pole stones up to one cm in size, especially when accompanied by mechanical percussion following ESWL. Pearle and Lingeman [20] observed no statistical significance in the stone-free rate between ESWL and URS (35% vs. 50%) after three months' follow-up using spiral tomography and concluded that ESWL was related with improved patient acceptability and quicker convalescence.

Our study showed that SFR at two weeks and three months were higher and significant for F-URS group(75% at 2 weeks,87.5% at 3 months) than ESWL group(17.5 % at 2 weeks,50% at 3 months)(p=0.001).this consistent with Singh BP et al study [13]. Access to the LP has been enhanced by recent technological developments in F-URS, which have also raised the Success rate. Bozkurt et al [19] exhibited comparable SFR of F-URS and PCNL (89.3% - 92.8%) for 1.5-2 cm LP stones with less complications in F-URS and concluded that F-URS had adequate effectiveness for medium-sized LP stones with reduced morbidity. Although the LP research group favored PCNL and Raman and Pearle chose PCNL or F-URS, % of urologists surveyed on the Internet favoured ESWL for stones of intermediate size [13]. Koo et al [21] discovered ESWL to be more cost - effective and efficient for LP calculi less than 2 cm with a mean stone size less than 1 cm. El-Nahas et al [18] showed In a recent retrospective study, 1-2 cm LP calculi had a considerably greater SFR and a low RR in F-URS (vs. SWL). Multiple variables that have a detrimental impact on fragmentation can influence SWL's success (obesity, stone density, and chemical composition) [22] or clearance (unfavorable LP anatomy) [23]. In the current study, patients with high body mass index were excluded from focusing as clearly as possible on the issue of the LP. As none of the various interventions (controlled inversion therapy, [24] mechanical percussion, [25] and irrigation through a retrograde cobra catheter [26] suggested to improve LP stone clearance after ESWL has gained wide acceptance, they were not used in the present study.

Grasso and Ficazzola [27] revealed that Similarly to ESWL, the success of F-URS is greatly determined by LP anatomy. Stav et al [28] Notified that technical issues during ureteroscope angulations accounted for the majority of F-URS failures. In our analysis, researchers faced difficulty in fragmentation in five individuals due to severe angulations. In all other cases, the stone was successfully repositioned from the LP to a more favorable place, either whole or after fragmentation into bigger pieces, resulting in a higher SFR.

Schuster et al [29] found that Repositioning the stone into a suitable calyx resulted in a considerable increase in SR (from 29% for in situ stones to 100% for moved stones) in stones of intermediate size. For the therapy of residual stones, ESWL and F-URS were well complimentary in the present study. Two patients in the current study who had large residual fragments following a single session of F-URS were effectively treated with ESWL. Similarly, 14 patients with substantial residuals were treated with F-URS in the ESWL group.

In the current study, the majority of complications were Clavien grades I and II and were treated conservatively in both groups. Two patients in the F-URS group experienced ureteric damage of grade III [30] During the extraction of large fragments, they were treated with a DJ stent for eight weeks, and six months later they were asymptomatic and doing well. Four ESWL patients developed steinstrasse; three were treated by DJ stenting and one was handled conservatively.

Despite the increased invasiveness of F-URS, the patient satisfaction rating was greater in our study. In terms of desire to undertake the same surgery again in the future, F-URS was chosen above ESWL. The requirement for several sessions was the primary cause for the significantly greater dissatisfaction rate (p=0.37) in the ESWL group. This appeared to be the most influential factor in determining patient satisfaction.

## 5. Conclusions

Regarding treatment of lower pole renal stones 10-20 mm, F-URS was superior to ESWL in terms of SFR, retreatment and Auxiliary treatment. Regarding residual fragments, ESWL and F-URS were complementary to each other.

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