REAL LIFE RETROGRADE FLEXIBLE URETERORENOSCOPY *VERSUS* EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY IN PYELOCALICEAL STONES UNDER 20 MM

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REAL LIFE RETROGRADE FLEXIBLE URETEROSCOPY VERSUS EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY IN PYELOCALICEAL STONES UNDER 20MM (Abstract): The **aim** of our study was to highlight groups of patients with single pyelocaliceal stones less than 20 mm in whom flexible retrograde ureterorenoscopy (FURS) or extracorporeal shock wave lithotripsy (ESWL) are superior in terms of stone-free rate and complications. **Materials and methods:** We formed two groups of patients, consisting of patients with single kidney stones under 20 mm in whom FURS was applied (the study group) and another in whom ESWL was performed (the control group). We compared the profile of the patients, the presence of double-J catheters before the procedure, the stone-free rate and the occurrence of complications. **Results:** Patients in the study group were older ($p<0.001$), had larger stones ($p<0.001$) and were more likely to have concomitant diseases ($p<0.001$). The stone-free rate in patients with stones up to 10 mm was similar in both groups (81.25% vs 78.94%, $p=0.777$), while for stones between 11 and 19 mm the stone-free rate was higher in the study group (77.77% vs 45.45%, $p=0.008$). The rate of complications was similar in both groups ($p=0.555$). **Conclusions:** FURS has superior efficacy compared to ESWL in patients with single kidney stones between 11 and 19 mm and similar efficacy in patients with single kidney stones up to 10 mm. The complication rate is low and similar in both groups.
Keywords: FURS, ESWL, STONE-FREE RATE.

According to European guidelines, *flexible retrograde ureterorenoscopy* (FURS) and *extracorporeal shock wave lithotripsy* (ESWL) are the treatment of first choice for single pyelocaliceal stones smaller than 20 mm (1), with the choice of one or the other method being at the discretion of the urologist or the patient, with no clear criteria in favor of one or the other method. In recent years, FURS has taken on an important role alongside ESWL and percutaneous nephrolithotomy (PCNL) among the treatment methods for renoureteral lithiasis (2). However, it has not succeeded in replacing ESWL for stones smaller than 20 mm or PCNL for stones larger than 20 mm

(1). Previous studies have shown that the efficacy of FURS is slightly higher compared to ESWL at over 90% (3, 4, 5) and the complication rate is relatively low for both methods (6, 7, 8). Although there are many studies comparing FURS with ESWL (9, 10, 6), they were performed on homogeneous groups, on selected patients, under ideal conditions, without previous presence of urinary tract obstruction with or without infection, i.e. without possible inflammation in the context, without the presence of ureteral catheters inserted for more than 2 weeks , and without other urological procedures previously performed for the same stones. Also, the surgical limitations due to patients' comorbidities, which can sometimes be important, were not considered when calculating the efficiency of FURS.

Some studies on the efficacy of FURS have focused on the types of lasers used (11) and not on patient characteristics, with the exception of inferior calyx stones, where the infundibulopelvic angle seems to play an important role in the efficacy of FURS (1). For this reason, we conducted a study to determine the efficacy of FURS in terms of stone extraction rate (stone-free rate) and the incidence of complications compared to ESWL under the conditions of daily practice in patients with the above-mentioned characteristics. In this way, we have attempted to specify the indications for the two methods by identifying groups of patients with single pyelocaliceal stones less than 20 mm in which a particular treatment would have a higher success rate and a lower complication rate.

MATERIALS AND METHODS

We conducted a case-control study on patients who underwent FURS for pyelocaliceal stones between 01.04. 2022 and 31.03.2024 at the Urology Clinic of the "Dr. C.I. Parhon" Teaching Hospital in Iasi, Romania, and who constituted the study group. The control group consisted of patients hospitalized at Elytis Hope Hospital in Iasi, Romania, where ESWL was performed for pyolocaliceal stones, between 01.04. 2023-31.03.2024. In this group, we analyzed only the patients who were hospitalized during one year in , as we achieved a ratio of more than one to one compared to the study group. In this way, increasing the number of patients in the control group would not have increased the significance of the statistical tests used. The study was approved by the ethics committees of both hospitals. The patient data were taken from the electronic patient records. We included all patients with pelvic or calyx stones, single, up to 20 mm in size, whether or not they had a double-J ureteral catheter.

We excluded patients under 18 years of age, patients with multiple stones, single stones over 20 mm, stones associated with various renal or pyeloureteral malformations and patients with incomplete data in the electronic registries from the study. Among the patients in the study group, we also excluded patients who underwent FURS due to tumor pathology or exploratory.

The diagnosis of lithiasis was based on an ultrasound examination and a simple kidney X-ray. Computed tomography, which can accurately determine the size of the stones, was not used for diagnosis. We therefore divided the patients into two groups only, according to the size of the stones, and not in many groups, due to relative inaccuracy of the measurement methods. Patients with stones up to and including 10 mm and patients with stones between 11 and 19 mm. When performing

FURS, a 7Ch double J-ureter catheter (24-28 cm) was routinely inserted at least two weeks before the procedure. The reusable flexible ureteroscope (Olympus Comp. Germany) was used. ESWL was performed in the same way by all urologists, using the ramping method, with maximum intensity achieved after a minimum of 500 and a maximum of 3000 shock waves administered. A maximum of 2 procedures were performed one month apart. If fragments of more than 4 mm were still present, the procedure was considered a failure. The Siemens Modulith Lithotripter (Siemens Comp. Germany) was used.

We recorded the demographic data of the patients from the two groups, namely age, sex, location of stones, size of stones, and the presence of comorbidities, DM, obesity, renal failure, anemia, and cardiac diseases such as hypertension and ischemic heart disease. We then comparatively analyzed the frequency and reasons for previous double-J catheter insertion, presence of previous urinary tract infections and type of germs, history of lithiasis, duration of double-J catheter wear until the procedure, and history of urological maneuvers performed for the same stone. In terms of efficacy, we compared the stone-free rate and the occurrence of immediate complications (occurring in the first 7 days after the procedure). These included urinary tract infection, pain and hematuria. We considered "stone-free" status if, after the FURS or ESWL procedure, no remaining fragments were detectable at the 14 day follow-up or if the remaining fragments were less than 4 mm in size, as determined sonographically or radiologically. We considered urinary tract infection if a positive urine culture was highlighted after the procedure, up to 2 weeks, performed after the onset of febrile syndrome or low urinary symptoms. We considered the urine culture positive if more than 10^5 UFC/ml was highlighted in the culture by the qualitative technique.

Of the patients in the study group who were admitted to "Dr. C.I. Parhon" Hospital during the 2-year period, there were 78 patients. Among them, there were 10 patients who underwent FURS for multiple calyceal lithiasis, 4 patients with stones larger than 20 mm, 2 patients with associated renal or pyeloureteral malformations, and one patient who underwent FURS to investigate hematuria diagnosing an upper urothelial tumor. As for the control group, there were a number of 128 patients with kidney stones who underwent ESWL at Elytis Hospital during the above-mentioned period. Of these, we excluded 2 patients under 18 years of age, 4 patients with stones larger than 20 mm, 16 patients with multiple stones and 27 patients with incomplete data in the electronic registries.

Statistical analysis.

The quantitative variables were described by the mean and standard deviation and compared with the t-student test. Due to the large number of patients included in the study, it was not necessary to perform homogeneity tests of the two groups. Qualitative variables were described by percentages and compared using the chi-square test. When we compared qualitative variables that occurred in rare cases (< 5), we applied the Fischer Exact Test for Contingency Table. The data was first entered into an Excel spreadsheet and then transferred to the *SPSS 22.0* program. We considered the difference to be statistically significant if the statistical p-value < 0.05.

RESULTS

During the study periods mentioned, there were 61 patients in the study group who were treated with FURS and 79 patients in the control group who were treated with ESWL. The demographic characteristics of the patients in the 2 groups are listed in first table.

TABLE I.
The characteristics of the 2 groups.

		FURS group (n=61)	ESWL group (n=79)	*p* value chi square
Age (years) mean ± SD		55.87±13.96	46.3±14.66	**<0.001** t-student
Gender	Male (no., %)	21 (34.42%)	47 (59.49%)	**0.003**
	Female (no., %)	40 (65.58%)	32 (40.51%)	**0.003**
Affected kidney	Right kidney	28 (45.9%)	42 (53.16%)	0.394
	Left Kidney	33 (54.1%)	37 (46.84%)	0.394
Stone localization	Pelvis	30 (49.2%)	35 (44.30%)	0.566
	Upper + middle calyx	19 (31.1%)	24 (30.38%)	0.922
	Lower calyx	12 (19.7%)	24 (25.32%)	0.430
Stone size (mm) mean ± SD		13.26±3.84	0.98± 4.82	**<0.001** t-student
≤ 10mm		16 (26.2%)	57 (72.15%)	**<0.001**
11-19 mm		45 (73.8%)	22 (27.85%)	**<0.001**
Comorbidities	Diabetes mellitus (DM)	16 (26.22%)	4 (5.06%)	**<0.001**
	Obesity	18 (29.5%)	10 (12.66%)	**0.013**
	Kidney failure	11 (18.03%)	2 (2.53%)	**0.001** Fisher test
	Anemia	11 (18.03%)	1 (1.26%)	**<0.001** Fisher test
	Heart disease (HBP. ischemic cardiomyopathy)	31 (50.81%)	12 (15.19%)	**<0.001**

The patients in the study group were older ($p<0.001$), the female gender predominated ($p=0.003$) and they had larger stones ($p<0.001$) than the control group. On the other hand, there were no statistically significant differences between the two groups in terms of right/left location ($p=0.394$), pelvic level location ($p=0.566$), upper and middle calyx ($p=0.922$) and lower calyx ($p=0.43$).

In terms of comorbidities, patients in the study group had a statistically significantly higher proportion of DM ($p<0.001$), obesity ($p=0.013$), chronic kidney disease

(p=0.001), anemia (p<0.001), and heart disease (p<0.001).

Table II shows a comparison of the proportion of the presence of preoperative double-J catheter according to their indication and indwelling time, the presence of stones, and the frequency of other urological procedures performed for the same stones that failed to completely solve the stones, requiring FURS or ESWL as a secondary "rescue" treatment for the elimination of remaining stone fragments over 5 mm.

TABLE II.

The presence of double J catheters, history of lithiasis and previous urological procedures for the same stones.

		FURS group (n=61)	ESWL group (n=79)	*p* value for chi-square
Double-J stent inserted for infected hydronephrosis		15 (24.59%)	17 (21.52%)	0.667
Double-J stent inserted for hydronephrosis		35 (57.37%)	5 (6.33%)	**<0.001**
Double-J stent inserted without previous hydronephrosis/infection		10 (16.39%)	0 (0%)	**<0.001** Fisher test
Personal history of lithiasis		30 (49.18%)	14 (17.72%)	**<0.001**
Total nr. of patients with preprocedural double-J catheters		60 (98.5%)	22 (27.85%)	**<0.001**
Preoperatory indwelling time of ureteral double-J catheters	< 1 month	13 (21.31%)	15 (18.99%)	0.733
	1-2 months	18 (29.50%)	7 (8.86%)	**0.001**
	> 2 months	29 (47.54%)	0 (0%)	**<0.001** Fisher test
Interventions after other procedures for the same stone	PCNL	4 (6.56%)	2 (2.53%)	0.402
	URS	11 (18.03%)	2 (2.53%)	**0.002**
	ESWL	6 (9,48%)	0 (0%)	**<0.001**

URS-semirigid retrograde ureteroscopy

Patients in the study group had a higher proportion of double-J catheters inserted preoperatively for hydronephrosis (p<0.001) and to dilate the ureter and facilitate access of the flexible ureteroscope (p<0.001) compared to the control group. They also had a higher proportion of patients with a history of lithiasis (p<0.001), patients in whom the double-J was inserted earlier than two months (p=0.001) and more than 2 months (p<0.001), and more patients who had previously undergone ESWL for the same stone (p<0.001) or semi-rigid retrograde ureteroscopy (p=0.002). On the other hand, there was no statistically significant difference between the two groups in the proportion of patients in whom the double-J catheter had been previously inserted for infected hydronephrosis (p=0.667), in whom the double-J catheter had been inserted earlier than one month preoperatively (0.733) and in patients with a history of PCNL treatment for the same stones (p=0.402).

Table III shows the incidence of urinary tract infections in the two groups, divided by type of germs.

TABLE III.

The frequency of preoperative urinary tract infections by type of germs.

Previous UTIs (No., %)	FURS group (n=61)	ESWL group (n=79)	P Fisher Exact Test for 2x2 Contingency Table
E. coli	9 (14,76%)	2 (2,53%)	**0.010**
P. mirabilis	3 (4,92%)	0 (0%)	0.080
Enterococcus spp.	3 (4,92%)	0 (0%)	0.080
Klebsiella pn.	3 (4,92%)	1 (1,26%)	0.317
S. agalactie	1 (1,63%)	0 (0%)	0.435
P.s aeruginosa	1 (1,63%)	0 (0%)	0.435
Total	20 (32,78%)	3 (3,79%)	**<0.001**

The study group had a higher incidence of preoperative urinary tract infections ($p<0.001$) and urinary tract infections with *E. coli* ($p=0.010$).

For comparisons of stone-free rates in the two groups, including separate comparisons for stones less than 10 mm and greater than 10 mm, as well as the incidence of immediate complications (tab. V).

TABLE IV.

Stone-free rate and the complications incidence in the 2 groups.

		FURS group (n=61)	ESWL group (n=79)	*P* Chi-square
Stone-free		48 (78.69%)	58 (73.41%)	0.47
Stone-free rate for stones ≤ 10mm		13 (81.25%)	48 (78.94%)	0.777
Stone-free rate for stones > 10mm		35 (77.77%)	10 (45.45%)	**0.008**
Complications	Reflux pyelonephritis	2 (3.28%)	1 (1.26%)	0.580 Fisher test
	Clostridium difficile infection	1 (1.63%)	0 (0%)	0.435 Fisher test
	Renal colic	1 (1.63%)	5 (6.32%)	0.232 Fisher test
	Hematuria > 24h	5 (8.19%)	3 (3.79%)	0.295 Fisher test
Total no. of complications		9 (14.75%)	9 (11.39%)	0.555

The overall stone-free rate and the stone-free rate for stones smaller than 10 mm was similar in both groups ($p=0.47$ and $p=0.777$, respectively). However, the stone-free rate for stones larger than 10 mm was higher in the study group than in the control group ($p=0.008$). The incidence of complications was lower in both groups, with no significant differences in any of the complications examined ($p=0.555$). Clostridium difficile digestive infection appeared in one case in the study group.The stone-free rate in patients who underwent FURS surgery was similar regardless of stone size ($p=0.08$), while in the group of patients who underwent ESWL, the stone-

free rate was statistically significantly higher in patients with stones smaller than 10 mm compared to stones larger than 10 mm ($p<0.001$).

DISCUSSION

Our study showed similar efficacy of FURS and ESWL for pyelocaliceal stones up to 10 mm. In contrast, the efficiency of FURS proved to be superior to ESWL for pyelocaliceal stones between 11 and 19 mm. The rate of complications was reduced in both patient groups, with no statistically significant differences.

The main limitation of our study is the retrospective nature and the fact that the procedures were performed by different urologists, leading to some variability in the results, although the same surgical technique was used for FURS and the same method of shock wave administration was used for ESWL.

However, to our knowledge, there is little data in the literature comparing the two procedures and considering special patient groups, such as patients with double J ureteral probes inserted for hyperalgesic renal colic or infected hydronephrosis, as well as patients with comorbidities.

When analyzing the results obtained, we note that the average age of the patients in the study group was higher than in the control group. This could be due to certain treatments of the patients, such as treatment with anticoagulants, which contraindicate ESWL, and perhaps also to the preference of some surgeons who considered a continuous hospitalization in case of FURS to be safer for the patients, as opposed to ESWL, which is performed on an outpatient basis, with the patient being monitored only for a few hours after the procedure and returning for control in a maximum of 2 weeks or in case of complications. We attribute the fact that the female sex predominated in the study group and the male sex in the control group to a coincidence, without a physio pathological explanation.

As was to be expected, the frequency of stones on the right and left side was the same, as there are no anatomical features that lead to an increased frequency on a particular side. The location of stones in the pyelocaliceal system was also similar in both groups, which increases the reliability of the statistical tests, as we know that the stone-free rate is lower for stones in the lower calyx than for stones in the renal pelvis or upper/middle calyx, for both FURS and ESWL.

We found that patients in the FURS-treated group had significantly larger stones than patients in the control group. Stones between 11 and 19 mm predominated, while stones up to 10 mm predominated in the control group. This can be explained by the preferences of the surgeons, who perhaps intuitively recognized that FURS could provide better results compared to ESWL.

As far as comorbidities are concerned, we observe an increased incidence in the study group, which is probably due to the older age. An interesting aspect is that the FURS was performed after the patients had previously been admitted to the emergency room due to recurrent renal colic or infected hydronephrosis and were only later scheduled for FURS. However, due to the large volume of patients in our clinic, they waited over 1-2 months until the procedure, which increases the risk of double-J catheter carriers for the occurrence of urinary tract infections or double-J catheters intolerance. On the other hand, patients for ESWL had no previous emergency room procedures, and they went to an outpatient

ESWL service. The fact that the patients in the study group had larger stones may have caused the more frequent occurrence of complications, obstructions with and without infection.

Another interesting finding of our study was the fact that FURS was performed in a significant percentage as a second-line treatment after the failure of semi-rigid URS or ESWL, whereas the ESWL procedure was predominantly performed as a first-line treatment.

In addition to the prolonged preoperative presence of double-J probes (12), another factor that may have compromised the efficacy of FURS was the presence of urinary tract infections, which can cause inflammation and make advancement of the FURS access sheath difficult. In the case of ESWL, this procedure was performed under ideal conditions, without double-J probes and without preoperative infections. We mention that all ESWL sessions were performed after confirming the absence of UTIs by urine culture, while FURS was also performed during antibiotic treatment for UTIs, without expecting the negative urine culture, which was, however, illusory in the presence of double-J catheters. In contrast to other studies (13, 14), in which many patients did not have double-J catheters in place before the FURS procedure, all but one patient in our study had a stent in place preoperatively. Double J catheters are widely used in urology, not only for drainage of hydronephrosis, but also in open procedures (15, 16), helping to protect the ureter or favoring the healing of some ureteral sutures. However, if you keep them for longer than a month, they can cause irritating urinary tract symptoms (12), which may even require premature suppression.

It is somewhat surprising that the stone-free rate was also below 80% with FURS, not only with ESWL. If ESWL was to be expected according to other studies (17, 18, 19), the lower efficiency of FURS compared to other studies (20) is explained by the fact that it was not performed under ideal conditions, but in patients who had double-J catheters for more than 1-2 months, with associated infections, with comorbidities. Another element to remember is that in 2 patients the technical problems of the equipment forced the abandonment of the procedure, perhaps unjustifiably reducing the efficiency of the method in our study. However, in patients with stones between 11 and 19 mm, the efficiency of FURS was clearly superior, despite all the limitations in terms of patients and equipment.

Compared to other studies (6, 21-23), the rate of complications was reduced in both groups, although there were specific characteristics for each procedure. For example, reflux pyelonephritis and one case of digestive infection with *Clostridium difficile* occurred after FURS, while renal colic occurred after ESWL. Macroscopic hematuria over 24 hours was rare, proving that with adequate technique the risk of hemorrhage is low in both procedures. On the other hand, we had no cases of ureteral lesions or sepsis after FURS, as in other studies (24, 25). The low rate of postoperative infections was consistent with other studies (26), but the development of sepsis should not be neglected (27). The rate of complications in ESWL was also lower in our study than in other studies (23, 28).

Our study is useful for urologists treating such cases as it helps them to make the best decision for the procedure depending on the specifics of the patients and not on

subjective personal preferences.

CONCLUSIONS

FURS and ESWL have equal effectiveness in treating patients with single pyelocaliceal stones up to 10 mm. For patients with single pyelocaliceal stones between 11 and 19 mm, FURS has a superior efficacy. The complication rate is low, both procedures proving high safety. Future prospective studies will be necessary to validate our data.

CONFLICT OF INTEREST AND FUNDING

The authors declare that there is no conflict of interest and they received no funding.

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