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Failed insertion of ureteral access sheath during flexible ureterorenoscopy: A randomized controlled trial comparing second session flexible ureterorenoscopy or same session mini percutaneous nephrolithotomy

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Abstract

We aimed to compare different treatment approaches in patients with failed ureteral access sheath placement during first flexible ureterorenoscopy (f-URS) session. Patients with kidney stones measuring 1-2 cm, presented to our urology clinic between April 2019 and April 2021, were included in the study for evaluation. Patients were randomized into two groups, in case of a failed ureteral access sheath placement during the first f-URS session. In group 1, ureteral JJ stent was placed for dilation and second session of f-URS was planned 4-6 weeks later. In group 2, mini percutaneous nephrolithotomy (mPNL) was performed in the same session. Pre-operative demographic data, operative and post-operative characteristics including complications and success rates were compared. Patients were assessed by Short-Form-36 (SF-36) questionnaires to compare overall life quality after each procedure. Twenty-four patients were included in each group. Pre-operative demographic data and stone characteristics of the patients in each group were comparable. Operation time, fluoroscopy time, and hospital stay were significantly higher in the mini-PNL group (p:0.001, p:0.001 and p:0.001, respectively). When SF-36 values were compared, physical function, pain, role limitation, and general health value scores were improved in both groups after treatment. The improvement in physical function and pain parameters was statistically significant in the mPNL group (p:0.026 and p:0.017).In patients with failed ureteral access sheath placement, placing a JJ stent for dilation and postponing f-URS for 4-6 weeks provides the advantages of low hospitalization time for each admission, shorter fluoroscopy and operation time. Performing mPNL in the same session, results in better improvements in SF-36 parameters such as pain and physical function compared to f-URS. The success and complication rates of the two procedures were comparable.

Introduction

Urolithiasis is an important health problem that clinicians frequently encounter. In recent years, the incidence of the disease continued to increase due to increased incidence of obesity, changes in climate characteristics, and altered dietary habits [1]. Percutaneous nephrolithotomy (PNL), flexible ureterorenoscopy (f-URS), extracorporeal shock wave therapy (SWL), and open and laparoscopic surgery methods are used in the therapy of kidney stones. Factors affecting the choice of treatment can be listed as stone characteristics (stone size, stone localization, stone composition), kidney anatomy, patient characteristics, and surgeon preference [2]. With the developments in endourological surgery, open and laparoscopic surgery have been replaced by endourological interventions such as f-URS and PNL in recent years [3].

According to current European Association of Urology (EAU) guidelines, PNL is the gold standard recommended treatment technique for kidney stones larger than 20 mm. For kidney stones between 10–20 mm, both SWL or f-URS are recommended as the first choice of treatment and PNL is recommended as the second. Both PNL and f-URS are safe and effective methods for stones of this size with high success rates [4].

In patients who are planned to undergo f-URS, a ureteral access sheath (UAS) is placed in the ureter at the beginning of the operation in order to provide a better image, reduce intra-renal pressure, easier stone fragment retrieval and shorter operative time. In certain cases, such as ureteral stricture, kink or edema, the ureteral access sheath may not be able to successfully inserted into the ureter. At this stage, double-J (JJ) stent can be inserted into the ureter to create passive dilatation, and a second f-URS session can be scheduled a few weeks later [5]. Another option is to perform PNL operation to the patient in the same session. In this randomized prospective study, we aimed to compare these two different surgical approaches in terms of patient comfort and surgical success in patients with kidney stones between 10–20 mm in which access sheath insertion was failed in the initial f-URS session.

Materials And Methods

Patients with renal calculi between 1–2 cm in diameter who were admitted to a tertiary health institution between April 2019 and April 2021 were evaluated prospectively. Patients who were unsuitable for SWL treatment or who did not benefit from SWL sessions were included in the study. Patients with kidney anomalies, (malrotated and horseshoe kidneys, kidneys with duplicated systems) pregnant patients, patients younger than 18 years of age, and patients who did not consent for inclusion in the study were excluded from the study. Informed consent was acquired from all patients. Before the procedure, the patients were asked to complete the Turkish language validated form of the short form-36 (SF-36) questionnaire. The study protocol was confirmed by the ethics committee of Haseki Training and Research Hospital (EC approval no: 2020 – 174).

A total of 48 patients in whom ureteral access sheath insertion has failed during initial f-URS session were randomly divided into 2 groups. Group 1 underwent a JJ stent insertion and procedure terminated, while group 2 underwent mPNL operation in the same session after prone positioning. Group 1 underwent f-URS 4–6 weeks later. One month after the operation, stone-free status was evaluated with computed tomography (CT) and the patients were asked to complete SF-36 questionnaire after the second session. Operative and postoperative data, SF-36 results, success, and complications were compared between the groups.

Surgical technique

All surgeries were performed by the same team of experienced surgeons in with high expertise in endourology. A guidewire was placed in the ureter in the lithotomy position. Ureterorenoscopy was performed with an 8 Fr ureterorenoscope for active dilatation. An 11–13 Fr UAS was attempted to be placed under fluoroscopy. In cases where the UAS could not inserted, a 26 cm, 4.8 Fr JJ stent was placed under fluoroscopy in the f-URS group, and the procedure was terminated. In the mPNL group, same session mPNL procedure was performed.

After initial JJ stent placement, patients in group 1 underwent a second f-URS session, 4–6 weeks later. After the JJ stent was removed, an 11–13 Fr UAS was placed in the ureter. Digital flexible

ureterorenoscope (Vision medical-UF30, China) was used as the flexible ureteroscope. Stone fragmentation was performed in dusting mode using a Ho:YAG laser with a 272 μ probe. After fragmentation, a 26 cm 4.8 Fr JJ stent was inserted into the ureter.

For patients in group 2, after placing a 5 Fr ureteral open-ended catheter, patients were positioned in prone position and access was performed to the appropriate calyx with an 18-gauge percutaneous access needle using the triangulation technique accompanied by fluoroscopy, in the first session. After the guidewire was introduced into the pelvicalyceal system, sequential dilatation was applied with Amplatz dilatators, and a 21 Fr metallic sheath (Karl Storz, Tuttlingen, Germany) was placed. Stones were fragmented with a Ho:YAG Laser lithotripter (Sphinx, Lisa laser, USA). At the end of the procedure, a 14 Fr nephrostomy catheter was placed in according to the residual stone, hemorrhage, and perforation status. In other cases, the procedure was concluded as totally tubeless.

Short Form-36

The Short Form-36 Questionnaire is an inquiry form created to determine people's quality of life. This questionnaire evaluates both the psychological factors and physical conditions of the patients. It examines eight parameters of health, such as social functioning, physical functioning, role emotional, role physical, vitality (energy), mental health, bodily pain, and general health with 36 questions. This form, which can be filled in by the patient in a short duration of time, is sensitive in detecting minor changes in patients' the quality of life. Each parameter evaluated ranges between the scores of 0-100, and high values for each category indicate favorable conditions for the patient.

Statistical analysis

Study sample size analysis was computed using the G*Power (Erdfelder, Faul, & Buchner, 1996) program. Statistical analysis was performed with 'Statistical Package for the Social Sciences' (SPSS) 25 program. The normality assessment of the distribution of the data was analyzed with the Shapiro-Wilk test and Kolmogorov-Smirnov test. Mann-Whitney U test was used to compare the variables with non-normally distribution and independent samples t-test was used for variables with normal distribution. Quantitative data were presented as mean ± standard deviation values. Chi-square test was used to compare qualitative data. Paired-sample t-test was used to compare SF-36 data before and after the procedure. The data were analyzed at 95% confidence level and the values with $p < 0.005$ were noted statistically significant.

Results

There were 24 patients in both groups. There was no statistically significant difference between the groups in terms of demographic characteristics (age, sex, body mass index, and ASA score). Stone characteristics such as stone size, stone localization, and stone burden were also similar between groups. (Table 1).

Table 1
Comparison of patients' demographic data and stone characteristics

	f-URS (n = 24)	mPNL (n = 24)	p value
Age (years)*	42.3 ± 13.7	42.0 ± 14.2	0.934
Sex	11 (%45.8)	16 (%66.7)	0.146
Male	13 (%54.2)	8 (%33.3)	
Female			
BMI (kg/m²) *	26.3 ± 3.8	27.2 ± 3.3	0.383
ASA score*	1.4 ± 0.6	1.6 ± 0.8	0.317
Stone burden (mm²) *	156.2 ± 33.5	165.9 ± 54.5	0.467
Stone size (mm)*	13.7 ± 2.3	13.0 ± 2.0	0.269
Stone localization	4 (16.7%)	4 (16.7%)	0.950
Upper calyx	3 (12.5%)	4 (16.7%)	
Middle calyx	12 (50.0%)	10 (41.7%)	
Pelvis	5 (20.8%)	6 (25.0%)	
Lower calyx			
Stone opacity	21 (%87.5)	18 (%75.0)	0.267
Opaque	3 (%12.5)	6 (%25.0)	
Non opaque			
Side	11 (%45.8)	13 (%54.2)	0.564
Right	13 (%54.2)	11 (%45.8)	
Left			
Previous stone surgery	15 (%62.5)	13 (%54.2)	0.558
Primer	9 (%37.5)	11 (%45.8)	
Seconder			
*mean ± standard deviation			
ASA: American Society of Anesthesiologists, BMI: Body mass index			

Results from thecomparison of operative data and postoperative data are shown in Table 2. The stone-free rate was calculated as 79.2% in the f-URS group and 87.5% in the mPNL group, and there was no statistically significant difference between the groups (p: 0.439). Hemoglobin decrease was found to be

significantly lower in the f-URS group compared to the mPNL group (0.4 ± 0.3 and 1.1 ± 0.7, respectively) (p:0.001). Operation and fluoroscopy times were found to be significantly longer in the mPNL group (p:0.001 and p:0.001, respectively). The mean hospitalization time was 21.7 ± 7.4 hours in the f-URS group and 40.0 ± 23.9 hours in the mPNL group (p: 0.001). Complications were evaluated in accordance with the Clavien-Dindo classification, and the overall complication rates as well as minor and major complication rates were similar between the groups (p: 0.477, p: 0.683 and p: 0.551, respectively).

Table 2
Comparison of operation data and postoperative follow-up results

	f-URS (n = 24)	mPNL (n = 24)	p value
Hemoglobin decrease (g/dl)*	0.4 ± 0.3	1.1 ± 0.7	0.001
Creatinine increase (mg/dl)*	0.1 ± 0.2	0.1 ± 0.2	0.452
Operation time (min)*	53.7 ± 12.9	82.4 ± 17.3	0.001
Fluoroscopy time (min)*	0.3 ± 0.1	0.8 ± 0.6	0.001
Hospitalization time (hours)*	21.7 ± 7.4	40.0 ± 23.9	0.001
Stone free rate*	19 (%79.2)	21 (%87.5)	0.439
Complications	4 (%16.7)	6 (%25.0)	0.477
Clavien-Dindo 1–2	3 (%12.5)	4 (%16.7)	0.683
Clavien-Dindo 3–5	1 (%4.2)	2 (%8.3)	0.551
* mean ± standard deviation			

The comparison of patients' quality of life in accordance with the SF-36 questionnaire is shown in Table 3. The values of all sub-parameters were compared before and after each procedure in f-URS and mPNL groups. Physical functioning values improved significantly after the procedure in both groups (p: 0.017 and p: 0.001, respectively). Similarly, role physical values improved after the operations (p: 0.007 and p: 0.004, respectively). Bodily pain and general health status values were among the parameters that showed significant improvement in the f-URS group (p:0.029 and p:0.019, respectively). Likewise, these two values improved after the mPNL procedure (p: 0.001 and p: 0.001, respectively).

Table 3
Comparison of preoperative and postoperative values of Short Form-36 parameters within groups

	f-URS		mPNL	
	Mean ± SD	p value	Mean ± SD	p value
Physical functioningBefore	52.4 ± 12.9	0.017	55.1 ± 12.6	0.001
After	57.3 ± 9.1		67.9 ± 11.7	
Role physical	46.3 ± 12.4	0.007	44.5 ± 11.6	0.004
Before	55.6 ± 11.7		55.4 ± 12.0	
After				
Role emotional	57.9 ± 14.5	0.627	54.9 ± 16.48	0.244
Before	60.3 ± 15.8		60.5 ± 14.0	
After				
Vitality	52.4 ± 14.1	0.354	49.6 ± 14.1	0.818
Before	49.4 ± 10.8		50.6 ± 11.1	
After				
Mental health	57.2 ± 13.8	0.423	60.8 ± 15.9	0.675
Before	60.1 ± 14.2		63.4 ± 14.2	
After				
Social functioningBefore	61.1 ± 16.3	0.623	63.2 ± 16.5	0.645
After	59.5 ± 14.5		65.4 ± 15.9	
Bodily pain	47.6 ± 9.6	0.029	41.4 ± 9.9	0.001
Before	55.3 ± 15.3		58.0 ± 12.5	
After				
General health	52.9 ± 10.1	0.019	49.7 ± 11.1	0.001
Before	60.2 ± 10.6		61.7 ± 10.4	
After				
SD: standard deviation				

The pre-procedure and post-procedure differences in the values of the SF-36 sub-parameters were compared between the groups (Table 4). While physical functioning improved by 4.9 points in the f-URS group, this difference was 12.8 in the mPNL group and there was a statistically significant difference

between the groups, favoring mPNL group (p: 0.026). When the differences in bodily pain values were compared, significantly better improvement was observed in the mPNL group (p:0.017). Differences in other parameters were similar between the groups (Table 4).

Table 4
Comparison of the preoperative and postoperative differences of Short Form-36 parameters between groups

	f-URS	mPNL	p value
Physical functioning	4.9 ± 9.4	12.8 ± 13.9	0.026
Role physical	9.3 ± 15.4	10.9 ± 16.6	0.733
Role emotional	2.4 ± 23.6	5.6 ± 22.9	0.635
Vitality	3.0 ± 15.5	1.0 ± 10.2	0.451
Mental health	2.9 ± 10.2	2.5 ± 11.4	0.865
Social functioning	-1.6 ± 11.5	1.8 ± 9.7	0.367
Bodily pain	7.7 ± 16.2	16.6 ± 15.6	0.017
General health	7.2 ± 14.1	12.0 ± 9.8	0.177

Discussion

The surgical management of kidney stones has been performed with high success rates in recent years with the technological advancements in the endourological field. Although PNL is the gold standard treatment for renal calculi larger than 20 mm, the use of f-URS in the therapy of these stones has also increased in recent years. There are many studies in the literature which compared f-URS and mPNL procedures for the treatment of 1–2 cm renal stones In a meta-analysis that has been published recently, both treatment modalities are found to be effective with high success and low complication rates [6]. From this point of view, our study will provide a different perspective to the literature by evaluating the advantages and disadvantages of these two surgical options for patient with failed ureteral access sheath placement during f-URS.

With the developments in the field of endourology, both f-URS and mPNL operations are applied today with high stone-free rates. In their series, Kiremit et al. reported 86.1% success rate for f-URS, and 83.6% success rate for mPNL procedure. [7]. Also, Akbulut et al. reported that the success of f-URS and mPNL for lower calyceal stones of 2 cm or less was shown to be 85.7% and 90.3%, respectively [8]. In our study, both treatment methods had a high success rate, and no significant difference was observed between the two treatment methods.

The time spent on both positioning the patient and gaining percutaneous access to the kidney prolongs the operation time for mPNL. Fluoroscopy is used in f-URS procedure during access sheath insertion and

stone localization. In the mPNL operation, fluoroscopy is used for varying periods of time during the access, and fluoroscopy assistance is used for evaluation of stone-free status. When the studies in the literature were evaluated, it was observed that the operative and fluoroscopy times were longer in the mPNL operation [9, 10]. In a study conducted by Ergin et al. in 2018 with a high patient volume, both fluoroscopy time and operative time were found to be significantly higher for the mPNL group [10]. In our study, in accordance with the literature, f-URS seems to be more advantageous in terms of operative and fluoroscopy time.

For the treatment of kidney stones, both f-URS and mPNL operations are minimally invasive procedures and are safely performed with low complication rates. Postoperative complications have been compared in many studies using the Clavien-Dindo classification [11, 12]. In a study conducted by Wang et al. in 2021, no significant difference was found between f-URS and mPNL in terms of postoperative complications [13]. In another recent study, Coskun et al. reported higher complication rates in the mPNL group than in the f-URS group [14]. In a multicenter randomized controlled study published in 2018, complication rates of mPNL and f-URS were found to be similar [15]. According to our results, both operations can be performed safely with low and similar complication rates.

Kidney stone disease impairs the quality of life of patients physically, socially, and mentally. The SF-36 is an internationally accepted questionnaire used in the assessment of the quality of life. Bensalah et al. reported that physical functioning, emotional role, general health, and bodily pain parameters were found to be lower in patients with kidney stone disease compared to the normal population [16]. In a study conducted by Perez-Fentez et al., the SF-36 values of the patients before and after the mPNL operation were compared. It was observed that the physical function, physical limitation, pain, and social function values of the patients improved significantly after the procedure [17]. According to the results of our study, removal of kidney stones by surgery had positive effects on the quality of life of the patients. SF-36 parameters such as physical function, pain, limitation of physical role, and general health parameters improved significantly after the procedures in both f-URS and mPNL groups.

Although it is known that both types of operations improve the quality of life of the patients, it has not been debated in the literature until now which surgery shows a better improvement in the patients. In our study, the differences between the pre- and post-procedure SF-36 parameters of both groups were evaluated and compared between the groups. Although bodily pain decreased in both groups, this difference was higher in the mPNL group than in the f-URS group. Also, the mPNL group had better results in the physical function parameter, similar to pain parameter. In the f-URS group, irritation of the JJ stent and the spontaneous passage of the fragmented calculi can be responsible for these results.

There are some limitations of our study. The cost of the procedures has not been calculated. Pain assessment was not performed with the visual analog scale (VAS) score of the patients in the early post-procedure period. Stone analyses were not taken into consideration. We think that our results should be supported by studies to be conducted with higher patient numbers.

Conclusion

Both f-URS and mPNL operations are successfully applied in the surgical treatment of kidney stones between 1–2 cm. In case the UAS can not be inserted in the ureter in patients for whom f-URS is planned, placing a JJ stent and scheduling a second session f-URS provides the advantages of shorter hospital stays, operative time and fluoroscopy time. Planning mPNL in the same session provides better improvements in some SF-36 parameters such as bodily pain and physical functioning, compared to f-URS. The complication and success rates of the two approaches are similar. A shared decision-making process with the patient should be performed considering the existing advantages and disadvantages of different surgical techniques.

Declarations

Author contributions: UC and FA conceived the study. AE, BU, and FY designed the study protocol. UC and FA led the development of the manuscript. UC performed statistics. AA, FY, MB, FO, and OS performed data extraction and analysis. FO, BU, and FA reviewed the paper for critical intellectual content. All authors participated in manuscript writing, review, and approval of the final version of the manuscript for submission.

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