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ORIGINAL PAPER

Ultra-mini flexible percutaneous nephrolithotomy in the treatment of moderate-size kidney stones: a new instrument, a preliminary prospective study

Fatih Kursat Yilmazel[1] · Ahmet Emre Cinislioglu[1] · Ibrahim Karabulut[1] · Ali Haydar Yilmaz[2] · Fatih Ozkaya[3] · Senol Adanur[3]

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Abstract

Ultra-mini PNL is increasingly preferred in the treatment of kidney stones. Unlike routine applications of the ultra-mini PNL technique, we aimed to perform kidney stones treatment with an epiduroscopic device that can pass through 11–13-Fr ureteral access sheaths with a flexible structure and which is routine in neurosurgical practice. The study was planned prospectively. The study included 52 patients with mid-sized kidney stones who had presented to our clinic between July 2017 and January 2019. The ultra-mini percutaneous nephrolithotomy was carried out with epiduroscopy routinely used in neurosurgery practice, which can pass through 11–13-Fr ureteral access and has a flexible structure. The perioperative and postoperative parameters were analyzed. The mean operation time was 45.6 ± 4.8 min and entry was provided through a single entry (from the calyx appropriate to the lower pole) in all patients; a second entry tract was not required. No DJ catheter or nephrostomy tube was installed in any patient and the procedures were completed totally without a tube. The mean reduction in hemoglobin values was determined as 0.33 (0.1–1.1) g/dL. None of the patients needed transfusion and no patient developed acute kidney injury. Clinically significant (≥ 3 mm) residual stone was observed in 2 (4%) of the 52 patients, while clinically insignificant (≤ 3 mm) stones were observed in 50 patients (96%). The mean length of hospital stay was 2.5 ± 0.9 days. Ultra-mini flexible percutaneous nephrolithotomy is an effective and safe method in the treatment of medium-sized kidney stones.

Keywords Renal stones · Percutaneous nephrolithotomy · Ultra-mini flexible percutaneous nephrolithotomy

Introduction and objective

Percutaneous nephrolithotomy (PNL) was first described by Fernström and Johansson in 1976 in the treatment of kidney stones [1]. Compared to open surgery, PNL has become the preferred method in time due to its high success rate, short recovery and hospital stay, in addition to its cosmetic superiority [2, 3]. The high stone-free rates of PNL constitute its most important advantage compared to minimally invasive procedures such as retrograde intrarenal surgery (RIRS) and shock-wave lithotripsy (SWL). The most important drawback for this effective surgical procedure is the bleeding complication (11.2–17.5%), which is rather

✉ Ahmet Emre Cinislioglu
emrecinisli@hotmail.com

Fatih Kursat Yilmazel
kursatyilmazel@hotmail.com

Ibrahim Karabulut
karabulutibrahim36@gmail.com

Ali Haydar Yilmaz
alicerrahcom@yahoo.com

Fatih Ozkaya
drfatihm@gmail.com

Senol Adanur
s.adanur61@hotmail.com

[1] Department of Urology, University of Health Sciences Turkey, Erzurum Regional Training and Research Hospital, Erzurum, Turkey

[2] Department of Urology, Bilecik State Hospital, Bilecik, Turkey

[3] Department Of Urology, Ataturk University Medical Faculty, Erzurum, Turkey

frequently observed compared to other endourological procedures [4].

Bleeding is the most feared complication of the PNL method and there are opinions arguing that this technique should not be considered a minimally invasive procedure due to this complication. A great deal of research has been carried out on this technique to reduce the bleeding rate. It has been shown that reducing the diameter of the tract, choosing the balloon dilation method and using flexible devices for stones in hard-to-reach locations reduce the likelihood of bleeding [5, 6].

Ultra-mini PNL (UMPNL) is a PNL intervention with a reduced system size. The UMPNL system consists of a sheath with 11–13-Fr size and a 7.5-Fr rigid nephroscope specially designed for use through the sheath. It provides reduction of the surface area at an approximate ratio of 1/8 compared to the 28–30-Fr access sheath used in original PNL. This difference reduces the renal trauma and contributes to reduction of bleeding. However, although thin devices are used for stones in hard-to-reach localizations, complications such as tearing and bleeding in the parenchyma can be observed during manipulations with rigid tools [7]. Unfortunately, there are no flexible devices designed for the UMPNL technique to overcome this problem.

In this study, we aimed to perform the Ultra-Mini Flexible Percutaneous Nephrolithotomy (UMFPNL) procedure, which we defined in the literature for the first time, and investigate its effectiveness by making use of the flexible structure and other technical features of the epiduroscopy tool that has a wide area of use in the neurosurgery clinic.

Methods

The study was designed prospectively, and the Health Sciences University Erzurum Regional Training and Research Hospital Ethics Committee approval was obtained prior to the study. A total of 52 patients who had presented to our clinic between July 2017 and January 2019 were included in our study. Of the 52 patients included in the study, 20 (38%) were resistant to SWL, and 13 (25%) were patients in whom the Retrograde Intrarenal Surgery (RIRS) procedure had failed since the pelvicalyceal system anatomy was inappropriate. The patients included in the study were patients with 10–20 mm stone in a single renal unit. Patients under the age of 18, those with morbid obesity, serious cardiovascular or neurological diseases, urinary tract infection, those with increased serum creatinine levels, bleeding disorders, abnormal kidney anatomy (such as horseshoe kidney, duplex kidney, or bifid renal pelvis), and patients with urinary obstruction at any level in the ipsilateral kidney unit were excluded from the study.

Detailed anamnesis was obtained from all patients before the operation. Routine laboratory tests including urine culture, complete blood count, complete urinalysis, blood biochemistry and hemostatic parameters were performed preoperatively and patients with sterile urine culture were considered suitable for surgery. In line with the recommendation of the European Association of Urology (EAU) and the American Urological Association (AUA) guidelines, routine non-contrast computed tomography (NCCT) was performed in all patients prior to the procedure. In line with these recommendations, the patients were diagnosed and followed up with the NCCT as the monotype imaging method to avoid confusion in determining the stone size of the patients. The stone size was determined by measuring the longest axis in NCCT. Surgical success was considered as being completely stone free or the presence of clinically insignificant (≤ 3 mm) residual stone. Perioperative and postoperative complications, length of hospital stay, and the stone-free rates were recorded. Postoperative fever was defined as fever that developed within 24–48 h after surgery.

Surgical technique

The "VEELER (Seawon Meditech) Directional Neurolysis Video-Guided Catheter" device was used as the flexible nephroscope in UMFPNL. The joysticks on both sides of the video-guided catheter hand grip allow the device to do flexion and deflexion. Through the lock system in the middle of the device, the laser probe and the telescope can be fixed at the desired level. The UMFPNL device has an outer diameter of 9 Fr, which is constant throughout the entire device. The device has a length of 300 mm. The device has two working channels. The diameter of the working channels is 1.3 mm. These channels also allow the passage of irrigation fluid. A flexible telescope with 1.2-mm outer diameter, 85-cm length and 15,000-pixel image can be placed in one of these channels. The bending range of this flexible device (deflection + flection angles) is between 170 and 180° in total. Laser probes of different diameters ranging from 150 to 572 microns or stone extraction forceps (Dakota 1.9 Fr × 8 mm × 120 cm, Boston Scientific) can pass through the other working channel. The external view of the UMFP device, the view of its technical features and intra-operative views are shown in Fig. 1.

The basic steps in UMFPNL were the same as conventional PNL, and the entire procedure was performed under general anesthesia. In the lithotomy position, an open-ended 5-Fr ureter catheter was inserted into the kidney that was to be treated with the guidance of fluoroscopy. The patient was placed in the prone position and entry into the kidney was made with an 18-G TLA needle. Radiopaque material was injected from the open-ended ureter catheter during the process of entering the kidney. Entry was made to the selected

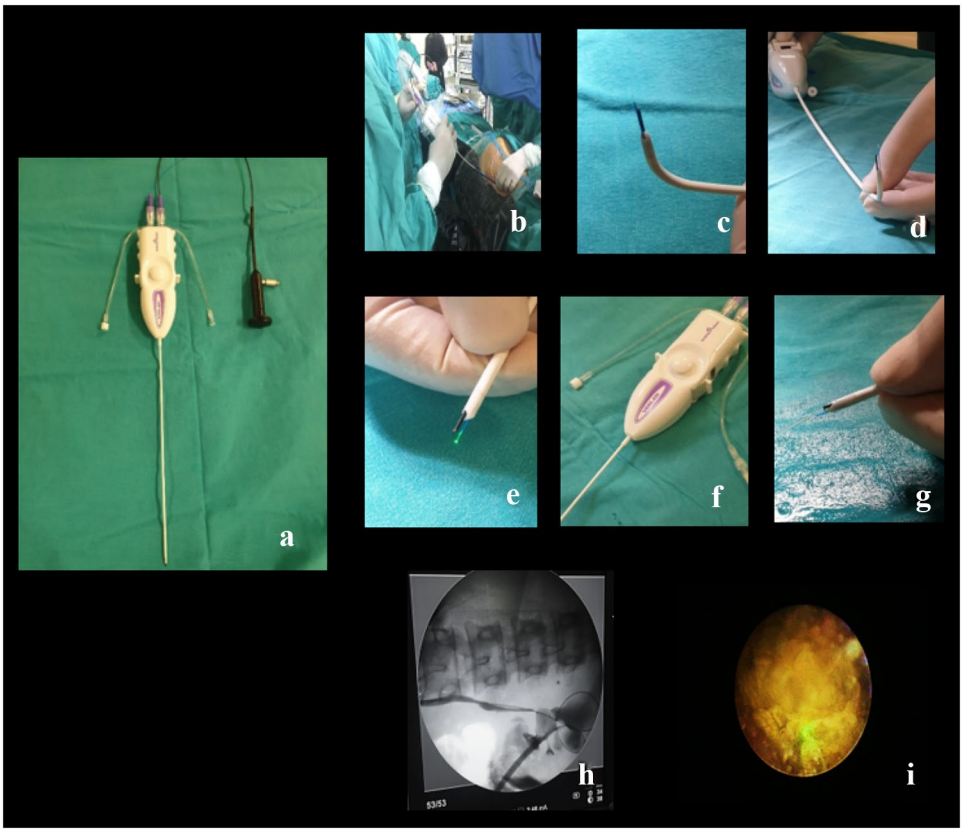


Fig. 1 External view of the UMFP device and intra-operative views. External view of the UMFP device (**a**), intra-operative view of the UMFP device (**b**), view of the UMFP device in flexion (**c**), external view of the UMFP device during flexion (**d**), view of the telescope and laser in the working channels of the UMFP device (**e**), view of the bilateral water irrigation channels of the UMFP device (**f**), the appearance of the UMFP device during water irrigation (**g**), intra-operative fluoroscopy view (**h**), endovision stone view of the UMFP device (**i**)

kidney calyx with the guidance of fluoroscopy. After entering the kidney, a 0.035-inch guidewire was inserted into the kidney through the needle. Dilation up to 10 Fr was performed over the guidewire with the guidance of fluoroscopy. Instead of the standard access sheath used in UMPNL, a modified 11–13-Fr ureteral access sheath was used. The inner part of the obturator was removed out and the outer sheath was used as an access.

Laser probes with a diameter of 272 microns were preferred to provide a better view in the fragmentation of the stones. In the breaking of the stones, the energy of the laser was adjusted to 0.8–1.2 J and its frequency was adjusted to 5–10 Hz depending on the suitability of the stone. Stones that had been broken up to the size that could pass through the access ($\leq$ 11 mm) were removed from the access with the help of stone forceps, and stones of smaller sizes were removed with passive drainage by creating a water jet effect. Stones that escaped to different poles during the process were tracked and fragmented with the aid of the flexible structure of UMFPNL. The procedure was terminated when no stones were observed in the calyces reached with UMFPNL under fluoroscopy. Among a total of 52 mini percutaneous nephrolithotomy cases, we needed to use 3 UMFP devices. No intra-operative nephrostomy tube or Double-J (DJ) catheter was installed in any patient. The transurethral Foley catheter and the ureteral catheter inserted during the operation were removed on the first postoperative day in all patients.

Statistical analysis

The statistical summary of the data was obtained based on the means and standard deviations. The distribution of normality was assessed with the D'Agostino–Pearson test. All statistical analyses were performed using the R statistical software package (R Studio, Vienna, Austria).

Results

Fifty-two patients were included in the study. The mean age of the patients was 44.8 ± 11.3 years. Of the 52 cases, stones were located in the inferior pole in 32 (61.6%), in the mid pole in 10 (19.2%), in the superior pole in 2 (3.8%) and in the renal pelvis in 8 patients (15.3%). The patient characteristics have been presented in Table 1.

The mean operation time was 45.6 ± 4.8 min and entry was provided through a single entry (from the calyx appropriate to the lower pole) in all patients; a second entry tract was not required. No DJ catheter or nephrostomy tube was installed in any patient and the procedures were completed

Table 1 Demographic data of patients

Characteristics	
Number of patients	52
Sex (male: female)	31/21
Mean age (year)	44.8 ± 11.3
Side stone (%)	
Right	31 (59.6)
Left	21 (40.3)
Mean BMI (kg/m^2)	25.1 ± 1.6
Mean Hounsfield Unit (HU)	867.8 ± 122.2
Mean stone size (mm^2)	15.3 ± 2.9
UMFPNL performed patients (%)	
Failed SWL	20 (38)
Failed RIRS	13 (25)
Stone locations (%)	
Inferior pole	32 (61.6)
Mid pole	10 (19.2)
Superior pole	2 (3.8)
Pelvis	8 (15.3)

UMFPNL ultra-mini flexible percutaneous nephrolithotomy

Table 2 Perioperative and postoperative results

Parameters	
Number of patients	52
Mean operation time (min)	45.6 ± 4.8
Mean hospital stays (day)	2.5 ± 0.9
Number of entries (%)	
Single entry	52 (100)
More than one	0 (0)
Double-J stent and/or nephrostomy (%)	
Totally tubeless	52 (100)
With tube	0 (0)
Complication rate* (%)	
Clavien I	2/52 (3)
Clavien IIIa	1/52 (2)
Clavien (II, IIIb. IV,V)	0 (0)
Postoperative complication (%)	
Fever	2 (3)
Hydronephrosis	1 (2)
Mean hemoglobin decrease (g/dL)	0.33 (0.1–1.1)
Stone-free rate (%)	50/52 (96)
Residual stone (≥ 3 mm) (%)	2 (3.8)

*According to the modified Clavien–Dindo classification

totally without a tube. The mean length of hospital stay was 2.5 ± 0.9 days.

The overall complication rate is 5.7%. Among these complications, 3.8% were identified as modified Clavien–Dindo classification grade I, 1.9% as modified Clavien–Dindo classification grade IIIA. While 2 (3%) of the 52 patients included in the study developed fever as an early postoperative complication, 1 (2%) patient developed hydronephrosis due to obstruction by the broken stone fragments in the ureter as a late complication. Patients who developed fever were discharged with oral medical treatment on the postoperative 3rd day after clinical recovery and normalization of laboratory parameters following the appropriate antibiotic treatment. A DJ catheter was placed in the patient who developed hydronephrosis and the catheter was removed 15 days later. The perioperative and postoperative results of the patients have been displayed in Table 2.

Complete blood count was performed on the first postoperative day in all patients. The mean reduction in hemoglobin values was determined as 0.33 (0.1–1.1) g/dL. None of the patients needed transfusion and no patients developed acute kidney injury. In the postoperative period, the pain in 12 of the 52 patients (23%) was controlled by IM or IV analgesics; while in 40 patients (76%), oral analgesics were sufficient for pain control. Evaluation of the stone-free rates of patients was made with NCCT performed at the postoperative 4th week, in line with the recommendation of EAU guidelines. A clinically significant (≥ 3 mm) residual stone was observed in 2 (4%) of the 52 patients; while, clinically insignificant (≤ 3 mm) stones were observed in 50 patients (96%).

Discussion

The PNL procedure, first described by Fernströmand Johansson, has become the standard treatment option for large kidney stones today [8]. In the current guidelines, SWL and RIRS are the recommended treatment methods for treatment of stones with a volume of less than 2 cm [9]. While factors affecting SWL's success include localization, size, number, density, stone–skin distance and renal anatomy of the stone [10], these factors in RIRS include size, number and localization of the stone [11].

In prospective randomized studies comparing SWL and RIRS with PNL, PNL has been shown to stand out with its higher stone-free rates despite its high morbidity rates. The high morbidity rates render necessary the continuous development and modification of the PNL procedure [12]. For this reason, the mini PNL (15–18 Fr) and the ultra-mini PNL (11–13 Fr), which use thinner access and optical systems, have been used to reduce PNL morbidity [13].

In Desai's study [14] investigating the effectiveness of UMPNL in kidney stones on 98 patients in 2017, stone-free status was reported in 83% of patients 4 weeks after surgery. In another study where Zhang et al. [15] compared UMPNL with RIRS and SWL in 2019, the stone-free rate was

determined as 98% in the UMPNL group, which included a total of 60 patients. In the systematic review on UMPNL that included a total of 7 studies and 262 patients, which was conducted in 2018 by Jones et al. [16], the stone-free rates were reported as 88.3% after UMPNL. In our study, a 96% stone-free rate was determined with NCTT performed at the 4th week after the operation. Compared to the results of Desai's study [14] and the systemic review of Jones et al. [16], the stone-free rate obtained in our study was found to be higher. In contrast, our stone-free rates were similar to the results of the study of Zhang et al. [15]. However, since no standardized method compatible with the literature was preferred in determining the stone-free rates in the study of Zahng et al. [15], we think that the results of our study are more significant compared to this study. We think that our high stone-free rates depend on the effectiveness of the flexible structure of the UMFPNL device in reaching the stones and the availability of active extraction of the fragmented stones, not only by passive drainage, but also by stone forceps, compared to UMPNL. In addition, we believe that the flexibility of the UMFPNL device contributes to our high stone-free rate.

The duration of operation is an important limiting factor for minimally invasive procedures [16]. The literature review showed that the duration of the operation in UMPNL was measured as 54 min, 68 min and 88 min in Desai's study [14] (2017), Zhang et al.'s study [15] (2019) and Jones et al.'s study [16] (2018), respectively. In our study, the duration of operation was measured as 45.6 ± 4.8 min. Compared to UMPNL, we think that shortening of the duration of operation depends on the ability to remove the stones without being broken into smaller pieces, to complete our process totally without a tube and the ability to break the stones faster with the laser probe up to 572 micron in diameter in appropriate stones.

With the introduction of percutaneous surgery, complications in open surgery have decreased significantly. However, it should always be taken into account that significant complications can occur even after minimally invasive procedures [17]. In a recent systemic review on treatment of kidney stones, it has been predicted that updated modifications in kidney stone treatment with PNL will reduce the complications and the patients' recovery durations [18]. Reviewing the literature, the complication rates were reported as 6.2% in UMPNL in the systemic review of Jones et al. [16], who had the most comprehensive series on this subject. In our study, this rate was determined as 5%. We think that this numerical difference and the less tissue damage were due to the flexible structure of the ureter access sheath we used instead of metallic access, and due to the flexible structure of the UMFPNL device. In this very first series, we did not encounter any major complications or bleeding requiring transfusion.

After UMPNL surgery, a nephrostomy tube is placed to tamp and drain the percutaneous tract. Recently, applications such as not using a drainage tube and placing a ureteral stent instead or ending the procedure totally without a tube are widely preferred [19]. In UMPNL, the stones are removed with passive drainage after fragmentation. Stones left in the kidney from these fragmented pieces can cause "stonestreet". To prevent this complication, a DJ catheter placement is required during the procedure [20]. Five studies on the placement of DJ catheter after UMPNL were reported in the systemic review of Jones et al. [16]. In these studies, the mean DJ catheter placement rate distribution was determined as 44.5% (0–100%). In a study carried out by Desai [14], the rate of post-case nephrostomy tube placement was determined as 13%. In our study, no DJ catheters were placed in any patient due to the efficient cleansing of patients' stones (extraction and passive drainage with forceps) during the procedure. At the same time, the flexible configuration and use of small-diameter UMFPNL in our study did not cause complications such as ureter occlusion, collecting system perforation and/or severe bleeding; therefore, our study was completed totally without a tube.

The rigid nephroscope or semi-rigid ureteroscope used during the PCNL procedure cannot access the renal calyxes that are at an acute angle with the entrance calyx, which may increase the needs of multiple punctures during the procedure or postoperative procedures such as SWL or RIRS. Multiple entry into the kidney to maneuver various parts of the pelvicalyceal system for fragments of broken stones during the treatment of kidney stones increases the potential risks of morbidity. In addition, postoperative procedures such as SWL or RIRS may cause more costs. Therefore, we believe that new techniques need to be developed to properly balance cost-effectiveness and reliability in PCNL procedures. In the market analysis, we performed, it was identified that the average cost of rigid ultra-mini PNL sets often preferred in our country is 15.000 € (Richard-Wolf ® and Karl Storz® sets). In our 52-case study, the cost per case is 291 € when rigid ultra-mini PNL is used. The cost of the UMFPNL device is 250 € and we used 3 devices throughout the study. In the series of 52 cases, the device cost was 750 € and we identified the cost per patient as 14 €. When these per patient costs are compared, we believe that the UMFPNL device is more cost effective.

The first results are promising in our 52-patient series with UMFPNL. The advantages of the procedure can be listed as being totally tubeless and having low complication and high stone-free rates. Thanks to the flexible structure of UMFPNL, there is no need for second or third entries required in UMPNL due to the stone escaping to other calyces of the kidney or to reach other stones in the upper–middle poles. We think that there is another advantage, namely enabling kidney stone analysis as a result of mechanical

extraction of the stones. We also think that it is an important advantage to minimize the insertion of DJ catheters to patients and, thus, prevent consequent hospital visits.

The limitations of our study can be listed as having no control group, including no kidney stones larger than 20 mm in diameter and having no long-term results. One of the disadvantages of the system is that, due to the low calibration of the two irrigation channels, even small amounts of bleeding can impair vision and pressure irrigation becomes necessary to obtain a better view. It does not seem possible to replace the standard PNL in large kidney stones and Staghorn stones. Despite these limitations, this study is the first report on the ultra-mini flexible PNL technique in the literature. Multicenter randomized prospective studies are needed to demonstrate the effectiveness of UMFPNL in the future.

Conclusion

In our study, the UMFPNL procedure was applied safely and effectively to kidney stones smaller than 20 mm. The high stone-free and low morbidity rates in the very first results obtained suggest that the UMFPNL method may be a promising alternative to RIRS, SWL and UMPNL in the treatment of low volume kidney stones. Comparative studies with conventional SWL, UMPNL and RIRS techniques are needed in the future.

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Compliance with ethical standards

Conflict of interest No potential conflict of interest was declared by the authors.

Ethical approval All procedures performed in the study involving human participants were in accordance with ethical standards. Health Sciences University Erzurum Regional Training and Research Hospital Ethics Committee approval was obtained prior to the study.

Informed consent Informed consent was obtained from all individual participants included in the study.

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