The Impact of Sheath Size in Miniaturized Percutaneous Nephrolithotomy in Adult Patients; A Matched-pair Analysis

Akif Erbin[1], Burak Ucpinar[1], Alkan Cubuk[1], Ozgur Yazici[1], Harun Uysal[2], Metin Savun[2], Seref Basal[1], Mehmet Fatih Akbulut[1]

[1]Department of Urology, Haseki Traning and Research Hospital, Istanbul, Turkey

[2]Department of Anesthesiology, Bezmialem Vakif University, Istanbul, Turkey

Keywords: Kidney stone; Miniaturized; Nephrolithiasis; Percutaneous Nephrolithotomy; Sheath sizes

Abstract

Purpose: The miniaturized percutaneous nephrolithotomy (mPNL) can be performed by using a very wide range of different access sheaths (14-22 Fr).It has been well known that tract size is one of the main parameters affecting the complication rates in PNL. We aimed to compare 21 Fr with 16.5 Fr mPNL tract sizes in adult patients.

Material and Methods: From May 2013 to April 2018, 604 patients with kidney stone underwent mPNL in our department. The study was designed as retrospective and match-pair analysis was the preferred method for the formation of groups. The 21 Fr mPNL cases were matched with 16.5 Fr mPNL cases at a 1:1 ratio, according to the patients' age, gender, body mass index, American Society of Anesthesiologists (ASA) score, stone characteristics (stone size, opacity and localization) and hydronephrosis. Patients with solitary kidney, renal anomalies, musculoskeletal abnormalities, and pediatric patients (< 18 years old) were excluded from the study. Both groups (21 Fr and 16.5 Fr) were compared in terms of demographics, stone characteristics, operative data and post-operative outcomes.

Results: A total of 260 patients were included in the study (130; 21 Fr mPNL group and 130; 16.5 Fr mPNL group). The operation time was significantly shorter in 21 Fr group (21 Fr; 85.2±37.5, 16.5 Fr; 101.7±37.7 minutes, p: 0.001). Complete stone clearance rates were 76.9% and 62.3% in 21 Fr and 16.5 Fr mPNL, respectively (p: 0.01). There was no significant difference between the groups in terms of overall operative and post-operative complications. However, in subgroups analysis, post-operative fever was higher in 16,5 Fr mPNL (4 patients in 16.5 Fr, no patients in 21 Fr group, p: 0.044); steinstrasse, renal colic and post-operative JJ stent requirement rates were higher in 21 Fr mPNL procedure (p: 0.018, p: 0.031 and p: 0.046, respectively). The hospitalization time was significantly higher in 21 Fr (p: 0.01).

Conclusions: Although 21 Fr mPNL procedure has advantages such as better success rates and shorter operation time, some post-operative complications (steinstrasse, renal colic, post-

operative JJ stent requirement) are against of 21 Fr mPNL when compared with 16.5 Fr mPNL procedure. Further randomized prospective studies with larger patient volume are needed to confirm these results.

Introduction

Main treatment modalities for urinary tract stones are extracorporeal shockwave lithotripsy (ESWL), ureterorenoscopy (URS), percutaneous nephrolithotomy (PNL) and open or laparoscopic surgery. With technological advancements, endourologic procedures (URS and PNL) have gained more popularity among other surgical treatments. Since its first description in 1976, percutaneous nephrolithotomy (PNL) has become the mainstay of treatment for large kidney stones(1). The European Association of Urology (EAU) guidelines on urolithiasis recommends PNL as the first treatment of choice for kidney stones larger than 2 cm(2). In standard PNL, renal access is obtained through 24-30 Fr access sheaths. Attempts to minimize the blood loss during PNL by reducing the sheath size and hence, decreasing the area of parenchymal and infundibular injury, gave rise to the concept of miniaturization. Although a clear definition does not exist in the literature, the miniaturized PNL (mPNL) is accepted as the use of 14-22 Fr access sheaths by EAU Urolithiasis Guidelines Panel(3). The mPNL technique was introduced by Jackman et al in 1998 (4). Recently, systems with even smaller diameters, such as ultra mini-PNL (11–13 Fr) and microperc (4.8–10 Fr), have been introduced as alternative techniques to reduce procedure-related morbidity(5,6). Smaller access sheaths were initially introduced for paediatric use, but are now widely utilised for the adult patients.

The mPNL can be performed by using a very wide range of different access sheaths (14-22 Fr). The primary goal of PNL is to achieve maximal stone clearance with minimal morbidity. It has been well known that tract size is one of the main parameters affecting the complication rates in PNL. However, reducing the tract size may adversely affect some procedure-related factors such as operation time[3]. There is no clear data on which tract size has more advantages in adult mPNL procedures. The aim of the study was to compare 21 Fr with 16.5 Fr mPNL tract sizesin adult patients, using 1:1 match pair analysis.

Material and Methods

Study design

The study protocol was approved by the Institutional Review Board at Haseki Training and Research Hospital. From May 2013 to April 2018, 604 patients with kidney stone which have underwent mPNL in our department were evaluated for inclusion. The study was designed as retrospective and match-pair analysis was the preferred method for the formation of groups. We used our stone database to identify the procedures which were applied through 21 and 16.5 Fr access sheaths. The 21 Fr mPNL cases were matched with 16.5 Fr mPNL cases at a 1:1 ratio, according to the patients' age, gender, body mass index (BMI), American Society of Anesthesiologists (ASA) score, stone characteristics (stone size, stone opacity, stone localization) and hydronephrosis (HN) [7,8]. Patients with solitary kidney, renal anomalies, musculoskeletal abnormalities, and pediatric patients (< 18 years old) were excluded from the study. Patients who had missing data during follow up period were also excluded. Both groups (21 Fr and 16.5 Fr) were compared in terms of demographics, stone characteristics, operative data and post-operative outcomes. Treatment success was defined as 'complete stone clearance' with no residual fragments. Operative and post-operative complications were evaluated according to the Satava and modified Clavien-Dindo classification system, respectively [9,10]. Satava classification system was introduced in order to define the possible operative complications. In the following years, it has been widely used for many endourological procedures.

Preoperative evaluation

Before surgery, all patients signed an informed consent form. Patient assessment included medical history, physical examination, complete blood count, coagulation tests, serum biochemistry, urinalysis and urine culture. Anticoagulant drugs were discontinued at least 7-10 days before the operation. All patients were evaluated preoperatively by intravenous urography and/or non-contrast abdominal computed tomography (CT). Stone size was determined by the measurement of the stones' longest diameter. In case of multiple calculi, the sum of the greatest diameter of each stone was calculated. All patients had sterile urine culture prior to surgery. Second generation cephalosporins were administered as antibiotic prophylaxis. The first dose was administered intravenously when anesthesia was initiated, and the second dose was given 12 hours later.

PNL technique

After the induction of general anesthesia, a 5 Fr ureteral catheter was placed to the ureter and fixed on the Foley catheter in the lithotomy position. The patient was then repositioned to the prone position. Percutaneous access was achieved under C arm fluoroscopy (Sire Mobil Compact, Siemens) guidance. The puncture was performed with an 18 gauge percutaneous access needle (Boston Scientific Corporation, Natick MA). After achieving access to the pelvicalyceal system (PCS), a 0.035 inch guidewire (Boston Scientific Corporation, Natick MA) was advanced through the needle into the PCS or ureter. The track was dilated sequentially using fascial dilators and the 16.5 or 21 Fr metallic sheaths (Karl Storz, Tutlingen, Germany) were advanced over their metal dilators under fluoroscopic guidance. A rigid 12 Fr nephroscope (Karl Storz, Tuttlingen, Germany) was advanced through the sheath. Stone disintegration was achieved using a Holmium YAG Laser lithotripter (Sphinx, Lisa laser, USA) and 550 μm laser fibers at an energy of 1.0–1.5 J and a rate of 8–10 Hz. Stone fragments were removed with tipless nitinol stone baskets(Boston Scientific, Natick, MA, USA).At the end of the procedure, retrograde pyelography was performed to assess the integrity of the pelvicalyceal system. If no sign of perforation was detected under fluoroscopy and if there was no sign of evident bleeding, procedures were terminated in a tubeless fashion and the incision at the access tract site was sutured (tubeless mPNL) with or without placing a JJ stent. Otherwise, a nephrostomy tube was left in place. All procedures were performed by two experienced urologistsat the tertiary referral center.

Post-operative evaluation

A complete blood count and renal function test according to the glomerular filtration rate measured by the Cockroft-Gault formulawere obtained from all patients within 6 hours after the operation. On first post-operative day, a plain x-ray of the kidneys, ureters and bladder was obtained. In cases with a nephrostomy tube, the tube was removed on first or second post-operative day after obtaining an antegrade nephrostography which was performed to prove the lack of obstruction in ipsilateral ureter. If leakage from the nephrostomy tract persists longer than 48 hours, this situation was defined as ‘prolonged urine leakage’ and a JJ stent was placed. All patients were evaluated with renal function tests and a non-contrast abdominal CT 1 month after the operation.

Statistical analysis

Data were analysed by using Statistical Package for the Social Sciences software package version 20 (SPSS Inc., Chicago, IL, USA). Quantitative data were expressed as mean ± standard deviation on tables and categorical data were expressed with frequency (n) and percentages (%). The distribution of the variables was measured by the Kolmogorov Smirnov test. Independent t test was used to compare independent groups. Pearson Correlation test was used to examine the relationship between variables. Pearson Chi-Square and Fisher Exact tests were used to compare the categorical data. The data were analysed at 95% confidence level and the threshold forstatistical significance was accepted as $P < 0.05$ for all analyses.

Results

A total of 260 patients were included in the study (130; 21 Fr mPNL group and 130; 16.5 Fr mPNL group). Patient demographics and stone characteristics were similar between groups and are demonstrated in Table-1.

Table-2 summarizes the operative data. Nephrostomy tube and JJ stent placement rates were significantly higher in 16.5 Fr. There was no significant difference between the groups in terms of intraoperative complications, which were classified according to the Satava classification system. Overall intraoperative complications occurred in 4 patients (3,1%) in 21 Fr and 2 patients (1.6%) in 16.5 Fr (p: 0.693). Grade 2a complication (pelvicalyceal system perforation proven by contrast media extravasation) observed in 3 patients in 21 Fr and 1 patient in 16.5 Fr. These patients were treated with prolonged ureteral stenting up to 4 weeks. Grade 2b complication (severely bleeding requiring termination of the procedure) observed only 1 patients in 16.5 Fr. This patient was treated with blood transfusion and supportive treatment.

Complications and post-operative outcomes are summarized in Table-3. When post-operative complications were compared according to the modified Clavien-Dindo classification, overall and subgroup complication rates were comparable between groups. Grade 4 or grade 5 complications were not observed in any patient. Fever was observed in 4 patients in 16.5 Fr during post-operative period, whereas, none of the patients in 21 Fr experienced fever (p: 0.044). Steinstrasse was encountered in 10 (7.7%) patients in 21 Fr and 2 (1.5%) patients in 16.5 Fr (p: 0.018). Renal colic during post-operative period was more common among 21 Fr, as well (p:0.031). Post-operative JJ stent placement was required in 19 patients (14.6%) in 21 Fr and 9 patients (6.9%) in 16.5 fr (p: 0.046). Both groups were similar in terms of hemoglobin drop, blood transfusion rates and bleeding which requires angioembolization.

The hospitalization time was significantly higher in 21 Fr (68.1±32.7 vs 51.3±31.6 hours, p: 0.01). Complete stone clearance was achieved in 100 patients (76.9%) in 21 Fr and 81 patients (62.3%) in 16.5 and the difference was statistically significant (p: 0.01).

Discussion

Different types and sizes of instruments are available for PNL procedure and selection between these different instruments are dependent on surgeons' preference. We compared two different sheath sizes, 21 Fr and 16.5 Fr, which were both classified under the name of mPNL and found out that21 Fr had higher operation success rates with decreased operation duration, whereas, 16.5 Fr had shorter fluoroscopy duration. In terms of complications; steinstrasse, renal colic and need for post-operative JJ stent placement was more common among 21 Fr, whereas, fever was more common among 16.5 Fr.

The duration of an operation is an important parameter especially in high-risk patients. Application of general anesthetic agents for a prolonged duration may have negative impacts on patients' overall health[(11)].Percutaneous nephrolithotomy procedure is performed under continuous irrigation. So, prolonged operation time may increase the intrapelvic pressure, especially in mPNL, and thereby increase the risk of pelvicalyceal rupture, septic and metabolic complications. Many studies have demonstrated the limitation of mPNL procedures as longer operation times when compared with conventional PNL procedure[(3)].Laser lithotripters are the commonly preferred method for stone fragmentation in mPNL cases and laser fragmentation of stones during mPNL is quite time consuming. In addition to laser lithotripters, miniaturized ultrasonic and pneumatic lithotripters, with or without aspiration mechanisms, can also be preferred for stone fragmentation. However, stone fragmentation and aspiration with these instruments during mPNL cases is not as fast as fragmentation with large-bore instruments during conventional PNL cases. Additionally, fragmentation of stones into very small pieces (dusting) is required, since bigger fragments can not be expelled out via smaller access sheaths. We emphasized that using a 21 Fr sheath instead of a 16.5 Fr sheath, allows bigger fragments to be expelled out and thereby, may shorten the operation time by decreasing the duration of laser fragmentation.

The fluoroscopy time was longer in 21 Fr mPNL. We use serial fascial and metallic dilators for tract dilatation. Fluoroscopy is most needed during tract dilatation. Traction dilatation occurs at more steps in 21 Fr operations and this causes prolonged fluoroscopy time.The majority of urologists utilize fluoroscopy to obtain renal tract access. But radiation exposure is the major drawback both for surgeon and patient. Ultrasound guidance access can be preferred to minimize radiation exposure(12).

Many studies have compared the effectiveness of mPNL and conventional PNL. A meta-analysis including 18 studies (2 randomized controlled trials, 6 non-randomized comparative studies, and 10 case series) have demonstrated the equal effectivity of mPNL and conventional PNL(3). In a recently published randomized prospective study, equal effectivity of mPNL and conventional PNL have been shown for the treatment of large kidney stones(9). Even though there are some studies which have compared mPNL with conventional PNL in the literature, there are no studies which have compared different sheath sizes of mPNL in adult patients. In our study, 21 Fr was significantly superior to 16.5 Fr in terms of complete stone clearance. We have emphasized that, effective retrieval of stone fragments from a larger access sheath was the reason of higher stone free rates.

A major advantage of mPNL over conventional PNL is its' less hemoglobin drop and less transfusion requirement[13]. Operating through smaller access sheaths decrease the injury on renal parenchyma and thereby, decrease the amount of bleeding during surgery. Even though our procedures were classified under mPNL, our sheath sizes were different between groups and bleeding was an important parameter in our study. However, no significant difference was detected between groups, in terms of hemoglobin drop, transfusion requirement and necessity of angioembolization. Besides bleeding, additional complications may be encountered during and after PNL surgeries. Operative complications can be listed as major bleeding and pelvicalyceal system perforation during surgery[14]. Performing the percutaneous access and dilation through an appropriate calyx at an appropriate angle lowers these complications, so, tract size can be considered as a determinant factor for these complications. But, in our study, we have detected no difference between 21 Fr and 16.5 Fr and concluded that they are both equally safe in terms of operative complications.

A wide range of post-operative complications can be encountered after PNL surgery. According to recent EAU guidelines, complications like fever can be encountered as frequent as 10.8% of all patients and other complications can be listed as bleeding, pelvi-calyceal perforations, prolonged urinary leakage, thoracic complications, sepsis, organ injury and death [2]. In our study, overall post-operative complications were similar between groups. However, there were significant differences when complications were evaluated individually. Fever was encountered in 3.1% of patients in 16.5 Fr. In contrast, none of the patients in 21 Fr group experienced fever. Nephrostomy and/or JJ stent placement rates were higher in 16.5 Fr group due to higher rates of residual calculi detected at the end of each operation.We have emphasized that, higher rates of instrumentation (nephrostomy or JJ stent) resulted in higher rates of fever during post-operative period. Additionally, decreased drainage of irrigation fluid and increased intrapelvic pressure in 16.5 Fr group might have resulted in this significant difference. In our study, we have detected significantly higher rates of steinstrasse, renal colic and necessity of post-operative JJ stent placement in 21 Fr group. Steinstrasse is one of the bothersome complications, which may result in renal colic episodes, prolonged urinary leakage and prolonged hospitalization times. We have emphasized that,higher rates of steinstrasse was due to the creation of bigger stone fragments in 21 Fr group and migration of these stone fragments into the ureter before effective clearance. If spontaneous passage of these fragments could not achieved, post-operative JJ stent placement was inevitable. This was the main reason of increased hospital stay in 21 Fr group.

Contrary to the fact that the present study is a matched pair study, it has some limitations, mainly related to its retrospective nature and non-randomization. The other important limitation of our study was the lack of our usage of flexible ureteroscope during surgery. Flexible instruments might haveincreased the final stone free status rates and decrease the need for a second-look procedure. Although the total number of patients was sufficient, the number of data was small in effectively comparing some parameters (eg. complications) and this can be listed as another limitation of our study.

Conclusion

The 21 Fr mPNL procedure has significantly higher successrates and shorter operation time when compared with 16.5 Fr mPNL. Although overall operative and post-operative complications were similar between groups,operative nephrostomy and JJ stent placement andpost-operative fever rates were higher in 16.5 Fr, whereas;steinstrasse, renal colic, post-operative JJ stent requirement rates and hospitalization time were higher in 21 Fr mPNL procedure. Although this is the first study which evaluates different sheath sizes of mPNL in adult patients, future prospective randomized studies are required to clarify which sheath size is more advantageous in mPNL.

Conflict of interest

The authors report no conflict of interest.

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Corresponding author:

Dr. Akif Erbin, (Urology specialist)

Department of Urology, Haseki Traning and Research Hospital, Istanbul, Turkey

Tel: +90 506 543 1062

Fax: +90 212 529 4400

E-mail: akiferbin@hotmail.com

Table-1: Demographic data and stone characteristics of patients included in the study

	21Fr mPNL (n:130)	16.5Fr mPNL (n:130)	p
Sex (female/male)*	40/90	48/82	.296
Age (years) *	46.6±12.9	45.6±12.4	.550
BMI (kg/m²)*	27.1±4.3	27.6±4.5	.379
ASA score*	2.0±1.0	1.8±1.1	.712
Previous ESWL / surgery			
ESWL	33 (25.4%)	26 (20.0%)	.302
PNL	31 (23.8%)	27 (20.8%)	.553
Open surgery	13 (10.0%)	12 (9.2%)	.834
Stone opacity (opaque / non-opaque)*	120/10	116/14	.393
Stone localization *			.938
Isolated lower calyx	27	27	
Isolated middle calyx	6	6	
Isolated upper calyx	7	7	
Isolated pelvis	30	30	
Multiple calyx	57	59	
Partial staghorn	3	1	
Stone size (mm) *	26.0±8.6	26.3±8.6	.323
Hydronephrosis (mild/severe) *	91/39	95/35	.584
Operation side (right / left)	71/59	63/67	.323

***** 1:1 matching parameters

Abbreviations:

BMI; Body Mass Index

ASA; American Society of Anesthesiologists

ESWL; Extracorporeal Shockwave Lithotripsy

Table-2: Operative details of patients included in the study

	21 Fr mPNL (n:130)	16.5 Fr mPNL (n:130)	p
Operation time (min)	85.2±37.5	101.7±37.7	**.001**
Fluoroscopy time (min)	5.0±3.5	3.5±3.1	**.001**
Access			.225
Solitary			
Lower pole	109 (83.8%)	104 (80.0%)	
Middle pole	11 (8.5%)	7 (5.4%)	
Upper pole	4 (3.1%)	11 (8.5%)	
Multiple access	6 (4.6%)	8 (6.2%)	
Intercostal access	7 (5.4%)	14 (10.8%)	.112
Nephrostomy placement	89 (68.5%)	114 (87.7%)	**.001**
JJ stent placement	21 (16.2%)	44 (33.8%)	**.001**
Intraoperative complication			.693
No complication	126 (96.9%)	128 (98.5%)	
Satava grade 1	1 (0.8%)	0	
Satava grade 2a	3 (2.3%)	1 (0.8%)	
Satava grade 2b	0	1 (0.8%)	

Table-3: Comparison of post-operative outcomes of 21 fr mPNL and 16.5 fr mPNL groups

	21 fr mPNL	**16.5 fr mPNL**	**p**
Overall complications, n (%)	28 (21.5%)	23 (17.7%)	0.437
Complications, n (%)			
Fever (>38 °C)	0	4 (3.1%)	**.044**
Renal colic	9 (6.9%)	2 (1.5%)	**.031**
Steinstraisse	10 (7.7%)	2 (1.5%)	**.018**
Urine leakage	11 (8.5%)	6 (4.6%)	.211
Post-operative DJ placement	19 (14.6%)	9 (6.9%)	**.046**
Pleural effusion	1 (0.8%)	2 (1.5%)	.563
Hemoglobin drop (gr/dl)	1.9±3.4	1.1±3.0	.051
Blood transfusion	3 (2.3%)	3 (2.3%)	.000
Embolization	0	1 (0.8%)	.318
Modified Clavien-Dindo classification			.238
Grade 0	103 (79.2%)	107 (82.3%)	.531
Grade 1	5 (3.8%)	8 (6.2%)	.395
Grade 2	3 (2.3%)	2 (1.5%)	.653
Grade 3a	0	2 (1.5%)	.157
Grade 3b	19 (14.6%)	11 (8.5%)	.120
Hospitalization time (hours)	68.1±32.7	51.3±31.6	**.001**
Complete stone clearance, n (%)	100 (76.9%)	81 (62.3%)	**.010**