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Comparison of Flexible and Rigid Cystoscopy-Assisted Ureteral Catheter Insertion Before Percutaneous Nephrolithotomy: A Prospective Randomized Trial

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Abstract

Background and Purpose: To compare the advantages of flexible and rigid cystoscopy-assisted ureteral catheter placement before prone percutaneous nephrolithotomy (PCNL).

Patients and Methods: From March to September 2012, a total of 80 patients with kidney stones underwent PCNL by the same surgical team. The patients were randomly assigned into one of the groups according to the technique used for ureteral catheter insertion: Flexible cystoscopy (group 1, n = 40) or rigid cystoscopy (group 2, n = 40). Patient demographics and operation-related factors were compared. The preparation period included positioning, cystoscopy-assisted stent insertion, and patient repositioning for PCNL. In addition, discomfort scores of the operating room (OR) staff were measured.

Results: The demographic values of the groups in terms of patient sex, age, body mass index, and stone size were comparable. While the mean preparation period was calculated as 9.9 ± 2.3 minutes in the flexible cystoscopy group, it was significantly longer (19.7 ± 2.9 minutes) in the rigid cystoscopy group ($P < 0.0001$). In addition, the discomfort score of the OR staff was found to be significantly higher in the rigid cystoscopy group (1.1 ± 0.9 *vs* 2.05 ± 0.68, $P < 0.0001$). The rest of the operative and postoperative parameters were similar.

Conclusions: The insertion of a ureteral catheter with a flexible cystoscope before prone PCNL shortens the preparation period and minimizes the discomfort of OR staff related to patient positioning and transfer.

Introduction

Achieving an appropriate percutaneous renal access is the initial and an important phase before performing percutaneous nephrolithotomy (PCNL). For this purpose, the collecting system is generally visualized and distended with injection of contrast medium through the ureteral catheter under fluoroscopy. At this stage, the ureteral catheter plays an important role for several reasons. It allows the visualization of the collecting system, retrograde insertion of a guidewire, and drainage of the kidney, and prevents the down migration of large stone fragments into the ureter.

The ureteral catheter could be inserted with a rigid or flexible cystoscope with the patient in the supine or lithotomy position according to the instrument used after the intubation of the patient.[1,2] Flexible cystoscopy is accepted as an office-based and frequently performed procedure.[3] Studies have reported that flexible cystoscopy is associated with less pain and discomfort and without need for operating room table and patient positioning.[3–5] Its routine use for ureteral stent placement before PCNL, however, is restricted because of limited experience and availability of the instrument especially in developing countries. Although the advantages of flexible cystoscopy have been the subject of many studies,[6,7] the effect of flexible cystoscope use for ureteral stent placement before PCNL has not been explored.

In this study, we aimed to compare the advantages of flexible and rigid cystoscopy during insertion of the ureteral stent before PCNL.

Patients and Methods

From March 2012 to September 2012, a total of 80 patients with kidney stones underwent PCNL by the same surgical team. The patients were randomly assigned into one of two groups according to the technique used for ureteral catheter insertion: Flexible cystoscopy (group 1, n = 40) or rigid cystoscopy (group 2, n = 40). Randomization was performed using computer-based simple random tables in a 1:1 ratio. The study was approved by the local ethics committee, and all

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Table 1. Demographic Values of the Patients

	Overall	*Group 1 (flexible)*	*Group 2 (rigid)*	P
N	80	40	40	
Male/female	52/28	26/16	28/12	0.58
Mean age (years)	49.3 ± 11.4 (25–77)	49.3 ± 13.4 (25–77)	49.4 ± 8.81	0.99
Mean BMI (kg/m^2)	28.9 ± 4.4 (19.4–40)	28.9 ± 4.5 (20.8–40)	29 ± 4.4 (19.4–38.6)	0.91
Stone size (mm)	24.5 ± 11.5 (10–60)	26.6 ± 12.1 (10–60)	22.5 ± 10.7 (10–60)	0.1

BMI = body mass index.

patients signed the written informed consent. Patient demographics (age, sex, body mass index [BMI], and stone size), preparation period (ureteral stent insertion and patient positioning), and operation-related factors (duration of PCNL procedure, success and complication rate, hemoglobin drop), and the discomfort of the operating room (OR) staff related to patient transfer and positioning were compared.

Patients in whom the ureteral stent could not be advanced or additional transurethral or ureteroscopic procedures were needed and patients younger than 18 years old were excluded from the study. In addition, patients with any other urethral or bladder pathologies were excluded. The presence of any orthopedic abnormality leading to difficulty in positioning of the patient was also another criteria for exclusion.

The routine preoperative laboratory tests, including complete blood cell count, serum creatinine level, coagulation profile, and urine culture, were obtained from all patients. Radiologic assessment was performed with plain radiography, renal ultrasonography, and intravenous urography and/or CT in all cases. Stone size was measured by radiologic techniques.

Preparation period

Ureteral catheter insertion was performed by the same senior urologist (AT) in all patients enrolled in the study. In group 1, a 70 cm and 5F ureteral catheter (Geotec Medical, Ankara, Turkey) was inserted under direct vision through the 15.5F flexible cystoscope (Karl Storz, Tuttlingen, Germany) with the patgient in the supine position on the operating table under general anesthesia as described previously.[6] The procedure was performed in frog-leg position in female patients. Fluoroscopy was not used as an imaging modality during the catheter insertion in all cases. The ureteral catheter was gently inserted through the ureteral orifice. An additional 5F pusher catheter (Geotek Medical, Ankara, Turkey) helped to insert the ureteral catheter up to the kidney. The insertion was terminated when difficulty was felt. The drainage of urine through the ureteral catheter confirmed the proper localization of the ureteral catheter. The urethral catheter was attached to the urethral Foley catheter. Then the patient was placed in the prone position by the OR staff on the operating table for PCNL.

In group 2, the ureteral catheter was inserted under direct vision through the 19F rigid (Karl Storz, Tuttlingen, Germany) cystoscope with the patient in the lithotomy position on the operating table under general anesthesia. After the attachment of the ureteral catheter to the Foley catheter, the patient was placed in the prone position.

The duration of the preparation period included three phases: (1) Patient positioning for cystoscopy, (2) cystoscopy-assisted stent insertion, and (3) patient repositioning for PCNL. Overall discomfort of the OR staff was also evaluated using a modified validated questionnaire[8] (0: no, 1: little, 5: severe) at the end of the preparation period in both groups.

Operative technique

A standardized PCNL was performed as described previously.[9] The localization of the ureteral catheter was controlled by fluoroscopic imaging. If it was pushed up the upper calix, it was pulled down to the pelvis. After distention and opacification of the collecting system with the contrast medium injection through the ureteral catheter, percutaneous renal access was performed by the same senior urologist (AT) under C-arm fluoroscopy. The tract was dilated with Amplatz renal dilators up to 30F and an Amplatz sheath was placed. Stone disintegration was accomplished through the 24F nephroscope using the pneumatic lithotripters, and fragments were retrieved using the graspers. At the end of the procedure, a 14F nephrostomy tube was inserted in the majority of the patients after endoscopic and fluoroscopic visualization of stone-free status. The duration of the operation was measured as the period between starting the access creation and nephrostomy tube placement. The preparation period, including ureteral catheter insertion and patient positioning, was excluded from the operation time.

Follow-up

The patients were assessed with plain radiography on postoperative day 1. Unless complications demanded prolonged drainage, the nephrostomy tube was removed on postoperative day 2. The modified Clavien classification system was used to grade the postoperative complications.[10] All of the patients were evaluated with CT at the first month postoperatively.

Statistical analysis

The values are presented as the mean ± standard deviation. Data were analyzed using SPSS-16 for Windows (SPSS, Inc, Chicago, IL). A required sample size of 32 was based on a proposed clinically significant difference of 2 minutes between two groups, with a beta error level of 80% and an alpha error of 5%. To increase the power of the study, however, a total of 40 patients were enrolled in each group. A normality test (Kolmogorov-Smirnov test, $P > 0.05$) was performed to evaluate distributions of numeric variables. Because the distribution of numeric variables was normal, statistical analysis was performed using the parametric Student *t* test. The Mann-Whitney *U* test, however, was used to evaluate numeric variables with a skewed distribution such as hemoglobin

Table 2. Comparison of the Results Related to the Preparation Period of Percutaneous Nephrolithotomy

	Overall	*Group 1*	*Group 2*	P
Duration (minutes)	14.8 ± 5.6 (7–26.5)	9.92 ± 2.3 (7–16)	19.7 ± 2.9 (14–26.5)	< 0.0001
Discomfort score (0–5)	1.6 ± 0.9 (0–4)	1.1 ± 0.9 (0–3)	2.05 ± 0.68 (1–4)	< 0.0001

0 = no discomfort/pain; 1 = little discomfort/pain; 5 = severe discomfort/pain.

drop and hospitalization time. Proportions of categorical variables were analyzed using the chi-square or Fisher exact test because the minimum expended count was less than 5; comparisons of categoric variables rate were performed by Fisher exact test.

Results

The demographic values of the groups in terms of patient sex, age, BMI and stone size were similar (Table 1). No patient with abnormal habitus was observed in either group. The ureteral stent insertion using either a flexible or rigid cystoscope was performed successfully in both groups.

While the mean preparation period was calculated as 9.9 ± 2.3 (range 7–16) minutes in the flexible cystoscopy group, it was significantly longer (19.7 ± 2.9 min) in the rigid cystoscopy group. During this period, the discomfort score of the OR staff was found to be significantly higher in the rigid cystoscopy group (1.1 ± 0.9 *vs* 2.05 ± 0.68) (Table 2).

The operative parameters, including duration of operation and hospitalization time, access number, success and complication rate, and postoperative hemoglobin drop were comparable between the groups. The mean fluoroscopy time, however, was found to be longer in group 1 (Table 3). Prolonged urinary leakage from the tract (n = 1) (Clavien grade III complication) and bleeding necessitating blood transfusion (n = 1) (Clavien grade II complication) were observed as complications.

Discussion

The treatment of patients with renal calculi has shifted from open surgery to the endoscopic methods since the last three decades. Today, PCNL is accepted as the gold standard for large renal calculi.[11–14] Although PCNL has been traditionally performed in patients in the prone position, the other positions have been popularized in recent years.[11–14] Despite drawbacks such as need for patient repositioning after stent insertion, inability to perform simultaneous retrograde intrarenal surgery and cystoscopy, anesthesiologic concerns, and longer operatiin time, the prone position is the generally accepted position for PCNL among urologists.[12–14] The superiority of the supine PCNL to prone PCNL mainly originates from the lack of patient repositioning and allowing combined ureteroscopic procedures simultaneously. In the present study, PCNL was performed with patients in the prone position. We suggest minimizing the duration of the pre-PCNL phase and workload of OR staff, however, by using the flexible cystoscope and compare it with the rigid cystoscope.

Since the introduction of endoscopes in urology, the cystoscope has been the most commonly used instrument by the urologist to evaluate patients with hematuria, recurrent urinary tract infection, lower urinary tract symptoms, and bladder cancer.[3,7] In addition, the cystoscope allows the catheterization of the upper urinary tract and removal of ureteral stents.[3–7,15] The use of the flexible cystoscope for the evaluation of the bladder neck was first reported by Tsuchida and associates[16] in 1973. At present, with the widespread availability of flexible instruments, cystoscopy has been an office-based urologic procedure. The insertion of the ureteral catheter by using the flexible cystoscope was described previously. Because of the limited experience and availability of the instrument, however, ureteral catheter insertion is still not routinely performed with flexible cystoscopy, especially in developing countries. In this study, all procedures were performed by the same senior urologist experienced in usage of flexible instruments.

The main advantage of flexible cystoscopy is its feasibility with the patient in the supine position. This advantage becomes more apparent in patients with contractures of the lower extremities preventing positioning of the patient in the lithotomy position. In the present study, the patients with such conditions were excluded.

On the other hand, the lithotomy positioning of a patient for rigid cystoscopy carries some risks for patient and operating team.[17–19] Patient lifting and positioning for cystoscopy and PCNL necessitate manpower. The lifting and transfer of obese and especially morbidly obese patients are challenging problems for the OR staff.[20] Researchers have shown that healthcare workers are significantly at risk for occupational injuries related to patient lifting and transfer.[17,18] In the United States, nurses are exposed to back pain related to

Table 3. Comparison of Operative and Postoperative Outcomes

	Overall	*Group 1*	*Group 2*	P
Duration of operation (minutes)	64.7 ± 35.3 (20–210)	64.3 ± 28.5 (30–120)	65.15 ± 37.8 (20–210)	0.79
Fluoroscopy time (minutes)	2.5 ± 2.1 (0.5–12)	3.07 ± 2.25 (1–12)	2.05 ± 1.76 (0.5–8)	0.002
Access number	1.1 ± 0.3 (1–2)	1.15 ± 0.4 (1–2)	1.05 ± 0.2 (1–2)	0.14
Hemoglobin drop (g/dL)	1.18 ± 0.9 (0–3.5)	1.25 ± 0.74 (0–3)	1.14 ± 0.93 (0.1–3.5)	0.42
Hospitalization time (days)	2.03 ± 0.9 (1–7)	2.05 ± 0.93 (1–7)	2 ± 0.91 (1–7)	0.66
Success rate	68/80 (85%)	33/40 (82.5%)	35/40 (87.5%)	0.76
Complication rate	2/80 (2.5%)	1/40 (2.5%)	1/40 (2.5%)	1

patient transfer and positioning with an annual prevalence of 40% to 50% and lifetime prevalence of 35% to 80 %. In addition, the occupational back pain in nurses leads annually to a loss of an estimated $10 billion dollars.[17,18]

Edlich and colleagues[18] advised the use of mechanical patient lifting systems to prevent the musculoskeletal injury and provide patient safety. In a recently published study, the authors defined a new bariatric lift system used for positioning for endoscopic management of a 311-kg morbidly obese man with bladder carcinoma.[20] In another study to decrease the workload and manpower during PCNL, the awake endotracheal intubation technique and patient self-positioning for PCNL was described by Wu and coworkers.[21] In our routine practice, all procedures were performed with patients under general anesthesia, and we do not use mechanical devices for patient positioning.

Although there are studies evaluating the discomfort of the urologist during laparoscopic or endoscopic surgery,[8,22] this is the first study to investigate the discomfort of OR staff related to patient positioning and lifting. All procedures were performed by the same OR staff and senior urologist in the present study. The discomfort score was significantly higher in the rigid cystoscopy group related to patient positioning ($P < 0.0001$). During this period, however, occupational back injury was not observed in members of the OR staff.

In the studies exploring the factors affecting the operative time of PCNL, the preparation period before PCNL was overlooked.[23,24] The stone type and size, hydronephrosis are factors found to affect the operative time.[23,24] In the present study, the duration of the preparation phase of the procedure, including the patient positioning, cystoscopy, ureteral stent placement, and repositioning for prone PCNL, was more prolonged with the use of a rigid cystoscope rather than the flexible one (9.92 ± 2.3 minutes *vs* 19.7 ± 2.9 minutes, $P < 0.0001$). The prolonged preparation period leads to longer anesthesia and a higher dose of anesthetic agents.

In the present study, the operative and postoperative outcomes, such as operation and hospitalization time, success and complication rates, and hemoglobin drop, were comparable regardless of the stent insertion technique. The prolonged fluoroscopy time might be associated with the higher number of renal access in group 1.[25]

There are some limitations to the study. Although it is well known that the rigid cystoscope is cheaper and more durable than the flexible one, the cost efficiency was not compared in the present study. In addition, the pain related to cystoscopy was not compared because all procedures were performed under general anesthesia. Evaluating the cystoscopy-related pain solely was difficult because other factors (nephrostomy tube, urethral and ureteral stent) could affect the postoperative pain. The effect of the rigid and flexible cystoscope on urethral tissue was not evaluated. It is clear, however, that thinner and flexible instruments are more atraumatic than the larger sized and rigid instruments.

Conclusion

The results of our prospective randomized study demonstrate that the insertion of a ureteral catheter with a flexible cystoscope significantly shortens the preparation period of PCNL. In addition, it minimizes the discomfort of the OR staff related to patient transfer and positioning. These advantages might become more apparent especially in centers where volumes of PCNL are performed.

Disclosure Statement

No competing financial interests exist.

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Abbreviations Used

BMI = body mass index
CT = computed tomography
OR = operating room
PCNL = percutaneous nephrolithotomy