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Characteristics of Patients Requiring Double-J Placement Because of Urine Leakage After Percutaneous Nephrolithotomy*

Murat Binbay, M.D.,[1] Erhan Sari, M.D.,[1] Abdulkadir Tepeler, M.D.,[1] Akif Erbin, M.D.,[1] Ozturk Savas, M.D.,[2] Ahmet Yaser Muslumanoglu, M.D.,[1] and Ahmet Tefekli, M.D.[1]

Abstract

Objectives: Prolonged urine leakage (PUL) from the percutaneous tract after percutaneous nephrolithotomy is a major complication that necessitates the placement of a urethral Double-J stent. We analyzed the characteristics of patients who had this complication to find out its risk factors.

Patients and Methods: During a 6-year period, 1407 standard percutaneous nephrolithotomy procedures were performed at our institution. Medical charts were reviewed focusing on the patients who required Double-J placement because of PUL from the percutaneous tract for more than 24 hours after removal of the nephrostomy tube. A total of 81 patients in whom a Double-J stent was placed because of ureteropelvic injury or pelvicaliceal extravasation or as a part of percutaneous endopyelotomy were excluded from the study. Factors that are considered to have an impact on this untoward event were analyzed and compared.

Results: Double-J stent was placed in a total of 57 (4.3%) patients who were found to have PUL. Stone size was significantly larger in the stented group ($10.0 \pm 5.6\,cm^2$ vs. $7.8 \pm 5.3\,cm^2$). The stones were classified as complex in 68.4% of patients in the stented group and in 53.4% of patients in the nonstented group, and this difference was also statistically significant. Stone-free rate was significantly higher in the nonstented group ($p < 0.05$). Residual stone and additional treatment rates were statistically higher in the stented group ($p < 0.05$). Access number and location as well as per-operative bleeding were not predictive factors for PUL development.

Conclusion: The necessity for Double-J placement due to PUL from the percutaneous tract, diminishes with increase in stone-free rates. Stone size and stone complexity are other predictive factors for PUL development.

Introduction

The surgical management of urinary stone disease has undergone marked changes with the implementation of technological innovations in the field of urologic surgery over the past 3 decades. Currently, percutaneous nephrolithotomy (PNL) is accepted as a first-line treatment for renal stones larger than 2 cm, with high success rates exceeding 90%.[1] However, complications after or during PNL may occur, with an overall complication rate of up to 83%, including urinary extravasation (7.2%), bleeding necessitating transfusion (10.9–17.5%), and postoperative fever (4–32.1%), whereas major complications such as septicemia (0.3–4.7%), colonic (0.1–0.8%), or pleural injury (0.3–3.1%) are rare.[2–4]

Conventionally, a nephrostomy tube is usually placed for about 1 to 2 days following the termination of PNL to provide external drainage of urine, hemostasis, and healing of the nephrostomy tube puncture site.[5] However, sometimes, urine leakage from the percutaneous tract persists after removal of the nephrostomy tube. Although this is a bothersome situation for both the physician and the patient, urine leakage resolves markedly after placement of a urethral Double-J stent.

Herein, we analyzed the characteristics of our patients who experienced this untoward event, investigated retrospectively how we can solve this problem, and tried to find out the risk factors that predict this complication.

Materials and Methods

Between October 2002 and August 2008, 1407 standard PNL procedures were performed at our institution. Medical charts, which were entered and maintained prospectively in our PNL Registry, were retrospectively reviewed focusing on patients who were in need of Double-J placement because of

Departments of [1]Urology and [2]Nephrology, Haseki Teaching and Research Hospital, Istanbul, Turkey.
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prolonged urine leakage (PUL) from the percutaneous tract for more than 24 hours after removal of the nephrostomy tube following PNL. A total of 81 patients, in whom tubeless PNL was performed and Double-J stent was placed because of ureteropelvic injury or pelvicaliceal extravasation or as a part of percutaneous endopyelotomy, were excluded from the study. The factors that were suspected to have an effect on Double-J stent requirement because of urine leakage after PNL were evaluated.

Preoperative complete blood count, serum creatinine, platelet count, bleeding and coagulation profile, and urine cultures were obtained from all patients. The use of anticoagulant drugs was stopped at least 1 week before the operation. Radiological evaluation, intravenous urography, and urinary-tract ultrasonography, as well as noncontrast computed tomography (CT) were performed in selected cases. The stone burden rate was determined by radiographic studies, and the stones were basically classified as simple (isolated renal pelvis or isolated caliceal stones) or complex (partial or complete staghorn stones, renal pelvis stones accompanying caliceal stones, multiple caliceal stones), regardless of their size.

Each patient underwent PNL, beginning with cystoscopy and insertion of a ureteral catheter, as previously described elsewhere.[6] Briefly, patients were placed prone and percutaneous access was obtained by the attending urologist at a single setting using C-armed fluoroscopy. After proper caliceal puncture, the tract was dilated with a high-pressure balloon dilatator (Nephromax; Boston Scientific, Boston, MA), and a 30F Amplatz sheath was placed. Nephroscopy was performed with a rigid, 26F nephroscope. Additional tracts were created, when indicated, in the same session. The stones were fragmented using either pneumatic lithotripter (Vibrolith®, Elmed®, Ankara, Turkey) or ultrasonic lithotripter (Lithoclast®, EMS®, Nyon, Switzerland). Stone clearance and the integrity of the collecting system were confirmed intraoperatively by fluoroscopy and antegrade nephrostotography. A 14F nephrostomy tube was placed into the renal pelvis or the involved calix as the final step in the treatment of cases.

Antibiotic prophylaxis was maintained by administration of quinolones. The first dose (500 mg ciprofloxacin) was administered intravenously when anesthesia was initiated, and the second dose was given 12 hours later. The patients were then given oral ciprofloxacin until their nephrostomy tubes were removed, unless their postoperative urine culture revealed significant colony-forming units of uropathogens, in which case the treatment was given accordingly. A fever of $\geq 38^\circ$C was considered significant.[7]

On postoperative day 1, the Foley and ureteral catheters were removed if the urine was not hematuric. A plain film of the kidneys, ureters, and bladder was obtained. The nephrostomy tube was removed on postoperative day 2 after antegrade nephrostography showing ureteral drainage down to the bladder. Repeat-PNL, ureteroscopy (URS), and extracorporeal shockwave lithotripsy (SWL) were considered as auxiliary treatment alternatives when indicated.

The patients in whom urine leakage persisted for more than 24 hours after nephrostomy tube removal were initially evaluated with helical CT scan to determine residual stones which may cause obstruction in the ipsilateral pelvicaliceal system; therefore, a 4.8F Double-J catheter was considered and additional treatments, including SWL or URS, were performed when indicated.

Serum creatinine levels and blood counts were obtained in all patients postoperatively. All patients were evaluated with intravenous urography or helical CT scan (if the stone was radiolucent) on the 3rd month after the operation. The PNL procedure was considered successful if the patient was either free of stones or had any clinically insignificant residual fragments (CIRFs), defined as <4 mm, nonobstructive, noninfectious, and asymptomatic residual fragments.[6]

The patients requiring Double-J placement because of PUL for more than 24 hours after nephrostomy tube removal following PNL (group 1) were compared with patients who had no urine leakage after nephrostomy tube removal (group 2). The preoperative and per-operative findings of the patients were evaluated in terms of body mass index (BMI), mean age, mean operation time, mean stone size, blood transfusion rates, mean access number, access location, stone-free rate, CIRF rate, and auxiliary treatment rates. The data were entered into an Excel™ (Microsoft, Redmond, WA) database and analyzed with an SPSS™ version 16.0 (SPSS, Chicago, IL) statistical software package using the χ^2, Student's t, and Fisher's exact tests. Odd ratios were calculated, and statistical determinations were within the 95% confidence interval. All p-values were two tailed, and $p < 0.05$ was considered statistically significant.

Results

The mean patient age was 43.1 ± 14.6 years (range: 7–83). The mean BMI was $26.3 \pm 4.7\,\text{kg/m}^2$ (range: 15.2–46.9). Three hundred and eight patients (23.2%) had a history of open surgery. The mean stone size was $7.9 \pm 5.3\,\text{cm}^2$ (range: 1–35). The stones were classified as simple in 609 patients (45.9%) and as complex in 717 patients (54.1%). The mean access number was 1.2 ± 0.5 (range: 1–6). Multiple accesses were required in 175 patients (13.2%). At the 3rd month follow-up, an overall success rate of 89.4%, including CIRFs in 15.3%, was achieved. Auxiliary treatment alternatives, including SWL in 74, repeat PNL in 48, and URS in 11 patients, were performed in a total of 125 (9.4%) patients. A total of 57 (4.3%) patients underwent Double-J placement because of PUL after PNL.

The comparison of both groups in terms of factors related to patients is summarized in Table 1. The two groups were comparable in age, sex, and BMI. The ratio of patients with previous open surgery, previous SWL, and previous PNL were similar in both groups. Stone opacity and degree of hydronephrosis were not different in both groups. The mean stone sizes in groups 1 and 2 were $10 \pm 5.6\,\text{cm}^2$ (range: 2–25) and $7.8 \pm 5.3\,\text{cm}^2$ (range: 1–35), respectively, and the difference between the two groups was statistically significant ($p = 0.003$). The rate of stone complexity was statistically higher in group 1, compared with group 2 (68.5% vs. 53.5%, $p = 0.003$).

The comparison of both groups in terms of factors related to the procedure is summarized in Table 2. The mean operation time and blood transfusion rates were not different in both treatment groups ($p > 0.05$). The hospitalization time was 3.9 ± 2.9 days (range: 1–19) and 2.8 ± 1.5 days (range: 1–21) in groups 1 and 2, respectively, and the difference between the two groups was statistically significant ($p = 0.000$). The caliceal access, access number, and intercostal access did not correlate with the development of PUL. Mean stone-free rate in group 1 was statistically lower than in group 2 (70.8% vs. 86.7%, $p = 0.000$). However, residual stone rate was signifi-

Table 1. Comparison of the Stented and Nonstented Patients in Terms of Factors Related to the Patient

	Group 1 Double-J stent (+) n = *57*	*Group 2 Double-J stent (−)* n = *1269*	p
Age (years)	43.9 ± 12.8 (7–70)	43.1 ± 14.7 (8–83)	0.690
Sex (female/male)	24/33	546/723	0.891
BMI (kg/m²)	26.4 ± 3.4 (20.6–37.1)	26.3 ± 4.7 (15.2–46.9)	0.834
Mean stone burden (cm²)	10.0 ± 5.6 (2–25)	7.8 ± 5.3 (1–35)	**0.003**
Previous SWL	11 (19.3%)	308 (24.3%)	0.390
Radio-opacity			
Radiolucent	0 (0%)	31 (2.4%)	0.476
Radio-opaque	56 (98.2%)	1221 (96.2%)	
Semiopaque	1 (1.7%)	17 (1.33%)	
Hydronephrosis			
Grade 0	2 (3.5%)	52 (4.1%)	0.452
Grade 1	14 (25.5%)	398 (31.3%)	
Grade 2	35 (61.4%)	640 (50.4%)	
Grade 3	6 (10.5%)	179 (14.1%)	
Stone localization			
Partial koraliform	14 (24.5%)	157 (12.4%)	**0.003**
Simple stone	18 (31.6%)	591 (46.6%)	
Pelvis + lower calices	11 (19.3%)	342 (27%)	
Multiple calices	14 (24.5%)	179 (14.1%)	

SWL = extracorporeal shockwave lithotripsy; BMI = body mass index.

cantly higher in group 1, compared with group 2 (36.8% vs. 16.8%, $p = 0.000$).

After evaluation of the patients with PUL using CT scan, ureteral stone was diagnosed in 10 (17.5%) patients, and URS was indicated. Residual renal stone was detected in four patients (7%) who were considered stone free at the end of the procedure. Auxiliary treatment alternatives for both groups are shown in Table 3. The necessity of URS treatment was significantly higher in group 1, compared with group 2 ($p < 0.05$).

Discussion

PNL has become the treatment modality of choice for large-volume, complex renal stones.[1,8] It has the advantages of higher stone clearance, cost-effectiveness, and early convalescence compared with other modalities such as SWL and open surgery.[2,8] Besides its superiority to other treatment modalities, a large scale of complications can occur after this minimal invasive surgery.[3,4]

PUL from the nephrostomy tract after removal of the nephrostomy tube, which necessitates Double-J stent placement, is considered as grade 3 complication according to the modified Clavien system.[4] The factors such as blood clots, edema, and residual stones with resultant urinary obstruction are expected to be responsible for this major complication, and the problem is generally solved with a Double-J stent placement. Although urine leakage may stop spontaneously after a while in some of the cases, there is no consensus on the

Table 2. Comparison of Stented and Nonstented Groups in Terms of Factors Related to the Procedure

	Group 1 Double-J stent (+) n = *57*	*Group 2 Double-J stent (−)* n = *1269*	p
Mean operation time (minutes)	67.8 ± 25 (30–145)	62.3 ± 24.7 (10–195)	0.102
Mean hospitalization time (day)	3.9 ± 2.9 (1–19)	2.8 ± 1.5 (1–21)	**0.000**
Mean access number	1.3 ± 0.6 (1–6)	1.2 ± 0.6 (1–3)	0.803
Access location			
Multiple	9 (15.8%)	166 (13.0%)	0.093
Lower calices	37 (64.9%)	977 (77%)	
Middle calices	6 (10.5%)	59 (4.6%)	
Upper calices	5 (8.8%)	67 (5.3%)	
Intercostal access	10 (17.5%)	124 (9.8%)	0.057
Mean success rates			
Stone-free	31 (54.4%)	952 (75.0%)	**0.000**
CIRF	9 (17.6%)	194 (15.3%)	
Rest	15 (28.0%)	125 (9.7%)	
Complications			
Bleeding	6 (10.5%)	124 (9.8%)	0.999
Fever	2 (3.5%)	23 (1.8%)	
Urosepsis	1 (1.7%)	20 (1.5%)	

CIRF = clinically insignificant residual fragment.

Table 3. Necessity of Auxiliary Treatment for Both Groups

	Group 1 Double-J stent (+) n = *57*	*Group 2 Double-J stent (−)* n = *1269*	p
SWL	10 (17.5%)	64 (11.6%)	0.065
URS	10 (17.5%)	1 (0.2%)	**0.000**
Re-PNL	3 (5.2%)	45 (3.5%)	0.999

PNL = percutaneous nephrolithotomy; URS = ureteroscopy.

exact definition of PUL. Lee et al[9] reported nine (1.5%) patients in whom urine leakage persists for more than 1 week from the percutaneous tract without a Double-J stent placement. However, in our series, 57 patients (4.3%) underwent Double-J stent placement because of urine leakage persisting for more than 24 hours after removal of the nephrostomy tube.

On the other hand, patients experiencing with this problem want to get rid of urine leakage as soon as possible even if an invasive treatment modality stands out to be the choice of treatment. As our clinic is a reference center in the field of urinary stone disease in our country, the patients are referred from all around the country. They desire to go back to their home immediately after the operation and so force the physician to manage such complication as soon as possible. Moreover, extravasation of urine through the fresh nephrostomy tract and into the retroperitoneum creates nidus for bacterial growth, thereby increasing the risk of sepsis.[10] For these reasons, in our clinical practice, Double-J stent placement was performed in patients who had urine leakage for more than 24 hours, with the patient's approval.

Success of the operation was found to be the strongest predictor of Double-J stent placement after PNL because of PUL. Reported success rates of PNL ranged from 51% to 100% in various patient groups[11] and our success rate (89.4%) was similar to those in the literature. If stone fragments remain after PNL, they can cause PUL with obstruction of the pelvicaliceal system. Moreover, these stones may not be detected by conventional imaging modalities such as plain X-ray.[12] All patients with PUL have to be examined with helical CT scan to exclude the possibility of residual stones causing upper urinary-tract obstruction.

We found that both increased stone size and complex stone configuration promote PUL development after PNL. Recent studies showed correlation between stone burden and stone-free rates and pointed out that overall stone-free rates decrease with increasing stone burden and with complex stone configuration.[13,14] In the light of these data, stone burden and stone configuration might be significant predictive factors of PUL because of their impact on success rates. Further, our present data demonstrate stone burden and stone complexity as preoperative predictors of PUL, suggesting the use of tubeless approach in the treatment of noncomplex, smaller renal stones.[15]

We were of the opinion that excessive bleeding necessitating blood transfusion might have an effect on PUL development by a mechanism of small blood clot formation causing pelvicaliceal system obstruction. Usually, small blood clots cannot be detected easily using the currently available radiological imaging tools. Bergman et al[16] reported a case with ureteral obstruction due to blood clots after percutaneous renal biopsy. Bleeding occurred in about 10% of patients in both groups, similar with the literature. However, our data indicated that there was no statistical correlation between bleeding and PUL development necessitating Double-J stent placement.

During the assessment of reasons other than residual stones that might lead to ureteropelvic junction obstruction, the operation time was considered as a predictive factor for PUL. Because of the type and duration of general anesthesia, which influence the extent of inflammation, it can be predicted that in longer operations, the inflammatory indices and the risk of pelvicaliceal edema can increase.[17] Moreover, exposure to irrigation fluids for a longer period may also amplify the risk. Unexpectedly, the mean operation time was not significantly different in both groups and was not found as a predictive factor for PUL.

Nephrostomy tube caliber is an important concern that has been shown to be related to PUL. There may also be less chance of PUL after removal of nephrostomy tube with a smaller caliber.[18] However, leakage around the *in situ* nephrostomy tube (e.g., due to blockage by blood clot or stone fragment or compression of the tube) is more likely if the tube is too narrow or soft. We preferred smaller tube caliber about 14F diameter and found no significant complications related to the nephrostomy tube.

Rarely, Double-J stent placement ends up with undesirable results. For cases with lower urinary-tract obstruction, placement of a stent may increase the amount of urine drainage from the percutaneous tract because of transitory vesicoureteral reflux that results from high bladder pressure.[10] One of the patients with a history of lower urinary-tract symptoms experienced increased urine leakage after a Double-J stent placement for PUL. However, this situation was markedly resolved 1 day after placing the urethral stent.

This study has some limitations that are derived from its retrospective nature. First of all, these data reflect results from several different attending surgeons working at an academic training program with fellow and resident case participation. Second, the Double-J stent was placed in the earlier period (>24 hours) in case of PUL after removal of the nephrostomy tube. Another limitation of the study is that not all of the patients were assessed postoperatively by CT, but they were generally followed by urography, which overestimates success rates. Finally, the study could be more valuable with the evaluation of some metabolic diseases such as diabetes and ischemic cardiovascular disease that impair wound healing.[19]

Besides all the benefits of Double-J stent, it has to be remembered that bladder irritation, hematuria, and flank pain seem to be the major side effects that may be caused by vesicoureteral reflux, irritation, infection, and obstruction caused by encrustation or stent migration.[20,21] These problems are likely to occur in patients with long indwelling times.[20] Although there is no evidence-based study evaluating the duration of Double-J stent placement for PUL after PNL, the duration of 1 to 2 months is expected to be suitable for the healing of percutaneous tract.[20] The patients, in whom a Double-J stent has been placed, should be informed about the side effects of the stent if it is not taken out of the body at the appropriate time.

Conclusions

Our results confirmed that the necessity for Double-J placement, because of PUL from the percutaneous tract, diminishes with increase in stone-free rates. The stone size and stone complexity are other predictive factors for PUL development. However, the number and location of percutaneous accesses as well as per-operative complications were not related to the development of this complication. The patients with PUL have to be examined with helical CT scan to exclude the possibility of any residual stone causing upper urinary-tract obstruction. It may be better to place a Double-J stent peroperatively to preserve the patient from a second intervention in the early postoperative period if a significant residual stone has been suspected at the end of the procedure.

Disclosure Statement

No competing financial interests exist.

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Address correspondence to:
Murat Binbay, M.D.
Department of Urology
Haseki Teaching and Research Hospital
Rio de Jenerio cd O19 D7
3-4. kisim Atakoy
İstanbul 34217
Turkey

E-mail: muratbinbay@yahoo.com

Abbreviations Used

BMI = body mass index
CIRFs = clinically insignificant residual fragments
CT = computed tomography
PNL = percutaneous nephrolithotomy
PUL = prolonged urine leakage
SWL = extracorporeal shockwave lithotripsy
URS = ureteroscopy

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Editorial Comment

"To leak or not to leak?" That is the question! Percutaneous nephrolithotomy (PCNL) has become the standard of care for large renal calculi since its introduction in 1976. Traditionally, a nephrostomy tube catheter is placed at the completion of PCNL and aims at avoiding or reducing complications ranging from bleeding, to obstruction and urinary leakage.

However, one cannot deny the fact that an increasing number of papers challenge the established protocol questioning the "need of postprocedural nephrostomy catheter" after PCNL. The results of the different series are still contradictory and have led to a confusion rather than providing clarity on the subject of "tubeless PCNL."

In the present work, the incidence of urine leakage after PCNL as well as the characteristics of those patients ultimately requiring Double-J placement to solve the leakage is presented. The authors concluded that stone-free rate, stone size, and stone complexity are predictive factors for prolonged urine leakage (PUL).

Let us have a closer look at these three risk factors identified in the series. How strong does the literature support these findings, starting with the stone-free rate? How can we best judge this "stone-free rate concept"? Should we assess the absence of residual fragments performing a flexible endoscope examination of the caliceal system after conventional rigid PCNL? Is a second look PCNL indicated to rule out the presence of possible obstructive fragments or do we rely our assessment on the postoperative antegrade imaging of the urinary system?

From the work of Raman et al[1] we can learn that any of the aforementioned options may be logistically difficult and that the stone-free status can only be confirmed following computed tomography studies. Small residual fragments are most likely the cause of PUL. However, postmanipulation edema may not be ruled out as the origin of transitory PUL even in the absence of residual fragments.

Second, the authors identified stone size and stone complexity as predictive risk factors for PUL. Other authors have not confirmed this finding. For example, Shah et al[2] actually indicated that the application of a tubeless procedure can be virtually extended to any patient without increased risk of complications. The latter affirmation was reinforced by the work of Falahatkar et al.[3] These authors reported on tubeless PCNL without significant complications in selected patients undergoing PCNL for staghorn calculi.

I strongly feel that in PCNL, as in any other surgical procedure, three factors have to be taken into account for an uneventful course: patient's characteristics, progress of the surgical procedure, and surgeons' experience. The latter is an unavoidable process and can only be improved (and eventually reached) by gaining experience. The other two factors are open for discussion and rely on the good clinical practice and critical preoperative evaluation. Investigators have been in the search for the holy grail to reduce the need of postoperative upper tract drainage following PCNL with minimal complications. One of these unfavorable complications is PUL. During the past years several approaches have been studied, including sealing agents to avoid leakage. Unfortunately, none has really proven its efficacy. More recently, Okeke et al[4] presented cryotherapy of the nephrostomy tract to decrease hemorrhage and urinary leakage after tubeless percutaneous renal surgery.[4] The fact that we have not reached our goal as yet is confirmed by a recent paper from Bellman's team.[5] He introduced the concept of tubeless PCNL over a decade ago but still continues to drain internally to obtain a dry flank.

I therefore think we may safely conclude that at present we have no reliable indicators predicting in whom PUL may occur or not. Obviously, we will continue our search for the holy grail in the benefit of our patients with renal stones.

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Address correspondence to:
Jean de la Rosette, M.D., Ph.D.
Department of Urology
Academic Medical Center
University of Amsterdam
Amsterdam 1105 AZ
The Netherlands

E-mail: j.j.delarosette@amc.uva.nl