

# Totally tubeless percutaneous nephrolithotomy: a prospective randomized controlled study

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**Abstract** The purpose of this study was to perform a randomized controlled trial to evaluate the role, safety, and effectiveness of totally tubeless PCNL and whether this procedure is less morbid in terms of analgesia requirement, related complications and convalescence. A total of 131 patients, with impacted ureteropelvic junction stone or single renal pelvic stone larger than 20 mm, were prospectively randomized (using random numbers table) into two groups, and underwent conventional (63 patients) or totally tubeless (68 patients) PCNL. Preoperative data included urinalysis, urine culture, complete blood count, biochemistry study, renal ultrasonography, intravenous urography and Tc 99m DTPA clearance for determination of selective glomerular filtration rate. Intraoperative findings, operative time, and outcome were also recorded. All patients were followed regularly at clinic every 3 months during year 1 and every 6 months, thereafter, and Tc 99m DTPA clearance for the determination of selective glomerular filtration rate, renal ultrasonography and intravenous urography was performed to assess the kidney function 6 months later. There was no difference between the groups with regard to serum creatinine change, hemoglobin decrease, morphology improvement, resumption of normal activity and complication grading. The length of stay, pain visual analog scale and analgesic requirements favored the tubeless group with statistical significance. There was significant statistical difference in relative perfusion rate between preoperative and postoperative in both

groups. This trial demonstrates that totally tubeless PCNL is safe and well tolerated in selected patients and associated with decreases in length of stay, postoperative pain and analgesia requirement. Most importantly, patients undergoing uncomplicated PCNL are not mandated to have a nephrostomy or ureteral stent placed for specific indications.

**Keywords** Tubeless percutaneous nephrolithotomy · Length of stay · Analgesia requirement

## Introduction

Percutaneous nephrolithotomy (PCNL) is a minimally invasive surgical modality for management of most renal stones. Technologic advancements and refinements have contributed to the high success rate and low-morbidity of stone removal with PCNL [1–4]. In addition, several modifications and refinements have been incorporated into the PCNL technique to further lower its morbidity, such as the use of a smaller working sheath and nephroscope (mini PCNL) [1], avoidance of a nephrostomy tube (tubeless PCNL) [2], sealing of the percutaneous access tract with hemostatic agents [3–5], and substituting general anesthesia with regional blocks (ambulatory spinal tubeless PCNL) [6].

In most tubeless PCNL procedures, internal drainage is provided with a double-J stent or a temporary ureteral access catheter, whereas, in a totally tubeless PCNL, internal drainage is not provided. A randomized trial with the evaluation of intraoperative and postoperative outcome was undertaken to evaluate the role, safety, and effectiveness of totally tubeless PCNL and whether this procedure is less morbid in terms of analgesia requirement, related complications and convalescence. The study may assess

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the influence of nephrostomy tube and ureteral double-J drainage after PCNL on postoperative morbidity.

## Materials and methods

Our institutional review board approved the study, and all patients signed an informed consent form before participating. The study was designed as a randomized controlled trial and carried out from February 2005 to January 2008. To detect a 40% difference in the proportion of trial parameter (hospital stay, complication rate) in the treatment groups at a significance level of 0.05 and a power of 90%, a sample size of 45 patients per group was needed. Adult patients were included, if they were scheduled for percutaneous nephrolithotomy due to impacted ureteropelvic junction stone or single renal pelvic stone larger than 20 mm and lesser than 40 mm. Patients were excluded from the study, if they had a stone is <20 mm in diameter, a history of ipsilateral renal surgery, bilateral stones, urosepsis or the patient had a solitary kidney, more than one tract, a second look (>24 h), or if supracostal approach was used.

A modified technique was used for PCNL. Following placement of a 16Fr Foley catheter, the patient was turned prone under endotracheal general anesthesia, and access to the collecting system was obtained using a puncture needle under sonographic guidance. The track was formed using serial plastic dilators until Amplatz sheath (Fr 30) was inserted. The stones were fragmented with pneumatic lithoclast and removed piece by piece with stone forceps for analysis. At the end of the procedure, the surgeon conducted a visual and fluoroscopic check for residual stone fragments. A Simultaneous second look or flexible nephroscopy was performed to acquire stone-free status, if above check revealed any residual fragments. The stone-free was defined as radiographic absence of calculi. Finally, we changed irrigation fluid from physiologic saline to distilled water. The bleeding points were cauterized by a conventional electric cauterizer (roller) using a resectoscope to pass through the tract. By careful inspection, bleeding points would be identified and cauterized. To avoid adjacent organ or renal pedicle injury, the electrode touched the bleeding points on the surface of the tract and renal pelvis for a few seconds without putting pressure on them. Therefore, a bloodless tract could be obtained and there was no need for further percutaneous procedures. Patients in the conventional group underwent antegrade double-J catheter (Fr 7.0) and nephrostomy tube (Fr 20) placement after bloodless procedure. After removal of the working sheath, the wound was closed with 3-O Nylon sutures for subcutaneous bleeding control. All procedures were performed by the same urologist to ensure uniform

skill and experience level. Operative time was recorded from tract puncture to skin closure.

A total of 131 patients were prospectively randomized (using random numbers table) into two groups, before they entered the operative room. In the conventional group, a total of 63 patients were available for consideration. Among them, five patients had a second look in the study and nine patients were lost to follow-up (<6 months). So a total of 63 patients (mean age 58.7 years old) were enrolled and they received conventional PCNL. In the tubeless group, a total of 68 patients were available. Among them, eight patients had a second look in the study and eight patients lost to follow-up (<6 months). So a total of 68 patients (mean age 59.2 years old) were enrolled and received totally tubeless PCNL. Preoperative data included urinalysis, urine culture, complete blood count, biochemistry study, renal ultrasonography, intravenous urography and 99 m technetium diethylenetriaminepentaacetic acid (Tc 99 m DTPA) for determination of selective glomerular filtration rate (GFR). Intraoperative findings, operative time (from insertion of the puncture needle to the end of the procedure), and outcome were also recorded. Successful PCNL (stone-free) was defined as the complete removal or the radiographic absence of calculi by KUB at follow-up. Besides, the patients with a second look investigation were included as failures of the treatment. In the conventional group, the nephrostomy tube was removed when the urine ran clear (around 24–48 h) and the double-J stent was removed under cystoscopy 2 weeks later.

During hospitalization, all patients were prescribed parenteral cefazolin 1 gm q6h, oral Ketorolac 10 mg three times per day to minimize urinary tract infections and pain, and allowed to use sublingual buprenorphine 0.2 mg on demand. Overall dosage was documented and compared. A 10-cm linear visual analog scale was performed to assess for pain at 2 h postoperatively. Complete blood count and serum creatinine were checked again. The modified Clavien grading system was used to evaluate the perioperative morbidity of PCNL treatment [7]. Pipemidic acid trihydrate 250 mg, twice per day, for 2 weeks after discharge was given.

Two patients in each group received adjuvant extracorporeal shock wave lithotripsy (ESWL) for residual major fragments and scheduled 4 weeks later.

All patients were followed at clinic regularly every 3 months during year 1 and every 6 months, thereafter. At each visit, plain X-ray KUB, urinalysis, urine culture, and serum creatinine were performed. Besides, Tc 99 m DTPA clearance for determination of selective glomerular filtration rate, renal ultrasonography and intravenous urography were performed to assess the kidney function 6 months later. Based on intravenous urography, hydronephrosis can be classified into five grades, grade 1 is the least and grade

5 is the worst. Statistical analysis was performed using commercially available software. The Chi-square test, two-sample independent *t* test and Fisher's exact test was used as appropriate. *p* value less than 0.05 was considered significant.

## Results

A total of 131 patients undergoing PCNL for impacted ureteropelvic junction stones or single renal pelvic stones completed the study protocol, 63 patients in the conventional group, and 68 patients in the totally tubeless group. No significant statistical difference was observed in patient age, gender distribution, body mass index, stone size, operative time, follow-up period, and stone laterality and composition (Table 1). The success rate was 74.6 and 73.5% in conventional group and totally tubeless group, respectively, with no significant statistical difference.

There was no difference between the groups with regard to serum creatinine change, hemoglobin decrease, morphology improvement, return to normal activity and Clavien grading system (Table 2). However, the length of stay ( $3.60 \pm 0.98$ ) in the tubeless group was shorter than that in conventional group with significant statistical difference. Pain visual analog scale and analgesic requirements favored the tubeless group with statistical significance. Three patients required blood transfusions. Of these, one patient in the tubeless group presented with hematuria 5 days after PCNL. He was initially treated with blood transfusion and cystoscopic clot evacuation. However, because hematuria recurred after 2 days, selective renal angiography and angioembolization of a pseudoaneurysm were performed. However, no patients changed treatment protocol due to bleeding or residual stone fragments.

There was also no difference between the groups with regard to morphology change by renal ultrasonography and intravenous urography, and the relative perfusion rate and glomerular filtration rate by Tc 99 m DTPA clearance,

**Table 1** Patients demographics and perioperative data

| Characteristic            | Tube                | Tubeless            | <i>p</i> value                           |
|---------------------------|---------------------|---------------------|--|
| Patients ( <i>n</i> )     | 63                  | 68                  | 0.552 <sup>#</sup>                       |
| Age (year)                |                     |                     |  |
| Mean                      | 58.70 ± 10.85       | 59.22 ± 12.44       | 0.799 <sup>#</sup>                       |
| Range                     | 33–79               | 39–80               |  |
| Gender ( <i>n</i> )       |                     |                     |  |
| Male                      | 50                  | 51                  | 0.436 <sup>*</sup>                       |
| Female                    | 13                  | 17                  |  |
| Body mass index           |                     |                     |  |
| Male                      | 25.06 ± 2.64        | 25.04 ± 2.51        | 0.914 <sup>#</sup>                       |
| Female                    | 25.14 ± 2.61        | 25.16 ± 2.41        | 0.722 <sup>#</sup>                       |
| Female                    | 24.79 ± 2.83        | 24.71 ± 2.82        | 0.654 <sup>#</sup>                       |
| Stone sizes (mm)          |                     |                     |  |
| Length (mm)               | 24.86 ± 2.78        | 24.74 ± 2.69        | 0.799 <sup>#</sup>                       |
| Width (mm)                | 15.29 ± 4.50        | 16.40 ± 3.65        | 0.122 <sup>#</sup>                       |
| Laterality                |                     |                     |  |
| Right                     | 32                  | 34                  | 0.909 <sup>*</sup>                       |
| Left                      | 31                  | 34                  | (0.928 <sup>*</sup> )                    |
| Follow-up period (months) | 18.92 ± 4.88        | 17.99 ± 4.61        | 0.262 <sup>#</sup>                       |
|                           | (19.02 ± 5.13) (54) | (18.43 ± 4.15) (60) | (0.245 <sup>#</sup> )                    |
| Operative times (min)     | 33.14 ± 6.17        | 31.72 ± 6.97        | 0.220 <sup>#</sup>                       |
|                           | (32.91 ± 6.31) (58) | (32.05 ± 7.16) (60) | (0.745 <sup>#</sup> )                    |
| Success rate              | 47 (74.6%)          | 50 (73.5%)          | 0.508 <sup>^</sup> (0.776 <sup>^</sup> ) |
|                           | (60–95.2%)          | (64–94.1%)          |  |
| Stone composition         |                     |                     |  |
| Struvite + apatite        | 5 (7.9%)            | (8–11.8%)           | 0.305 <sup>^</sup>                       |
| Uric acid                 | 2 (3.2%)            | 0 (0%)              |  |
| Whewellite                | 24 (38.1%)          | (30–44.1%)          |  |
| Whewellite + apatite      | 19 (30.2%)          | (13–19.1%)          |  |
| Weddellite                | 13 (20.6%)          | (17–25%)            |  |

The values in the parenthesis show all collectable perioperative data

<sup>#</sup> Two-sample independent *t* test

<sup>^</sup> Fisher's exact test

<sup>\*</sup> Chi-square test

**Table 2** Surgical results and complications

|                                  | Tube                             | Tubeless                         | <i>p</i> value                                 |
|----------------------------------|----------------------------------|----------------------------------|--|
| Patients ( <i>n</i> )            | 58 (63)                          | 60 (68)                          |  |
| Mean length of stay (days)       | 4.21 ± 1.27<br>(4.19 ± 1.23)     | 3.37 ± 1.07<br>(3.60 ± 0.98)     | <0.001 <sup>#</sup><br>(0.003 <sup>#</sup> )   |
| Mean Cr change (mg/dl)           | 0.09 ± 0.12<br>(0.08 ± 0.11)     | 0.10 ± 0.12<br>(0.09 ± 0.11)     | 0.589 <sup>#</sup><br>(0.770 <sup>#</sup> )    |
| Mean Hb decrease (gm/dl)         | 2.04 ± 0.50<br>(2.02 ± 0.53)     | 1.91 ± 0.51<br>(1.92 ± 0.52)     | 0.150 <sup>#</sup><br>(0.257 <sup>#</sup> )    |
| VAS POD 2 (10 cm)                | 6.26 ± 0.98<br>(6.32 ± 0.99)     | 4.97 ± 1.15<br>(5.15 ± 1.03)     | <0.001 <sup>#</sup><br>(0.001 <sup>#</sup> )   |
| Ketorolac (mg)                   | 75.52 ± 16.24<br>(75.56 ± 16.44) | 61.50 ± 15.49<br>(63.38 ± 15.22) | <0.001 <sup>#</sup><br>(< 0.001 <sup>#</sup> ) |
| Buprenorphine dosage (mg)        | 0.26 ± 0.79<br>(0.24 ± 0.76)     | 0.11 ± 0.17<br>(0.09 ± 0.16)     | 0.157 <sup>#</sup><br>(0.093 <sup>#</sup> )    |
| Return to normal activity (days) | 7.12 ± 1.44<br>(7.16 ± 1.39)     | 6.47 ± 1.14<br>(6.46 ± 1.11)     | <0.001 <sup>#</sup><br>(0.002 <sup>#</sup> )   |
| Urine leak >12 h                 | 3 (5.56%)<br>(3) (4.8%)          | 5 (8.33%)<br>(5) (7.35%)         | 0.717 <sup>^</sup><br>(0.536 <sup>^</sup> )    |
| Clavien grading system           |                                  |                                  |  |
| 0                                | 53 (84.1%)                       | 56 (82.4%)                       | 0.932 <sup>^</sup>                             |
| 1                                | 4 (6.3%)                         | 6 (8.8%)                         |  |
| 2                                | 6 (9.5%)                         | 4 (5.9%)                         |  |
| 3a                               | 0                                | 2 (2.9%)                         |  |

The values in the parenthesis show all collectable perioperative data

<sup>#</sup> Two-sample independent *t* test

<sup>^</sup> Fisher's exact test

preoperative and postoperative. However, there was a significant statistical difference in relative perfusion rate compared with baseline in both groups group (Table 3). However, no late ureteropelvic junction stricture developed during the follow-up.

## Discussion

Percutaneous renal surgery is a frequent procedure for the practicing urologist [8]. Although the major indication is the removal of renal and upper-ureteral stones, this

**Table 3** Morphology and function of corresponding kidney

|                                     | Tube (54)           | Tubeless (60)       | <i>p</i> value     |
|-------------------------------------|---------------------|---------------------|--------------------|
| IVU (preoperative)                  |                     |                     |                    |
| I                                   | 12 (22.2%)          | 13 (21.7%)          | 0.997 <sup>^</sup> |
| II                                  | 29 (53.7%)          | 19 (31.7%)          |                    |
| III                                 | 12 (22.2%)          | 24 (40.0%)          |                    |
| IV                                  | 1 (1.9%)            | 4 (6.7%)            |                    |
| IVU (6 months later)                |                     |                     |                    |
| I                                   | 21 (38.9%)          | 27 (45.0%)          | 0.979 <sup>^</sup> |
| II                                  | 22 (40.7%)          | 18 (30.0%)          |                    |
| III                                 | 7 (13.0%)           | 6 (10.0%)           |                    |
| IV                                  | 3 (5.6%)            | 4 (6.7%)            |                    |
| O                                   | 1 (1.9%)            | 5 (8.3%)            |                    |
| IVU improvement                     | 31/54 (57%)         | 36/60 (60.0%)       | 0.373 <sup>^</sup> |
| Glomerular filtration rate (ml/min) |                     |                     |                    |
| Preoperative                        | 59.87 ± 14.03       | 58.3 ± 12.9         | 0.253 <sup>#</sup> |
| 6 months later                      | 67.69 ± 12.56       | 66.57 ± 12.24       | 0.303 <sup>#</sup> |
| Relative perfusion rate (%)         | <0.001 <sup>#</sup> | <0.001 <sup>#</sup> |                    |
| Preoperative                        | 38.88 ± 4.06        | 37.94 ± 4.08        | 0.093 <sup>#</sup> |
| 6 months later                      | 41.81 ± 3.72        | 41.10 ± 3.25        | 0.123 <sup>#</sup> |
| <i>p</i> value                      | <0.001 <sup>#</sup> | <0.001 <sup>#</sup> |                    |

<sup>#</sup> Two-sample independent *t* test

<sup>^</sup> Fisher's exact test

procedure has also been used for the treatment of pelvi-ureteral stricture and management of transitional-cell carcinoma of the upper urinary tract. Percutaneous nephrolithotomy has a major role in the treatment of urolithiasis, in that, it provides a minimally invasive approach to nearly all portions of the upper urinary tract. The morbidity of percutaneous renal surgery has decreased dramatically with improvements in the equipment and experience. Although ESWL has revolutionized stone management, there remain several situations in which percutaneous renal surgery is the treatment of choice [9].

PCNL has significantly decreased the morbidity associated with open stone surgery. Traditionally nephrostomy tube drainage after PCNL has been advocated for several reasons. It provides reliable urinary drainage, it provides hemostatic tamponade to the fresh percutaneous renal tract and continuous access to the renal collecting system should be a secondary percutaneous procedure required. Despite these obvious and important advantages, nephrostomy tubes, especially, in the vicinity of a rib, are thought to contribute to postoperative pain and morbidity [3]. As a result, certain investigators have recently proposed tubeless PCNL in an attempt to avoid nephrostomy tube drainage after uncomplicated, straightforward percutaneous procedures [10, 11]. In this approach the nephrostomy tube is replaced by internal double-J ureteral stent drainage. Limb and Bellman reported that the tubeless approach was reasonably safe in selected patients with uncomplicated percutaneous procedure and a low-calculus burden. Alternative strategies to avoid morbidity related to nephrostomy tube. Placement of a double-J stent after endourological intervention has been a standard practice. The reported advantages are that, it may reduce colic caused by ureteral obstruction secondary to edema [12, 13] and prevent stricture formation [14]. On the other hand, indwelling ureteral stents may be associated with significant symptoms and signs such as pain, urgency, dysuria and hematuria may lead to complications such as stent migration and urosepsis [15, 16]. This study was designed to assess, in a prospective randomized fashion, the influence of nephrostomy tube and internal double-J drainage after PCNL on postoperative morbidity. The nephrostomy tube was removed when the urine ran clear (around 24–48 h) and the double-J stent indwelled for 2 weeks, then removed under cystoscopy. Internal double-J stent served as internal drainage after the nephrostomy tube was removed. However, internal double-J stent would be the source of associated pain and negative factor of quality of life as Joshi et al. [16] reported.

In the present study, standard Fr 20 nephrostomy tube and internal double-J drainage was associated with a significantly greater pain VAS score and analgesia requirement compared with totally tubeless PCNL. This finding

may suggest an association between pain and lack of tubes. Unfortunately, the usage of both an internal stent and a nephrostomy tube may confuse the origin of associated pain and cannot clarify the role of internal or external drainage. We should admit that a cleaner study would just compared nephrostomy or internal stent with totally tubeless study.

We used the traditional transurethral resectoscope with working sheath in situ for cauterization, because of the concern that more in and out movements using that instrument would result in a tendency for more bleeding. After stone extraction, the bleeding usually arises just beneath the torn collecting system or beneath the urothelium, where the access tract enters the collecting system. Only a few bleeding points could be found at the parenchymal portion of the access tract. The bleeding of the small peripheral interlobular vessels surrounded by parenchyma, usually, diminished by tamponade with the working sheath during the procedure. The key to cauterization is to cauterize the bleeding under direct visualization and right on the point of bleeding. Most bleeding was stopped by cauterization. Some bleeding could not be stopped by cauterization, but would usually diminish [17]. Another concern was the use of hypotonic solution during the cauterization. This would increase the risk of hemolysis or electrolyte imbalance when the intrapelvic pressure elevated as Troxel [18] reported. No patients developed such complications in our series, which may be due to the short period of cauterization.

Although, there was no significant statistical difference between the groups with regard to urine leakage and return to normal activity. While a urine leak from the percutaneous tract site can often be bothersome to the patient, it usually resolves spontaneously. The duration and caliber of the percutaneous nephrostomy tube usually determine the duration of leakage. Since the double-J stent provides reasonable urinary drainage in the initial postoperative period, the tubeless approach is usually associated with minimal urine leakage from the percutaneous access site. A concern with the tubeless approach is the potential for extravasation and perinephric urinary collection. None of the patients in the present study showed any perinephric collection on routine renal ultrasonography during the follow-up period.

Although, the electrocauterization of bleeding points at the end of PCNL with a rollerball resectoscope is safe. Post-PCNL bleeding needed blood transfusion which was inevitable. On the other hand, to decrease the risk of bleeding after tubeless PCNL, several investigators used hemostatic material applied in the working tract. Noller et al. [19] reported that tubeless PCNL using fibrin sealant at the renal parenchymal defect appears to be safe and feasible. Lee et al. [20] concluded that injection of a gelatin



matrix hemostatic sealant into the nephrostomy tract may be of value in preventing bleeding after PCNL. Recently, Aghamiret al. [21] used Surgicel<sup>R</sup> (oxidized cellulose) to seal the working tract and concluded that such sealing of the nephrostomy tract after totally tubeless PCNL did not decrease bleeding or urinary extravasation.

Although, the change in selective GFR of 10% or greater of the basal value was considered significant [22]. Our Tc 99 m DTPA renal scan and intravenous urography revealed improvement in GFR and morphology in both groups post-operatively. However, there was no significant statistical difference between the groups. Additionally, comparison of the mean preoperative relative perfusion rate of both groups corresponding to kidney ( $38.88 \pm 4.06\%$ ,  $37.94 \pm 4.08\%$ ), with mean value at follow-up ( $41.81 \pm 3.72\%$ ,  $41.10 \pm 3.25\%$ ) showed an improvement of statistical significance ( $p < 0.001$ ). The previous studies showed that open and endourological procedures caused no significant changes in preoperative renal function measured by dimercapto-succinic acid scan [23, 24] or conventional renogram [25]. Our results are contrary to the previous studies, but similar to that reported by Gad et al. [26]. Such observation may be attributed to case selection, limiting to a small mean stone size or impacted ureteropelvic junction stone in both groups. The improvement may be associated with the duration of stone impaction, although it is hard to define the existence and duration of obstruction. However, our results reveal that treatment of renal stone will perverse or improve the renal function. As Koga et al. [27] stated that conservative therapy destroyed the kidney and early complete removal of these stones is advisable. Further study of massive stone burden should be designed to clarify this point.

The study demonstrates that totally tubeless PCNL in selected patients is safe and there were no readmissions and no episodes of ureteral colic. This can be attributed to careful case selection to ensure that no residual stone remained or excessive bleeding occurred. However, we recognize that the trial was inevitably unblinded and so possible bias may have occurred, although these patients were treated by the same urologist with standard criteria.

The importance of identifying even tiny residual stones is underscored by the reports that residual fragments previously considered clinically insignificant often result in significant future morbidity [28]. The superior sensitivity of CT would result in the detection of even tiny residual stones, inevitably affecting stone-free outcomes. The relationship between the sensitivity of the imaging modality and the stone-free rate was also noted in the initial lower pole stone study, in which, the stone-free rate for SWL and PCNL were notably lower than those reported in the meta-analysis [29], likely due to the use of nephrotomograms as opposed to plain X-rays in the former [30]. Now CT seems to be a new standard for judging stone-free status.

Unfortunately our IRB did not approve the application of CT to define the status of stone due to the concern of radiation over exposure.

It must be stressed that this patient population is a selected group as evidenced by the small mean stone size in each. It is unlikely that patients with larger, more complex stones would benefit from this approach. Differences between available facilities among countries and centers will determine the likelihood that these patients will undergo uncomplicated PCNL for relatively small stones.

## Conclusions

This study demonstrates that the totally tubeless approach is safe and well tolerated in selected patients and associated with less postoperative pain and analgesic requirements. These data give definitive proof that totally tubeless PCNL is a good option after an uncomplicated percutaneous renal procedure. Most importantly, patients undergoing uncomplicated PCNL are not required to have a nephrostomy or ureteral stent placed.

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