Int Urol Nephrol (2007) 39:57–63
DOI 10.1007/s11255-006-9040-6

ORIGINAL PAPER

Tubeless percutaneous nephrolithotomy in selected patients: a prospective randomized comparison

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Received: 12 March 2006 / Accepted: 9 May 2006 / Published online: 14 December 2006

Abstract
Objectives To prospectively compare the outcome of standard and tubeless percutaneous nephrolithotomy (PNL) in a selected group of patients with renal stones.
Methods Patients with simple, isolated renal pelvis or lower pole caliceal stones and no significant hydronephrosis were randomly enrolled to undergo either standard PNL, in which routine nephrostomy tube was placed at the end of operation, or tubeless PNL. Occurrence of intraoperative complications, total operative time exceeding 2 h, indication for additional access or second-look PNL due to residual stones were exclusion criteria.
Results There were 11 isolated lower pole caliceal stones (mean stone burden: 3.1 cm^2) and 6 isolated renal pelvis stones (mean stone burden: 2.8 cm^2) in the tubeless PNL group (*n*: 17), and 9 isolated lower pole caliceal stones (mean stone burden: 3.4 cm^2) and 9 isolated renal pelvis stones (mean stone burden: 3.1 cm^2) in the standard PNL group (*n*: 18). Mean operation time was 59.6 ± 9.1 (range: 50–90) min in the tubeless group, and 67.3 ± 10.1 (range: 60–115) min in the standard PNL group ($P > 0.05$). Successful stone removal was achieved in all patients, and no significant complication was observed in any case. The mean postoperative analgesic requirement was significantly less in the tubeless group ($P < 0.05$). Mean hospital stay was 1.6 ± 0.4 (range: 1–3) days in the tubeless group, and 2.8 ± 0.9 (range: 2–4) days in the former group ($P < 0.05$).
Conclusion Our results indicate that tubeless PNL is safe in the management of selected patients and that mean analgesic requirement as well as hospitalization time is diminished with this modification.

Keywords Kidney stones · Percutaneous nephrolithotomy · Nephrostomy tube · Analgesia · Hospitalization

Introduction

The widespread acceptance of percutaneous nephrolithotomy (PNL) in the management of renal stones minimized indications for open surgery [1]. Recent technological advances have contributed to the high success rates of PNL and further modifications have been made to PNL technique in an attempt to decrease the morbidity while maintaining efficacy [2, 3].

Presented at the 23rd World Congress on Endourology and SWL, August 23–26, 2005, Amsterdam, The Netherlands

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To date, the standard of care has been to place a nephrostomy tube after completion of percutaneous renal surgery. The postoperative nephrostomy tube has been thought to serve multiple purposes, including allowing proper homeostasis, permitting future access for a second stage procedure, allowing the renal puncture to heal, and permitting proper drainage of the collecting system [4]. However, the tube itself may be associated with increased morbidity [5, 6]. Recent randomized studies have shown that, avoiding external nephrostomy tube drainage, termed as the 'tubeless PNL' procedure, significantly decreased pain and morbidity of PNL, and diminished related expenses in selected patients [5–9].

Herein, we prospectively compared the outcome of standard and tubeless PNL in a selected group of patients with renal stones.

Patients and methods

During a 1-year period between 2003 and 2004, a total of 219 patients with upper urinary tract stones were treated with PNL at our institution, and 38 (17.4%) of them were enrolled to this prospective randomized study.

Inclusion criteria were simple, isolated renal pelvis or lower pole caliceal stones, mild or moderate stone burden, and no significant hydronephrosis. Patients with active urinary tract infection, previous history of renal surgery or extracorporeal shock wave treatment, congenital urinary tract anomalies, elevated serum creatinine levels, and solitary functioning kidneys were excluded. Occurrence of procedure related intraoperative complications, operation times exceeding 2 h, need for multiple (≥2) percutaneous punctures were other exclusion criteria. Presence of clinically significant residual stone burden necessitating a staged second-look PNL, or ESWL as an auxiliary treatment was also contraindication to enrolment.

Preoperative complete blood count, serum creatinine, platelet count, bleeding and coagulation profile, and urine culture were obtained from all patients, while radiological evaluation included intravenous urography (IVU) and urinary tract ultrasonography, with the addition of non-contrast computed tomography in selected cases. The stone burden was determined by radiographic studies.

A 5Fr ureteral catheter was placed in all patients, except those with a preexisting double-j stent, before PNL, and this external ureteral stent was left secured to the Foley catheter. Percutaneous access was performed on patients in prone position on urological table (ModularisUro, Siemens) with all pressure points padded. Percutaneous access was obtained at a single setting in the operating room with C-armed fluoroscopy, and the tract was dilated with high-pressure balloon dilator (Nephromax™, Boston Scientific) up to 18-atmosphere pressure, using an inflator (Leveen™ Inflator, Boston Scientific), and a 30Fr Amplatz sheath (Amplatz sheat, Boston Scientific) was placed over the inflated Nephromax™.

Nephroscopy was performed with a rigid, 26Fr nephroscope. Fragmentation of the stone burden was accomplished using a pneumatic lithotriptor (Vibrolith, Elmed). Additional tracts were created when indicated in the same session. Stone clearance and the integrity of the collecting system were confirmed intraoperatively by fluoroscopy and antegrade nephrostography.

At the end of the procedure, a 14-F nephrostomy tube was placed in 19 patients in group I (standard PNL group), while no nephrostomy tube was placed in 19 patients in group II (the 'tubeless' PNL group). Patients were stratified into each group by one-by-one randomization. The nephrostomy site was closed with homeostatic No 1 silk sutures with the guidewire in place in group II and when active bleeding was not evident for a few minutes, the guidewire was removed [4].

The external ureteral catheter was removed on postoperative day 1. In the tubeless PNL group, pre-existing double-J catheters were left in place for internal drainage in two patients for 4 weeks postoperatively. The nephrostomy tube in patients in group I was removed after at least 48 h.

Demographic findings of patients in each group and outcome of the procedure, as well as inpatient narcotic use (i.m. diclofenac and/or morphine) and hospital stay were analyzed. The narcotic requirement was determined simply according to the pain felt by the patient.

Spiral non-contrast computed tomography was obtained in several initial patients on postoperative day 1, and all patients underwent postoperative renal ultrasonography before discharge to assess perinephric collection. A complete blood count was performed 24 h after surgery to determine the decrease in serum hemoglobin level.

Follow-up included routine radiological imaging studies. The procedure was considered successful if the patient was either free of stones or had only clinically insignificant residual fragments (CIRF's). Results were classified as 'Stone-free', presence of 'clinically insignificant residual fragments (CIRF)', and 'Unsuccessful (presence of residual stones)' at the 3rd month of the follow-up. CIRF's were considered as ≤4 mm, non-obstructing, non-infectious, and asymptomatic residual fragments.

Results were expressed as mean ± standard deviation (SD). Differences in percentages (qualitative variables) were analyzed by the χ^2-test. Differences between quantitative variables were evaluated with the Student's-*t* and Fisher's exact tests. Statistical analyses were performed using the SPSS for Window's (version 11.5). The *P* value ≤0.05 was considered significant.

Results

Both groups were similar with respect to age, sex distribution, and stone size (Table 1). Overall, complete data of 35 patients were available.

The mean stone size was 3.1 ± 0.9 (range: 1.5–8) cm^2, and 3.0 ± 0.7 (range: 1.5–6) cm^2 in group I and II, respectively (Table 1). There were 9 isolated lower pole caliceal stones and 9 isolated renal pelvis stones in group I, and 11 isolated lower pole caliceal stones and 6 isolated renal pelvis stones in group II.

Mean operative time, including preparation period, was 67.3 ± 10.1 (range: 60–115) minutes in group I, and 59.6 ± 9.1 (range: 50–90) min in group II ($P > 0.05$). Mean decrease in serum hemoglobulin level (1.3 vs. 1.6 gr/dl) and duration of hematuria (1.4 vs. 1.5 days) was also similar in both groups (Table 2).

Mean postoperative analgesic requirement was significantly ($P < 0.01$) higher in group I. Postoperative analgesia was achieved by intramuscular administration a mean dosage of 200.0 ± 66.1 mg diclofenac in group I and by 110.3 ± 52.2 mg diclofenac in group II. Furthermore, 8 (44.4%) patients in group I required additional analgesics (i.m. morphine) on their postoperative course (Table 2).

Group II was associated with a shorter hospital stay (1.6 ± 0.4 days) compared to group I (2.8 ± 0.9 days; $P < 0.05$). Besides increased hospitalization period, need for fluoroscopy and contrast agent for nephrostomy tube removal further increased related costs (Table 2). None of the patients showed evidence of perinephric collection on postoperative renal ultrasonography and computed tomography (Fig. 1). There was no readmission to the hospital due to postoperative problems.

At the 3rd month of the follow-up, successful stone removal was achieved in all patients. CIRF's were encountered in 11% and 6% of patients in group I and II, respectively, and no significant complication was observed in any case. No patient required any auxiliary procedures.

Discussion

PNL is a minimally invasive technique capable of removing even the largest and most complex

Table 1 Patient and stone characteristics (PNL: Percutaneous nephrolithotomy)

	Standard PNL (group I)	Tubeless PNL (group II)
N	18	17
Mean age (years)	41.3 ± 14.7 (range: 17–75)	38.4 ± 12.3 (range: 19–63)
Male/Female	11/7	8/9
Stone location and size:		
Renal pelvis	*n*: 9 (mean size: 3.1 cm^2) (range: 1.5–8 cm^2)	6 (mean size: 2.8 cm^2) (range: 1.5–6 cm^2)
Lower pole calyx	*n*: 9 (mean size: 3.4 cm^2) (range: 1.5–4.5 cm^2)	11 (mean size: 3.1 cm^2) (range: 1.5–4 cm^2)

Table 2 Outcome data (PNL: Percutaneous nepholithtomy, SF: stone-free, CIRF's: clinically insignificant residual fragments)

	Group I Standard PNL	Group II Tubeless PNL	*P* value
Postoperative drainage			
Nephrostomy tube	*n*: 18 (2–4 days)	0	
External ureteral catheter	*n*: 16 (1–2 days)	*n*: 15 (1–3 days)	
Double-J catheter	0	*n*: 2 (4 weeks)	
Mean operation time	67.3 ± 0.4 min) (range: 60–115)	59.6 ± 9.1 min (range: 50–90	>0.05
Postop hemoglobin drop	1.3 ± 0.2 gr/dl (range: 0–3)	1.7 ± 0.6 gr/dl (range: 1–4)	>0.05
Mean analgesia requirement			< 0.05
Diclofenac (i.m.)	200.0 ± 66.1 mg	110.3 ± 52.2 mg	
Morphine (i.m.)	24.3 ± 4.5 mg	No morphine	
Mean hospitalization	2.8 ± 0.9 days (range: 2–4)	1.6 ± 0.4 days (range 1–3)	< 0.05
Additional expenses			< 0.05
Antegrade nephrostography	*n*: 18	0	
D-J removal	0	*n*: 2	
Outcome			>0.05
Complete SF	*n*: 16 (89%)	*n*: 16 (94%)	
CIRF(+)	*n*: 2 (11%)	*n*: 1 (6%)	

renal calculi. Although the selection criteria for patients requiring PNL are well delineated, a worldwide-accepted algorithm for nephrostomy tube selection does not exist currently. The choice of nephrostomy tube to be placed after PNL usually varies widely by institution [4–11].

In a recent retrospective analysis by Kim et al. [11] an algorithm for nephrostomy tube selection after PNL for large or complex stones has been proposed. It was underlined that nephrostomy tube placement was necessary for all PNL procedures for complex stones, and that small diameter tubes would suffice in most instances, as they provide better patient comfort [11]. However, placement of a re-entry tube was suggested when there was gross residual stone burden or pyonephrosis, or when pain was not an issue (i.e., patients with spinal cord injury), while circle-loop nephrostomy tubes were advised for difficult renal anatomy necessitating multiple accesses for the clearance of the stones. On the other hand, tubeless upper-pole puncture with concomitant lower pole nephrostomy tube was advocated to minimize pleural morbidity if the kidney appeared to be stone-free at the conclusion of PNL [11].

The impact of nephrostomy tube size on postoperative discomfort has also attracted the attention of several researchers. Using visual analog scales, quality of life data, and comparing analgesic requirements, it has been shown that smaller nephrostomy tubes improve patient discomfort after PNL [12–14]. Prospectively randomized studies indicate that postoperative pain scores are significantly greater with larger diameter nephrostomy tubes [12–14].

In order to further minimize patient discomfort and hospitalization period, the possibility of eliminating the nephrostomy tube after PNL, termed as the 'tubeless' procedure, has been examined [15]. In the tubeless approach, a ureteral stent or a ureteral catheter is placed instead of a nephrostomy tube. Bellman et al. [15] were the first to underline that the urinary tract could heal without complications in the vast majority of patients, providing proper drainage to the urinary tract with the use of a ureteral stent. Following studies have demonstrated that the tubeless approach is feasible in a highly selected population that generally excludes patients requiring multiple percutaneous access points, lasting longer than 2 h, with intraoperative bleeding, or with a question of residual fragment [4, 5]. Furthermore, prospectively randomized comparative studies have shown a reduction in analgesic

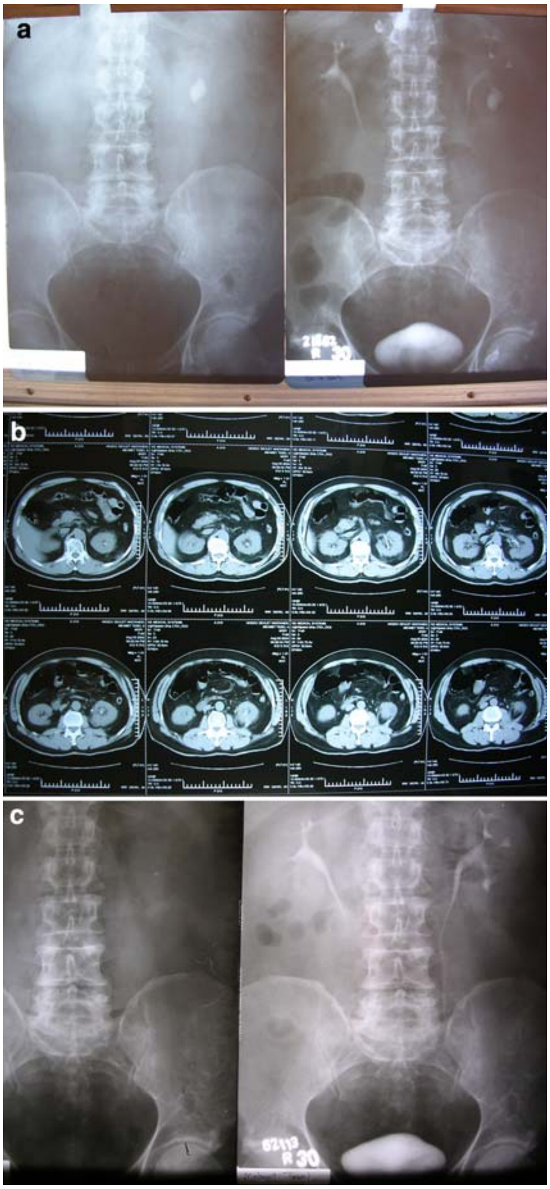

Fig. 1 (**a**) Preoperative abdominal X-Ray and intravenous urography in a patient with isolated left lower pole caliceal stone (2 × 1 cm). (**b**) Non-contrast spiral CT of the same patient 1 day after tubeless PNL shows the indwelling double-J stent but neither perirenal collection nor residual stone fragment. (**c**) Intravenous urography of the same patient 3 months after tubeless PNL, revealing a successful outcome

requirement, hospitalization period and quicker convalescence when ureteral stents were left in place for drainage instead of nephrostomy tubes [5, 8].

Indeed, Wickham et al. [16] who were the first to introduce the concept of one-stage PNL procedure, had described a 'truly tubeless' approach in their paper 1984. No external or internal draining tubes were used in 100 patients they operated, and their average hospital stay was 2.8 days [16]. However, these results were questioned by Winfield et al. [17] who reported 2 patients with simple renal stones they treated with 'tubeless' PNL procedures that were complicated by significant postoperative hemorrhage. Therefore, they recommended the use of nephrostomy tube for drainage after PNL [17] . In the years that followed, placement of nephrostomy tube became the routine standard of care after PNL procedures.

Probably due to the rapid improvements in PNL, Bellman et al. [15] and Bdesha et al. [18] independently challenged the requirement of routine placement of a nephrostomy tube after percutaneous renal surgery in 1997. The tubeless procedure they described involved the placement of internal ureteral stent, and hospitalization period, analgesia requirement, time to return to normal activities and cost were significantly less with this modification. Therefore, this new technique gained popularity. Subsequent studies with minor modification in terms of the placement of internal or external ureteral stents from other centers confirmed the efficacy and safety of the tubeless technique [19–21]. These were followed by a large number of prospective studies, comparing the outcome of tubeless PNL with the standard procedure, and all underlined the advantages of the tubeless procedure [5–10, 22]. In 2002, Limb and Bellman reported the largest series with the tubeless PNL and underlined the strict indications [4]. In their study, 112 patients were qualified for the tubeless approach and this consisted 28% of their PNL series operated during a 5-year period. Their inclusion and exclusion criteria were very strict. Furthermore, the mean stone burden in their tubeless PNL series, which included shock wave lithotripsy failures in 33%, can be considered small (mean 3.3 cm^2) for percutaneous surgery. Therefore, a high stone-free rate was achieved in their study [4]. Similarly, the mean stone burden managed with the tubeless PNL in published series is generally small, and it is not surprising to note high stone-free rates in these studies.

In the present study, a total of 38 patients were qualified for the tubeless PNL during a 1-year period, and this consisted 17.4% of the patients managed with percutaneous surgery during the same period. The mean stone burden in the tubeless group was 3 cm^2 (range: 1.5–6 cm^2), and all were located either in the renal pelvis or in the lower pole calix, rendering them to be classified as simple stones. Success was achieved in 96%, and with increasing experience; larger stones are being managed by the tubeless technique. Taking these into consideration, tubeless PNL can be regarded to be indicated in simple renal stones with mild-moderate size.

The major advantages of the tubeless procedure stand out to be the diminished hospitalization periods and postoperative analgesic requirement [6–9, 22–24]. In the present study, the mean hospitalization period in the tubeless group was 1.6 days, and 52.9% of them were sent home 24 h after surgery, whereas patients managed with standard PNL were hospitalized for a mean of 2.8 days. The nephrostomy tube seems to be a major determinant of postoperative pain as supposed by previously published series, and this can explain diminished analgesic requirement in the tubeless group.

Yew and Bellman [23] have recently reported a further modification using a tail-stent, which could be removed by pulling the string of the stent exiting the meatus 5–7 days after the tubeless PNL operation. In the present study, the simple (non-tail-head) ureteral stent, which was placed at the beginning of the PNL procedure, was left in place overnight as an external ureteral stent in patients without a pre-existing double-j stent in the tubeless PNL group. This ureteral stent was easily removed together with the urethral Foley catheter on postoperative day 1 without need for cystoscopy. Besides supplying drainage, the aim of leaving the ureteral stent overnight in the tubeless PNL group was to obtain ascending nephrograms in patients with prolonged leakage from the flank without any additional need for cystoscopy. However, no patient in the tubeless group experienced this complication in our series.

Diathermy coagulation of intrarenal bleeders in tubeless PNL was described by Aron et al. [24] but they could not show any statistically significant difference in operative times and drop in hemoglobin when compared with the control group, although they underlined a significant reduction in the length of hospital stay and postoperative analgesic requirement in the fulguration group. Electrocauterization of the bleeding points during PNL is being regarded to enable more patients suitable for the tubeless modification [25].

A totally tubeless as well as stentless PNL procedure, as initially described by Wickham et al. has recently been reported to be safe and effective [22, 26]. However, our experience suggests leaving the ureteral stent, placed preoperatively, overnight, since this does not cost additional expenses to the procedure.

Although the financial aspects were not assessed directly in this study, diminished hospital stay and analgesic requirement as well as elimination of the procedure for postoperative nephrostomy tube removal, which is ideally done under fluoroscopy, significantly curtail the total cost of the procedure. The cost of percutaneous surgery has been examined by Candela et al. from Los Angeles, and a cost saving of 2,112 $ per case has been found with the tubeless procedure [10].

Another technical modification initially reported again by Bellman et al. was the use of fibrin glue to occlude the percutaneous tract in tubeless PNL [27] Other authors have also examined instillation of hemostatic agents directly into the acute nephrostomy tract, and satisfactory preliminary results have been reported [28, 29]. Uribe et al. [30] investigated what would happen to the hemostatic agents when they get in contact with urine using in vitro experiments and concluded that only gelatin matrix remained as a fine particulate suspension in urine within 5 days. Further studies are awaited to adjust the exact place of hemostatic agents in percutaneous renal surgery, but the tubeless procedures will be probably performed more commonly with expanding indications with the widespread use of these hemostatic sealing agents.

Conclusions

Our results indicate that tubeless PNL is safe in the management of selected patients with simple renal stones of mild-moderate burden and that mean hospitalization time, as well as analgesia requirement is diminished with this modification. Further refinements will probably qualify increased number of patients as candidates for tubeless PNL.

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