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Questioning the wisdom of tubeless percutaneous nephrolithotomy (PCNL): a prospective randomized controlled study of early tube removal vs tubeless PCNL

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Accepted for publication 9 November 2009

Study Type – Therapy (RCT)
Level of Evidence 1b

OBJECTIVE

To establish the efficacy of early removal of a nephrostomy tube after percutaneous nephrolithotomy (PCNL), to challenge the wisdom of tubeless PCNL, as we hypothesized that it would result in a shorter hospital stay, comparable benefit and safety, while maintaining the option of check nephroscopy ensuring far superior stone clearance.

PATIENTS AND METHODS

In all, 22 patients were prospectively randomized equally into two groups, group 1 (early nephrostomy removal) or group 2 (tubeless) during a 1-month study period. Inclusion criteria for the study were: a simple stone of <3 cm, no significant bleeding, no perforation, single-tract access and 'on-table' complete stone clearance. In group 1, a 20 F nephrostomy, 6 F retrograde ureteric catheter and a Foley catheter were used, while in group 2 only a 6 F retrograde ureteric catheter and Foley catheter were placed at the end of the procedure. Computed tomography (CT) with no contrast medium was done on the first morning after surgery before removing all catheters/tubes, and patients discharged subsequently. The variables assessed were stone clearance, hospital stay, analgesic requirement, postoperative complications and auxiliary procedures.

RESULTS

The mean (SD) stone bulk was similar between the groups, at 2737 (946.9) and 2934.2 (2090.7) μL, respectively. Despite an on-table complete clearance, clearance assessed by CT was nine of 11 vs eight of 11 in groups 1 and 2, respectively. CT showed a 6 mm stone in one patient in group 1, while the remaining patients had stones of <4 mm. The mean (SD) analgesic requirement, haemoglobin decrease, urine leak and hospital stay in the two groups were 72.7 (51.8) vs 68.2 (46.2) mg of tramadol (P = 0.25), 1.6 (0.7) vs 1.6 (0.9) g/dL (P = 0.39), 13.9 (6.3) vs 7.1 (14.2) h (P = 0.018) and 72.8 (2.1) vs 70.2 (18.5) h (P = 0.09), respectively. Complications noted were early haematuria in none vs three (P = 0.21), urinoma none vs one, and fever in two vs one, respectively; one patient in group 1 required a check nephroscopy for a residual fragment. Overall clearance including re-treatment was 10/11 vs eight of 11 (P = 0.009), respectively.

CONCLUSION

Early tube removal after PCNL results in an equivalent analgesic requirement, decrease in haemoglobin and hospital stay as tubeless PCNL. It has a significantly lower incidence of early haematuria, better clearance rates and preserves the option of check nephroscopy. It can be considered as an accepted standard of care, with the preserved advantages of tubeless PCNL.

KEYWORDS

tubeless, modified PCNL, randomized control study

INTRODUCTION

Placing a nephrostomy tube after percutaneous nephrolithotomy (PCNL) is considered standard practice. The advantages of nephrostomy-tube drainage include adequate renal drainage, tamponade of tract bleeding and allowing the nephrostomy tract to 'mature' for a second-look procedure. There are many prospective randomized controlled studies [1–3] which concluded that patients with a nephrostomy have more postoperative discomfort, analgesic requirement and prolonged hospital stay than those with a tubeless PCNL. The latter is a safe and effective option for treating large renal calculi in selected patients. The stone clearance rate with tubeless PCNL is reported to be 73–100% [1].

To test the wisdom of using a tubeless PCNL, we modified our standard PCNL (early tube removal, group 1) technique. All the external body catheters/tubes, including nephrostomy, ureteric and Foley catheter, were removed in patients undergoing modified PCNL on the first day after surgery (group 2). This was advantageous in group 1, as patients benefited from the nephrostomy tract compression immediately after surgery, and a similar hospital stay as in group 2, where the catheter was removed irrespective of the findings on non-contrast enhanced CT. We prospectively evaluated 22 patients to establish whether tubeless PCNL (group 2) had any advantage over modified PCNL (early tube removal, group 1).

PATIENTS AND METHODS

Approval for the study was obtained from the institution's ethical committee, and informed consent obtained from all eligible patients (28) at the time of admission. The inclusion criteria for the study were: stones of <3 cm, single-tract access, no serious bleeding or perforation of the pelvicalyceal system and complete clearance at the end of the procedure, as judged by intraoperative fluoroscopy. The patients were given information about the study beforehand, and if they could not meet the criteria, a hospital protocol for standard PCNL was followed. In all, 28 patients gave consent for the study; six were excluded because they did not meet the intraoperative criteria, and thus the remaining 22 were assessed prospectively.

PCNL was carried out by a team of endourologists with the main operating surgeon being the same (R.B.S), as a one-stage procedure in an operating theatre equipped with ultrasonography and C-arm fluoroscopy. The patient was placed prone after cystoscopy and retrograde ureteric catheterization. Selective calyceal puncture, usually at the posterior lower pole calyx, was carried out with a 22 G Skinny Needle (Cook Medical, Bloomington, IN, USA) under ultrasonographic control. A guidewire was secured in position, preferably down to the ureter. The upper pole was the second-best guidewire position. Tract formation proceeded with metallic telescopic coaxial dilators to the final insertion of a 24–28 F Amplatz dilator working sheath (Cook Medical). Stones identified on rigid nephroscopy were fragmented by Lithoclast or removed intact. The patient was considered eligible for study randomization if no renal calculi were identified on intraoperative fluoroscopy.

The patients were then randomly assigned to either group 1 or 2, by selection of a pre-prepared paper by an independent observer, before removal of the sheath; 11 patients were allocated into either group during a 1-month study period, the number deemed necessary for statistical significance. Group 1 patients had a 20 F nephrostomy tube placed in the kidney over the guidewire, which was then removed. The nephrostomy was clamped in all patients in group 1 for 6 h immediately after the procedure was completed. Group 2 patients had the wire removed and the wound compressed for 5 min. In both groups the patient was monitored for stable vital signs. The analgesic requirement was defined as the amount of tramadol used. On the first morning after PCNL, all patients were assessed with non-contrast CT. Overall clearance was defined as complete clearance with no evidence of clinically insignificant residual fragments on CT. Re-treatment was defined as a check nephroscopy for a residual fragment of >4 mm. Re-treatment was applicable for group 1 patients who had a nephrostomy *in situ*, while only observation or an auxiliary procedure was done for group 2 patients. After CT, all the external body tubes, i.e. nephrostomy tube, ureteric and Foley catheter, were removed unless re-treatment was required. The duration of urine leakage was defined as the time between the nephrostomy/Amplatz removal to the last documented leak from the puncture site, as perceived by the patient. Re-treatment was planned after 24 h. In group 2, irrespective of the residual fragments, the Foley and ureteric catheters were removed. The patient was observed for ≥6 h before a decision was made about discharge. The groups were analysed when the last patient completed the 1-month follow-up. For study analysis, demographic details, including age, sex, laterality, body mass index (BMI), stone volume and kidney cortex were noted. Variable during and after surgery included in the analysis were size of Amplatz sheath placed, haemoglobin decrease, analgesic requirement, CT variables, e.g. residual stone number, size and collection, duration of urine leakage after nephrostomy or Amplatz sheath removal, re-treatment rates, auxiliary procedures and overall clearance rate in either group. Bleeding was defined as haematuria from the Foley catheter within 6 h after the procedure sufficient to alarm the treating endourologist.

The sample size of 22 patients (11 in each in group) for this randomized trial was taken from our in-house data for PCNL. The numeric and discrete variables between the groups were analysed by Student's *t*-test and chi-square contingency 2 × 2 table, respectively, with $P < 0.04$ considered to indicate statistical significance. The power of the study was 0.849 ($1 - \alpha$), obtained from a power and sample size calculation.

RESULTS

Of the 22 patients recruited, group 1 comprised seven left- and four right-side procedures, with a mean patient age of 42.5 years, and in group 2, six left- and five right-side procedures, with a mean patient age of 42.3 years ($P = 0.48$). The other patient demographics are shown in Table 1. There were no significant demographic or case selection differences between the groups.

Variables after surgery are also shown in Table 1; CT showed residual fragments in two patients in group 1 and three in group 2. One patient in group 1 (Fig. 1) was re-treated by check nephroscopy, while only observation was used in the other patients. The decrease in haemoglobin and the analgesic requirement was not significant in either group. There were no transfusions in either group. Initial haematuria was more common in group 2 but was not statistically significantly different. One patient in group 2 required a bladder wash for clot retention. Urine leakage was statistically less common in group 2; we did not place any tract sealant to reduce urine leakage. One patient in group 2 had a 9.5 × 8.4 cm collection in the left iliac fossa in the retroperitoneum on CT; the patient was symptomatic with abdominal pain and fever. The collection was aspirated. A retrograde dye study showed no leak and he subsequently had a JJ stent and Foley catheter drainage, after which he improved gradually.

The outcome variables are also shown in Table 1; the overall clearance after combining re-treatments in group 1 were statistically significantly different from that in group 2.

During the 1-month follow-up, the patients were assessed for general well-being, any complication and by abdominal ultrasonography. There were four patients with clinically insignificant residual fragments (CIRF) at the end of the procedure. One patient with CIRF in group 2 had acute-onset ureteric colic 3 weeks after surgery, followed by lithuria. The remaining three patients were asymptomatic at the 1-month follow-up.

DISCUSSION

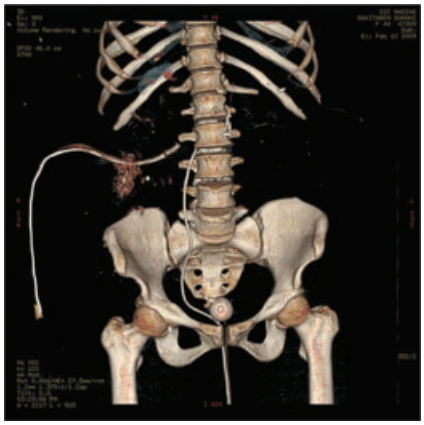
Standard PCNL is followed by nephrostomy tube drainage, the advantages of which include acute compression of the tract to stem bleeding, and using the same tract for check nephroscopy if required. Tubeless PCNL was promoted by Bellman *et al.* [4] in 1997 and consists of PCNL with no nephrostomy at the end of procedure. It is usually advocated in patients with normal renal function, single-tract access with complete clearance, and no

TABLE 1 Demographics, perioperative values and outcome

Mean (SD) or n variable	Group 1	Group 2	P
Age, years	42.5 (7.8)	42.3 (8.6)	0.48
BMI, kg/m^2	24.3 (3.2)	25.1 (3.1)	0.28
Stone bulk, μL	2737 (946.9)	2934.2 (2090.7)	0.18
Number of stones	1.8 (0.8)	1.5 (0.7)	0.19
Kidney cortex, mm*	18.4 (3.3)	17.4 (3.2)	0.25
Amplatz sheath, F	26.7 (1.0)	26.5 (1.3)	0.35
Fragmentation (Lithoclast)	7	7	0.65
Intact removal	4	4	0.65
CT max fragment, mm	6	4	0.67
Haemoglobin decrease, g/dL	1.6 (0.7)	1.6 (0.9)	0.39
Analgesic requirement, mg tramadol	72.7 (51.8)	68.2 (46.2)	0.25
Urine leakage, h	13.9 (6.3)	7.1 (14.2)	0.018
Hospital stay, h	72.75 (2.1)	70.2 (18.5)	0.09
Complications			
Initial haematuria	0	3	
Clot retention	0	1	
Fever	2	1	
Perinephric collection	0	1	
Outcome			
On-table fluoroscopic clearance	11/11	11/11	
Postoperative CT clearance	9/11	8/11	0.14
Re-treatment (check nephroscopy)	1	0	
Auxiliary procedure (JJ stenting)	0	1	
Overall clearance	10/11	8/11	0.009

**mid pole maximum cortical width as determined by ultrasonography.*

FIG. 1. Reconstructed abdominal CT of a group 1 patient having a residual stone of 6 mm, with nephrostomy and ureteric catheter in situ.



intraoperative complications. The safety of tubeless procedure has been confirmed in various series [1–9].

If the tubeless procedure is used the flank is compressed for a brief period to tamponade the bleeding. Also, various types of tissue sealants have been described, e.g. fibrin glue, gel matrix and diathermy cauterization of tract [6,10–12]. Advanced application techniques like occlusion balloons, as described by Lee *et al.* [11], add to the costs of a tubeless procedure. In the present study no tract sealant was used. There was a significantly higher incidence of early haematuria in these patients; one progressed to develop clot retention that required evacuation. However, the decrease in haemoglobin level was insignificant in both groups. Whether the increased incidence of early haematuria was due to not using a tract sealant is questionable, because few prospective studies have assessed the role of sealant with no further increase in the incidence of haematuria [13,14].

The incidence of postoperative collection (0–6%) is hypothesized to be greater in tubeless PCNL. Ultrasonography was used to assess this incidence, but CT is much more sensitive for this. Only one patient in group 2 had a collection requiring aspiration, retrograde dye study and JJ stenting. This might have been an isolated event, with fluid leaking across the Amplatz sheath during surgery. This patient had no leakage from the pelvicalyceal system during a retrograde study.

To improve safety it is worthwhile considering adequate nephrostomy drainage for a brief duration to overcome these early complications. In the standard PCNL, a postoperative clearance study with a plain abdominal film is usually done after 48 h, giving time for the bowels and haematuria to clear. A logical step forward in standard PCNL would be to find ways to reduce the time for tube removal and then question the wisdom of tubeless PCNL. This would theoretically reduce the discomfort of prolonged nephrostomy drainage and would shorten the hospital stay, reducing the advantage of a tubeless procedure. This, in addition to compressing the tract immediately after surgery to reduce tract bleeding, and use of the tract for a repeat procedure if required for residual stones to increase the clearance rate, would tilt the balance in its favour. The first modification applied was the use of a retrograde ureteric catheter instead of a JJ stent. The advantage of keeping a ureteric catheter are many. First, it reduces stent-related morbidity and avoids an endoscopic procedure for removal; second, it reduces the duration of urine leakage by preventing reflux; and finally, it reduces the cost. The second modification was the use of non-contrast CT on the first day after surgery. The purpose of this was first that the scan was not affected by bowel status, second, it was more sensitive for diagnosing residual stones, and third, it was more sensitive for diagnosing complications. With these modifications we showed that the advantages of tubeless PCNL were not significantly different from early tube removal. In addition, the incidence of early haematuria and collection were less, and clearance rates greater with early tube removal.

The success of any variation from standard PCNL can be gauged by the overall stone clearance rate. Brusky *et al.* [15] reported a 13% incidence of re-treatment in the tubeless group, for non-staghorn calculi; 15% of the patients needed an auxiliary procedure. Most of the stones remaining are CIRF; it was confirmed that CIRF can lead to symptomatic episodes in the future and hasten stone recurrence. Routine use of non-contrast CT after treatment might lead to over-detection

of CIRF, which is clinically relevant. Routine tubeless PCNL is followed JJ stenting, the purpose of which is to facilitate expulsion of these CIRF. It also leads to stent-related morbidity and secondary endoscopy for removal. Shah *et al.* [13] reported symptoms in 30% of patients, of whom 60% required medication. One of the advantages of early tube removal can be the use of the tract if the size of the residual fragment load is greater. We had one patient with a residual fragment of 6 mm, which to our surprise was not detected by on-table fluoroscopy. This patient benefited from a check nephroscopy and stone removal. When overall clearance was considered, group 1, because of this advantage, had a better rate than group 2 in our study. However, this has not been reported in other series. For CIRF of <4 mm, we do not think that the management should differ in either group. One patient with CIRF in group 2 had acute onset ureteric colic at 3 weeks after surgery, followed by lithuria, thus underscoring the importance of complete clearance.

The next question is whether tubeless PCNL is appropriate. We found that the analgesic requirement, decrease in haemoglobin level, and complications were the same in both groups. Moreover, the option of using the tract for removing residual fragments remains; even if there is bleeding or perforation of the pelvicalyceal system, the procedure can be used without jeopardizing the shorter hospital stay. We identified only one outcome variable where the tubeless procedure had an advantage; the duration of urine leakage was statistically less in the tubeless group. This can be explained, because in group 2 there was an initial period of antegrade drainage via the ureteric catheter on the day of surgery, but in group 1, there was no antegrade drainage as all the body tubes were removed at the same time. Overall, with the practice of removing the body tube drains on the first day after surgery, this could not translate into a longer hospital stay in group 1.

To increase the cost efficiency of the procedure, we used a ureteric catheter instead of JJ stents. In addition, the procedure per se did not require tissue sealants and applicators, reducing costs. Any patient who is clinically and intraoperatively fit for a tubeless procedure is fit for early tube removal. It can also be used in patients with more than one access tract, intraoperative bleeding and pelvicalyceal system perforation. However, the safety in these extended indications must be assessed in prospective studies.

In conclusion, the real challenge to the wisdom of the tubeless procedure is from our modified PCNL (early tube removal) technique. Our study showed that early tube removal was safer, more appropriate, effective and cost efficient than tubeless PCNL. Further prospective studies with adequately powered samples are needed to establish its superiority.

CONFLICT OF INTEREST

None declared.

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Abbreviations: **PCNL**, percutaneous nephrolithotomy; **BMI**, body mass index; **CIRF**, clinically insignificant residual fragments.

EDITORIAL COMMENT

Tubeless PCNL was introduced and popularized by Bellman and colleagues in the late 1990s. Since then, numerous reports have emerged advocating and scrutinizing the techniques and modifications, both in randomized and non-randomized fashion. However, most authors would elect to place a nephrostomy tube in selected cases when a second procedure is needed, or when significant bleeding or trauma occurs during the initial procedure. Therefore, leaving a nephrostomy tube for a 24-h period is not unique to those routinely using PCNL. This

report, with the conclusions of early PCN removal being equivalent to the tubeless technique, seems to me to be a backward step in the development of the PCNL procedure. Where many urologists have moved away from the use of a nephrostomy tube, this group is now advocating postoperative use but early removal, a practice that many have done for years. In my practice, ureteroscopy is routinely used for removing residual fragments of <1 cm, thereby facilitating the tubeless technique for most patients. Clearly, nephrostomy tubes continue to play a role in percutaneous stone management. Investigators must be seeking safer and more innovative ways to access kidneys, remove renal stones, seal the tract or percutaneously manoeuvre around the intra-renal collecting systems.

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