

Postoperative morbidity of tubeless versus conventional percutaneous nephrolithotomy: a prospective comparative study

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Abstract Percutaneous Nephrolithotomy (PNL) is an established technique for the treatment of renal calculi. Some reports have challenged the need for a nephrostomy tube at the end of the procedure, arguing that it accounts for a longer hospital stay and increased postoperative pain. During the last years, several series have addressed the feasibility and safety of tubeless PNL, where a double-J ureteral stent is left in place after the end of intervention instead of a nephrostomy tube. The aim of our study was to compare conventional versus tubeless PNL in terms of postoperative morbidity. Eighty-five patients who underwent PNL at a single center met the inclusion criteria (complete intraoperative stone clearance, no evidence of active intraoperative bleeding, single percutaneous access, and operative time shorter than 2 h) and were randomized at the end of the procedure to have placed either a nephrostomy tube (group 1) or a double-J ureteral stent (group 2). Outcomes assessed were postoperative pain, bleeding complications, leakage complications, and length of hospital stay. The patients in the tubeless group had a shorter hospital stay (3.7 vs. 5.8 days; $P < 0.001$), and less postoperative pain at postoperative days 2 and 3 ($P < 0.001$). No significant difference in bleeding or leakage complications was observed. This study supports

the feasibility and safety of tubeless PNL in a selected group of the patients, suggesting some intraoperative criteria to be considered when performing it. However, further controlled studies will have to determine its impact on stone-free rates prior to be considered the standard technique in these selected cases.

Keywords Nephrostomy · Percutaneous · Urinary catheterization · Postoperative period · Nephrolithiasis

Introduction

Urolithiasis has a significant morbidity. Its estimated prevalence is 2–3%, with a peak incidence between the third and fourth decades. Between 10 and 15% of cases will require some surgical intervention. Recurrence rate is of up to 50% without medical follow-up [1].

Alken [2], Clayman [3], and Segura [4] described a minimally invasive technique for treatment of renal calculi based on percutaneous nephrostomy described by Goodwin [5]. Percutaneous nephrolithotomy (PNL) quickly outmoded open surgery as treatment of choice for renal lithiasis due to its lower morbidity in the presence of equivalent outcomes, doubling the number of procedures carried out per year in the US between 1988 and 2002 [6]. Introduction of shockwave lithotripsy (SWL) in 1983 curtailed PNL indications. Today, PNL is considered the treatment of choice for renal stones larger than 2 cm, staghorn calculi, and lower calyx calculi larger than 1 cm [7, 8]. The conventional technique comprises the positioning of a nephrostomy tube in the percutaneous path once calculi have been extracted to improve hemostasis and allow adequate urine draining while avoiding its extravasation. It is also an useful tool for collecting system

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access in case of postoperative diagnostic and/or therapeutic procedures.

Some authors [9] have questioned the need for a nephrostomy, arguing that in a considerable number of the patients, postoperative bleeding is minimal and further procedures are not planned (stone-free patients). In these patients, the nephrostomy tube would be associated with more postoperative pain and longer hospital stays. According to this, the “tubeless” modification was introduced to the PNL technique, consisting in the omission of the nephrostomy tube, while placing an antegrade double-J ureteral stent instead. During the last years, there has been a growing interest in tubeless PNL. Since 1997, several studies have backed up the feasibility in performing tubeless PNL, including non-selected patients with PNL indication [10]. However, few studies have compared results of tubeless PNL to the conventional technique [11–13].

The aim of our study was to compare postoperative morbidity of conventional and tubeless PNL, under the hypothesis that the tubeless technique would result in less postoperative pain, shorter hospital stays and at least an equal rate of complications.

Patients and methods

Between November 2006 and December 2007, 90 patients undergoing PNL at our institution were enrolled in this study previously approved by the institutional review board. Informed written consent was obtained previous to enrollment. Eighty-five patients met the inclusion criteria, namely: single sub-costal access, complete endoscopic and fluoroscopic clearance of stone fragments, or presence of residual lithiasis <4 mm, and reduced intraoperative bleeding. The patients were randomized using the simple random allocation method. This information was disclosed to the surgeon by the operating room nurse once the inclusion criteria were fulfilled. By these means, 45 patients were assigned to group 1 (conventional technique) and 40 patients to group 2 (tubeless technique). All cases excluded from the study had residual fragments ≥ 4 mm.

All the patients received Ceftriaxone 1 g i.v. the day before surgery and during anesthetic induction. None of the patients presented urinary tract infection (UTI) at the time of surgery. All procedures were carried out under general anesthesia using intravenous Propofol, Rocuronium, and Fentanyl, and inhalatory Sevoflurane after endotracheal intubation. The puncture was performed with the patient in prone position, under fluoroscopic guidance, contrasting the collecting system by means of an ureteral catheter which had been placed previously in a retrograde fashion. Tract dilation was achieved by a set of fascial dilators (Cook Urological, Spencer, IN) obtaining a path of 28 FR

in diameter into which an Amplatz sheath was fitted. A Nephroscope (Karl Storz Endoskope, Germany) in a 24 FR sheath was used and intracorporeal lithotripsy was carried out with a pneumatic lithotripter (Brokstone, Chile).

Once stone extraction was completed, the patients in group 1 were fitted with an 18 FR Foley catheter into the percutaneous path, which was clamped on the second postoperative day and removed after 24 h if there was mild or no pain. The patients in group 2 were fitted with an antegrade 7 FR double-J ureteral stent. An oxidized cellulose gauze was placed on the extrarenal percutaneous path. The puncture site was sutured with separate 3/0 silk stitches. The double-J stent was removed by flexible cystoscopy with local anesthesia 10–14 days after surgery.

Initial postoperative analgesia consisted of a Metamizole Sodium i.v. as a continuous infusion. Pain was evaluated every 6 h by a trained nurse applying the visual analog scale of pain (VAS) [14]. The patients with moderate or severe pain (VAS score higher than 3) received Ketoprofen 100 mg i.v. or Tramadol 50 mg i.v. in the patients allergic to non-steroidal analgesics or with diminished glomerular filtration rate (creatinine clearance < 60 ml/min). Infusion was stopped if mild or no pain (VAS < 4). After that, Acetaminophen 1 g po t.i.d was prescribed.

All the patients were controlled on the first postoperative day after surgery with a renal ultrasound, a plain film (KUB) and a hematocrit. The patients were discharged after ruling out complications by these methods and if VAS < 4 under oral analgesia. Hospital stay length and occurrence of bleeding (assessed by hematocrit drop, transfusion requirements, and presence of hematoma on the renal ultrasound) and leakage (defined as the presence of urine extravasation or urinoma on the renal ultrasound) were recorded.

Statistical analysis was performed with the SPSS 15.0 Software (SPSS Inc, Chicago, IL). Means were compared using the *t* test for independent samples before application of Levene’s test to assess equality of variances. A *P* value of <0.05 was considered as significant.

Results

Demographic and clinical characteristics of both groups are listed in Table 1. Both groups were comparable regarding weight, height, body mass index (BMI), preoperative hematocrit, and stone size. Mean age was significantly higher for group 2 than for group 1 (*P* = 0.027). Stones were located on the lower pole (35.5%), pelvis (44.4%), or were staghorn calculi (20%).

Results are summarized in Table 2. In the VAS score analysis, results were comparable on postoperative day 1,

Table 1 Demographic and clinical characteristics

	Group 1	Group 2	<i>P</i> value
Age (years)	47.2 (10.1)	52.8 (12.5)	0.027*
Weight (kg)	76.1 (11.9)	76.6 (12.4)	0.868
BMI	27.8 (3.0)	28.7 (4.8)	0.308
Stone burden (cm ²)	7.8 (4.8)	6.4 (3.0)	0.120
Preoperative hematocrit	42.2 (5.2)	40.4 (3.8)	0.071

Values in brackets show standard deviation (SD). Comparison of means was made using student's *t* test. Asterisk denotes statistical significance ($P < 0.05$)

Table 2 Postoperative morbidity

	Group 1	Group 2	<i>P</i> value
Hospital stay post PNL (days)	5.0 (2.8)	3.2 (0.7)	0.001*
Hematocrit drop (g/dl)	5.9 (5.2)	4.6 (2.5)	0.22
VAS score day 1 (mean)	5.9 (1.2)	5.5 (1.1)	0.18
VAS score day 2 (mean)	5.0 (0.8)	3.4 (0.7)	<0.001*
VAS score day 3 (mean)	4.4 (1.1)	1.7 (1.1)	<0.001*

Values in brackets show standard deviation (SD). Comparison of means was made using student's *t* test. PNL percutaneous nephrolithotomy, VAS visual analog scale. Asterisk denotes statistical significance ($P < 0.05$)

however, group 2 patients presented significantly less pain than group 1 patients on the second and third postoperative days ($P < 0.001$). Accordingly, the overall rate of patients requiring additional analgesics was significantly higher on

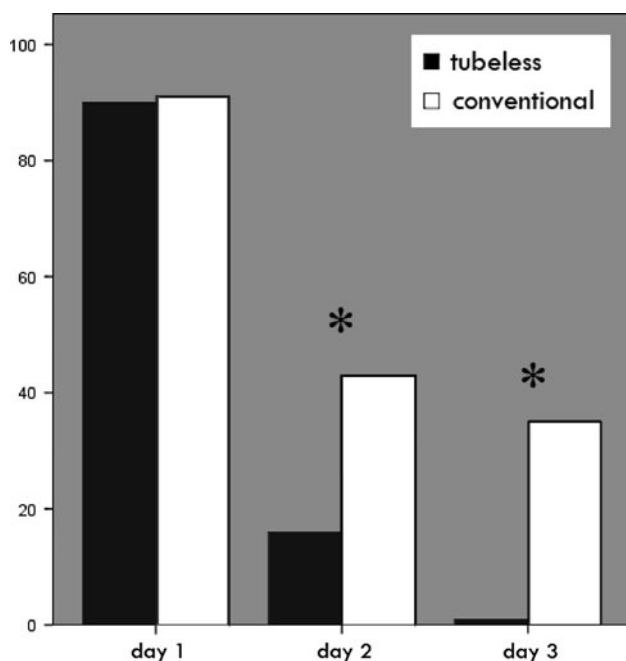


Fig. 1 Rate of patients requiring additional analgesia. Asterisk denotes statistical significance ($P < 0.05$)

postoperative days 2 and 3 ($P < 0.03$) (Fig. 1). Patients in group 2 were discharged earlier than those in group 1 ($P = 0.027$). Pain after clamping the nephrostomy tube accounted for most of this difference. The nephrostomy tube was removed before discharge in all the patients.

In terms of bleeding complications, both groups had a similar hematocrit drop ($P = 0.22$). One patient in group 1 presented with a retroperitoneal hematoma of 30×11 cm on postoperative renal ultrasound with a hematocrit drop of 26% (postoperative hematocrit of 23%). Two patients in group 2 presented retroperitoneal hematomas, one 8.7×4 cm and another 1×5 cm. They were all managed in a conservative way as they did not affect hemodynamics. Blood transfusions were not indicated since acute anemia was not noticed. No leakage complications were observed on either group.

Discussion

Following a single access PNL with complete stone clearance and no active bleeding, nephrostomy placement was compared to antegrade double-J stent placement, in terms of hospital stay length, postoperative pain, and complications. Conformably with previous reports [15–19], the tubeless variation appears to be feasible and can be performed safely in this selected group of the patients undergoing PNL, as there was no evidence of major bleeding or any other complication in the tubeless group. This study provides evidence that the tubeless PNL technique is associated with a significant decrease in hospital stay length, postoperative pain scores and analgesia requirements in the patients with a single sub-costal access, no evidence of active bleeding, and complete endoscopic and fluoroscopic clearance or residual fragments <4 mm. Care was taken to specify discharge criteria to make length of stay an objective measure of procedure outcome, but many factors may bias this variable, including health care system policies, patient concomitant morbidities, and investigator induced bias as this study was not blinded.

Pain is a subjective variable, and may be influenced by the patient age as nociception and pain responses decrease in elder patients. Patients in the tubeless group were significantly older than the patients in the nephrostomy group, however, it is unlikely that this difference is clinically significant, since it appears rather small and both groups belong to a similar range of age (52 vs. 47 years). One important drawback to be considered is that double-J stent associated morbidity was not taken into account in this study. Although no mortality attributable to the stent has been reported so far, a 30–80% overall quality of life impairment has been reported in stented patients [20–24]. According to Leibovici et al. [25], most common symptoms are dysuria, urinary frequency and urgency, presenting in up

to 50% of patients. Flank pain can present in up to 30% and macroscopic hematuria in up to 50% of the patients. Other complications include sexual dysfunction, anxiety and sleep disorders, urinary tract infections, upward migration, and incrustation. The need for cystoscopy to remove it was also not taken into account. This ancillary procedure increases the cost and may be also associated with morbidity such as the patient discomfort, bleeding, and urinary tract infection. Fortunately, these adverse events are rare [26].

The choice between a nephrostomy and an ureteral stent to ensure drainage after PNL is based on the surgeon clinical judgment. We attempted to define the group that would benefit from the tubeless technique, establishing inclusion criteria. Intraoperative bleeding is a subjective variable, where the surgeon's clinical judgment becomes relevant when assessing the percutaneous path to decide whether there is a vascular injury which would justify setting up a nephrostomy.

Another variable considered in this study was the number of percutaneous accesses used. In the conventional PNL technique, more than one access increases the possibility of posterior leakage when the nephrostomy is removed. For this reason it was deemed appropriate to perform the tubeless technique in the patients with only one transpapillary access.

Stone free or clinically insignificant residual fragments were defined as the absence of residual fragments >4 mm. We acknowledge the fact that the term "clinically insignificant" is derived from early shockwave lithotripsy studies, and might be misused because fragments smaller than 4 mm are associated with a risk of stone-related event of 40% after a mean follow-up of 37 months, of which up to 57% may require surgery [27]. The patients were evaluated per protocol using postoperative renal ultrasound and KUB, therefore our actual stone-free results (considering unenhanced computerized tomography as the gold standard) are unknown. The potential increase of clinically significant residual stones in this context, without the possibility of a second look in tubeless cases, should then be critically evaluated. Postoperative unenhanced CT has shown a better sensitivity than intraoperative fluoroscopy and renal ultrasound for evaluation of residual stones, and future studies should incorporate this method.

Finally, the use of a smaller bore nephrostomy tube or an externalized ureteral catheter placed at the beginning of the procedure for a short period instead of the double-J stent may be alternatives to reduce stent and cystoscopy-related morbidity.

Conclusions

Tubeless PNL is a feasible and safe procedure in selected patients, as shown by its reduced postoperative morbidity.

However, further controlled studies will have to determine its impact on stone-free rates, as this is still the main outcome of surgical therapy for urolithiasis.

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