

Immediate postoperative morbidity in patients with indwelling double-J stent versus overnight-externalized ureteral catheter after tubeless percutaneous nephrolithotomy: a prospective, randomized study

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Abstract The conventional technique for percutaneous nephrolithotomy (PNL) ends by placing a nephrostomy tube within the access tract. However, feasibility and safety of tubeless PNL have been widely demonstrated. In this modification, a ureteral stent is usually left in place instead of the nephrostomy tube. The aim of this study is to compare the use of a postoperative indwelling double-J stent versus an overnight-externalized ureteral catheter in patients undergoing tubeless PNL. Sixty-eight patients undergoing tubeless PNL were randomized either for a postoperative double-J stent (group 1) or for an overnight-externalized ureteral catheter (group 2). Outcomes evaluated included postoperative pain, hospital stay length, incidence of hemorrhagic complications, residual lithiasis and urinary leakage. Groups were similar according to age, sex, body mass index and stone burden. There were no significant differences in terms of postoperative pain, incidence of perirenal hematomas, residual lithiasis and urinary leakage. However, patients in group 1 presented longer hospital stays (3.7 ± 1.7 vs. 1.9 ± 0.3 days; $p < 0.001$) and greater hematocrit drops (4.9 ± 2.2 vs. 2.1 ± 1.8 %; $p < 0.001$). Our results confirm that among patients undergoing tubeless PNL, both alternatives (i.e. leaving a double-J stent or an overnight-externalized ureteral catheter) are reliable and safe. However, further considerations, like the need of double-J stent removal under cystoscopy,

need to be taken into account when deciding which modality to use.

Keywords Nephrolithiasis · Percutaneous nephrolithotomy · Tubeless · Double-J stent · Ureteral catheter

Introduction

Percutaneous nephrolithotomy (PNL), a minimally invasive technique for the treatment of renal calculi, is the standard of care for nephrolithiasis ≥ 2 cm and complex staghorn calculi. In addition, it is currently recommended over extracorporeal shock-wave lithotripsy (SWL) for lower calyx stones ≥ 15 mm [1].

The conventional PNL technique ends after the insertion of a nephrostomy tube within the percutaneous access tract. It provides hemostasia within the dilation tract, an adequate drainage avoiding urinary leakage and an access for a second-look procedure if necessary. Bellman et al. [2] questioned the need of leaving a nephrostomy tube, arguing that in most patients, postoperative bleeding is not significant, perforation of the pelvicalyceal system usually does not occur and that a need for further procedures will be necessary in a minority of cases. By these means, they reported a modified PNL technique, naming it “tubeless PNL”. The modification consisted in omitting the insertion of the nephrostomy tube and leaving an indwelling ureteral stent instead. Several reviews and meta-analyses have provided evidence of the feasibility and safety of tubeless PNL in patients with a single percutaneous access, reporting reduced amounts of intraoperative bleeding and absence of clinically significant pelvicalyceal perforation. Further benefits of this approach are less postoperative pain

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and analgesic requirements, shorter hospital stays and a consequent reduction of associated costs [3–7].

Modifications to the original tubeless technique have been proposed, in terms of leaving an externalized ureteral catheter overnight instead of indwelling. The feasibility and safety of this modification have been previously reported [8–11], but only two comparative studies have been published [12, 13]. Gonen et al. [12] showed that an externalized ureteral catheter was more comfortable for the patient, being as reliable and safe as an indwelling stent. However, Telha et al. [13] reported higher rates of urinary leakage among patients with the externalized catheter.

The aim of our study was to compare the use of an ureteral indwelling stent versus an overnight-externalized ureteral catheter in patients undergoing tubeless PNL in a prospective and randomized manner in terms of hospital stay length, incidence of hemorrhagic complications, urinary leakage and analgesia requirements in the immediate postoperative period.

Patients and methods

Sixty-eight consecutive patients undergoing tubeless PNL at our institution were prospectively enrolled between January 2009 and December 2010. The institutional ethics committee approved the study and an informed consent was obtained from every patient. All surgeries were performed by the same surgeon (FM). All patients received ceftriaxone 1 g i.v. the day before and during the anesthetic induction. Urinary tract infection was ruled out with a preoperative urine culture in all patients. However, three patients were under antibiotic treatment the day of surgery because of persistent, multi-resistant organisms. Surgeries were performed under general anesthesia with patients in prone-flexed position. After contrasting of the pelvicalyceal system by a retrograde ureteral catheter, percutaneous calyceal puncture was performed under fluoroscopic guidance and tract dilation was completed with a set of fascial dilators (Cook Urological, Spencer, USA) up to 28 Fr before installing the Amplatz sheath. A 24 Fr nephroscope (Karl Storz Endoskope, Germany) and intracorporeal pneumatic lithotripsy (Brok Stone[®]-600, Digital Precision Systems, Argentina) was used in all procedures.

All patients were selected according to previously established criteria for tubeless PNL (single access, reduced intraoperative bleeding, nephroscopic and fluoroscopic evidence of stone-free status) [7, 10]. After verification of these criteria, the operating room nurse randomized patients intraoperatively by means of simple method of random assignation. Thirty-three patients were assigned to group 1 (indwelling double-J stent) and 35 patients to group 2 (overnight-externalized ureteral stent). The stent in group 1

was inserted in an antegrade manner after removing the ureteral catheter. In patients of group 2, ureteral catheters were left externalized. A urethrovesical Foley catheter was left in place in all patients until the first postoperative day. It was then removed, along with the externalized ureteral catheter in group 2 patients. Otherwise, indwelling stents were removed 2 weeks after the procedure by an outpatient cystoscopy. Initial postoperative analgesia included an intravenous continued infusion of saline with metamizol and either ketoprofen or tramadol depending on history of allergy to non-steroidal anti-inflammatory drugs (NSAID) or renal impairment (creatinine clearance ≤ 60 ml/min). Pain assessment was performed every 6 h by a visual analog pain scale (VAS) applied by a trained nurse. Patients with severe or moderate pain (VAS ≥ 4) received ketorolac i.v. (30 mg) or meperidine i.v. (30 mg) if NSAIDs were contraindicated. Patients with mild (VAS < 4) or no pain were moved to oral analgesia using acetaminophen (1 g tid).

All patients were evaluated at the first postoperative day with a non-enhanced abdominopelvic computed tomography (CT) and a complete blood count (CBC). Patients underwent CT not later than 8 h after ureteral (group 2) or urethrovesical (both groups) catheter removal. Hospital stay length, occurrence of significant bleeding (drop in hematocrit, need of transfusion, presence of hematoma on the CT), residual stones and urinary leakage (detected on the CT) were recorded.

Statistical analysis was performed using the software Stata v10.0 (StataCorp, College Station, TX, USA). For each variable included in the analysis, a distribution test was performed in order to determine the best statistical test to compare groups. Proportions were compared with a test for proportions between independent samples. A *p* value < 0.05 was considered significant for every analysis.

Results

Both groups had similar preoperative characteristics (Table 1). The only significant difference observed was the hematocrit value, being higher for group 1 (40.9 ± 4.0 vs. 38.7 ± 3.4 %; *p* = 0.02).

With regards to postoperative variables (Table 2), patients in group 1 had a significantly longer hospital stay than those in group 2 (3.7 ± 1.7 vs. 1.9 ± 0.3 days; *p* < 0.001). Three patients in group 1 had a longer stay as they needed intravenous antibiotics for urinary tract infection caused by multi-resistant agents. However, even after excluding these patients from the analysis, group 1 still showed a significantly longer hospital stay (3.1 ± 0.6 days; *p* < 0.001). Although postoperative hematocrit values were similar between both groups (36.0 ± 4.0 vs. 36.7 ± 3.3 % in group 1 and 2, respectively; *p* = 0.49), hematocrit drop

Table 1 Preoperative characteristics

	Group 1 (mean ± SD), n = 33	Group 2 (mean ± SD), n = 35	p value
Age (years)	52.6 ± 11.9	48.9 ± 9.0	0.15*
Sex (n)			
Women	16	18	0.63 [§]
Men	17	17	
BMI (kg/m ²)	28.7 ± 4.3	26.7 ± 2.3	0.07 ⁺
Stone burden (cm ²)	5.8 ± 2.8	4.9 ± 1.7	0.09**
Preoperative hematocrit (%)	40.9 ± 4.0	38.7 ± 3.4	0.02*

BMI body mass index

* *t* test for samples with equal variances, [§] test of proportions for two independent samples, ⁺ non-parametric Wilcoxon test (Mann–Whitney), ** *t* test for samples with unequal variances

Table 2 Postoperative characteristics

	Group 1 (mean ± SD), n = 33	Group 2 (mean ± SD), n = 35	p value
Postoperative days	3.7 ± 1.7	1.9 ± 0.3	<0.0001 ⁺
Hematocrit drop (%)	4.9 ± 2.2	2.1 ± 1.8	<0.0001 ⁺
Postoperative hematocrit (%)	36.0 ± 4.0	36.7 ± 3.3	0.49*
Perirenal hematoma (n)	2	1	0.55 [§]
Residual lithiasis on CT (n)	2	7	0.09 [§]
Residual lithiasis on CT > 4 mm (n)	0	1	0.52 [§]
Urinary leakage	None	None	NA
VAS 24 h	4.3 ± 0.92	4.4 ± 1.1	0.82 ⁺
VAS 48 h	1.9 ± 0.87	1.8 ± 0.9	0.84 ⁺
Hospital re-admissions within 3 months	None	None	NA

NA not applicable, VAS visual analog scale

* *t* test for samples with equal variances, [§] test of proportions for two independent samples, ⁺ non-parametric Wilcoxon test (Mann–Whitney), ** *t* test for samples with unequal variances

was significantly more relevant in group 1 than in group 2 (4.9 ± 2.2 vs. 2.1 ± 1.8 %; $p < 0.001$). No patient required blood transfusion. Two patients in group 1 and one in group 2 developed perinephric hematomas, as detected by non-enhanced abdominopelvic CT ($p = 0.55$). All of them were managed in a conservative manner. Urinary leakages occurred in neither group. Residual lithiasis, unnoticed at the end of the surgery, was found in the CT of two patients in group 1 and seven patients in group 2 ($p = 0.09$). Notably, only one patient presented with a residual fragment >4 mm (in group 2). There was no difference in postoperative pain between groups at 24 and 48 h

($p = 0.82$ and 0.84 , respectively). Finally, no hospital readmissions were registered within the first 3 postoperative months.

Discussion

In this study, we were able to show no significant differences in terms of incidence of hemorrhagic complications, urinary leakage and analgesia requirements in the immediate postoperative period between patients with postoperative indwelling double-J stent and patients with postoperative overnight-externalized ureteral catheter after undergoing tubeless PNL. In addition, we did not observe any hospital readmissions during the first 3 postoperative months. These findings support the reliability and safety of leaving an externalized ureteral catheter and are in agreement with previous studies [8–12].

Regarding hospital stay length, reports in the literature are contradictory. In our series, we observed a shorter hospital stay length in patients getting an overnight-externalized ureteral catheter (1.9 days), similar to the hospital stay length reported by Mouracade et al. [9]. However, Lojanapiwat et al. [10] reported a mean hospital stay length of 3.63 days with the use of an externalized ureteral catheter, similar to what we observed in the group getting an indwelling double-J stent (3.7 days). Among comparative studies, Gonen et al. [12] did not find any differences between groups in terms of hospital stay length, while Telha et al. [13] showed a longer hospital stay in the group left with an externalized catheter.

In our study, even after excluding three patients with prolonged stays due to intravenous antibiotic treatment, getting an indwelling stent was still related to a statistically significant shorter hospital stay ($p < 0.001$). We are not able to explain this difference on the basis of the type of catheter used and this is a limitation of our study, since we did not explore other factors potentially contributing to this difference. However, one possible explanation may be the postoperative evaluation being made by a non-blinded physician. Therefore, a biased decision for hospital discharge cannot be ruled out. Other factors may be related to patient's comorbidities (not evaluated) or administrative issues (e.g. avoidance of discharges during weekends, patient-related health insurance policies).

The incidence of hemorrhagic complications did not differ significantly between groups. Two patients in group 1 and one in group 2 developed perirenal hematomas that were managed in a conservative manner. The higher hematocrit drop in group 1 seems not be related to the use of a double-J stent and is more likely associated to intraoperative factors determining an increased bleeding during and after the procedure. Meanwhile, there were no

clinically relevant hemorrhagic complications since the mentioned hematocrit variation had no impact on patient's hemodynamics, required no blood transfusions and did not determine the need of further interventions. These findings are consistent with those of previous studies [8–13], in terms of the absence of significant differences in terms of hemorrhagic complications. The strict selection of patients in all of these studies, excluding patients with significant intraoperative bleeding may explain this low rate of hemorrhagic complications.

Similar to the study by Gonen et al. [12], we found no differences in the incidence of urinary leakage between both groups. However, contrary to our findings, Telha et al. [13] reported a higher incidence of urinary leakage and perirenal collections in patients with externalized ureteral catheter. They related this finding to the spontaneous passage of residual stone fragments after the catheter removal, determining obstruction with subsequent urinary leakage and perirenal collections. Interestingly, stone-free rate (65 %) was lower than those seen in our study and that of Gonen (82 and 91 %, respectively). Both higher stone-free rates and the small size of residual fragments (92 % <4 mm) may explain the lower rates of these complications in our study.

The use of externalized ureteral catheters has been reported to be associated with less postoperative pain [11]. Nonetheless, Gonen et al. reported a slightly, though not significant, higher postoperative pain in patients using an externalized ureteral catheter. However, those differences were not clinically relevant.

A significant limitation of our study is that we did not assess stent-related symptoms. They may be bothersome, with up to 50 % of the patients with double-J stent reporting clinically significant symptoms [12]. However, most patients describe these symptoms as not severe, but around 15 % of them may still need treatment with anticholinergic agents. This issue should be considered when deciding about leaving externalized ureteral catheters or indwelling double-J stents after tubeless PNL. Concerning costs, we did not specifically address this topic, but it is obvious that all patients randomized to the indwelling double-J stent group incurred into additional expenses, since they required a cystoscopy for stent removal. In addition, further expenses were probably necessary to alleviate stent-related symptoms. This is an item that needs further evaluation. However, it is probably an argument for recommending externalized ureteral catheters rather than indwelling double-J stents.

Conclusion

In conclusion, our results do not support the superiority of externalized ureteral catheter over indwelling double-J

stent after tubeless PNL, but confirms that both alternatives are safe and reliable. However, further studies are necessary to better define the role of each modality, focusing on the evaluation of symptoms and complications.

Conflict of interest The authors declare that they have no conflict of interest.

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