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ORIGINAL PAPER

Percutaneous nephrolithotomy: tubeless or not tubeless?

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Abstract The objective of this study is to evaluate the safety and outcomes of tubeless PCNL in comparison with standard PCNL. Since June 2002, we have performed 99 tubeless PCNL. Tubeless technique involves antegrade placement of a 6Fr double-J stent without nephrostomy tube at the end of the procedure. This series has been compared with a total of 110 patients in which revision of operative reports ruled out the presence of intraoperative conditions necessary to candidate a patient to tubeless procedure but standard PCNL was performed because prior to its introduction or because of surgeon's attitude afterward. Mean stone burden was 5.4 for standard group and 4.9 cm^2 for tubeless group, respectively. Mean BMI was 24.1 in the first group and 23.6 in the second one. In this retrospective study, complications rate, postoperative pain, length of hospitalization and convalescence were evaluated by chart review. Hematocrit drop did not differ significantly between tubeless PCNL and standard PCNL (5.5 vs. 5.9%). Conversely, there was statistically significant difference between tubeless and standard PCNL in terms of the amount of analgesics (49.5 vs. 84.2 mg), immediate postoperative patients' discomfort, hospitalization (2.2 vs. 5.3 days) and time to resume normal activities (11.0 vs. 16.5 days). In conclusion, in our series, tubeless approach did not determine increase in complication rate. Conversely, tubeless PCNL reduced analgesics' requirement, patients' discomfort, hospitalization and time to recovery. As such, at our institution, tubeless PCNL has become routine procedure that actually is feasible in almost two-third of renal calculi suitable for percutaneous treatment.

Keywords Urolithiasis · Percutaneous nephrolithotomy · Outcomes

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Introduction

Since its introduction two decades ago, percutaneous nephrolithotomy (PCNL) has replaced open surgery as standard of care in the treatment of renal calculi greater than 20 mm. [1] Progressive improvements to the PCNL technique, together with the introduction of new devices, have progressively decreased its morbidity. Thus, following the widespread increasing recognition of SWL limitation, PCNL is regaining in popularity among many urologists who were reluctant to offer this procedure as a first-line choice.

In an effort to reduce hospital stay and patient discomfort related to PCNL, while maintaining the same positive outcomes, the need for the nephrostomy tube after completion of the procedure recently has come into question. The issue is whether the placement of a percutaneous tube is truly mandatory to achieve satisfactory hemostasis, urinary drainage and renal healing. Some recent reports [2–6] have challenged this cornerstone of the PCNL technique, demonstrating that in selected cases performing tubeless renal surgery (only antegrade placement of a double-J stent without an external drainage tube) is not as hazardous as thought during the pioneering era of endourology. Herein, we present a retrospective study on our experience with tubeless PCNL at our stone centre.

Materials and methods

Since opening of our "stone center" back in 1997, according to worldwide established criteria, stones greater than 2 cm or less than that but SWL resistant has been treated percutaneously [1, 8, 9]. Since June 2002, we have performed 99 tubeless PCNLs (30Fr Amplatz sheath with antegrade placement of only a 6Fr double-J stent without nephrostomy tube at the end of the procedure) for renal calculi. Patients were candidates for the tubeless procedure only when the following conditions were strictly met: single percutaneous tract, absence of major perforation of collecting system and bleeding, and complete stone clearance as assessed by intraoperative flexible nephroscopy and fluoroscopy at the end of the procedure. This series has been compared with a total of 110 patients in which revision of operative reports ruled out the presence of intraoperative conditions necessary to candidate a patient to tubeless procedure but standard PCNL (30Fr Amplatz sheath with 20Fr nephrostomy tube without a double-J stent) was performed because prior to tubeless technique introduction back in June 2002 or because of surgeon's attitude after that date. All tubeless procedures have been carried out by a single surgeon (GG), while standard PCNLs have been carried out by three different surgeons (GG, GP, GT) with analog expertise in percutaneous surgery (more than 100 cases each). As such, this study is not biased by surgeons' skill because only one surgeon performed tubeless PCNL just due to personal attitude.

For this study, the medical records of all patients were reviewed with respect to stone burden, operative time, length of hospitalization, postoperative discomfort, complication rate and time to resume normal activities. Patients' demographics, stones' and procedures' characteristics are reported in Tables 1 and 2. The stone burden was defined as the two-dimensional area (cm^2) calculated by measurement of length and width of the stone on a preoperative plain abdominal radiograph. In case of multiple stones, the total stone burden was calculated as the sum of the area of each calculus.

Table 1 Demographics

	Standard PCNL	Tubeless PCNL
Number of patients	110	99
Male/female	70/40	61/38
Mean age (years)	48.3 (29–70)	51.5 (23–77)
BMI	24.1	23.6
Right/left	60/50	56/43 (+1 simultaneous bilateral)
Solitary functioning kidney (%)	7 (6.3%)	1 (1.01%)

Table 2 Stones' and procedures' characteristics

	Standard PCNL (110 cases)	Tubeless PCNL (99 cases)
Stone burden (cm^2)	5.4 ± (2.2–27.2) cm^2	4.9 (2.1–12.0) cm^2
Number of stones (%)		
Single	34 (30.9%)	33 (33.3%)
Multiple	42 (38.2%)	38 (38.3%)
Staghorn	34 (30.9%)	28 (28.4%)
Radiopacity of stones (%)		
Opaque	101 (91.8%)	92 (92.9%)
Lucent	9 (8.2%)	7 (7.1%)
Location of access site		
Infracostal	99	97
Supracostal	11	2

Postoperative pain was assessed using a validated pain questionnaire including a visual analog scale (VAS) and a verbal rating scale (VRS) [10]. The pain questionnaire was administered on the first postoperative day and at the 10-day postoperative follow-up visit after outpatient flexible cystoscopy was performed under local anesthesia to remove the stent. Patients are asked to rate their pain by moving the marker on the 10-cm-long VAS (0 = no pain to 10 = very severe pain). Patients were also asked to qualify the amount of their pain by choosing the most appropriate description among the following categories: none, mild, moderate, severe or very severe pain. Their choices were then converted to an ordinal scale of 1, 2, 3, 4 and 5, respectively, for statistical analysis.

Data are described as number and percentage or mean and standard deviation, as appropriate. Differences between groups were evaluated with Student's *t* student test. *P* values <0.05 were considered significant.

Tubeless surgical technique

Standard and tubeless procedure does not differ from a technical point of view until the end of lithotripsy.

PCNL begins after induction of general endotracheal anesthesia with the patient in the prone split-leg position to place an occlusion balloon retrograde. After percutaneous access is obtained, the tract is dilated up to 30Fr by means of a dilating balloon to place a 30Fr Amplatz working sheath. Lithotripsy is mainly performed with ultrasonic lithotripter. A holmium laser is always available for those cases in which flexible nephroscopy is needed to reach fragments migrated in calices not accessible by means of rigid instruments. After the completion of the PCNL, a tubeless procedure is chosen if no major perforations of the collecting system occurred and complete stone clearance is confirmed by intraoperative flexible nephroscopy and

fluoroscopy. Once the occlusion balloon is removed, a 6Fr double-J stent is placed antegrade over the safety guidewire. The correct distal coil position is verified fluoroscopically; the proximal position is confirmed endoscopically to be entirely intrarenal and, when needed, adjusted by means of a grasping forceps. The working sheath is then removed with the safety guidewire still in place. The patient is carefully observed for 2 min to verify no active bleeding, in which case the guidewire is removed and the nephrostomy wound is closed with a single deep 2 ethibond stitch. An indwelling 18Fr Foley catheter is left in place overnight. A blood sample is obtained 3 h postoperatively and again the following morning. Renal ultrasound is routinely performed on postoperative day 1 to exclude urinary retroperitoneal extravasation. In case of an uneventful postoperative course, stable hematocrit, and pain controllable with oral analgesics, patients are discharged in the afternoon after tubeless PCNL. Stent is then removed at first routinary follow-up visit after a period of time ranging between 7 and 10 days by means of flexible cystoscopy under local anesthesia on outpatient basis.

Results

Operative and postoperative data are summarized in Table 3. The mean operative time of the standard PCNL group was longer than that of the tubeless group (112.3 vs. 98.1 min) according with difference in stone burden between two groups. There was no significant difference between standard PCNL and tubeless PCNL in terms of decrease in hematocrit (5.9 vs. 5.5%, $P = 0.230$), nor were the transfusion rates significantly different (standard PCNL: 5.45%, 6 out of 110 patients; tubeless PCNL: 2.02%, 2 of 99 patients). For instance, among tubeless group, one of the two patients who required blood transfusions experienced progressive postoperative bleeding (total ΔHt after 4 days: 18.5% with transfusion of two units of blood) that led to the development of bulky palpable retroperitoneal hematoma that spontaneously tamponated and resolved within 1 mo. The other patient developed acute massive postoperative bleeding (ΔHt: 21.3%) that required urgent transfusion with four units of blood; the situation was managed conservatively by means of selective percutaneous embolization of a bleeding segmental artery performed by our interventional radiologists. There was a statistically significant difference between the tubeless and standard PCNL groups in terms of amount of analgesics (49.5 vs. 84.2 mg of ketorolac, $P = 0.003$). This measure paralleled the results of the VAS and VRS pain scores obtained on the first postoperative day. The pain questionnaire was also administered after outpatient flexible cystoscopy to remove the stent; at this time, however, we found no significant difference in VAS and VRS pain scores between the two groups (Table 3).

The stone-free rate was 95.4% in the standard PCNL group (105 of 110 patients), whereas radiographic follow-up of the tubeless series showed a 98.9% stone-free rate (98 out of 99 patients).

In terms of mean hospitalization, tubeless PCNL resulted in a superior outcome compared to standard PCNL (2.2 vs. 5.3 days, $P < 0.001$). Finally, the time required to return to normal activities was significantly shorter for the tubeless PCNL group than the standard PCNL group (11.0 vs. 16.5 days, $P < 0.001$).

Discussion

Since its introduction two decades ago, PCNL has become the gold standard of care for large renal calculi, making open surgery become anecdotal. Due to the great enthusiasm that accompanied the advent of SWL, PCNL seemed to be doomed to early disappearance from endourologists' armamentarium. It has become clear, however, that SWL cannot be considered the panacea for all stones because of its low stone-free rate and its high retreatment rate in cases of stones larger than 1.5 cm and those located in the lower calices with unfavorable anatomy on radiological examination [11].

In addition, some important modifications to the PCNL technique have led to a dramatic decrease of this procedure's morbidity. For instance, the introduction of balloon dilators instead of Amplatz teflon dilators and/or metallic coaxial Alken dilators has significantly reduced bleeding and operative time related to tract dilation and reduced the frequency of collecting system perforation, which usually occurs when non inflatable dilators are inadvertently advanced too far medially [12].

At our institution, we are experiencing an increasing number of requests from patients to achieve stone-free status as soon as possible without the need for the multiple treatments and ancillary maneuvers often related to SWL treatment of larger stones. We have also noted a significant decrease in the number of patients with major staghorn calculi; such cases should undergo a lengthier PCNL procedure with multiple accesses that usually imply a second look procedure through a mature tract. As such, more patients are likely to undergo a PCNL lasting less than 2 h and be able to achieve complete stone clearance in a single step.

Based on these changes and to reduce patient discomfort, we now routinely perform tubeless PCNL in those patients who meet the following criteria: single percutaneous tract, absence of major perforation of collecting system

Table 3 Overall results and statistical evaluation

	OR time (min)	ΔHt (%)	Transfused patients	Analgesics (mg)	Hospital stay (days)	Time to normal activities (days)	VAS score day 1 postop	VRS score day 1 postop	VAS score at first follow-up visit	VRS score at first follow-up visit
Standard PCNL (110)	112.3	5.9%	6/110 (5.45%)	84.2	5.3	16.5	6.1	3.1	1.93	1.36
Tubeless PCNL (99)	98.1	5.5%	2/99 (2.02%)	49.5	2.2	11.0	3.5	1.9	2.04	1.45
Statistical evaluation		$P = 0.230$		$P = 0.003$*	$P < 0.001$*	$P < 0.001$*	$P < 0.001$*	$P < 0.001$*	$P = 0.428$	$P = 0.386$

* Statistically significant

and bleeding and complete stone clearance as assessed by intraoperative nephroscopy and fluoroscopy at the end of procedure. As early as 1984 Wickham et al. [13] reported a tubeless and stentless series with an acceptable complication rate. However, these results were not reproducible. But a following paper by Winfield et al. in [14] reported about 2 two cases of premature nephrostomy tube removal in which significant postoperative bleeding and urinary extravasation occurred, requiring a prolonged hospital stay; the authors concluded this morbidity was not negligible and classified the omission of nephrostomy as a hazardous procedure. After publication of this report, the placement of a nephrostomy tube at the end of the PCNL procedure was considered a mandatory step. In 1997, Bellman et al. [2] reported the first series of 50 tubeless PCNLs with results superior to standard PCNL in terms of reduced hospital stay, analgesic administration and time to resume normal activities with comparable complication rates between the groups. Subsequent series provided similar results, demonstrating that the placement of an external tube was more due to habit than to clinical necessity [3–7].

Our series strongly corroborates these later findings. In particular, the lack of tamponade due to the presence of nephrostomy did not cause significant decrease in hematocrit value in the tubeless PCNL group compared to the standard group (Table 3). Nevertheless, we did experience two cases of major bleeding whose management was not without some concerns since a detailed step by step management of such event after tubeless PCNL has never been reported before. Dealing with such worrying complication is just what every urologist really does not want to do. In fact, once tubeless procedure has been chosen and the safety guidewire removed, the access to collecting system through parenchymal tract is definitely lost so that all of the tricks of the trade that may usually be attempted to minimize blood loss are impossible to be actuated. Bleeding after PCNL can originate from different sources and may arise from the mucosa of the collecting system, renal parenchyma, an arteriovenous fistula or the intercostal or subcutaneous vessels. As such, once this unfortunate event happens, different scenarios may occur. In case of venous bleeding, the absence of nephrostomy reproduces the usual first step endourologists perform after standard PCNL, i.e., clamping the nephrostomy in order to tamponade the tract and collecting system, enabling coagulation and hemostasis to occur. So the collecting system fills with clots, which consequently occludes the venous vessels and promotes self limitation of the hemorrhage as likely happened in our first case of major bleeding with slow development. On the contrary, hypothesizing an injury to a segmental artery of the parenchyma, placement of Kaye tamponade catheter is not possible since access to collecting system is already lost. In such case, urgent percutaneous embolization should

be performed by interventional radiologists. Our experience in our second acute massive bleeding demonstrates that the radiological management in tubeless procedure offers same outcome as in standard PCNL. Similarly, interventional radiologist should be involved in case of arteriovenous fistula. Instead when superficial bleeding is detected by inspection of skin incision, mattress deep suture guarantees prompt and definitive bleeding control.

As such, it is questionable whether the routine use of biological sealant in tubeless procedures to prevent bleeding, as described in some reports [15–17], should be strongly recommended. None of these studies were prospective, the number of patients in each series was very small ($N = 7$, 10, 20, respectively), and the results are similar to those of our series in which sealants were not used. Strong evidence that the application of fibrin glues can be effective enough to stop major bleeding is still lacking. In addition, the price of these glues, when utilized routinely, is not a negligible issue [FloSeal (Baxter Medical, Fremont, California), €365].

Another major concern about not placing a nephrostomy is whether proper urinary drainage is guaranteed with a solely internal double-J stent and indwelling 18Fr Foley catheter overnight. Among the first 20 patients in this series, urinary extravasation never developed, so we abandoned the routine ultrasound control on the first postoperative day before discharging patients. No urinomas have been experienced afterward. Of note, even in the simultaneous bilateral case, who also presented with a high degree of hydronephrosis together with a significant loss of parenchyma, no urinary extravasation was demonstrated by ultrasound and the postoperative course was uneventful; the patient was discharged the day after the procedure, as usual. As such, in our experience, the potential hazard of placing a solely internal double-J stent has become the key point to avoid prolonged urinary leakage through percutaneous tract and consequently to allow for quick discharge the day after the procedure in cases with an uneventful postoperative course. According to the findings of Stoller et al. [18], however, in those cases with multiple tracts and/or major perforation of the collecting system, our policy is still to place an external drainage tube together with a double-J stent.

Our series indicated that tubeless PCNL results were superior in terms of less patient discomfort and reduced hospital stay. Patients who underwent tubeless PCNL required significantly less analgesics than the standard PCNL group ($P = 0.003$; Table 3), and the tubeless group had lower VAS and VRS pain scores on the first postoperative day as well. This finding suggests that the discomfort is mainly related to the presence of the tube itself rather than to its bore [6, 19–21].

The reduction of hospitalization is an advantage that clearly emerges from both our experience and all other reports on this issue. In this series, the hospital stay after tubeless PCNL was significantly shorter than that required after standard PCNL ($P < 0.001$). This provides obvious cost savings; for instance, at our institution the cost of hospitalization is about €250 per day. In our experience as urologists who routinely perform tubeless PCNLs, in the morning of the first postoperative day, once the bladder catheter is removed, most patients leave their beds and ask for a quick discharge. Conversely, patients who have undergone standard PCNL tend to be much more reluctant to leave the hospital; they sometimes have some residual urinary leakage from the flank after removal of a painful tube that was draining bloody urine until a few hours before their discharge time.

In our opinion, these same reasons have a substantial impact on quality of life. With regard to this issue, patients in the tubeless group required a significantly shorter period of time to resume normal activities compared to those in the standard group (11.0 vs. 16.5 days; $P < 0.001$).

Some urologists [7] have argued that the reduced patient discomfort offered by a tubeless procedure might be outweighed by the sometimes-bothersome indwelling double-J stent and by pain during outpatient flexible cystoscopy under local anesthesia. This is not consistent with our findings [22]. In fact, even though the VAS and VRS pain scores collected at first routinary postoperative follow-up visit were higher in tubeless group, these differences between the two groups were not statistically significant ($P = 0.428$ and 0.386, respectively; Table 3).

Based on these encouraging results, our confidence in tubeless technique increased with time and similarly raised the percentage of PCNL carried out in tubeless fashion (Table 4). As such, tubeless PCNL has become a routine procedure at our institution and actually is feasible in nearly two-thirds of patients with renal calculi suitable for percutaneous treatment.

Conclusion

In this series, omitting placement of nephrostomy in rigorously selected patients did not result in serious intraoperative

Table 4 Tubeless PCNL rate throughout years

	Tubeless/standard PCNL (rate)
2002	4/20 (20%)
2003	12/48 (25%)
2004	17/51 (33.3%)
2005	20/40 (50%)
2006	28/43 (65.1%)
2007	18/27 (66.6%)

complications. In addition, the tubeless approach offered significant advantages in terms of reduced amount of analgesics, less discomfort and shorter hospital stay and time to return to normal activities.

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