Assessment of bilateral supine and prone tubeless percutaneous nephrolithotomy

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Introduction: *To assess the outcome of same-session bilateral tubeless percutaneous nephrolithotomy (BPCNL) in supine and prone positions and to compare them to unilateral tubeless PCNL (UPCNL).*

Materials and methods: *Consecutive PCNL patients treated at two institutions between 2006-2016 were analyzed. Tubeless BPCNL was performed when indicated.*

Results: *Fifty-eight patients underwent BPCNLs [30 supine (SBPCNL) and 28 prone (PBPCNL)], while 1395 patients underwent UPCNLs. Demographics and baseline data were similar for all groups ($p > 0.05$). SBPCNL had a longer operating time (124 ± 38 minutes versus 105 ± 36 minutes; $p = 0.49$) and a significantly longer hospital stay (3.6 ± 1.9 versus 2.4 ± 1.3 days, respectively; $p = 0.019$) in comparison to PBPCNL. Seven planned BPCNLs were converted to UPCNL, resulting in a BPCNL success rate of 58/65 (89%). When compared to UPCNL, BPCNL patients had a significantly increased postoperative creatinine level (0.74 ± 0.3 versus -0.04 ± 0.8 g/dL; $p = 0.07^{E-7}$), a decreased postoperative hemoglobin level (2 ± 1.1 versus 1.4 ± 1.7 mg/dL; $p = 0.026$), a higher blood transfusion rate (9% versus 2%; $p = 0.023$), and a longer hospital stay (3 ± 1.7 versus 1.6 ± 1.7 days; $p = 0.001^{E-4}$). Stone-free and overall complication rates were similar for both groups.*

Conclusion: *BPCNL can be routinely offered to patients with a bilateral indication. BPCNL is associated with higher blood transfusion rates and longer hospital stays, but it may spare patients from repeat anesthesia and hospitalization. SBPCNL takes longer to perform than PBCNL, but without clinical ramifications.*

Key Words: bilateral, calculi, endourology, PCNL, supine

Introduction

Bilateral large and complex renal calculi represent one of the most challenging urological pathologies. Affected patients are exposed to renal functional deterioration, recurrent infections, and repeated endourologic interventions that are usually performed under general anesthesia and require long periods of hospital stay. Percutaneous nephrolithotomy (PCNL) is the most effective treatment in these cases.[1,2] Although it has become well established and a procedure commonly performed in specialized centers, PCNL is still considered an advanced and demanding surgical intervention with a complication rate of 20.5%-31%.[3-6] Moreover, when performed bilaterally during the same operative session, PCNL is inarguably a difficult surgical procedure. Such bilateral same-session operations have been undertaken by experienced endourologic teams with the intention to reduce the hospital stay and to avoid a second anesthesia.[7-11]

Most of the reported series were performed without the use of tubeless techniques, and with the patient in the prone position. Descriptions of tubeless supine bilateral PCNLs (SBPCNLs) did not appear until 2015.[12] These new approaches for avoiding postoperative nephrostomy tubes and the use of SBPCNLs warrant further investigation in order to establish the optimal

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setting for same-session bilateral PCNL (BPCNL). In addition, more evidence of the advantages and disadvantages of the bilateral versus the unilateral approach is needed in order to aid in choosing the procedure most suitable for both the patient and the surgeon. Accordingly, we sought to compare tubeless SBPCNLs with tubeless prone bilateral PCNLs (PBPCNLs), and to assess the differences between the outcomes of BPCNLs and USPCNLs.

Materials and methods

Patients' files treated by PCNL in two institutions were retrospectively analyzed from November 2006, when both teams implemented the tubeless technique, until June 2016. Our percutaneous treatment policy conforms to the American Urological Association/ Endourological Association and EAU Guidelines.[1,2] In addition, when patients present with indications for bilateral percutaneous treatment, we offer them a same-session BPCNL. There was no preoperative selection for these cases and the suitability for completion of the bilateral procedure in a single session was decided intraoperatively. Supine PCNL have been performed since 2006 in one of the participating institutions and since 2014 in the other. The techniques are similar since the principal surgeons in both institutions underwent the same training.

The study was approved by the Institutional Review Board and patients signed informed consent acknowledging that the procedure will begin with the symptomatic or clinically significant side and continue on the contralateral side unless contraindicated for any reason. There was a total of 1452 patients suitable to enter that study. They were divided into three groups according to surgical procedure: SBPCNL = 30 patients, PBPCNL = 28 patients and UPCNL = 1395 patients. Both SPCNL and BPCNL patients were operated consecutively without having been selected to either supine or prone positions. Namely, one institution performed 25 consecutive SBPCNL while the other performed 28 consecutive PBPCNL followed by 4 consecutive SBPCNL. These groups were compared in terms of demographics, preoperative clinical data, operative time calculated from the time of the first cystoscopy to the time of the final wound suture, pre and postoperative variations in hemoglobin and creatinine levels, tubeless procedures rate, stone-free rate (SFR) as demonstrated on postoperative non-contrast computerized tomography (NCCT), complications as classified by the Clinical Research Office of the Endourology Society (CROES) Clavien validated score[13] and length of hospital stay. Stone size was given as the maximal diameter measured on the preoperative NCCT. SFR was assessed by postoperative NCCT. Ancillary procedures, including second-look PCNL, ureteroscopy, or retrograde intrarenal surgery (RIRS), were conducted according to the size and the location of residual fragments.

All procedures were intended to be accomplished in a tubeless fashion by means of avoiding postoperative nephrostomy tubes. A modified variation of the Valdivia combined with the Galdakao position was used for the SBPCNL.[12] Patients were placed with the treated side at the edge of the table, with a flank elevation of 15-20 degrees and the ipsilateral arm flexed, rotated over the thorax and padded on an arm support while the legs are in an asymmetrical lithotomy position. Using a flexible cystoscope, a guidewire followed by a ureteral catheter was inserted into the renal pelvis of the first treated unit, and a Foley 14Fr catheter was left in the bladder. A retrograde pyelography was performed and the puncture was carried out under fluoroscopic combined with ultrasonic guidance. Once access was gained, a guidewire was passed down to the bladder and the tract was balloon dilated to working sheath of 24-30FR. Ultrasonic and pneumatic lithotripsy was carried out through rigid nephroscopy, followed by flexible nephroscopy and real-time fluoroscopy to ensure complete stone clearance. A nephrostomy tube was left only in cases of significant bleeding or an expected need for a second-look procedure. Otherwise, an internal stent was placed and the wound is sutured. Once the operation on the first side has been uneventfully accomplished, the patient was re-positioned in a specular supine position and was approached in a similar fashion as done for the first side.

For the prone position, the patient was prepped and draped from the beginning for approaching both sides. The legs were slightly abducted to allow for flexible cystoscopy, and bilateral guidewires were inserted simultaneously, followed by ureteral catheters and a Foley catheter in the bladder. The puncture was achieved under fluoroscopic control using either bull's eye or triangulation techniques, and the principles of the operation follow those described for the supine position. The differences between the SBPCNLs and the PBPCNLs are that both the patient and the room configuration (C-arm, video tower and screen locations) are changed so that they are rotated to the non-operated side in the former, while the patient is not re-positioned when changing the sides and only the room configuration is changed to fit the approach of the contralateral side in the latter. Further details on our supine[12] and prone[14] techniques have been reported elsewhere.

Patients left with nephrostomy tubes were assessed by NCCT in the first postoperative day to decide

TABLE 1. **Demographics and baseline clinical data of the study groups**

Criteria	SBPCNL (n = 30)	PBPCNL (n = 28)	p value	BPCNL (n = 58)	UPCNL (n = 1395)	p value
Mean age (years)	49 ± 13	51 ± 16	0.67	50 ± 14	52 ± 17	0.34
Male/female	19/11	16/12	0.41	35/23	879/516	0.68
BMI (kg/m^2)	26 ± 4	27 ± 3.5	0.46	26 ± 4	28 ± 5	0.15
Stone size (maximal diameter/unit, mm)	31.5 ± 8	36.1 ± 13	0.11	33.7 ± 11	34.5 ± 13	0.68
Previously operated kidneys	3 (10%)	7 (25%)	0.13	10 (17%)	209 (15%)	0.34
ASA score	1.4 ± 0.7	1.6 ± 0.6	0.41	1.6 ± 0.7	1.8 ± 0.7	0.06

PCNL = percutaneous nephrolithotomy; SBPCNL = supine bilateral PCNL; PBPCNL = prone bilateral PCNL; BPCNL = bilateral PCNL; UPCNL = unilateral PCNL; BMI = body mass index; ASA = American Society of Anesthesiology

whether there was a need for a second-look PCNL. Otherwise, the patients were released home and the stents were self-extracted by the patients within 1 week after the operation. Follow up in the outpatient clinic at 1 month postoperatively included a complete blood count, creatinine test, urinary culture and NCCT.

The study was designed to initially compare the SBPCNL and PBPCNL groups followed by comparison of all BPCNLs as a group to UPCNL group. Statistical assessment was conducted using comparison of continuous data by analysis of variance and discrete variables by Fisher's exact and chi-square tests, defining significance at a p value < 0.05.

Results

The SBPCNL, PBPCNL and UPCNL groups were found to be well matched in terms of demographics and baseline clinical data, Table 1. The first analysis compared the SBPCNL and the PBPCNL groups, Table 2. There was a trend toward longer operative time in the SBPCNL group (124 ± 38 versus 105 ± 36 minutes; p = 0.049). The hospital stay was significantly longer in the SBPCNL group (3.6 ± 1.9 versus 2.4 ± 1.3 days, respectively; p = 0.019), Table 2. Two important clinical parameters that were significantly different postoperatively for the BPCNL group was the mean

TABLE 2. **Outcome of the SBPCNL compared to the PBCNL approaches**

Criteria	SBPCNL (n = 30)	PBPCNL (n = 28)	p value
Operative time (minutes)	124 ± 38	105 ± 36	0.049
Hospital stay (days)	3.6 ± 1.9	2.4 ± 1.3	0.019
Non-tubeless procedures	2 (7%)	0	0.25
Unilateral tubeless	4 (14%)	2 (7%)	0.32
Bilateral tubeless	23 (79%)	26 (93%)	0.14
Drop in hemoglobin (g/dL)	2.1 ± 0.6	1.9 ± 1.5	0.74
Blood transfusion	1 (3%)	4 (14%)	0.16
Δ creatinine 1st postoperative day (mg/dL)	0.73 ± 0.2	0.75 ± 0.4	0.90
Δ creatinine 1 week postoperatively (mg/dL)	-0.78 ± 0.3	-0.74 ± 0.2	0.61
Ancillary procedure per patient	5 (17%)	2 (7%)	0.23
SFR per patient before ancillary procedures	24 (80%)	24 (86%)	0.38
Overall complications	8 (27%)	5 (18%)	0.29

PCNL = percutaneous nephrolithotomy; SBPCNL = supine bilateral PCNL; PBPCNL = prone bilateral PCNL; Δ = delta; SFR = stone-free rate

TABLE 3. **Comparison between successful and failed BPCNL in terms of entry data, intraoperative course and outcome**

Criteria	Successful BPCNL (n = 58)	Failed BPCNL (n = 7)	p value
Mean age (years)	50 ± 13	53 ± 12	0.61
Male/female	35/13	3/4	0.32
BMI (kg/m^2)	26 ± 4	26 ± 2.3	0.95
Stone size (maximal diameter/unit, mm)	31.5 ± 8	28.3 ± 14	0.20
Previously operated kidneys	7 (12%)	0	0.43
ASA score (average)	1.5	2	0.08
Position: supine/prone	24/34	5/2	0.13
Operative time per unit (minutes)	62 ± 39	102 ± 12	0.0006
Drop in hemoglobin (g/dL)	1.97 ± 1	2.7 ± 0.9	0.06
Blood transfusion	5 (1%)	3 (42%)	0.03
Ancillary procedures per patient	7 (12%)	2 (29%)	0.24
0verall complications	13 (22%)	3 (42%)	0.22
SFR per patient before ancillary procedures	83% (48/58)	71% (5/7)	0.38

BPCNL = bilateral percutaneous nephrolithotomy; BMI= body mass index; ASA = American Society of Anesthesiology; SFR = stone-free rate

drop in the postoperative hemoglobin level (2 ± 1.1 mg/dL) and the mean increase in the postoperative creatinine level (0.74 ± 0.3 g/dL; $p < 0.0005$), with complete recovery at 1 week (mean decrease of 0.62 ± 0.3 g/dL; $p < 0.005$). The primary SFR was 80% and 86% for the SBPCNL and PBPCNL groups, respectively. After the performance of one second-look PCNL and four RIRS in the SBPCNL group, and one second-look PCNL and one RIRS in the PBPCNL group, the SFR increased to 90% and 93%, respectively. Complications occurred in eight (27%) SBPCNL and five (18%) PBPCNL patients, with a similar distribution as determined by the Clavien CROES validated classification: grade I = seven patients (54%), grade II = three patients (23%), grade IIIA = two patients (15%) and grade IIIB = one patient (8%).

Five patients (5/35; 14%) planned for SBPCNL and two patients planned for PBPCNL (2/30; 7%) underwent UPCNL ($p > 0.05$). The reason for switching to a unilateral procedure in these patients were too long

TABLE 4. **Outcome of the BPCNL compared to the UPCNL approaches**

Criteria	BPCNL (n = 58)	UPCNL (n = 1395)	p value
Operative time (minutes)	109 ± 39	94 ± 31	0.015
Hospital stay (days)	3 ± 1.7	1.6 ± 1.7	0.001^{E-4}
Tubeless procedures	50 (86%)	1051 (75%)	0.06
Mean postoperative hemoglobin drop (g/dL)	2 ± 1.1	1.4 ± 1.7	0.026
Blood transfusion	5 (9%)	28 (2%)	0.023
Δ creatinine 1 postoperative day (mg/dL)	-0.04 ± 0.8	0.74 ± 0.3	0.007^{E-7}
Ancillary procedures per patient	7 (12%)	140 (10%)x	0.33
SFR after ancillary procedures	52 (90%)	1264 (87%)	0.47
Overall complications per patient	13 (22%)	223 (16%)	0.19

PCNL = percutaneous nephrolithotomy; BPCNL = bilateral PCNL; UPCNL = unilateral PCNL; Δ = delta; SFR = stone free rate

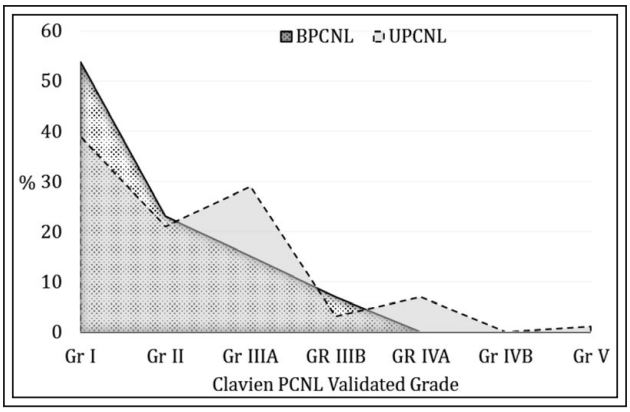

Figure 1. Distribution of complications in the bilateral tubeless percutaneous nephrolithotomy (BPCNL) and unilateral tubeless percutaneous nephrolithotomy (UPCNL) groups according to the Clavien PCNL validated classification.[13]

operative time for the first approached kidney in four (57%) cases and significant venous bleeding in three (43%) cases. These UPCNL patients were considered as failed bilateral procedures. As such, the success rate of BPCNL was 89% (58/65). A sub-analysis did not detect possible preoperative factors for failure. However, the failure group was characterized by a significantly longer operation time with a higher rate of blood transfusions, Table 3.

The second analysis looked at the BPCNL group as a whole (n = 58 patients) in comparison to the UPCNL group, Table 4. The UPCNL operations were significantly shorter, and they were associated with less bleeding, decreased blood transfusion rate and no significant change in the renal function as reflected by postoperative creatinine findings. In addition, the hospitalization of the UPCNL patients was significantly shorter. There was no significant difference in the complication rate between these two groups. However, analysis of the distribution of complications by Clavien grade identified a trend toward more complications that were greater than grade II in the UPCNL group compared to the BPCNL group (50% versus 20%, respectively), Figure 1. This difference did not reach a level of significance (p = 0.09).

Discussion

Colón-Pérez et al[15] first reported same session BPCNL on three patients in 1987. In this series the average operative time was 4 hours, the average hospital stay was 5.6 days, and one patient was left with small non-significant fragments. Five years later, Regan et al[16] stated that this procedure was feasible, safe and well tolerated by their three reported patients. Awalat et al[17] reported 16 cases operated by BPCNL within an average of 83 minutes, with a SFR of 81.3% and a high blood transfusion rate (25%). More comprehensive data were provided by Dushinsky and Ligeman[7] in a series of 52 patients planned for BPCNL of whom 48 were finally approached bilaterally. The reasons that four patients were switched to a staged procedure were prolonged complicated operations on the initial side in three and pyonephrosis necessitating drainage in one. The mean operative time was 269 minutes, the complication rate was 25%, the blood transfusion rate was 4%, the ancillary procedure (mostly SWL and second-look PCNL) rate was 77%, the mean hospital stay was 5.6 days and the final SFR after the ancillary procedures 96.9%. Those authors showed a trend towards a linear relation between the drop in postoperative hemoglobin level and the number of tracts without clinical implications.

PCNL is in a continuous process of implementing new technologies and devices which, together with the experience gained in high volume centers and shared through educational programs, have resulted in increased safety, efficacy and decreased operating time and hospital stay. BPCNL was a natural extension of this active search for improvement and diversification. It had already been reported as being safe and effective when performed in a tubeless fashion, in pediatric patients and with the patient in a supine position.[10,12,18] The bilateral approach continues to be demanding and challenging for the surgeon, and there are also clinical concerns related to the patient as well as cost-effective issues related to the healthcare providers. The potential advantages for undergoing bilateral treatment are shorter cumulative anesthesia time, avoidance of an additional anesthesia session for the contralateral side, shorter cumulative hospital stay and decreased stress.[19] Disadvantages are mostly related to a relatively higher rate of complications. In one study that compared 78 UPCNLs to 47 BPCNLs and used a modified Clavien classification, the overall complication rates were 31% and 51%, respectively (p = 0.01). However, the significance was reached only for the low grade complication group.[6] Contrarily, Holman et al reported no significant differences in the overall complication rates between 300 UPCNL and 150 BPCNL procedures.[8] The potential risk of renal function impairment when operating bilaterally had been analyzed both in animal models and in clinical studies. In one animal model mimicking BPCNL in pigs, there was a significant postoperative decrease in

the glomerular filtration rate, effective renal plasma flow, renal extraction of para-aminohippurate, urine flow, absolute sodium excretion and fractional sodium excretion, although those functional responses for BPCNL were comparable to those after UPCNL.[20] In humans, the changes in the creatinine serum levels following BPCNL were non-significant and transient.[8,9,11] Bleeding, another clinical concern, appears to be increased after BPCNL in comparison to UPCNL, as indicated by the transfusion rates reported in literature (4.1%-25%).[7,17,19] Blood loss has been linearly related with the size of the stones and the number of tracts, but it was not clear whether it was related to the bilateral approach.[7,8,19] Noteworthy, this data should be regarded with prudence since the decision to administer blood was not based on standardized criteria in any of these studies.

The cost-effectiveness issue is controversial. While some studies showed superiority for BPCNL in terms of absolute cost, the reimbursement policy of the insurance companies may abrogate these savings since the second procedure is only partially or not at all reimbursed in many countries.[12,19,21,22] This limitation may discourage urologists to offer a bilateral approach.

The present study has the particularity of comparing tubeless BPCNL performed in supine and prone positions and both procedures to UPCNL. Our results showed a trend toward longer operative time for SBPCNL in comparison to PBPCNL. That difference may stem from the need to reposition the patients and re-locate the operative facilities in the room during the supine approach, while the prone position allows a single positioning of the patients for access to both sides. We did not find a reliable clinical explanation for the significantly shorter hospital stay of the patients in the PBPCNL groups. This result could be influenced by different hospitalization policies in the two institutions, since 25 (86%) of the SBPCNLs were done in one institution and all 28 PBPCNLs were performed in the other. Whatever the reason, the mean hospital stay in our study (3 ± 1.7 days) was significantly shorter than that reported in previous series and it may be the result of implementing a tubeless approach.[6-11,15-19]

We were able to accomplish BPCNLs in 89% (58/65) of the planned patients. This result compares favorably with the 30% failure rate reported by Ugras et al.[23] Based on a series of 42 planned BPCNLs, combined with reports in literature and various arbitrary restrictions, those authors proposed criteria according to which the surgery should be aborted after the first side. Those criteria include: operative time longer than 180 minutes for the initial side, an absolute hemoglobin of less than 11 g/dL, a drop of more than 3 g/dL in hemoglobin, a systolic blood pressure of less than 100 mmHg, decreased oxygen saturation (SaO_2) under 95%, acidosis with a pH less than 7.35, and hyponatremia of less than 128 mEq/L. Most of these criteria clearly represent an indication to stop any surgical procedure, not only a PCNL. We believe that the decision of whether or not to proceed with the second procedure should rely on a mutual intraoperative assessment by the urologist and the anesthesiologist based on the intraoperative course.

The difference in outcome between UPCNLs with BPCNLs was clear. UPCNLs were significantly shorter procedures, they had a lower blood transfusion rate, and the patients had a shorter hospital stay. Although the complication rate was similar in both groups, it tended to be of higher severity in the UPCNL group. That finding may possibly be influenced by inclusion of the seven patients planned to undergo BPCNL and switched to UPCNL after the initial side due to long operative time and bleeding.

We are aware of some limitations related to our study. It is retrospective, non-randomized and the numbers of patients in the groups compared for patient positioning on the operating table are relatively small. In addition, it is possible that adding a comparison group of patients with an indication for BPCNL but who had been preselected for a staged procedure could enhance some of the analyzed data. However, the provision of such an analysis was precluded by the study not having been prospective and the fact that all patients were offered BPCNL without preoperative exclusion. We believe that dealing with a consecutive series of patients and giving the statistical similarity in demographics and clinical data there is enough strength to support our study. Another potential bias is related to the assessment of SFR at different time points: immediate NCCT for patients left with nephrostomy tubes, and delayed NCCT within 1 month after the treatment for the other patients. The rationale behind this follow up design was dictated by logistic and economic limitations related to the medical system's regulations which do not permit us to perform ureteroscopic procedures as a second operation during the same hospitalization. Therefore, we believe that reporting SFRs before the patients undergo ancillary procedures is appropriate under these circumstances.

Conclusion

In conclusion, we believe that BPCNL has already passed the point of needing to prove safety and feasibility. It is already an established procedure and may be routinely offered to patients with bilateral

renal calculi. Patients should be informed that BPCNL is associated with a higher blood transfusion rate and a longer hospital stay in comparison to UPCNL, but that it may spare them from repeat anesthesia and hospitalization. This study is the first to evaluate positioning as a variable and as such, it may enrich the general knowledge regarding tubeless BPCNL. Bearing in mind that the aim of any PCNL is to render the patient stone free in a minimum number of interventions and with no complications, each surgeon should decide to choose the best approach according to his/her experience as well as the patient's preferences. □

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