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ORIGINAL PAPER

Simultaneous bilateral tubeless percutaneous nephrolithotomy of staghorn stones: a prospective randomized controlled study

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Abstract A randomized controlled study was performed to evaluate the feasibility and outcome of staged versus simultaneous bilateral tubeless PCNL for bilateral renal staghorn stones. A total of 99 patients, with bilateral renal staghorn stones, were prospectively randomized into two groups, and underwent staged tubeless PCNL (49 patients) or simultaneous bilateral tubeless PCNL (50 patients). Preoperative data included urinalysis, urine culture, complete blood count, biochemistry study, renal ultrasonography, intravenous urography, and Tc 99m DTPA clearance for the determination of selective glomerular filtration rate. Intraoperative findings, operative time, and outcome were also recorded. All patients were followed regularly at clinic every 3 months during year 1 and every 6 months thereafter, and Tc 99m DTPA clearance for determination of selective glomerular filtration rate was performed to assess the kidney function 6 months later. There was no difference between the groups with regard to serum creatinine change, hemoglobin decrease, and complication grading. The length of stay, convalescence period, pain visual analog scale, analgesic requirements, and direct cost favored the simultaneous bilateral tubeless group with statistical significance. There was no significant statistical difference in relative perfusion rate between preoperative and postoperative in both groups. This study demonstrates that simultaneous bilateral tubeless PCNL is a safe, efficacious, and cost-effective option in bilateral renal staghorn calculi, which is associated with low morbidity, short hospital stay, high stone-free rate, and early return-to-normal activity.

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Abbreviations

PCNL	Percutaneous nephrolithotomy
Tc 99m DTPA	99m technetium diethylenetriaminepentaacetic acid
GFR	Glomerular filtration rate
ESWL	Extracorporeal shock wave lithotripsy
VAS	Visual analog scale

Introduction

Percutaneous nephrolithotomy (PCNL) is the standard of care for the treatment of large and/or complex renal calculi [1, 2]. Traditionally, patients with bilateral large or complex stones warranting PCNL were treated with staged PCNL. In recent years, a number of investigators have demonstrated favorable outcomes in patients undergoing simultaneous bilateral PCNL instead [3–8]. Furthermore, with a growing realization that substantial postoperative pain and morbidity after PCNL are caused by the use of nephrostomy tubes, attempts have been made to modify standard PCNL procedures by using smaller working sheaths associated with compatible nephrostomy tubes, a procedure known as "mini-PCNL", [9–11] or avoiding the use of a nephrostomy tube altogether by placing an internal ureteral stent to drain the urine after surgery, also known as "tubeless PCNL" [12].

To our knowledge, no studies have specifically evaluated the feasibility and outcome of staged versus simultaneous bilateral tubeless PCNL for bilateral renal staghorn

stone. We conducted a randomized controlled study to evaluate simultaneous bilateral tubeless PCNL in the treatment of bilateral renal staghorn stones.

Materials and methods

Our Institutional Review Board approved the study, and all patients signed the written informed consent before participating. The study was designed as a randomized controlled trial and was carried out from October 2005 to September 2009. A sample size of 45 patients per group was determined to detect a 40% difference in the proportion of trial parameters (including the stone-free rate, and the length of hospital stay) in the treatment groups at a 0.5 level of significance and a power of 90%. Adult patients with bilateral renal staghorn stones who met the inclusion criteria were enrolled, and randomized into two groups. The inclusion criteria were normal renal function, American Society of Anesthesiologists classifications for systemic disease Class 1 and 2, absence of congenital abnormalities, and coagulopathy. Patients were excluded from the study if they had a history of renal surgery, or urosepsis, or if a supracostal approach was used.

Before undergoing surgery, 113 patients were prospectively randomized into two groups using random numbers table. In the staged tubeless PCNL group, 56 patients were considered; 3 of them withdrew their written informed consent and 4 were lost to follow-up (after less than 6 months), so were removed from the study, leaving a total of 49 patients (mean age 58.1 years old) who were enrolled to receive staged PCNL. Among them, 21 patients had bilateral complete staghorn stones and 28 patients had unilateral complete staghorn stones. In the simultaneous bilateral tubeless PCNL group, 57 patients were initially considered; 4 withdrew their written informed consent and 3 were lost to follow-up, so were removed from the study, leaving a total of 50 patients (mean age 57.1 years old) who were enrolled to receive simultaneous bilateral tubeless PCNL. Among them, 20 patients had bilateral complete staghorn stones and 30 patients had unilateral complete staghorn stones.

Preoperative data included urinalysis, urine culture, complete blood count, biochemistry study, renal ultrasonography, intravenous urography, and 99m technetium diethylenetriaminepentaacetic acid (Tc 99m DTPA) to determine selective glomerular filtration rates (GFR). Intraoperative findings, operative time (from insertion of the puncture needle to the end of the procedure), and outcomes were also recorded. All patients underwent a nonenhanced CT and antegrade nephrostogram (by radiologist under fluoroscopic guidance) on the first postoperative day to identify any residual fragments (defined as any residual calculus regardless of size). The double-J stent was removed under cystoscopy guidance 2 weeks later.

During hospitalization, all patients were prescribed parenteral cefazolin 1 g q6h, oral Ketorolac 10 mg 3 times per day to minimize any urinary tract infections and pain, and allowed to use sublingual buprenorphine 0.2 mg on demand. Overall dosage was documented and compared. A 10-cm linear Visual Analog Scale (VAS) was performed to assess for pain at 2 h post-operatively. Complete blood count and serum creatinine were checked again. The modified Clavien grading system was used to evaluate the perioperative morbidity of the PCNL treatment [13]. Pipemidic acid trihydrate 250 mg twice per day for 2 weeks was prescribed after discharge. Detailed cost information was obtained from the hospital billing department, including the costs for room and board, laboratory, pharmacy, radiology, use of operating room, surgical supplies, anesthesia, and use of the recovery room.

All patients were followed up at the clinic regularly every 3 months during year 1 and every 6 months thereafter. At each visit plain X-ray KUB, urinalysis, urine culture, and serum creatinine were obtained. Also, Tc 99m DTPA clearance for determination of selective glomerular filtration rate was performed to assess the kidney function 6 months later.

The symptomatic or more complicated side was treated first. Staged PCNL was performed 4 weeks later. The tubeless technique was used for all PCNL procedures. Following placement of a 16 Fr Foley catheter without ureteral occlusion catheter, the patient was turned prone under endotracheal general anesthesia and access to the desired collecting system (intersection of major calices) was obtained using a puncture needle under fluoroscopic guidance. The track was formed using serial plastic dilators until an Ampltz sheath (30 Fr) was inserted. The stones were fragmented with a pneumatic lithoclast and removed piece-by-piece with stone forceps for chemical analysis. After rigid nephroscopy and stone debulking, a flexible nephroscopy was used to inspect the collecting system and remove any residual stones. Finally, we changed the irrigation fluid from physiologic saline to distilled water. The bleeding points were then cauterized by a conventional electric cauterizer (roller) using a resectoscope to pass through the tract. With careful inspection, bleeding points would be identified and cauterized. To avoid an adjacent organ or renal pedicle injury, the electrode touched the bleeding points on the surface of the tract and the renal pelvis for a few seconds without putting pressure on them. Therefore, a bloodless tract could be obtained and there was no need for an indwelling nephrostomy tube.

All patients underwent placement of an antegrade double-J catheter (7.0 Fr) after the bloodless procedure. After removal of the working sheath, the wound was closed

with 3–0 Nylon sutures to control any subcutaneous bleeding. All procedures were performed by the same urologist to ensure uniform levels of skill and experience. Operative times were recorded from the tract puncture until skin closure.

Before commencing the contralateral PCNL, blood pressure, heart rate, and serum hemoglobin were checked for evaluation of hemodynamic status. Chest fluoroscopy was performed to identify a hydropneumothorax. Simultaneous contralateral tubeless PCNL was performed afterwards.

All patients underwent a nonenhanced CT and antegrade nephrostogram on the first postoperative day to identify residual fragments (defined as any residual calculus regardless of size). Any fragments observed on the CT excluded the possibility of stone-free status. All patients with residual fragments underwent a second-look flexible nephroscopy (along the original tract as possible with the assistance of radiologist using fluoroscopic guidance) on the second or third postoperative day to retrieve residual stones. The primary end point of the study was the comparison of the stone-free rate and the length of stay. The second end point was the comparison of analgesic consumption, the complication rate, and total hospital costs.

Statistical analysis was performed using SPSS software. The chi-square test, 2-sample independent t test, and Fisher's exact test were used when appropriate. A p value below 0.05 was considered significant.

Results

A total of 99 patients undergoing PCNL for bilateral renal staghorn stones completed the study protocol, 49 patients in the staged tubeless PCNL group, and 50 patients in the simultaneous bilateral tubeless PCNL group. No significant statistical difference was observed in patient age, sex distribution, body mass index, stone burden, follow-up period, or composition (Table 1). The stone-free rate was 71.43 and 72.00% in the staged tubeless PCNL group and the simultaneous bilateral tubeless PCNL group, respectively, with no significantly statistical difference.

There was no difference observed between the groups with regard to changes in serum creatinine levels, decrease hemoglobin levels, buprenorphine dosage, or Clavien grading system (Table 2). Furthermore, there was no urinoma, peri-nephric fluids collection, or hematoma detected by postoperative nonenhanced CT. However, the lengths of stay (3.62 ± 1.03 days) in the simultaneous bilateral tubeless PCNL group were shorter (6.37 ± 1.55 days) than those of the staged tubeless PCNL group to statistically significant degree. The pain Visual Analog Scale (VAS) and analgesic requirements favored the simultaneous bilateral tubeless PCNL group with statistical significance. Convalescence periods (return-to-normal activities) (6.44 ± 1.15 days) and direct costs (55470.20 ± 2701.05 NT$) were nearly uniformly higher for patients undergoing the staged tubeless PCNL compared to those undergoing simultaneous bilateral tubeless PCNL.

There was also no difference between the groups with regard to the relative perfusion rate and glomerular filtration rate by Tc 99m DTPA clearance, both preoperative and postoperative. (Table 3) Adjuvant extracorporeal shock wave lithotripsy (ESWL) for residual major fragments was performed 19 sessions in 11 staged tubeless PCNL patients and 17 sessions in 9 simultaneous bilateral tubeless PCNL patients, respectively, and scheduled 4 weeks later.

Discussion

Staghorn calculi are branched stones that occupy a large portion of the collecting system. Unfortunately, there is no consensus regarding the precise definition of a staghorn calculus. Typically, they fill the renal pelvis and branch into several or all of the calices. The term "partial staghorn" calculus designates a branched stone that occupies part, but not all of the collecting system while a "complete staghorn" calculus refers to a stone that occupies virtually the entire collecting system. Furthermore, the designation of "partial" or "complete" staghorn calculus does not imply any specific volume criteria [14]. In this study, a renal staghorn stone means a renal huge branched stone and the bulky stone presents with square millimeter as its stone burden. An untreated staghorn calculus is likely to destroy the kidney and/or cause life-threatening sepsis [15, 16]. Complete removal of the stone is an important goal in eradicating any causative organisms, relieving obstruction, preventing further stone growth, and any associated infection, and preserving kidney function. Furthermore, PCNL allows the removal of large renal stones with minimal morbidity, especially for bilateral renal staghorn stones.

In the treatment of patients with staghorn calculi, outcomes typically evaluated include stone-free rates, number of procedures per patient, and rates of complications. The stone-free rate in our study compared well with other reported series [14]. The number of procedures per patient was in accordance with previous reports and our rate of complications compared to AUA guidelines [14]. No serious complications were observed in the study, such as pneumothorax, retroperitoneal colon fistula, and late postoperative bleeding. In addition, when compared to staged bilateral tubeless PCNL, simultaneous bilateral tubeless PCNL was associated with shorter operative times, lengths

Table 1 Patient demographics and perioperative data

Characteristics	Staged tubeless PCNL	Simultaneous bilateral tubeless PCNL	
Patients (*n*)	49	50	
Age (year)			
Mean	58.10 ± 11.03	57.08 ± 10.61	0.639[a]
Range	33–76	39–78	
Gender (*n*)			0.743[b]
Male	38	37	
Female	11	13	
Body mass index	24.71 ± 2.84	24.94 ± 2.62	0.712[a]
Stone burden (mm)	4656.90 ± 1567.8	4624.64 ± 1425.1	0.915[a]
Tract numbers	2.53 ± 0.87	2.62 ± 0.92	0.621[a]
Follow-up period (months)	18.31 ± 4.66	18.04 ± 4.62	0.776[a]
Operative times (min)	286.12 ± 68.8	244.92 ± 29.0	<0.001[a]
Stone-free rate	35 (71.43%)	36 (72.0%)	0.950[c]
Stone composition			0.514[c]
Struvite + Apatite	5 (10.2%)	6 (12.0%)	
Uric acid	1 (2.0%)	2 (4.0%)	
Whewellite	18 (36.7%)	20 (40.0%)	
Whewellite + Apatite	14 (28.6%)	9 (18.0%)	
Weddellite	10 (20.4%)	12 (24.0%)	
Cystine	1 (2.0%)	1 (2.0%)	

[a] 2-sample independent *t* test; [b] chi-square test; [c] Fisher's exact test

Table 2 Surgical results and complications

	Staged tubeless PCNL	Simultaneous bilateral tubeless PCNL	*p* value
Mean length of stay (days)	6.37 ± 1.55	3.62 ± 1.03	<0.001[a]
Mean Cr change (mg/dl)	0.08 ± 0.11	0.08 ± 0.12	0.989[a]
Mean Hb decrease (gm/dl)	2.01 ± 0.51	1.99 ± 0.52	0.846[a]
VAS POD 2 (10 cm)	6.31 ± 0.98	5.08 ± 1.07	<0.001[a]
Ketorolac (mg)	116.33 ± 23.34	63.00 ± 15.94	<0.001[a]
Buprenorphine dosage (mg)	0.08 ± 0.11	0.08 ± 0.15	0.975[a]
Convalescence (days)	11.76 ± 2.41	6.44 ± 1.15	<0.001[a]
Direct cost (NT$)	90237.96 ± 8164.58	55470.20 ± 2701.05	<0.001[a]
Clavien grading system			0.906[b]
0	41 (83.7%)	42 (84.0%)	
1	8 (16.3%)	5 (10.0%)	
2	2 (4.1%)	3 (6.0%)	

[a] 2-sample independent *t* test; [b] Fisher's exact test

of stay, and convalescence as well as lower analgesic consumption and direct costs.

Cost analysis revealed a significant cost advantage for simultaneous versus staged bilateral tubeless PCNL, with direct cost savings of NT$ 34,767 (38.5%). Increased resource usage and costs associated with staged procedures are evident throughout the hospital stay. In some cases, there is a need for repeated preoperative blood work before the second procedure, and preoperative antibiotics and other hospital administered medications (including anesthetics, postoperative analgesics, etc.) are required for both operative procedures. Intraoperatively a staged approach entails the use of a larger number of disposable instruments during each of the two procedures, which can be reused during a simultaneous procedure, further adding to a greater financial burden in staged bilateral tubeless PCNL cases. Postoperative imaging is duplicated in the staged approach, but can be combined afterwards in the simultaneous approach. Finally, the shorter cumulative lengths of stay for patients undergoing simultaneous bilateral tubeless PCNL are reflected in a significantly lower cost of room and board.

Physician reimbursement was NT$ 2,000 (24.6%) less for simultaneous versus staged PCNL. It was quite similar

Table 3 Morphology and function of corresponding kidney

	Staged tubeless PCNL	Simultaneous bilateral tubeless PCNL	*p* value
Glomerular filtration rate (ml/min)			
Pre-operative	59.274 ± 14.16	59.40 ± 13.32	0.823[a]
6 months later	64.27 ± 13.48	65.36 ± 12.97	0.897[a]
p value	0.798[a]	0.846[a]	
Relative perfusion rate (%)			
Pre-operative	39.27 ± 4.00	39.09 ± 3.97	0.961[a]
6 months later	41.52 ± 4.24	41.42 ± 3.38	0.681[a]
p value	0.427[a]	0.623[a]	

[a] 2-sample independent *t* test

with that reported by Bagrodia et al. [17] and provided a significant financial disincentive for the surgeon to perform simultaneous bilateral PCNL. The disparity between the advantage to insurers and third-party payers and the disadvantage to the surgeon in performing simultaneous bilateral PCNL is particularly glaring as third-party payers benefit from the direct cost savings, as presumably hospital charges are likewise reduced.

Blood transfusion is a major complication of PCNL. In the present study, 2 patients in the staged tubeless PCNL group and 3 patients in the simultaneous bilateral tubeless PCNL group required intraoperative blood transfusion because of significant blood loss due to multiple tracts. No patients required any blood transfusion for postoperative hemorrhaging. The incidence of blood transfusion after bilateral simultaneous PCNL has varied in published reports from 4.2 to 28.6% [3, 5, 8]. Because the drops in mean hemoglobin drop in both groups were comparable, we did not need for a blood transfusion in the study group to the group of the tubeless procedure. Other investigators also did not experience increased transfusion requirements in their studies of tubeless PCNL [4, 12, 18–21].

Postoperative pyrexia is a common complication in PCNL of infectious calculi. In this series, a postoperative fever >38.5°C was recorded in 13 patients. The rate of postoperative fever (16.3 and 10.0%) was lower than the 26% rate reported by Troxel and Low [22]; prophylactic antibiotics may have contributed to this difference [23, 24]. Multiple factors contributed to a postoperative fever after PCNL. There were 4 out of 5 patients in the staged tubeless PCNL and 5 out of 6 patients in the simultaneous bilateral tubeless PCNL group, who developed postoperative fever, even though prophylactic parenteral antibiotics had been prescribed. The 3 patients in the staged tubeless PCNL group developed postoperative pyrexia during every procedure. These patients suffered from bilateral renal staghorn stones composed of struvite and ammonium phosphate. A possible explanation for the fever correlating with the infection calculi, but not the urinary tract infection, may be that, in this series, even though prophylactic antibiotics were administered to all patients, and patients with infections (as evidenced by urinary tract infection suggested by the urinary routine examination, fever, and preoperative high white blood cell count in the blood) were treated initially with a complete course of culture-specific antibiotics, followed by suppressive therapy until the PCNL was rescheduled. In fact, a preoperative urinary sterile status was easily attained, although with conventional antibiotics, eliminating the microorganisms inside the calculi completely was difficult [25], and most calculi contained a high dose of endotoxins [26]. In the procedure of comminution of calculi, these endotoxins and microorganisms inside the calculi were released, and a systemic absorption of irrigation fluid containing bacteria or endotoxins contributed to a chill during the operation and a postoperative fever.

The present study was limited by its inherent biases in regional costs, derived from the National Health Insurance Bureau of Taiwan. These costs may not apply to other countries.

Conclusions

This study demonstrates that simultaneous bilateral tubeless PCNL is a safe, efficacious, and cost-effective option in cases of bilateral renal staghorn calculi, which is associated with low morbidity, short hospital stays, high stone-free rates, and early return-to-normal activity times.

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