ORIGINAL RESEARCH

Analysis of Clinical Outcomes of Tubeless Standard-Sized PCNL (TSPCNL) for Large Volume Renal Stones: A Single Center Retrospective Study

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Objective: To describe the outcomes of standard-sized tubeless PCNL (TSPCNL) in terms of clinical efficacy (stone-free rate, operative time and length of hospital stay) and safety (transfusion rate, infection and complications).

Methods: A chart review was done on all patients who underwent standard-sized PCNL from 2017 to 2019. All cases of TSPCNL were identified. The patient and stone demographics were analyzed including intraoperative and postoperative outcomes. Complications were analyzed using the Clavien-Dindo classification.

Results: Seventy-nine consecutive cases of prone, single-tract, upper pole access, tubeless PCNL were identified and analyzed. The mean age was 52.74±11.26 with a female to male ratio of 1:1.4. The Guy's Stone Score showed 12 (15.2%) Grade 1; 23 (29.1%) Grade 2, 11(13. 9%) Grade 3 and 33 (41.8%) Grade 4 renal stones. Mean stone size was 33.7±14.1mm. The stone-free rate was 98.73%. The mean hemoglobin change was 13.6±13.9 g/L. The mean creatinine change was 2.65±23 umol/L. The mean length of hospital stay was 2.46±1.84 days. Twenty-four (30.4%) experienced significant pain, which required analgesics in the form of opioid derivatives. According to the modified Clavien-Dindo classification, 6/79 (7.6%) had Grade 1; 4/79 (5.1%) had Grade 2 and 2/79 (2.5%) had Grade 3 complications. There was no mortality.

Conclusion: The authors' experience adds to the growing evidence that TSPCNL is a reasonable, efficient and safe approach for large volume nephrolithiasis. Clear indications are needed prior to nephrostomy tube placement after standard-sized PCNL.

Keywords: Renal Complications, Renal Stones, Tubeless Percutaneous Nephrolithotomy

Introduction

Percutaneous nephrolithotomy (PCNL) has rapidly evolved to become the gold standard of management for renal stones >20mm. The usual practice of most urologists includes post-procedural insertion of a nephrostomy tube (NT) primarily for drainage of the collecting system, and may also serve as tamponade for the percutaneous access tract to prevent bleeding, and to facilitate a staged PCNL, if an interval procedure is necessary.[1-2]

Recently, this routine use of NT after a standard sized PCNL was challenged. Tubeless percutaneous nephrolithotomy was found to be safe and offered the following advantages such as shorter hospital stay, less postoperative pain and less analgesia requirement.[3-4]

In a study done by Agrawal and Agrawal, tubeless PCNL is recommended in patients with the following inclusion criteria: stone burden <30 mm, a single and small caliber access tract such as mini PCNL, no significant residual stones, no significant perforations, minimal bleeding, and no requirement for a secondary percutaneous procedure.[5] For safety reasons, some investigators conducted studies on modifications of tubeless PCNL wherein a sealant such as fibrin glue or hemostatic plug was utilized to minimize hemorrhage and urinary leakage per access site.[6-7]

Tubeless PCNL is typically applied to mini-PCNLs (where the access tract and Amplatz sheath size is <18Fr). Majority of such procedures are intended to treat solitary or multiple stones with an aggregate size of <20mm. This is the first report involving a large subject population with renal stones (>30cm) subjected to tubeless standard-sized PCNL (28-30Fr).

This study aimed to describe the outcomes of standard-sized tubeless PCNL (TSPCNL) in terms of clinical efficacy (stone-free rate, operative time and length of hospital stay) and safety (transfusion rate, infection and complications). This helps the urologist understand the indication and the authors' method of a tubeless approach.

Methods

A retrospective chart review was done on all the PCNL cases that were performed from January 1, 2017 to December 31, 2019 was done. All patients who were treated with a standard-sized tubeless percutaneous nephrolithotomy (TSPCNL) were included in the study. Data were collected from a total of 79 consecutive patients. Parameters gathered included the following: Patient demographics (Age, Sex, BMI, comorbidities), stone demographics (size, Guy's stone score and laterality), intra-operative parameters (operative time, estimated blood loss, transfusion requirements), post-operative outcomes (stone-free rates, changes in hemoglobin and changes in creatinine levels, length of hospital stay, urine leak per access site). Complications were classified using the modified Clavien-Dindo classification.

Standard Surgical Technique

All patients had general endotracheal anesthesia. After standard antisepsis and sterile drapes have been applied and while the patient in lithotomy position, under fluoroscopic control, a 6Fr open-ended ureteral catheter is inserted into the ureteral meatus until its tip is positioned in the upper pole calyx. Patient was then repositioned to prone position and draped in a sterile manner. A retrograde air and contrast pyelogram were performed by injecting through the ureteral catheter. An appropriate site on the skin was then chosen, which corresponds to the upper posterior calyx. Using the bullseye method (hub-over-tip), an 18G percutaneous access needle was advanced to the upper pole calyx for about 7cm. The depth is verified with a 20-30 degrees oblique view and saline is injected through the ureteral catheter to see if there is efflux back into the needle. Any adjustment is done in increments until the proper positioning of the needle is achieved. Once the proper location was confirmed and egress of saline is noted, an Amplatz super stiff guidewire was then inserted through the collecting system into the ureter and down to the bladder. A Desilet-Hoffman coaxial catheter or a dual lumen guidewire introducer was then used to reintroduce another safety guidewire following the principles of duplication. The access site was serially dilated to 28 or 30Fr through the super stiff guidewire, depending on surgeon preference. A 26Fr Karl Storz nephroscope is inserted and once the stone is visualized, fragmentation is performed using an (EMS Swiss Lithoclast Master) ultrasonic lithotriptor. Large stone fragments were also extracted with either a grasper or a stone basket. Stone clearance was confirmed via nephroscope navigation through all the calyces and further confirmed with fluoroscopy. An indwelling 6Fr double J stent was inserted antegradely under fluoroscopic and endoscopic control. The Amplatz sheath is then removed. Pressure is applied to the access site for about 5 minutes, after which the skin is then approximated with either 4.0 Silk sutures or with steri-strips.

Ethical Considerations

Personal information of patients included in the study was accessible only to the principal investigator, co-author and research assistant. A number or code was assigned to each patient after all pertinent data have been gathered. All data gathered were used only for research purposes. This study was conducted in accordance with ICH-GCP principles and guidelines and commenced only upon approval by the NKTI-REC.

Results

Out of 939 standard-sized PCNLs during the study period of January 1, 2017 to December 31, 2019, seventy-nine (79) consecutive cases of TSPCNL were identified and analyzed. Table 1 shows demographics and comorbidities of patients who underwent TSPCNL in NKTI. Most were male (46; 58.2%) compared to the female population (33; 41.8%) with a female to male ratio of 1:1.4. The mean age was noted to be 52.74±11.26 (28-86 years old). The largest number of patients were overweight (35, 44.3%) followed by those who were in the normal weight category (30, 38%). There were 11 patients who were obese (13.9%) and three were underweight (3.8%). The largest number of patients had hypertension (36; 45.6%) followed by 22 patients who had diabetes mellitus (27.8%). There were five (6.3%) patients noted to have chronic kidney disease and three (3.8%) were found to have cerebrovascular disease. Lastly, one patient (1.3%) had COPD and two (2.5%) patients who had coronary artery disease who were on antiplatelet treatment which was withdrawn a week prior to the procedure. Both patients had normal bleeding parameters prior to surgery.

With regard to previous stone surgery, the majority had none (69, 87.3%) while 6 (7.6%) patients who had open stone surgery and 4 (5.1%) patients who had previous PCNL. A few patients (8, 10.1%) had previous failed ESWL while the rest of these patients 71/79 (89.9%) had no previous ESWL. Table 2 summarizes the stone characteristics. In the investigation, patients who had TSPCNL had a stone size of 33.7mm±14.1. Guy's stone scoring was utilized to evaluate complexity. The stone score was mostly Grade 4 (33; 41.8%) where patients had complete staghorn calculus. This was followed by stone score Grade 2 (23; 291%) where there was an incidence of multiple stones in a patient with simple anatomy, then Grade 1 stone score (12; 15.2%) where patient had solitary stone in the middle or lower pole, or in the renal pelvis with normal anatomy. Lastly, Grade 3 score in 11 (13.9%) patients, all of which had partial staghorn calculus.

Stone laterality was equal, 39 (49.4%) patients had left sided stones and 32 (40.5%) had right sided stones. There were 8 (10.1%) patients with bilateral stones. Most patients (31; 39.2%) had incidence of moderate hydronephrosis, 26 (32.9%) patients

Table 1. Patients' clinico-demographics and co-morbid conditions.

Parameters	n	%
Age		
Mean±SD	52.74±11.26	
Sex		
Male	46	58.2
Female	33	41.8
Body Mass Index		
Underweight	3	3.8
Normal	30	38.0
Overweight	35	44.3
Obese	11	13.9
Co-Morbid Conditions		
Hypertension		
Absent	43	54.4
Present	36	45.6
Diabetes Mellitus		
Absent	57	72.2
Present	22	27.8
Cerebrovascular Disease		
Absent	77	97.5
Present	2	2.5
Chronic Kidney Disease		
Absent	74	93.7
Present	5	6.3
COPD		
Absent	78	98.7
Present	1	1.3
Coronary Artery Disease		
Absent	76	96.2
Present	3	3.8
Previous Stone Surgery		
None	69	87.3
Open	6	7.6
PCNL	4	5.1
Previous ESWL		
No	71	89.9
Yes	8	10.1

who had mild hydronephrosis and 17 (21.5%) patients who had no hydronephrosis. On the other hand, there were only five patients who had severe hydronephrosis (6.3%). All of the patients had radioopaque stones (79/79; 100%).

Single-tract, prone PCNL was done for all cases utilizing upper pole access. The overall stone-free rates detected by direct vision and fluoroscopy was 98.73% (78/79).

Intraoperative Outcomes

Table 3 summarizes the intraoperative outcomes. The mean operative time was 115±1.72 (40-305) minutes. Average blood loss of 244.1±273.5mL (50-2000) was noted. Only two patients (2.53%) required postoperative blood transfusion. One patient (1.3%) with bilateral stones measuring 30mm for each side who underwent bilateral synchronous PCNL needed one unit packed red cells and another patient (1.3%) with 50mm full staghorn calculus also needed transfusion with two units of packed red cells.

Postoperative Outcomes

Table 4 summarizes the postoperative outcomes. The drop in hemoglobin was insignificant with a mean of 13.6±13.9 g/L (2-58) while creatinine levels were stable. Change in creatinine levels obtained were noted to have a mean of 2.65±23 umol/L (8.84-119.34). Length of stay in the institution after TSPCNL was determined and showed to have an average of 2.46±1.84 days (1-13). Significant postoperative pain was experienced by 24/79 (30.4%) requiring intake of opioid derivatives. Most number of patients did not request for breakthrough pain medications (55; 69.6%). Of these patients, there were 18 (22.8%) patients who requested for breakthrough pain medications once throughout the entire course of postoperative period while there were five patients (6.3%) who requested twice and only one (1.3%) who requested thrice. There was no incidence of urine leak per access site noted in all subjects (79/79; 100%).

Complications

Table 5 summarizes the complications among patients who had TSPCNL. According to the

Table 2. Stone demographics of patients.

Parameters	n	%
Stone Size		
Mean±SD	33.7mm±14.1	
Stone Score		
Grade 1	12	15.2
Grade 2	23	29.1
Grade 3	11	13.9
Grade 4	33	41.8
Stone Laterality		
Left	39	49.4
Right	32	40.5
Bilateral	8	10.1
Incidence of Hydronephrosis		
Absent	17	21.5
Mild	26	32.9
Moderate	31	39.2
Severe	5	6.3

Table 3. Intraoperative parameters of patients.

Parameters	n	%
Operative Time		
Mean±SD	115 mins ±1.72	
Blood Loss		
Mean±SD	244.1 mL ±273.5	
Transfusion Requirements		
None	77	97.5
1 unit	1	1.3
2 units	1	1.3

Table 4. Post-operative outcomes of patients.

Parameters	n	%
Drop in Hemoglobin		
Mean±SD	13.6 g/L ±13.9	
Change in Creatinine		
Mean±SD	2.65 umol/L ±23	
Length of Hospital Stay		
Mean±SD	2.46 days ±1.84	
Request for Breakthrough Pain Medications		
None	55	69.6
1	18	22.8
2	5	6.3
3	1	1.3
Urine Leak Per Access Site		
Absent	79	100
Present	0	0

modified Clavien-Dindo classification, majority of the patients (67/79; 84.8%) were free of any complications and had unremarkable postoperative course. There were six patients (6/79; 7.6%) who had Grade 1 (fever due to atelectasis and phlebitis) but none had sepsis. Four patients (4/79; 5.1%) had Grade 2 (2 patients had blood transfusion and another 2 had mild pleural effusion which were managed conservatively) and lastly, two patients (2/79; 2.5%) had Grade 3 (pleural effusion requiring ultrasound-guided thoracentesis). These patients presented with shortness of breath postoperatively and were documented to have pleural effusion by chest x-ray and chest ultrasound. Pleural effusion was noted at the same laterality on which PCNL was done. There was no mortality.

Table 5. Complications and morbidity among patients.

Parameters	n	%
Complications		
None	67	84.8
Grade 1 (Fever)	6	7.6
Grade 2	4	5.1
Blood Transfusion	2	2.5
Pleural effusion without thoracentesis	2	2.5
Grade 3 (Pleural effusion with thoracentesis)	2	2.5

Discussion

PCNL is the procedure of choice for patients with renal stones measuring >20 mm, multiple renal stones and <20mm renal stones in lower calyx with narrow infundibulopelvic angle and failed extracorporeal shock wave lithotripsy or ureteroscopy.[8] Standard practice includes placement of nephrostomy tube after intracorporeal lithotripsy has been completed. The main indication is primarily for urinary drainage, hemostasis and facilitate re-entry if a staged procedure is warranted. However, studies have reported morbidities associated with placing nephrostomy tubes such as greater postoperative pain requiring greater narcotic use and longer hospital stay.[9] Tubeless percutaneous nephrolithotomy was introduced to limit the incidence of these adverse events.

Postoperative hemorrhage from the percutaneous access tract has always been a concern among urologists and this has led to the routine use of a nephrostomy tube. Present study disproves this claim. The authors used 28-30Fr Amplatz sheaths in all their patients and demonstrated that bleeding is not a common occurrence. The average mean obtained from drop in hemoglobin was insignificant, with a mean of 13.6±13.9 g/L (2-58). Even in those two patients who required transfusions (one case of bilateral synchronous PCNL and a case of a full staghorn), transfusion requirements were modest. At the same time, there was no evidence of ongoing clinical bleed from the renal access site, nor was there any evidence of massive peri-renal hemorrhage. There was no life-threatening hematuria. Most patients had clear urine output on postoperative day 2 or 3. In a systematic review and meta-analysis by Shen, et al., it was found that there were no significant statistical differences in postoperative transfusion incidence among tubeless group and those groups with nephrostomy tube (small tube, middle tube and large tube groups).[10]

The renal function remained stable on all the patients. None had deterioration of renal function attesting to the minimal renal trauma that is sustained in percutaneous nephrolithotomy. The results were consistent with previous studies showing that there are no significant changes in creatinine level when tubeless percutaneous nephrolithotomy is done compared with standard procedure.[11]

One of the most common urologic complaints in standard PCNL is drainage-tube related pain.[12] In the study, significant postoperative pain was only experienced by 24 (30. 4%) patients who requested for breakthrough opioid derivatives which signifies minimal postoperative pain. The results were augmented in a meta-analysis by Xun Y, et.al, comparing standard PCNL and tubeless PCNL, the latter has been shown to be associated with decreased postoperative pain and analgesic requirements.[12] Although it was not directly measured in this study, the patients were generally satisfied for not having an external device postoperatively. This encouraged early mobility, leading to earlier recovery of bowel function and avoidance of other serious complications such as pulmonary infection and deep venous thrombosis.

In the study, the length of hospital stay in patients who had TSPCNL was reasonable with a mean of 2.46±1.84 days. In all probability, this could be brought about by the fact that these patients had minimal post-operative pain and morbidity, hence, fast recovery was expected. The results were consistent with other studies where patients who had tubeless PCNL had faster recovery since there was less pain at the operative site. In another meta-analysis by Wang J, et al., patients who had tubeless PCNL were reported to have lesser analgesic requirements, and length of hospital stay.[4] Such data were found to be in concordance with the present study.

Another significant finding in this study was the absence of urinary leakage among all patients. In a study by Agrawal et al., they compared tubeless PCNL to standard PCNL and reported that postoperative urinary leakage was associated in the standard group.[5] All patients in the present study had indwelling ureteral stents. The authors believe this is key to the success of a tubeless standard-sized PCNL. When patients are stented, the patency and continuity of the collecting system is assured and the renal access site dries easily. In fact, majority had dry access sites in less than twenty-four hours or on postoperative day one. On the average, the authors maintained the indwelling stents for about two to four weeks and remove them on an outpatient basis.

Lastly, the data disclosed few complications noted among patients who had TSPCNL. In fact, majority of these patients at NKTI never experienced any complications directly attributable to TSPCNL. The authors believe this is because the preferred access site is a posterior upper pole calyceal puncture. This increases the risk of developing pleural effusion postoperatively. However, even postoperative pleural effusion can be managed conservatively such as in these two present cases who were medically managed with fluid restriction, diuretics and incentive spirometry. In severely symptomatic patients though such as in these two of our cases, a timely ultrasound guided aspiration was life-saving. In a multi-center observational study by Dela Rosette, et al. pleural injuries were relatively rare and were only observed in 2.3-3.1% of patients.[13]

Pertinent to the mentioned findings in the present study, several studies have augmented these data which found that tubeless PCNL had fewer complications compared to the conventional approach.[14] These were further demonstrated in other studies where they found that "tubeless" (no NT but stented) and "totally tubeless" PCNL (no stent and NT) were safe and effective, and that these approaches had less post-operative pain and discomfort.[15-17] A group of investigators have emphasized that the tubeless PCNL is the new gold standard. This is an effective approach to treating renal stones since it only has a 9% complication rate, and that it could also significantly decrease length of hospitalization, lower analgesic requirement and complications.[18]

Conclusions

The authors' experience adds to the growing evidence that TSPCNL is a reasonable, efficient and safe approach for large volume nephrolithiasis. The authors believe that there is not enough reason to place a nephrostomy tube routinely for patients undergoing standard-sized PCNL.

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