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PROSPECTIVE RANDOMIZED STUDY COMPARING SAFETY AND EFFICACY OF STANDARD VERSUS TUBELESS PERCUTANEOUS NEPHROLITHOTOMY

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Abstract

Tubeless percutaneous nephrolithotomy (PCNL) is the non-placement of a nephrostomy tube at the end of the procedure. The benefits of a nephrostomy tube placement are numerous as it provides adequate renal drainage. It may also tamponade bleeding and allow for an easier second-look nephroscopy. However, majority of authors consider the nephrostomy tube as a source of morbidity. Tubeless PCNL is an effective and safe procedure for treatment of renal stones in selected cases. This procedure can even be chosen for patients with previous renal surgery, and hemorrhagic tendency. By using this method, less postoperative pain and a shorter hospital stay can be achieved, when compared with conventional PCNL.

This study is to prospectively compare the feasibility and safety of tubeless percutaneous nephrolithotomy (PCNL) Vs standard PCNL. A 220 patients undergoing PCNL were randomized into two groups: Group A (tubeless PCNL) with antegrade placement of a Double-J stent without nephrostomy and group B (standard PCNL) with nephrostomy tube placement postoperatively with 110 patients in each group. Inclusion criteria were a stone size more than 2 cm, single tract puncture with complete clearance, less than three stones with a diameter <25mm and minimal bleeding at completion. The two groups were comparable in age and sex, operative time, access tract, stone size, stone disease in the opposite kidney and ureter, preoperative creatinine and associated comorbidities were recorded. Patients were followed up in the post-op period with a drop in Hb, need for blood transfusion, need for analgesia, hospital stay, complications and need for the ancillary procedure.

There was no significant difference between the two groups for patient demographics and stone characteristics. There was no statistically significant difference between the two groups for the complications, stone clearance, need for ancillary procedure, mean postoperative drop in haemoglobin, need for blood transfusion. The mean postoperative ana;gesic requirement, operative time and hospital stay was statistically significantly higher in the tubeless PCNL group compared with the standard PCNL group with p values of 0.000, 0.040, 0.001 respectively. In-conclusion, Tubeless PCNL is considered a safe and efficient technique in any tract location (upper, middle, lower), in patients with bilateral disease and effective procedure if done in a selected group of patients.

Keywords: Percutaneous nephrolithotomy, Nephrostomy, Complications, Hospitalization duration, Tubeless percutaneous Nephrolithotomy, Renal stones .

Introduction

Urinary stones are defined as polycrystalline aggregates composed of variable amounts of crystal and organic matrix components. The occurrence of stone disease is 2 to 3 times more in young males than females in the past nevertheless this difference is now declining. The estimated prevalence of the renal stone disease is 1% to 5%. Soucie et al proposed that the prevalence of the stone disease is 10% in males and 4% in females [1]. Whites are commonly affected than Asians and Afro-Americans. The incidence of stone disease is highest in the fourth to sixth decades. Hot arid climate, obesity and sedentary lifestyle predispose to stone formation.

Since its first description in 1976 by Fernström and Johansson percutaneous nephrolithotomy (PCNL) has developed into a mainstream urologic approach for the management of large renal stones [2]. Today, the standard approach to PCNL includes the placement of a nephrostomy tube designed to drain the kidney and tract created during the procedure. The rationale for nephrostomy tube placement was derived primarily from the 1986 study performed by Winfield et al [3]. Winfield's 1986

report evoked a movement within the urologic community to include nephrostomy drainage with percutaneous stone treatment [3]. Since adopting this "standard," most urologists currently continue its practice, instilled within urologic training, and continue to perpetuate the notion that percutaneous drainage following PCNL is a requirement. Stent and drainage-tube related pain are some of the most common urologic complaints in the operative patient [4].

Modern techniques have begun to re-explore the idea of PCNL without standard nephrostomy drainage. "Tubeless PCNL" refers to internal drainage by use of a ureteral stent without nephrostomy tube placement post-procedure. Several studies have demonstrated the safety and efficacy of this approach [5, 6, 7]. Multiple prospective randomized controlled studies have demonstrated that the length of hospital stay, pain profiles, and use of analgesics was significantly lowered in patients undergoing the tubeless PCNL technique [8]. In the case of PCNL, the best way to move toward an outpatient setting would be to demonstrate the safety and efficacy of a tubeless or tubeless approach.

Objectives: to systematically review and compare tubeless percutaneous nephrolithotomy (PCNL) with standard PCNL in regards to safety, effectiveness, feasibility, postoperative pain, morbidity and hospital stay.

Patients and methods

This is a prospective randomized study done between March 2016 to February 2020. A 220 cases of stone disease with a stone size more than 2 cm who underwent PCNL in the department of urology at our institute. Patients are divided into two groups (Group A & Group B). Group A-110 cases of tubeless PCNL and Group B-110 cases of standard PCNL. Inclusion criteria are stone size more than 2 cm who underwent PCNL as a primary procedure, single puncture tract, procedure lasting less than 2 hrs, less than three stones with a diameter <25mm, complete extraction of all stones, no significant bleeding at the end of the procedure. Exclusion criteria are residual calculi, significant bleeding at the end of the procedure, multiple puncture tracts.

Patients were evaluated with physical examination, urine analysis, urine culture and sensitivity, complete blood count, renal function test, X-ray KUB, and Plain CT. Group A underwent tubeless PCNL and Group B underwent standard PCNL after obtaining anaesthetic fitness for the procedure. All patients were administered 1 gm of Cefoperazone and 500mg of Sulbactam as standard antibiotic prophylaxis at the time of anaesthesia intubation.

Surgical technique: all patients underwent PCNL under general anaesthesia. Patients were placed in lithotomy position and a 5 Fr ureteric catheter was introduced. The contrast was used to identify the collecting system and to select the calyx for puncture. After prone positioning with adequate padding posterior calyceal puncture was done under fluoroscopic guidance. The level of puncture was decided as per the location of the stone to ensure complete clearance. The puncture was done using an 18 G two-part needle and a guidewire was placed within the system. Guide rod was introduced and serial coaxial dilatation of tract done with Alkens metal dilator. Amplatz sheath was placed. Using 18.5Fr Karl-Storz nephroscope and Karl-Storz pneumatic lithotripter stone fragmentation was done. After fragments were evacuated antegrade 5 Fr ureteric stent was placed in group A and skin incision sutured and compression bandage applied - Figure (4). A 16 Fr nephrostomy tube along with 5 Fr ureteric stent was placed in patients coming under group B- Figure (2).

Variables: preoperative parameters like stone size, stone disease in the opposite kidney and ureter, preoperative creatinine and associated comorbidities were recorded. Intraoperative parameters like operative time, access tract and the need for blood transfusion were recorded. Patients were followed up in the post-op period with a drop in Hb, need for blood transfusion, need for analgesia, hospital stay, complications and need for the ancillary procedure.

Post-procedure check X-ray KUB was taken before removing the nephrostomy tube in the first postoperative day in the standard PCNL group - Figures (1) & (3). In both groups; A & B ureteric stent was removed after 14 days.

Statistical analysis: all statistical analysis was performed using Statistical Package for Social Science (SPSS, version 17) for Microsoft windows. Descriptive statistics were presented as numbers and percentages. The data were expressed as mean and SD. An Independent sample student t-test was

used to compare continuous variables between two groups. A chi-squared test was used for comparison between two attributes. A two-sided p-value < 0.05 was considered statistically significant.

Results:

Sex group: In group A, there are 62 males and 48 females, whereas, in group B, there are 61 males and 49 females. On statistical analysis using the chi-square test, it was found that group A and group B are not statistically significant (p=0.892).

Age: In group A, the Mean age is 42.45 yrs. In group B, the Mean age is 45.44 yrs.

Laterality of stones: In group A, 57 patients had stones on the left side and 53 patients had stones on the right side, whereas in group B, 61 patients had stones on the left side and 49 patients had stones on the right side. On statistical analysis using the chi-square test, it was found that group A and group B are not statistically significant (p=0.589).

Hypertension: In group A, 9.1% had hypertension, whereas, in group B, 12.7% had hypertension. On statistical analysis using the chi-square test, it was found that group A and group B are not statistically significant (p=0.387).

Diabetes: In group A, 19.1% had diabetes, whereas, in group B, 17.3% had diabetes. On statistical analysis using the chi-square test, it was found that group A and group B are not statistically significant (p=0.727).

Associated stone disease: In group A, 9 patients had ureteric calculus and 11 patients had a renal stone in the opposite kidney whereas in group B, 7 patients had ureteric calculus and 18 patients had a renal stone in the opposite kidney. On statistical analysis using the chi-square test, it was found that group A and group B are not statistically significant (p=0.353).

Puncture site: In group A, 76 patients underwent inferior calyceal puncture, 24 patients underwent middle calyceal puncture, 10 patients underwent superior calyceal puncture. In group B, 85 patients underwent inferior calyceal puncture, 13 patients underwent middle calyceal puncture, 12 patients underwent superior calyceal puncture. On statistical analysis using the chi-square test, it was found that group A and group B are not statistically significant (p=0.138).

Table (1) Patient and stone characteristics

	Tubeless PCNL (Group A)	Standard PCNL (Group B)	P-value
Age average (years)	42.45	45.44	0.78
Sex-ratio	1.22	1.16	0.84
Laterality of stones	Right: 53(n) Left: 57(n)	Right: 49 Left: 61	0.59
Diabetes	19.1%	17.3%	0.72
HTN	9.1%	12.7%	0.38
Associated stone disease	Ureteric calculus – 9(n) Opposite kidney -11(n) calculus	Ureteric calculus - 7(n) Opposite kidney - 18(n) calculus	0.35
Puncture site	Superior calyx-10(n) Middle calyx-24(n) Inferior calyx-76(n)	Superior calyx-12(n) Middle calyx-13(n) Inferior calyx-85(n)	0.138

Complications in the group: In this study, 6.4% in group A had bleeding and 4.5% in group B had bleeding. 8.2% in group A had urosepsis and 12.7% in group B had urosepsis. On statistical analysis using the chi-square test, it was found that group A and group B are not statistically significant (p=0.480).

Stone clearance: In this study, 107 patients in group A had complete stone clearance and 3 patients in the same group had incomplete stone clearance. 105 patients in group B had complete stone clearance and 5 patients in the same group had incomplete stone clearance. On statistical analysis using the chi-square test, it was found that group A and group B are not statistically significant (p=0.471).

Ancillary procedure: In group A, 5 patients required Left URS for left ureteric calculus, 4 patients required Right URS, 5 patients needed Left ESWL and 1 patient required Right ESWL. In group B, 3 patients required Left URS for left ureteric calculus, 4 patients required Right URS, 4 patients needed Left ESWL and 5 patients required Right ESWL.

Number of blood transfusions: In this study, 4 patients in group A and 3 patients in group B required blood transfusions. On statistical analysis using the chi-square test, it was found that group A and group B are not statistically significant (p=0.148).

Table (2) Operative and post-operative data

	Tubeless PCNL (Group A) (n=110)	Standard PCNL (Group B) (n=110)	P-value
Complications			
Bleeding	7(6.4%)	5(4.5%)	0.48
Urosepsis	9(8.2%)	14(12.7%)	
Stone clearance			
Complete clearance	107	105	0.47
Incomplete clearance	3	5	
Ancillary procedure			
URS	Left-5 Right-4	Left-3 Right-4	---
ESWL	Left-5 Right-1	Left-4 Right-5	
Blood transfusions	4	3	0.148
Drop in haemoglobin	0.98gm/dl	1.187gm/dl	---
Analgesic requirement (use of Tramadol)	236.55gms	350.99gms	0.000 (Significant)
Operative time (Mean)	62.06mins	72.22mins	0.040 (Significant)
Hospital stay	2.78 days	3.90 days	0.001 (Significant)

Table (3) Published series comparing standard PCNL Vs Tubeless PCNL with our study

Series	Type of study	Results in the study	Criteria for nephrostomy tube placement	Important Notes in the study series
Singh et al. (2008)	Prospective randomized - Standard PCNL: 30 - Tubeless PCNL: 30	PCNL tubeless: Less length of stay and postop pain; Standard PCNL: Longer procedures with more X-ray exposition, urinary fistula, and hemorrhagic complications	Tubeless if stone < 3 cm	Standard PCNL: The procedure length and higher complication rates showcase the difficulties encountered in this group of patients.
Istanbulluoglu et al. (2010)	Retrospective: Standard PCNL: 92; Tubeless: 41; Totally tubeless: 43	Standard PCNL: Longer hospital stay, more opioids used in postop	Urine color	Selection bias: Tubeless was performed only in absence of hemorrhagic complications
Garofalo et al. (2013)	Retrospective: Standard PCNL: 203; Tubeless PCNL: 114	PCNL Tubeless: Shorter hospital stay; Standard PCNL: More postop pain	Tubeless if no bleeding, no renal cavity perforation, and no significant residual lithiasis	These inclusion criteria could explain the advantages found in the tubeless group
Rifaioglu et al. (2014)	Retrospective; Standard PCNL: 117; Tubeless: 107	Standard PCNL: Longer procedure, more hemorrhagic complications. PCNL tubeless: Better results	Surgeon's choice	The presence of residual calculi often motivated the placement of a nephrostomy which explains the higher stone-free rate in the tubeless group
Isac et al. (2014)	Retrospective; Standard PCNL: 76; Tubeless: 83	PCNL Tubeless: Shorter hospital stay and less postop pain	Surgeon habits: Tubeless PCNL: No nephrostomy regardless of complications and residual fragments	More staghorn stones in the standard PCNL group. Less residual stones in the tubeless group which could be explained by 1) experienced surgeon, 2) easier stones to treat
Zhao et al. (2016)	Prospective randomized; 15 patients: PCNL with nephrostomy without ureteral stent; 15 patients: PCNL without nephrostomy with ureteral stent	Nephrostomy group: More postoperative comfort. No difference concerning complications, length of stay, and postoperative pain.	2 randomized groups; Tubeless: No residual fragments	Selection of patients: 100% stone- free. Patients felt more discomfort with ureteral stents than with a nephrostomy catheter
Jiang et al. (2017)	Prospective randomized (90 patients): 30 PCNL (+ néphrostomy only); 30 PCNL (+ ureteral catheter only); and 30 PCNL (+ JJ stent only).	PCNL (with nephrostomy only): Longest hospital stay and more postop pain than other two groups; PCNL (+ JJ stent): More discomfort.	Randomized study; Selection criteria: stone < 2 cm, no bleeding, no residual calculi, no renal cavity perforation	Selection bias: Small stones, easier to treat - Fewer complications and perioperative difficulties.
Present study	Prospective randomized - Standard PCNL: 110 - Tubeless PCNL: 110	PCNL Tubeless: shorter Operative time, shorter hospitalization and reduced need for analgesics	Tubeless if no bleeding, no significant residual calculi, no evidence of collecting system perforation, no multiple puncture tracts	Selection of patients: stone size >2 cm, single puncture tract, less than three stones with a diameter <25mm, complete extraction of all stones, no significant bleeding at the end of the procedure

Figure (1) Post op X-ray with DJ Stent and PCN in situ

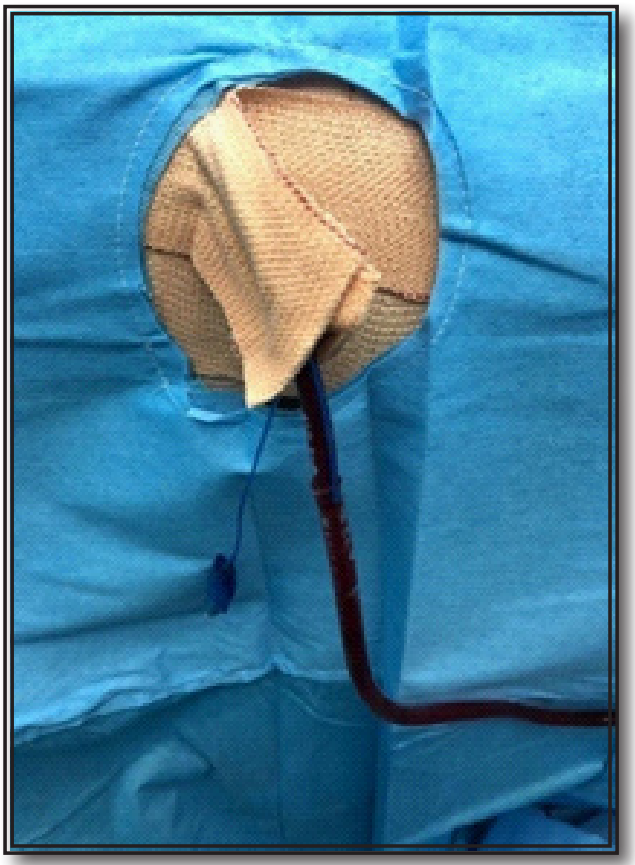

Figure (2) Standard PCNL with Nephrostomy tube in situ

Figure (3) Post op X-ray with DJ Stent in situ with no nephrostomy tube

Figure (4) Tubeless PCNL with no nephrostomy tube

Preoperative creatinine: In the group, the mean creatinine is 1.098. In group b, the mean creatinine is 1.010.

Drop-in haemoglobin: The mean drop in HB in group A is 0.98gm/dl. The mean drop in HB in group B is 1.187gm/dl.

Analgesic requirement: Average amount of Tramadol required in group A is 236.55gms whereas, in group B, it is 350.99gms. On statistical analysis using the chi-square test, it was found that amount of tramadol required in group A is lesser when compared to and group B and is statistically significant (p=0.000).

Operative time: Average OT time required in group A is 62.06mins whereas, in group B, it is 72.22mins. On statistical analysis using the chi-square test, it was found that amount of OT time required in group A is lesser when compared to and group B and is statistically significant (p=0.040).

Hospital stay: Average hospital stay in group A is 2.78 days whereas, in group B, it is 3.90 days. On statistical analysis using the chi-square test, it was found that the number of days in hospital in group A is lesser when compared to and group B and is statistically significant (p=0.001).

Discussion:

Percutaneous renal surgery is a common urological procedure for the treatment of upper urinary tract stone disease. When performing PCNL, placement of a nephrostomy tube after completion of stone extraction was traditionally considered to be standard practice [9, 10]. PCNL has the advantage in the management of large renal stones of decreasing morbidity and hospital stay in comparison to open surgery [11]. PCNL is a difficult operation to perform; even in the most experienced hands, complications may emerge in 1.1 to 7% of patients [12]. Surgical skills in PCNL improved a lot during the years and the procedure has become more perfect, meaning that the tract made is just sufficient for the procedure to be done and unnecessary tissue handling is avoided. Improvements in optics and miniaturization of endo instruments have also lessened the morbidity rates and thus increased the success rate. Haemorrhage, which was observed in 1 to 10% of patients, was the most important complication. Bleeding may occur during needle entry, tract dilatation, and nephroscopy [13].

The placement of a nephrostomy tube is considered a standard last step in PCNL to secure haemostasis, ensuring a pre-formed tract to allow for a 'second look' if needed and to maintain good drainage of the collecting system, but the tube can cause discomfort and pain, and prolong hospitalisation. The decision to close a PCNL operation using the standard or the tubeless technique is an intraoperative one. The surgeon must make sure that urine can spontaneously pass through the bladder without any blockage, and the vision through the nephroscope must be clear to prove that the procedure is bloodless [14].

Since the first report of tubeless PCNL in 1997 by Bellman et al, several investigations have focused on reducing morbidity and improving postoperative patient comfort without sacrificing the safety of the procedure in select patients. With the growth of experiences, the application of tubeless PCNL in more complicated stone diseases has been reported. Several studies since then have demonstrated that tubeless PCNL have equivalent outcomes in the properly selected patient group when compared to PCNL performed with the presence of a nephrostomy tube (with/without stent) [15].

In our study, we compared tubeless PCNL vs standard PCNL in patients with stone disease. Tubeless PCNL was performed with success in patients of age 18 to 68 years.

Tubeless PCNL was done even in patients with elevated renal parameters as 10 (11%) patients in group A had elevated renal parameters. The highest creatinine value in group A is 2.8mg/dl. Tubeless PCNL was safely done even in patients with DM, HTN as 10 (11%) patients had HTN and 21 (19.09%) patients had DM in the tubeless PCNL group. Tubeless PCNL was done in patients with stone disease irrespective of tract location (upper, middle or lower). 9 (8.2%) patients had associated ureteric calculi and underwent URS and PCNL in the same sitting.

Operative time was significantly shorter in group A compared to group B. (GROUP A 62.06 Min vs GROUP B 72.22 Min). The postoperative drop in HB and blood transfusion rate was similar in both groups under study. The presence of residual calculi was similar in both the groups and these residual calculi were treated with ESWL. The need for post-op analgesia was less with the tubeless PCNL group. The Group A patients needed 236.55 mg of tramadol whereas Group B needed 350.99

mg. This is statistically significant with a p-value of<0.001. Post-op complications were similar in both groups and were managed conservatively. Length of Postoperative hospital stay was longer in the standard PCNL group (3.90 days) compared to the tubeless PCNL group (2.78 days). This was statistically significant with a p-value of <0.001.
In our series, tubeless PCNL was performed in the absence of purulent retention, residual fragments, or significant bleeding. Good outcomes, as well as the rate of perioperative and postoperative complications, were similar to those of standard PCNL, apart from infectious complications which were more present in the standard PCNL group. Our results are consistent with those observed in almost all published series [Singh et al. (2008)[16], Istanbulluogluet al. (2010) [17], Garofalo et al. (2013) [18], Rifaioglu et al. (2014) [19], Isac et al. (2014) [20], Zhao et al. (2016) [21], Jiang et al. (2017) [22]] - Table (3).

Like most studies, we found a statistically significant difference between the two techniques regarding postoperative pain and length of hospital stay. Operative time was significant between the two groups which were compared to the rifaioglu et al study [19].

In prospective randomized studies, the choice to drain or not by a nephrostomy catheter by a surgeon whose tendency was to perform tubeless PCNL largely depended on the outcomes, difficulties, and complications encountered.

Conclusion:

The main indications for tubeless PCNL included cases with a single access tract, minimal blood loss, no evidence of collecting system perforation, no second look nephroscopy was intended. The tubeless procedure has fewer complications, improved postoperative patient comfort, shorter hospitalization, reduced need for analgesics. Tubeless PCNL is safe in any tract location (upper, middle, lower), in patients with bilateral disease and is a very safe and effective procedure if done in a selected group of patients.

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