

## Original Research Article

## A Prospective Study of Efficacy And Safety of Standard Versus Tubeless Percutaneous Nephrolithotomy

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### Abstract

**Introduction:** PCNL is considered to be the standard procedure in patients with large renal calculus. The essential step in standard percutaneous nephrolithotomy (PCNL) procedure is placement of a percutaneous nephrostomy tube for drainage. On the other hand, in recent years, the procedure has been reformed to one called as 'tubeless' PCNL in which a double-J stent without nephrostomy tube is placed for internal drainage.

**Materials and Methods:** This was a prospective comparative study, conducted in the department of Urology, Arupadai Veedu Medical College, Puducherry a period of 12 months from March 2020 to February 2021. A total number of 108 cases of tubeless PCNL was studied data collected and results analysed. Sample size estimated based on prevalence of the operable renal calculi (using formula  $S = 4pq/12$ ) Results of study group were compared with other group of traditional PCNL with 116 patients. **Results:** We evaluated the data of 224 cases undergoing PCNL in our hospital. We divided total cases in to 2 groups. There are 108 cases in group A who underwent totally tubeless PCNL and 116 patients in group B of traditional PCNL. Both groups has similar demographics according to age sex and comorbidities. Among these 108 cases (group A) 70 were male and 38 female patients. Male to female ratio is 1.66:1. The average age was 44.6 years with arrange of 20 to 65 years. Where as in group B male to female ratio is 2.3:1 and average age is 48.8 years. Out of 108 cases 12.9% (14) have hypertension, 9.25% (10) have diabetes mellitus, 4 patients have COPDs, 2 patients had hypothyroidism and 2 patients was known CKD. **Conclusion:** Our findings demonstrated that tubeless PCNLs can be safely and effectively performed by an experienced endourologic team without limiting the number of eligible candidates by preoperative patient selection. Tubeless PCNL has an obvious advantage of significantly reduced postoperative pain, less analgesic requirement and shorter hospital stays. Complications rate are less with tubeless PCNL and blood transfusion is less when compared with traditional PCNL. We believe that this study will contribute to the further popularization of the tubeless technique for the benefit of the patient, the medical team, and the health care system.

**Keywords:** Percutaneous nephrolithotomy, COPD, CKD, hypertension, diabetes mellitus.

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### Introduction

PCNL is considered to be the standard procedure in patients with large renal calculus. The essential step in standard percutaneous nephrolithotomy (PCNL) procedure is placement of a percutaneous nephrostomy tube for drainage. On the other hand, in recent years, the procedure has been reformed to one called as 'tubeless' PCNL in which a double-J stent without nephrostomy tube is placed for internal drainage[1]. Urinary stones are defined as the poly crystalline aggregates composed of variable amounts of crystal and organic matrix components. The most common stone types are calcium oxalate, calcium phosphate, uric acid, struvite i.e., magnesium ammonium phosphate and cysteine[2]. Urinary stone disease is one of those diseases well-known to affect humans ever since olden times. There has been deviation in the occurrence of stone disease from the lower to upper urinary tract. 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[3].

The estimated prevalence of renal stone disease is 1% to 5%. Soucie

et al proposed that the prevalence of stone disease is 10% in males and 4% in females. Whites are commonly affected than Asians and Afro-Americans[4]. The incidence of stone disease is highest in fourth to sixth decades. Hot arid climate, obesity and sedentary lifestyle predispose to stone formation. Hippocrates had described the renal colic symptoms as follows: "An acute pain is felt in the kidney, the loins, the flank and the testis of the affected side. The patient passes urine frequently. Gradually the urine is suppressed. With the urine, the sand is passed." There had been a vast progress in the evaluation, imaging and management of this disease. Initially the management procedures had significant morbidity and sometimes mortality[5]. With advances in surgical techniques, the mortality has reduced considerably. PCNL had improved reasonably over the last twenty years as a result of technical advancements and perfections in surgical skill for doing PCNL. A milestone in the history of PCNL is the introduction and development of the 'tubeless PCNL' which is now been proposed to have a comparatively lesser morbidity rates than the standard procedure. The purpose of this study is to analyse the evidence -based literature regarding the 'nephrostomy-free' or 'tubeless' PCNL and to assess the safety, efficacy, possibility, and benefits of tubeless PCNL over standard PCNL[6]. Purpose was to study outcomes and complications of tubeless PCNL and to systematically analyse the safety and efficacy of the tubeless PCNL.

### Materials and Methods

This was a prospective comparative study, conducted in the department of Urology, Arupadai Veedu Medical College, Puducherry a period of 12 months from March 2020 to February

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2021. A total number of 108 cases of tubeless PCNL was studied data collected and results analysed. Sample size estimated based on prevalence of the operable renal calculi (using formula  $S = 4pq/12$ ) Results of study group were compared with other group of traditional PCNL with 116 patients.

**Inclusion criteria:** Patients with renal and/or upper ureteric calculi of greater than 1.5cm, negative urine culture and no coagulopathy.

**Exclusion criteria:** Those patients with solitary kidney, more than 2 percutaneous accesses, significant perforation of the collecting system and significant intraoperative bleeding and patients with raised creatinine, patients with ectopic, malrotated and fused kidneys. Pre-operative assessment done with indication for surgery and patient's complete history and physical examination. Important laboratory parameters such as urine analysis and culture / sensitivity, haemoglobin, electrolytes and serum urea/creatinine, coagulation profile were checked before the surgery. Hb%, serum electrolytes, creatinine and urea repeated after surgery also. Pre-operative intravenous urography (IVU), plain CT KUB, early morning X-ray KUB on the day of surgery was performed in all cases. Ultrasound and/or X-ray KUB were repeated 24 hours after surgery. Mean stone burden was calculated in each case by the horizontal and vertical dimensions of the stone, as seen on IVU.

The surgical technique was carried out under general anaesthesia. A 5F transurethral ureteric catheter was placed. Percutaneous access was created in all cases under fluoroscopic guidance with the patient in prone position. The nephrostomy tract was dilated with metal dilators and Amplatz sheath was left in situ. A 26 Fr angled Storz nephroscope was used and calculus disintegration was performed using lithoclast.

On completion of the procedure, the Amplatz sheath was removed. The wound was stitched with Prolene 4/0 mattress suture. A Foley's catheter was left in the bladder at the end of the procedure, for all study cases totally tubeless methodology followed i.e no nephrostomy and no DJ stenting. After surgery fluoroscopy and endoscopy were used to assess stone free status.

Patients data such as age, stone size, stone site, type of puncture, duration of surgery, hemoglobin, complication rate, analgesic need, type of analgesic, dose of analgesic, duration of hospitalization and total cost of the procedure were noted.

#### Statistical Analysis

Collected data entered in to excel spread sheet and results analysed. The data was expressed in terms of Mean  $\pm$  standard deviation. The intergroup comparison done by unpaired t-test. All statistical tests were conducted with a significance of level of p value  $< 0.05$ .

#### Results

We evaluated the data of 224 cases undergoing PCNL in our hospital. We divided total cases in to 2 groups. There are 108 cases in group A who underwent totally tubeless PCNL and 116 patients in group B of traditional PCNL. Both groups has similar demographics according to age sex and comorbidities. Among these 108 cases (group A) 70 were male and 38 female patients. Male to female ratio is 1.66:1. The average age was 44.6 years with range of 20 to 65 years. Where as in group B male to female ratio is 2.3:1 and average age is 48.8 years. Out of 108 cases 12.9% (14) have hypertension, 9.25% (10) have diabetes mellitus, 4 patient have COPDs, 2 patient had hypothyroidism and 2 patient was known CKD.

Mean stone burden in group A is 2.24 cms with the smallest stone of 1.5 cm to largest stone of size 3.2cms. In 29 (53.7%) cases lower calyceal puncture done, 14 (25.9%) patients underwent upper calyceal puncture and for 11 (20.3%) cases middle calyceal puncture done. Single tract access was successful in most of the cases.

In addition, complications included high fever (more than 38.5°C) in 1 patient and prolonged renal pain were observed in 2 patient (1.85%) of totally tubeless PCNL patients. In Group A, for 102 (94.4%) patients and in Group B, for 106 (91.3%) patients complete stone clearance was achieved. In Group A, Four patients were treated by placing a double j stent, 2 (1.85%) patient underwent ureteroscopy for distal ureteric stone. In group B, 4 cases (3.44%) underwent ureterorenoscopy.

**Table 1: Comorbidities in both groups**

S. No	Comorbidity	Group A	Group B
1	Hypertension	14	16
2	Diabetes Mellitus	10	8
3	COPD	4	6
4	Hypothyroidism	2	2
5	CKD	2	4

**Table 2: Perioperative parameters in both groups**

S. No	Parameter	Group A	Group B	P Value
1	Age distribution	44.6 yrs	48.8 yrs	0.2152
2	Sex ratio	1.66	2.33	--
3	Stone burden	2.24 $\pm$ 0.84	3.15 $\pm$ 0.72	0.0001
4	Duration of surgery	56.4 $\pm$ 6.52	81.8 $\pm$ 8.21	0.0001
5	VAS score 1st hour	6.4 $\pm$ 1.6	7.5 $\pm$ 1.2	0.0010
6	VAS score 6th hour	4.8 $\pm$ 1.2	5.9 $\pm$ 1.3	0.0003

**Table 3: Post operative Issues**

S. No	Parameter	Group A	Group B	P Value
1	Mean duration of procedure (minutes)	56.4 $\pm$ 6.52	81.8 $\pm$ 8.21	0.0001
2	Bleeding requiring transfusion	6 (5.55%)	10 (8.62%)	-
3	Mean Length of hospitalization (days)	2.5 $\pm$ 0.93	4.8 $\pm$ 1.2	0.020
4	Mean analgesic requirement (tramadol iv)	62.4 $\pm$ 16.8 (mg)	116.5 $\pm$ 20.2 (mg)	0.0001
5	Stone free rate	68(94.4%)	72(90%)	-
6	Mean Procedure cost (rupees)	30145.5k	44895.4k	0.0001
7	Time to return of daily life activities	6.2 $\pm$ 0.18	10.5 $\pm$ 1.25	0.0001

#### Discussion

The concept of a tubeless technique represents a novel alternative in the search to miniaturize the procedure. Bellman et al. reported their

initial experience with a series of 50 patients who underwent various percutaneous procedures. Later Limb and Bellman completed 112 successful tubeless procedures, representing almost one-third of all

their percutaneous procedures[7]. Their Prospective randomized studies designed to compare tubeless vs. mini vs. standard PCNL confirmed the superiority of the tubeless PCNL. In Our present study, we compared the effectiveness and safety of Standard PCNL and tubeless PCNL for operative time, postoperative analgesia, hospital stay, and stone-free rate. In the present study, there was no statistically significant difference between both groups for the age and sex of patients, comorbidities, stone size and location, this minimised the effect of any of them on the outcomes of the procedures. There was no significant difference in initial stone burden between tubed and tubeless groups[8]. The mean operative time in our study was longer in the standard PCNL group than in the Tubeless PCNL group [for group A - 56.4min for group B 81.8 min, respectively] this difference was statistically significant. Ni et al. reported that tubeless PCNL had a reduced operative time versus standard PCNL. For the blood transfusion rate, there was a no significant difference between the two groups in the present study. Blood transfusion rate for group A was 5.55%, and for group B was 8.62%. In the study of Khairy Salem et al. there was no need for blood transfusion during or after the operation due to insignificant blood loss. In studies conducted by Gupta et al and Crook et al there is no statistically significant difference in blood transfusion rates between two groups i.e standard PCNL and tubeless PCNL[9]. Hospital stay plays an important role in the evaluation of a technique, in our present study it was lower in Tubeless PCNL group [2.5 versus 4.8 days] than standard PCNL group; this difference was statistically significant. This result was similar to other published studies, such as in the study of Khairy Salem et al. in which the mean (range) hospital stay was 1.7 (1–4) days in the tubeless PCNL group and 2.8 (3–4) days in the Standard PCNL[10]

#### Conclusion

Our findings demonstrated that tubeless PCNLs can be safely and effectively performed by an experienced endourologic team without limiting the number of eligible candidates by preoperative patient selection. Tubeless PCNL has an obvious advantage of significantly reduced postoperative pain, less analgesic requirement and shorter hospital stays. Complications rate are less with tubeless PCNL and

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