Original Research Article

A Prospective Observational Study of Tubeless Percutaneous Nephrolithotomy Procedure for Renal Stones

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Abstract

Background: Standard procedure for large renal stones (>1.5cm) is percutaneous nephrolithotomy. This standard procedure of doing percutaneous nephrolithotomy incudes placing of nephrostomy and DJ Stent and has significant pain and morbidity, which are related to these tubes. Various modifications were done to PCNL to decrease the morbidity. We report an observational study of PCNL without placing nephrostomy tubes.

Aim and objectives: Aim was to study the outcomes of tubeless PCNL, evaluate the outcomes and complications with tubeless PCNL and to compare the outcomes of tubeless percutaneous nephrolithotomy (PCNL) with standard PCNL.

Materials and methods: A total of 90 cases were included initially in this study with following inclusion criteria on patients with renal and/or upper ureteric calculi of greater than 1.5cm, less than equal to 3.0cm, negative urine culture and no coagulopathy. Further selection of cases was done after the PCNL procedure depending on whether procedure went uneventful. Finally 72 cases were included and 18 cases were excluded at the time of the procedure. The 18 patients who were excluded, required more than 2 tracts and had significant perforation of the collecting system and significant intra operative bleeding. The outcomes measured were the Hb drop, septic complications, pain score and analgesic need and hospital stay.

Results: There was no significant difference in mean operative time between standard and tubeless PCNL groups. Post-operative analgesic requirement was significantly low in our study group compared to Standard PCNL. No difference was found in the incidence of Sepsis, Hb drop. The incidence of urinary leak is significantly lower in our group. Hospital stay is shorter in our study which was statistically significant.

Conclusions: Tubeless PCNL can be adopted in majority of patients especially when the procedure went uneventful without much bleeding, without PCS injury and where complete clearance of the stone done with single tract. Tubeless PCNL is equally safer procedure with bleeding and sepsis complications comparable to Standard PCNL, but it has definite advantage of less post-operative pain requiring less analgesic, less post op urinary leak and most important shorter hospital stay.

Key words

Tubeless, Percutaneous, Nephrolithotomy, Renal stones.

Introduction

Kidney stones are one of the most prevalent surgical problems encountered in general population [1]. Fernstrom and Johansson (1976) first reported the formation of a percutaneous track for the specific purpose of subsequently removing an intrarenal stone [2]. This technique was rapidly taken up by other centres, with Alken, et al. (1981) [3] and Wickham, et al. (1981) [4] further demonstrating the effectiveness and safety of the procedure in disintegrating and clearing stones in renal pelvis.

Percutaneous nephrolithotomy (PCNL) is the preferred treatment for large (> 2 cm) renal or staghorn renal stones now a days. In the recent years, percutaneous nephrolithotomy (PCNL) has been used widely for urinary stone disease instead of open surgery.

PCNL is minimally invasive, having high success rate and low-morbidity. The standard PCNL procedure consists of a tiny percutaneous access to the kidney and the formation of a working tract connecting the flank surface with the intrarenal collecting system to allow endoscopic stone disintegration and removal. A temporary nephrostomy tube is usually left in place at the end of the procedure to allow drainage, tamponade of bleeding, and delayed second-look nephroscopy, along with a DJ Stent.

Tubeless PCNL

Studies have shown that the placement of nephrostomy tube in patients undergoing standard PCNL procedure can cause postoperative discomfort, analgesic requirement, and prolonged hospital stay and increased cost of the procedure. Thus standard PCNL has been modified to PCNL without postoperative nephrostomy tube (Tubeless PCNL)/ without nephrostomy tube and DJ stent (total tubeless PCNL).

A Tubeless percutaneous procedure-one that omits the postoperative nephrostomy tube-was initially proposed by Wickham and colleagues (1981) [4]. The concept was revived by Bellman and colleagues (1997) [5], with the addition of an internal ureteral stent left in place for a week or two.

Tubeless PCNL is mainly two types
-Tubeless with ureteral stent
-Totally tubeless PCNL.

With the introduction and increasing use of the Nitze cystoscope and the Hopkins rod-lens system, Hugh Hampton Young (1870–1945) was able to develop the cystoscopic lithotrite [6-8]. Since then, lithotrites and evacuators have undergone many modifications to produce the instruments currently in use.

There was another landmark in the history of urology, first planned nephrectomy performed in

1869 by Gustav Simon of Heidelberg [9]. In 1873, Ingalls in Boston carried out the first nephrotomy, Heinecke the first pyelotomy in 1879, and the first nephrolithotomy was in 1881 by Le Dentu (1841–1926) in France [10].

Max Brodel (1870–1941), major contribution to urology, was his description in 1901 of an avascular area of the kidney through which the kidney could be entered [11]. In England, Henry Morris was carrying out surgical procedures on the kidney for calculous disease, with 29% mortality for nephrolithotomy, 23% for nephrotomy and 30% for nephrectomy [1]. Many others carrying out these procedures had even worse mortality rates, and a recurrence rate of >50%. In an effort to preserve renal function, new procedures were constantly being developed.

As instrumentation improved, Hugh Hampton Young reported the first ureteroscopy in 1929. Percutaneous entry into the renal collecting system was first described in the 1950s, but it wasn‘t until the mid1970s and 1980s that percutaneous access to the renal collecting system was routinely utilized for the removal of nephrolithiasis. In 1980, Dornier MedTech introduced extracorporeal shock wave lithotripsy for breaking up stones via acoustical pulses, and this technique has since come into widespread use [12]. Although PNL initially proved to be an effective technique, the near-concurrent introduction of shockwave lithotripsy (SWL) resulted in a rapid and marked decrease in the utilization of PNL. However, Advancements in technique and instrumentation have improved PCNL outcomes and, consequently, limited the role of SWL in the treatment of staghorn calculi.

Commonly ascribed to Goodwin and colleagues (1955) [13], the first therapeutic percutaneous nephrostomy actually was performed by Thomas Hillier in 1865. Hillier,at the Hospital for Sick Children at Great Ormond Street, repeatedly aspirated the hydronephrotic kidney of a young boy for symptom relief over a 4year period until his death at 8 years of age. Subsequently there were a few reports of diagnostic percutaneous renal aspirations, but it was not until Goodwin and colleagues published their landmark report in 1955 that therapeutic percutaneous nephrostomy was rediscovered. Even then, the utility of percutaneous access to the upper urinary tract collecting system was limited to drainage of obstructed kidneys until Fernstrom and Johansson (1976) reported the percutaneous removal of renal calculi, termed ―percutaneous pyelolithotomy. In 1983, Clayman, et al. first reported PNL in the treatment of staghorn calculi [14]. Subsequent developments in urology include the introduction of percutaneous nephrolithotomy (PCNL) with thinner, longer and a variety of accessories to carry out stone extraction and the search for even less invasive treatments for stones, leading to the use of various energy sources for stone fragmentation.

With the introduction of percutaneous nephrolithotomy (PCNL) and then extracorporeal shock wave lithotripsy (ESWL), the management of patients with calculi has changed dramatically. Initially such technology was limited to patients with relatively small or uncomplicated calculi, but with time, the use of Percutaneous Nephrolithotomy was extended to treat patients with large branched calculi.

Percutaneous nephrolithotomy (PNL) is accepted as the procedure of choice for the treatment of large or complex renal calculi. Since its introduction in 1976, the operative technique and the endoscopic equipments have had constant evolution, increasing the success rates and decreasing complications and morbidity. Although early on SWL was used almost indiscriminately for the management of upper tract calculi, the limitations of the technique for large and complex stones became evident over time, and PCNL became firmly established in the therapeutic armamentarium of nephrolithiasis.

Indications for ureteroscopic management of upper tract stones have expanded, ureteroscopy (URS) has, in some cases, supplanted SWL and PCNL for the treatment of some stones.

Nonetheless, there have been efforts underway to reduce the morbidity and increase the efficiency and effectiveness of PCNL, by making it tubeless (without nephrostomy) and totally tubeless (without both nephrostomy and DJ Stent), making it more competitive with SWL and URS for the first-line management of upper tract stones. Percutaneous nephrolithotomy (PCNL) is the preferred treatment for large (>2 cm) renal or staghorn renal stones [15]. The planning and successful execution of the initial access into the kidney is crucial to the outcome of PCNL.

Aim and objectives

- Aim was to study the outcomes of tubeless PCNL.
- Objectives were to evaluate the outcomes and complications with tubeless PCNL and to compare the outcomes of tubeless percutaneous nephrolithotomy (PCNL) with standard PCNL.

Materials and methods

This was a prospective observational study, conducted in the Department of Urology, Gandhi Medical College and Hospital, Hyderabad, for a period of 36 months from January 2017 to December 2019.

A total number of 90 cases were included initially in this study, following the inclusion criteria given below. Out of which 18 cases were excluded at the time of the surgery, as these patients required more than one tract, or had excess bleeding during surgery or had significant perforation of the collecting system. Finally 72 patients were included in the study, data collected and results analyzed. Results of study group are compared with the parameters of traditional PCNL of our hospital.

The inclusion criteria: Patients with

- Renal and/or upper uretric calculi of greater than 1.5cm, less than or equal to 3.0 cm, 2)
- Negative urine culture and
- No coagulopathy.

Exclusion criteria: In those patients with

- Solitary kidney,
- More than 2 percutaneous accesses,
- Significant perforation of the collecting system and
- Significant intraoperative bleeding,
- Patients with raised creatinine,
- Patients with ectopic, malrotated and fused kidneys were excluded.

Pre-operative assessment included indication for surgery and patient's complete history and physical examination. Important laboratory parameters such as urine analysis and culture/ sensitivity, hemoglobin, electrolytes and urea/creatinine, coagulation profile were checked before the surgery. Hb%, serum electrolytes, creatinine and urea repeated after surgery. Pre-operative intavenous urography (IVU), plain CT KUB, X-ray KUB was performed in all cases. Intra operative stone free state demonstrated at the end by endoscopy and fluoroscopy. 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/CT Scan.

The surgical technique was carried out under anesthesia. 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 24 Fr angled Wolfe nephroscope was used and calculus disintegration was performed using pneumatic lithoclast.

On completion of procedure, a 4.5 Fr / 26cm DJ Stent was placed in antegrade fashion from renal pelvis to bladder, 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. After

surgery fluoroscopy and endoscopy were used to assess stone free status. In post-operative period all patients were given IM diclofenac 50mg whenever they complained pain. The level of pain was recorded on visual analog scale.

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, degree of pain, duration of hospitalization and total cost of the procedure were collected. Statistical analysis was done.

Results

A total of 72 patients were included in the study that underwent tubeless PCNL during the study period. Among these 72 cases, 46 were male and 26 female patients. Male to female ratio was 1.77:1. The average age was 44.6 years with a range of 20 to 65 years (**Table – 1, 2**).

Table – 1: Age Distribution.

Age (Years)	No. of patients
20-30	10
31-40	16
41-50	30
51-60	10
>60	6

Table – 2: Sex distribution.

Sex	No of patients
Male	46
Female	26

Table – 3: Comorbidities.

Comorbidity	No of patients
Hypertension	14
Diabetes mellitus	10
COPD	4
Hypothyroidism	2

Out of 72 cases, 19.4% (14 patients) had hypertension, 13.8% (10) had diabetes mellitus, 4 patients had COPDs, 2 patients had hypothyroidism (**Table – 3**).

Table – 4: Stone burden.

Stone size (cm)	No. of patients
1.5-2.0	30
2.1-2.5	22
2.6-3.0	20

Table – 5: Type of puncture.

Type of puncture	No of patient s
Lower calyx	42
Middle calyx	12
Upper calyx	18

Table – 6: Duration of surgery.

Duration of surgery (min)	No of patients
31-40	6
41-50	18
51-60	24
61-70	14
>70	10

Table – 7: VAS (pain).

Time of VAS	Mean VAS
At 6^{th} hour	6.4±1.6
At 24^{th} hour	4.8±1.2

Table – 8: Operative parameters.

Parameters	Values
Mean duration of procedure(minutes)	56.4
Mean Length of hospitalization (days)	2.5
Mean analgesic requirement (Diclofenac)	100.0 (mg)
Stone free rate	70 (97.2%)
Time to return of daily life activities(days)	6 .2
Mean drop in Hemoglobin	0.7 gm
Other complications	Fever 8, urine leak 2

Mean stone burden was 2.24 cm with the smallest stone of 1.5cm to largest stone of size 3.0 cm (**Table – 4**).

In 42 (58.3%) cases lower calyceal puncture done, 18 (25%) patients underwent upper calyceal puncture and for 12(16.6%) cases middle calyceal puncture done for patients.

Single tract access was successful in all cases (**Table – 5**). Mean duration of surgery i.e. from induction of anesthesia till the patient shifted from operation theatre was 56.4 minutes (**Table – 6**). Mean VAS score in 6th hour of surgery was 6.4 and after 24th hour of surgery mean VAS score was 4.8 (**Table – 7**).

Mean analgesic requirement throughout the hospital course was 90.0 mg Diclofenac. In addition, complications included high fever in 8 patients and urine leak in 2 patients in tubeless PCNL patients. Out of 72 patients, 8 patients had high fever (11.1%) and 2 patients had urine leak (2.7%). Mean duration of hospital stay was 2.5 days for tubeless PCNL group. The mean time to return daily activities in tubeless PCNL was 6.2 days (**Table – 8**).

Discussion

With advances in instrumentations and techniques, PCNL has become a safe procedure to perform with decreased post-operative complications, reduced pain and decreased hospital stay. As a standard of care, nephrostomy tube is placed post operatively in all patients to provide an effective tamponade to nephrostomy tract. Despite these obvious advantages, the nephrostomy tube is associated with significant post-operative discomfort and pain.

One of the clinically tested modifications is the mini-perc approach that was first reported in pediatric patients. This version of PCNL uses 13-20 Fr working sheaths and was soon adopted for adults. It did not, however, obviate the need for the placement of nephrostomy tubes.

Pietrow, et al. used a narrower tube (10 Fr instead 22 Fr) and noted greater comfort in the immediate postoperative period without sacrificing safety [27].

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 [28].

Prospective randomized studies designed to compare tubeless vs. mini vs. standard PCNL confirmed the superiority of the tubeless PCNL in terms of reduced postoperative patient discomfort, shorter hospitalization and fast recovery.

In our present study, we evaluated the effectiveness and safety of tubeless PCNL for operative time, postoperative analgesia, hospital stay, and stone- free rate and the results were compared with the parameters of Standard PCNL in our hospital. There was no significant difference between the age and sex of patients, mean stone size, stone side and location when compared with Standard PCNL. This minimized the effect of any of them on the outcomes of the procedures.

There was no significant difference in Mean operative time between the Tubeless and Standard PCNL groups. In the study of Khairy Salem, et al. [19]; and T.J Crock, et al. [24]; there was no statistically significant difference in operative time between the Standard PCNL and Tubeless PCNL groups.

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 5.9 days) when compared with the Standard PCNL of our hospital; this difference was statistically significant. This result was similar to other published studies, such as in the study of Khairy Salem, et al. [19]. 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. In the study conducted at AIIMS, New Delhi [20], the Mean hospital stay was 2.9 days in Standard PCNL group and 1.8 days for Tubeless PCNL group. Kara, et al., the mean hospital stay was 1.5 days for Tubeless

PCNL and 3.2 days for Standard PCNL [29]. Bilen, et al. [21], reported that the mean hospital stay was longer in Standard PCNL versus the Tubeless PCNL group (4.9 versus 3.1 days).

In our present study, the postoperative analgesic requirement (Diclofenac) was less than that of the patient who underwent Standard PCNL at our hospital (mean 100 versus 150 mg, respectively). This is advantage of tubeless PCNL and has also been reported in other studies, such as that of Zhong, et al. [22] as their overall results indicated that the tubeless PCNL group had a lesser analgesic requirement.

In our study, the Mean VAS pain score after 6th hour of surgery and after 24 hours of surgery was 6.4 and 4.8 in Tubeless PCNL patients, where in it was 7.5 and 5.9 in case of Standard PCNL of our hospital. Mean VAS score is significantly reduced at 6th hour and 24th hour after Tubeless PCNL compared with standard PCNL.

In the present study, there was no significant difference in the stone-free rate between the study group when compared with the patient undergoing Standard PCNL in our hospital, (i.e. 97.2% in Tubeless PCNL patients and 95.4% in Standard PCNL patients). This result is also similar to other published studies such as that of Ni, et al. [23], who reported no significant differences between tubeless and standard PCNL.

The incidence of complications was not significant between the study group and the patients of Standard PCNL of the hospital. Of the patients in the study group 8 patients had prolonged fever which subsided with Culture Sensitivity Antibiotics, Two patients had post operatively urine leak from PCNL site which subsided on per urethral catheterization. Of five comparative articles reporting post-operative pyrexia, incidences were generally lower in tubeless groups, illustrated best by Shah, et al. (11.4 versus 5.79%). These however were not statistically significant [31].

The mean drop in Hemaglobin was 0.7 gm% in the study group and 0.6 gm% in Standard PCNL patients of our hospital which was not significant. The results were similar to other published studies such as in the study of Khan A, et al. [36].

The mean time to return daily activities in our study group is 6.2 days and for standard PCNL it is 10.5 days. Zhong, et al. [22] reported that the time for return to normal activity in the Tubeless group was significantly lower than the Standard PCNL group. Comparison of intra-operative parameters was as per **Table – 9**. Surgical outcome was compared as per **Table – 10**.

Table – 9: Reference studies- intra operative parameters.

Reference study	**N**	**Mean stone burden**	**Post-operative drainage**	**Analgesia requirement**	**Average Hb drop Gm/dl**	**Stone free rates (%)**
Agarwal, et al. [35]	101	3.8 cm^2	JJs	81.7 mg MP	0.36 gm%	100
Desai, et al. [33]	10	2.5 cm^2	JJs	87.5 mg D	4.2 gm%	-
Feng, et al. [30]	8	4.4 cm^2	JJs	5.25 mg M	-	85.7
Singh, et al. [34]	30	250 mm	JJs	6 mg M, 415 mg D	1.2 gm%	100
Limb and Bellman [28]	112	3.3 cm^2	JJs	-	-	93
Goh and Wolf [25]	10	1.8 cm	EUC, JJs	-	-	80
Karami, et al. [17]	201	3 cm	EUC	-	-	91.04
Yang, et al. [37]	138	-	JJs	6.4 mg M	-	94.5

N-number of patients, JJs-Double J stents, MP-Meperadine, M-morphine sulphate, Ddiclofenac

Table – 10: Reference studies - Surgical outcome.

Reference study	N	Length of hospital stay(days)	Stone free rates (%)	Transfusion rates	Complications
Wickham, et al. [4]	100	2	94	NA	Bleeding (22%) infection (10%)
Winfield, et al. [26]	2	9	-	-	Not significant
Bdesha, et al. [32]	32	2	86	-	Not significant
Karami, et al. [17]	30	1.5	90	0	Infection
Aghamir, et al. [16]	43	1.6	100	0	Not significant
Gupta, et al. [18]	96	1.8	-	1.04	Not significant
Crook, et al. [24]	100	2.9	76	1	1 hydrothorax, 1 sepsis

Conclusion

Our Study demonstrated that Tubeless PCNL can be adapted in majority of patients when the procedure goes uneventful requiring only single tract, without much bleeding, without PCS injury and where complete clearance of stone done, Tubeless PCNL in selected cases is equally safe and as effective as Standard PCNL. It is better tolerated with less post-operative analgesic requirement and decreased post-operative morbidity with shorter hospital stay without any compromise in results when compared with Standard PCNL.

However, PCNL should be carried out in the standard fashion, leaving a nephrostomy tube in place in certain situations like

- Intraoperative uncertainty regarding residual stones
- Significant bleeding or perforation of PCS occurs
- Other major complications are suspected (e.g., hydrothorax, injury to adjacent organs).

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.

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