

## A prospective study of Tubeless Percutaneous Nephrolithomy in patients in a Tertiary Care hospital of Jammu, (J&K) India

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### Abstract:

**Introduction:** *Percutaneous nephrolithotomy (PCNL) is currently the procedure of choice for removing large and complex renal calculi and proximal ureteric calculi. However, based on the concept that purpose of nephrostomy is only to maintain adequate drainage of kidney, a tubeless approach has been developed by placing a J.J ureteric stent, ureteral catheter and Foley's catheter to provide*

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*drainage after PCNL in lieu of a nephrostomy tube. **Objective:** The study was undertaken to determine the efficacy and safety of tubeless PCNL in renal stone management and to assess post-operative morbidity in terms of hospital stay, requirement of analgesia and need for blood transfusion. **Material and methods:** It was a hospital based prospective study conducted in the Department of Surgery, Government Medical College, Jammu over a period of one and a half year from 1<sup>st</sup> May 2011 to 31<sup>st</sup> October 2012. All patients undergoing tubeless PCNL in our hospital for renal and upper ureteric stones and fulfilling the inclusion criteria of single percutaneous access tract, insignificant bleeding throughout surgery and insignificant bleeding after removal of amplatz sheath were included in our study. **Results:** Our study included 33 patients and majority of them were in their 4<sup>th</sup> and 5<sup>th</sup> decade of life (33.3% and 27.4%) respectively. Most of the participants were males (64%) About 69.7% of the patients presented with the symptom of dull aching pain and about 36.36% had stone size of 17-21mm. Mean duration of surgery was 48.33 minutes Majority of the patients (87.9%) had a VAS score in the range of 2-6 cms in the post-operative period and mean score in our study was 3.9 cm. Analgesia requirement for diclofenac was 75 mg in more than half of the patients (54.6%), followed by 150 mg (42.4%) of patients. After Tubeless PCNL, majority of the patients (91%) were stone free, (6%) had insignificant fragment < 4mm in size whereas only (3%) had residual fragment > 4 mm in size. **Conclusion:** Our study clearly indicates that tubeless PCNL is safe and effective in the management of selected patients with simple renal stones of mild to moderate burden.*

**Key words:** Renal calculi, Percutaneous nephrolithotomy, Nephrostomy

## INTRODUCTION

Although stone disease is one of the most common affliction of modern society, it has been described since antiquity. With westernisation of global culture, the site of stone formation has

migrated from the lower to the upper urinary tract and the disease once limited to men is increasingly becoming gender blind. Revolutionary advances in the minimally invasive and non invasive management of stone disease over the past two decades have greatly facilitated the ease with which stones are removed. However, open surgical treatments, although invasive are still in use to remove the offending stones.

The lifetime prevalence of kidney stone disease is estimated at 1% to 15% with the probability of having a stone varying according to age, gender, race and geographic location. In Asia, the incidence is between 1 and 5%. In India, approximately 57 million of people suffer from stone disease and at least 1/1000 of Indian population needs hospitalisation due to kidney stone disease every year.

Percutaneous nephrolithotomy (PCNL) is currently the procedure of choice for removing large and complex renal calculi and proximal ureteric calculi. Placing a nephrostomy tube is last step after completing PCNL & has been considered the standard of care for almost 20 years as it provides adequate renal drainage, allows renal healing and avoids urinary extravasation. It also tamponades bleeding and allows the nephrostomy tract to mature and making second look nephroscopy easy. However, based on the concept that purpose of nephrostomy is only to maintain adequate drainage of kidney, a tubeless approach has been developed by placing a J.J ureteric stent, ureteral catheter and Foley's catheter to provide drainage after PCNL in lieu of a nephrostomy tube<sup>1</sup>.

Recent randomized studies have shown that, avoiding external nephrostomy tube drainage, termed as 'tubeless percutaneous nephrolithotomy' procedure significantly decreases pain and morbidity of percutaneous nephrolithotomy, and diminishes related expenses in selected patients<sup>2</sup>.

However, no study has been done on tubeless PCNL in our hospital. Therefore, this study was undertaken to

determine the efficacy and safety of tubeless PCNL in renal stone management and to assess post-operative morbidity in terms of hospital stay, requirement of analgesia and need for blood transfusion.

## **METHODOLOGY**

It was a hospital based prospective study conducted in the Department of Surgery, Government Medical College, Jammu over a period of one and a half year from 1<sup>st</sup> May 2011 to 31<sup>st</sup> October 2012. All patients undergoing tubeless PCNL in our hospital for renal and upper ureteric stones and fulfilling the inclusion criteria were included in our study.

### **Inclusion Criteria**

Renal stone disease with:

- a) Single percutaneous access tract.
- b) No significant bleeding throughout surgery.
- c) No significant bleeding after removal of amplatz sheath.

### **Exclusion Criteria**

1. Presence of significant bleeding that persisted throughout surgery and was not adequately tamponaded by amplatz sheath.
2. Presence of significant residual stone burden necessitating a second stage look nephroscopy.
3. Significant perforation of collecting system.

### **Materials Used**

C-arm fluoroscopy machine, Contrast material (urograffin), Initial puncture needle 18 G, 0.035 inch J-tip/straight tip guide wire, Swiss Lithoclast (Pneumatic), Metal/Teflon dilators, 10-30 Fr, Nephrostomy tube, 24-30 Fr., Amplatz Sheath, 24-30 Fr,

Ureteral catheter, 6 Fr Open Ended, Cystoscope., Nephroscope (rigid/flexible), Ureteral Stent and double J 6Fr with both ends open Stone Grasper were used for the study.

### **Method Performed**

Patients who presented in the Department of Surgery (Emergency or Out Patient basis) with renal and/or upper ureteric stone were planned to undergo tubeless PCNL surgery keeping in consideration the inclusion criteria.

In addition to history (including present, past, family, personal, surgical, allergic and drug history), clinical examination and routine laboratory investigations, radiological evaluation including plain abdominal radiograph (KUB), abdominal ultrasonography and excretory urography (IVU) were performed in all patients. Apart from confirmation of the diagnosis and making the patient fit for general anaesthesia, the preoperative work-up included the following steps:

- 12 hours fasting before surgery.
- Pre-anaesthetic medication.
- Part preparation
- Informed and written consent.
- Plain x-ray abdomen (KUB) early in the morning on the day of surgery to confirm the exact site of stone.
- Antibiotic prophylaxis (intravenous) before the procedure.

### **Operative Technique**

#### **Tubeless PCNL**

- With patient in low dorsal lithotomy position, six Fr open ended ureteral catheter was introduced transurethraly into renal pelvis on the side of surgery under cystoscopic guidance.

- Collecting system was opacified by injecting contrast material and air.
- Patient was repositioned to prone position and puncture was done using 18 G initial puncture needle, preferably in the posterior calyx under C-arm guidance.
- When the needle appeared in the calyx, stylet was removed and correct position was verified by aspiration of urine.
- A flexible J-shaped guide wire was passed down the sheath of needle.
- With needle in position, 1cm skin incision was made and needle was removed and guide wire left in situ.
- Tract was serially dilated (24-30 fr) with the help of dilators depending upon the size of stone.
- Amplatz sheath of 24-30 Fr was introduced.
- Nephroscope was used for visualization and extraction of stone.
- A pneumatic lithoclast was use to fragment large stones.
- After complete clearance confirmed fluoroscopically and endoscopically, a 6 Fr JJ stent was placed antegradely.
- On completing the procedure with guide wire in situ and compression for five minutes, we looked for bleeding.
- Amplatz sheath was removed and wounds strapped with a pressure bandage and sutured with silk.

### **Post operative follow up**

- At six hours after surgery, patient was given visual analogue scale (VAS) to analyze pain intensity. The Visual Analogue Scale (VAS) is a subjective measure of pain. It consists of a 10cm line with two end-points

representing 'no pain' and 'worst pain imaginable'. Patients were asked to rate their pain by placing a mark on the line corresponding to their current level of pain. The distance along the line from the 'no pain' mark is then measured with a ruler giving a pain score out of 10.

- All patients had haemoglobin done on first day after surgery to determine decrease in haemoglobin.
- All patients were assessed with renal ultrasonography and radiography (KUB) region after 72 hours to confirm stone free status and exclude presence of urinoma.
- Catheter was removed after stone free status and absence of haematuria confirmed.

The operative time, change in haemotocrit, presence of urinary leakage, analgesic requirement, duration of hospital stay and return to normal activity were recorded.

#### **Ethical consideration:-**

Approval of ethical committee of our institution was sought before conducting the study. Informed & written consent from all the patients was taken. Confidentiality was maintained at all times during the course of the study. There was no financial burden to the patients.

#### **Statistical analysis:**

The data thus obtained was analyzed using SPSS software (version 20). Appropriate statistical methods (Chi-square, t-test and Logistic regression) were applied as per requirement. P value  $\leq 0.05$  was considered significant.

## RESULTS

Our study included 33 patients who fulfilled the inclusion criteria for tubeless percutaneous nephrolithotomy (PCNL) as per the protocol. Age of the patients with renal stone ranged from 11-60 years. Majority of the patients were in their 4<sup>th</sup> and 5<sup>th</sup> decade of life (33.3% and 27.4%) respectively. Further it was observed that the mean age of patients in our study was 38.30 years. Most of the participants were males (64%) and only 36% were females (**Table 1**).

About 69.7% of the patients presented with the symptom of dull aching pain followed by increasing frequency of micturition(18.2%), haematuria (9.1%) and dysuria(3%).As per Intra-venous Urography (IVU), most of the patients 23 (69.7%) had stone in the renal pelvis, followed by 7 (21.2%) in inferior calyx whereas only 3(9.1%) had stone in superior calyx. It was found that the stone size ranged from 12-31mm on KUB with an average size of 21.22 mm. Most of the participants (36.36%) had stone size of 17-21mm (**Table 2**).

Out of 33 patients studied, 26 (78.8%) had infracostal tract during the procedure and only 7 (21.2%) had supracostal tract. Mean duration of surgery was 48.33 minutes; minimum was 30 minutes and maximum 60 minutes (**Table 3**).

During post-operative period (after 6 hours of surgery), pain was assessed using Visual Analog Scale (VAS). Majority of the patients (87.9%) had a VAS score in the range of 2-6 cms and mean score in our study was 3.9 cm. Analgesia requirement for diclofenac was 75 mg in more than half of the patients (54.6%), followed by 150 mg (42.4%) of patients. Only 1 patient required 225 mg of diclofenac during post-operative period in the hospital. Majority of the patients (48.48%) had a decrease in haemoglobin of 0.4-0.6 g/dl. Mean decrease in hemoglobin level after the procedure was only 0.53 g/dl and none of our



patient required blood transfusion. In our study, the mean hospital stay after the procedure was just 3.18 days (**Table 4**).

Out of the total, 2 patients (6%) had hematuria, 2 (6%) had post operative fever and 1 (3%) had wound infection. None of the patients had sepsis, urinary leakage or bleeding (**Table 5**).

After Tubeless PCNL, majority of the patients (91%) were stone free, (6%) had insignificant fragment < 4mm in size whereas only (3%) had residual fragment > 4 mm in size. There was no need for ancillary procedure (Extracorporeal Shock Wave Lithotripsy-ESWL) in 97% whereas only 1 patient with residual fragment > 4 mm in size needed ancillary procedure (**Table 6**).

## DISCUSSION

It was a descriptive study and included 33 patients who fulfilled the inclusion criteria for tubeless PCNL. Various factors warrant consideration when analyzing the effectiveness of stone removing procedures, including the stone free rate, morbidity (both intra-operative and post-operative) and economic impact in the form of average number of post-operative days spent in hospital. Although our study was descriptive, we believe that certain valid conclusions can be drawn.

Stone occurrence is relatively uncommon before the age of 20 years but peaks in incidence in the 4<sup>th</sup> to 6<sup>th</sup> decade of life. Age wise distribution of patients in our study revealed that mean age was 38.3 years. Age pattern shows close resemblance with reports of various authors. Aatif Hussian Shaikh, Salman EJ Khalid, Noor Nabi (2007) in their series of 50 patients reported an average age of patients as 39.3 years<sup>3</sup>. Stone disease typically affects adult males more commonly than adult females. Males are three times more likely to be affected than

females. Tawfik H, Al-Badani, Khaleel M et al (2008) in their study of 121 patients reported that 68% were males and 32% were females<sup>4</sup>. Similar finding was observed in our study which included 64% males and 36% females.

In our study, 70% of our patients presented with dull aching pain, 9% had macroscopic hematuria, 3% had dysuria and 18% had increased frequency of micturition. The stone burden was assessed by measuring the greatest length dimension of stone on X-ray KUB region. Average stone size in our study was 21.2 mm (12-30 mm). Pascal M, Romain S, Harve L (2008) reported an average stone size of 17.25 mm which is almost similar to our study<sup>5</sup>. Considering the fact that the bigger stones required more than one access tract, so we selected only those patients for tubeless PCNL which had smaller stone size and as such required only one access tract.

Mean operative time in our study was 48.3 minutes (range 30-60 minutes). This was comparable to the study reported by Hemendra Shah et al (2008) with their mean duration of surgery 52.2 minutes<sup>6</sup>. A study by Sofer M et al (2007) reported an average operative time as 116 minutes in tubeless precutaneous nephrolithotomy group<sup>7</sup>. This was higher than our study as it also included multiple access, staghorn stones, anatomic anomalies and single kidney.

The average Visual Analog Scale (VAS) pain score of our patients was found to be 3.9 cm on a 0-10 cms scale. This was quite similar to the study conducted in R.G. Stone Urological Research Institute Mumbai, Maharashtra, where average visual analog scale pain score was 4.4 cm in tubeless precutaneous nephrolithotomy group. Madhu Sudan Agrawal et al (2008) conducted a study in which average visual analog scale pain score was 3.1cm<sup>8</sup>. This was lower than reported by our study as the score was analyzed on first post-operative day. The mean post-operative analgesia requirement in our study was calculated to be 111 mg of diclofenac (range being 75mg to

225mg). Ahmed Tefekli et al conducted a study on tubeless percutaneous nephrolithotomy in which mean post-operative analgesia requirement was 110.3 mg diclofenac, similar to our study<sup>2</sup>. The average hospital stay in our study subjects was 3.2 days (range 3-4 days). A study conducted by Lojanapiwat B, Soonthornphan S, Wudhikarn S (2001) reported an average length of hospitalization as 3.63 days which is similar to our study<sup>9</sup>. Average hospital was 1.8 days in the study conducted by Gupta NP, Mishra S, Suryawanshi M et al (2008)<sup>10</sup>. Longer hospital stay in our study can be attributed to catheter removal after 72 hours in view of patient safety as per our study protocol. The mean decrease in hemoglobin after the procedure was 0.53gm/dl. No patient in our study required blood transfusion. Tawfiq H et al (2008) in their study documented a mean decrease of hemoglobin as 1.57gm/dl<sup>4</sup>. This can be explained by the fact that stone burden as well as number of punctures were higher as compared to our study. The punctures were single in all the 33 patients in our study.

No intra-operative complications were observed. However, post-operative complications such as haematuria, post operative fever and wound infection were observed in 6 patients (15%). Pascal M, Romain S, Harve L (2008) reported post-operative complication rate of 15% (5 patients), 2 had pyelonephritis, 1 had urinary extravasation, 1 had sustained haematuria and 1 had renal colic<sup>5</sup>. However, none of our cases had such complications. This low post-operative complication rate clearly indicates the safety of tubeless percutaneous nephrolithotomy in selected patients.

Stone free rate at follow up was achieved in 30 patients (91%). Clinically insignificant residual stones (<4mm) was encountered in 2 patients (6%). 1 patient (3%) had significant residual stone (>4mm) and he underwent Extracorporeal Shock Wave Lithotripsy(ESWL) for the same. Pascal M, Romain S, Harve L et al (2007) reported a success rate of 95%,

quite similar to our study<sup>5</sup>. This was due to their selective inclusion criteria which were comparable to our study. A stone free outcome of 89.4% was observed in the study conducted by Shah HN, Kausik VB, Hegde SS et al (2005)<sup>1</sup>. This may be due to the fact that stone burden was much higher (322.8mm) in their study and the number of associated complexity was also high.

## CONCLUSION

Our study clearly indicates that tubeless PCNL is safe and effective in the management of selected patients with simple renal stones of mild to moderate burden and that the mean hospital stay, as well as analgesia requirement is diminished with this modification. Further refinements will probably qualify increased number of patients as candidates for tubeless PCNL.

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## Tables

**Table:-1 depicts the demographic characteristics of study participants**

Age (in years)	Number (N)	Percentage (%)
11-20	1	3.0
21-30	8	24.2
31-40	11	33.3
41-50	9	27.4
51-60	4	12.1
<b>Sex</b>		
Male	21	64
Female	12	36
<b>Total</b>	<b>33</b>	<b>100</b>

**Table:-2 shows the distribution of participants as per pre-operative evaluation**

Symptoms	Number(N)	Percentage (%)
Dull aching pain	23	69.7
Increasing Frequency	6	18.2
Haematuria	3	9.1
Dysuria	1	3
<b>Stone location( as per intravenous urography)</b>		
Renal Pelvis	23	69.7
Inferior Calyx	7	21.2
Superior Calyx	3	9.1
<b>Average stone size in mm (as per KUB)</b>		
12-16	5	15.15
17-21	12	36.36
22-26	11	33.33
27 – 31	5	15.15
<b>Total</b>	<b>33</b>	<b>100</b>

**Table:-3 shows the distribution of participants as post operative evaluation**

Site of Tract	Number (N)	Percentage (%)
Supracostal	7	21.2
Infracostal	26	78.8
<b>Mean duration of Procedure (minutes)</b>		
31 – 40	4	12.12
41 – 50	18	54.54
51 – 60	11	33.33
<b>Total</b>	<b>33</b>	<b>100</b>

**Table:4 depicts the parameters of participants in the post operative period**

Visual Analog Scale (VAS) score (cm)	Number (N)	Percentage (%)
0-2	0	0
2-4	15	45.5
4-6	14	42.4
6-8	4	12.1
8-10	0	0
<b>Analgesia Requirement (mg diclofenac)</b>		

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75	18	54.6
150	14	42.4
225	1	3
<b>Decrease in haemoglobin (g/dl)</b>		
0.1-0.3	6	18.18
0.4 – 0.6	16	48.48
0.7 – 0.9	10	30.30
1 – 1.2	1	3.03
<b>Duration of Hospital Stay (days)</b>		
3	27	81.8
4	6	18.2
<b>Total</b>	<b>33</b>	<b>100</b>

**Table:5 depicts the Post Operative complications in patients after Tubeless PCNL**

<b>Complications</b>	<b>Number (N)</b>	<b>Percentage (%)</b>
Wound Infection	1	3
Haematuria	2	6
Fever	2	6
<b>Total</b>	<b>5</b>	<b>15</b>

**Table:6 shows the outcome in patients after undergoing Tubeless PCNL**

<b>Stone related outcome</b>	<b>Number (N)</b>	<b>Percentage (%)</b>
Stone Free	30	91
Residual Fragment > 4mm	1	3
Insignificant Residual Stone < 4mm	2	6
<b>Need for ancillary procedure</b>		
Yes (ESWL)	1	3
No	32	97
<b>Total</b>	<b>33</b>	<b>100</b>