

ORIGINAL RESEARCH

A Prospective Study on comparison of totally tubeless Percutaneous Nephrolithotomy and standard percutaneous nephrolithotomy for management of renal and upper ureteric stones

¹Dr.Mushtaq Ahmed Meer,²Dr.RabiaKhanam,³Dr.Rajesh Khanna,⁴Dr.AshishPal Singh,⁵Dr.Pankaj Kumar Verma,⁶Dr.Aishwarya Avnish,⁷Dr.Rajat Pankaj,⁸Dr.Abhishek

^{1,4}Assistant Professor,³Professor, ^{5,6,7,8}M.Ch Resident, Department of Urology, MMIMSR, Mullana, Ambala, Haryana, India

²Assistant Professor, Department of Obstetrics & Gynaecology, MMIMSR, Mullana, Ambala, Haryana, India

Corresponding Author

Dr.Mushtaq Ahmed Meer

Assistant Professor, Department of Urology, MMIMSR, Mullana, Ambala, Haryana, India

Email: meer.mushtaq@gmail.com

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ABSTRACT

Aims and objectives:To evaluate and compare results of totally tubeless Percutaneous Nephrolithotomy with standard percutaneous nephrolithotomy technique for management of renal and upper ureteric stones.

Material and method: This prospective comparative study to evaluate safety and efficacy of the total tubeless PCNL in selected cases vs standard PCNL was undertaken in urology Department of MMIMSR, Mullana, Ambala from March 2019 to February 2020. A total of 100 patients were included in the study and divided into two group each having 50 patients after randomization. Group 1 (control group) is standard PCNL group which involves placement of nephrostomy tube and DJ stent at the end of the procedure and group 2 (Test group) is Total tubeless PCNL group in which insertion of both nephrostomy tube and double J stent are omitted. **Results:** The mean age of patients in group 1 and group 2 was 45.72±15.04 and 41.48±15.84 years respectively. Number of males and females in group 1 was 34(68%) and 16 (32%) respectively while in group 2 was 33(66%) and 17(34%) respectively. The comparison between two groups for Mean age, Male/Female ratio, distribution of stones, Mean stone burden, duration of surgery, HB fall, stone clearance and complications were statistically insignificant (P value >0.05). The comparison between two groups for post-operative pain score, postoperative analgesic requirement, hospital stay and return to normal activity were statistically significant (P value < 0.05).

Conclusion:In conclusion both standard PCNL and Total tubeless PCNL are safe, effective and accepted procedures for primary management of renal and upper ureteric calculi. Total tubeless PCNL has favourable results in selected patients if stone burden is less than 3 cm in absence of significant residual stones, pelvicalyceal perforation and bleeding. Total tubeless PCNL has added benefit of decreased postoperative pain and lesser analgesia requirement. **Key words:**Totally tubeless Percutaneous Nephrolithotomy, standard percutaneous nephrolithotomy, renal stones, upper ureteric stones.

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INTRODUCTION

Urolithiasis is an increasingly common condition with rising incidence globally and having a significant economic burden on the society.^(1,2) Nephrolithiasis is associated with high likelihood of lifetime risk of about 50%.⁽²⁾ Majority of

renal stones pass spontaneously; however up to 10–20% of renal stones require surgery. Percutaneous nephrolithotomy (PCNL), retrograde intrarenal surgery (RIRS) and shockwave lithotripsy (SWL) are the current management options for small renal calculi

while percutaneous nephrolithotomy (PCNL) is the gold standard for stones larger than 2.0 cm.^(3,4)

PCNL, which was first described in 1976^[1] has become the procedure of choice for large burden renal calculi and a management option for small renal calculi as well.⁽⁵⁾

Standard PCNL involves placement of nephrostomy tube and DJ stent at the end of the procedure. The placement of nephrostomy tube at the completion of PCNL procedure serves the advantage of tamponade of the renal bleeding, drainage of any infection in pelvicalyceal system and to have a relook to remove significant residual stones. Nephrostomy tube placement on the other hand is associated with several disadvantages such as prolonged hospitalisation, increased risk of infection, increased analgesic requirement and pain or discomfort.^(6,7) Tubeless percutaneous nephrolithotomy, a modification of standard PCNL was introduced in 1997. There is shifting trend towards tubeless PCNL which omits nephrostomy tube placement thus avoiding nephrostomy related complications.^(8,9,10) A ureteric stent after PCNL causes dysuria and needs another procedure to remove it. Delay in removal of ureteric stent may result in further complications.

The next modern modification after tubeless PCNL was totally tubeless PCNL in which insertion of both nephrostomy tube and double J stent are omitted.^(11,12) To reduce nephrostomy and stent related discomfort and to avoid additional procedure to remove the stent; a prospective comparative study to evaluate safety and efficacy of the total tubeless PCNL in selected cases vs standard PCNL was undertaken in urology Department of MMIMSR, Mullana, Amballa.

MATERIAL AND METHODS

Study location: This prospective observational study was carried out in Department of Urology at MMIMSR, Mullana, Ambala

Study design: A Prospective study conducted in the Department of Urology at MMIMSR, Mullana, Ambala

Study duration: It was carried out from March 2019 to February 2020.

Sample size: From the study conducted by Choi SW, et al.⁽¹³⁾ Analysis of Clinical Outcomes and Cost revealed Mean Group (m1) = 33.2, Mean Group (m2) = 45.2, Coefficient of variation = 150%, Standard deviation Group (σ_1) = 21.3, Standard deviation (σ_2) = 19.5, Change in the parameters (m1 – m2) = 12. With the above assumptions the sample size for 95% confidence level & 80% power works out 46 in each group. So, we took 50 sample size for the each group.

Randomization: Odd number patients were included in group-1 and even number patients were included in Group-2.

Study population: All patients with renal and upper ureteric calculus who were planned for PCNL, and satisfy inclusion/ exclusion criteria were included in

this study. Written informed Consent was taken after explaining the details of procedure, possible retreatment, shift to another treatment, complications and investigative nature of the treatment protocol. A total of 100 patients were included in this study.

Inclusion criteria was Renal or upper ureteric calculus < 3 cm, Radio-opaque calculus, Age > 15 years

Exclusion criteria was Patients with stone size > 3cm, Renal stone with PUJ obstruction, Uncontrolled comorbidity (diabetes, hypertension, severe cardiac dysfunction), Coagulopathy, Renal insufficiency, Intraoperative complication like pelvicalyceal perforation, bleeding and residual stone

Methodology: The patients were divided into two groups. Group 1 included the patients who underwent standard PCNL. The group 2 includes the patients who were treated with total tubeless PCNL. All patients were evaluated by a detailed clinical history, examination, Renal function test, Complete blood count, PTI, INR, urine routine examination, urine culture and radiological investigations in the form USG KUB region, X-ray KUB, and CT Urography. All patients were operated under general anaesthesia. The patients were placed in the lithotomy position and initial cystoscopy done using 20 F cystoscopes. Then to insert a 5-F open-tip ureteric catheter. Patients were turned into prone position. Access to the desired calyx was performed fluoroscopically guided and using 18-gauge needle after performing RGP through ureteric catheter to identify the anatomy of pelvicalyceal system. After confirming the needle position in the desired calyx a 0.035 inch chertumo straight tip guidewire was coiled into the pelvicalyceal system or parkered down the ureter into urinary bladder under C-ARM control. Dilatation was performed with facial dilator 8F over the guide wire followed by single step dilation over central guide rod using appropriate size Amplatz dilator and sheath. Nephroscopy done using wolf-nephroscope 22 F, stone fragmentation was carried out with a pneumatic lithotripter. The stone fragments were removed with the help of biphonged or triphonged stone forceps. At the completion of the procedure, the pelvicalyceal system was examined both endoscopically and fluoroscopically for any residual stone fragments, perforation of pelvicalyceal system or bleeding.

In Standard PCNL Nephrostomy tube and stent were kept while in Total tubeless PCNL both nephrostomy and stent were omitted. Per-urethral catheter was left insitu in both the groups. Ureteric catheter was left insitu in Total tubeless PCNL group at the end of the procedure and was removed the next day in the morning after X-ray kidney-ureter-bladder (KUB) along with per-urethral catheter. Postoperatively, patients were kept on injectable analgesics (Diclofenac sodium: 75mg, 8 or 12 hourly). In Standard PCNL group nephrostomy tube was removed on 1st postoperative day followed by per-urethral catheter on 2nd postoperative day.

Intraoperative events like duration of surgery, stone clearance and any complication were noted. Postoperative parameters, which were taken into account, were the visual analogue scale (VAS; 1 to 10) for pain, parenteral analgesic requirements, bleeding (hematuria or fall in hemoglobin), urinary soakage, and hemodynamic stability, need for blood transfusion, fever, hospital stay, readmission, retreatment. Patient were discharged when patient was fully conscious, tolerating orals, pain free, no hematuria and stable vital signs after evaluation by the lead surgeon. Each patient was given verbal and written instructions about indications for returning to the hospital. Follow up was done at 2 weeks to enquire about any complications, perform ultrasonography to confirm any perinephric collection or residual stone fragments and double J stent removal in Standard PCNL group under local anaesthesia. At

follow-up, parameters evaluated were any complication and day of returning to normal work. Medical records of these patients were collected, reviewed and analysed. Data was described in terms of range; mean \pm standard deviation (\pm SD), median, frequencies (number of cases) and relative frequencies (percentages) as appropriate. To determine whether the data was normally distributed, a Kolmogorov-Smirnov test was used. Comparison of quantitative variables between the study groups was done using Student t-test and Mann Whitney U test for independent samples for parametric and non-parametric data respectively. For comparing categorical data, Chi square (χ^2) test was performed and exact test was used when the expected frequency is less than 5. A probability value (*p* value) less than 0.05 was considered statistically significant. For statistical calculations SPSS 21 version was used.

RESULTS

Table 1: Demographic data and stone characteristics of Patients

Demographic Data		Group 1 (n=50) Standard PCNL	Group 2 (n=50) Totally tubeless PCNL	Chi-Square value	p-value
Age		45.72 \pm 15.04	41.88 \pm 15.84	3.227	0.358
Gender	F	16 (32%)	17 (34%)	0.045	0.832
	M	34 (68%)	33 (66%)		
Stone Laterality	Left	28 (56%)	29 (58%)	0.041	0.840
	Right	22 (44%)	21 (42%)		
Stone Burden (mm)		15.26 \pm 4.99	16.14 \pm 3.93	1.050	0.592

Table 2: Results in both the groups

Results	Group 1 (n=50) Standard PCNL	Group 2 (n=50) Totally tubeless PCNL	Chi-Square value	p-value
Duration of surgery (Minutes)	66.60 \pm 11.89	63.30 \pm 12.31	3.986	0.263
Post operative pain score	5.70 \pm 1.16	4.14 \pm 1.47	24.832	0.0001
Analgesic requirement (Diclofenac in mg)	249 \pm 65.07	156 \pm 39.63	46.615	0.0001
Fall in hemoglobin	0.85 \pm 0.48 g/dl	0.77 \pm 0.37 g/dl	4.674	0.193
Hospital Stay (Hours)	56.06 \pm 16.37	29.22 \pm 10.79	36.05	0.0001
Return to normal activity (Days)	6.26 \pm 1.64	4.54 \pm 1.23	21.106	0.0001

Table 3: Complications in both the groups

Post operative complications	Group 1 (n=50) Standard PCNL		Group 2 (n=50) Totally tubeless PCNL		Total	Chi-square value	p-value
	No. Of cases	(%)	No. Of cases	(%)			
Fever	1	2%	4	8%	5	1.895	0.169
Urinary leak	4	8%	0	0%	4	4.167	0.117
Hematuria	6	12%	5	10%	11	1.020	0.749
Urinoma	0	0%	0	0%	0	0.000	1.000
Perinephric hematoma	0	0%	0	0%	0	0.000	1.000
Residual calculi	5	10 %	4	8 %	9	0.122	0.727
Clot Colic	0	0 %	3	6 %	3	3.093	0.242
Hematuria	2	4 %	4	8 %	6	0.709	0.678
Fever	4	8 %	4	8 %	8	0.000	1.000
Pleural Effusion	1	2 %	1	2 %	2	0.000	1.000
Readmission	6	12 %	5	10 %	11	0.102	0.749
Stent Migration	1	2 %	N.A		1		

For data collection patients were interviewed and medical records analysed for estimating intervention outcomes, intraoperative and postoperative parameters. Patients were followed up at 2 weeks and follow up parameters were recorded.

The mean age of patients in group 1 and group 2 was 45.72 ± 15.04 and 41.48 ± 15.84 years respectively. Number of males and females in group 1 was 34(68%) and 16 (32%) respectively while in group 2 was 33 (66%) and 17(34%) respectively. Applying Chi square test, p value was 0.832 which showed that the difference was not statistically significant.

The distribution of stones in patients according to side between the groups was not statistically significant. Although there was a left sided preponderance in both the groups, the side distribution between the two groups was not statistically significant. Number of patients with stone on right and left side in group 1 was 22 and 28 respectively while in group 2 was 21 and 29 respectively. Applying Chi square test, p value was 0.84 which showed that the difference was not statistically significant.

There was no statistically significant difference in location of stone between the two groups. In group 1, most common location of stone was Pelvis (34%) followed by lower calyx (30%), upper calyx(16%), middle calyx (12%) and upper ureter (8%) . In group 2 the most common location was Pelvis (32%) followed by lower calyx (28%), upper calyx (22%), middle calyx (12%) and upper ureteric (6%).

Mean stone burden in group 1 and group 2 was 15.26 ± 4.99 mm and 16.14 ± 3.93 mm respectively. The difference between groups in location of stone were comparable and statistically insignificant as per chi-square test, p value was 0.866.

The mean duration of surgery in group 1 was 66.60 ± 11.89 minutes and in group 2 was 63.30 ± 12.31 minutes. Although duration of surgery was more in group 1 as compared to group 2 but this was statistically insignificant (p value=0.071).

The mean HB fall in group 1 was 0.85 ± 0.48 g/dl and in group 2 was 0.77 ± 0.37 g/dl. The difference between postoperative haemoglobin fall between two group was statistically insignificant (p value=0.763).

The mean postoperative pain score in group 1 was 5.70 ± 1.16 (range 3-8) and in group 2 was 4.14 ± 1.47 (3-8). The difference in postoperative pain score between two group was statistically significant (p value <0.0001).

The mean postoperative analgesic requirement in group 1 was 249 ± 65.07 mg and in group 2 was 156 ± 39.63 mg. The difference in postoperative pain score between two group was statistically significant (p<0.0001).

On comparing postoperative complication, in group 1, 1 (2%) patient developed fever, 4 (8%) developed urine leak, 6(12%) developed hematuria and 5(10%) had residual stones while in group 2 4 (8%) patients developed fever, 5(10%) developed haematuria,4(8%) had residual stones and no patient developed urine

leak. In both the groups no patient developed urinoma, perinephric hematoma. The difference in complication between two group was statistically insignificant.

In our study group 1 and group 2, mean hospital stay was 56.06 ± 16.37 and 29.22 ± 10.79 respectively. The difference in hospital stay between two groups is statistically significant (p<0.0001).

Comparison of follow up complications between the two groups showed that in group 1, no patient developed colic, 4 (8%) developed fever and 2(4%) developed hematuria while in group 2, 3(6%) patients developed colic, 4 (8%) patients developed fever, 4(8%) developed haematuria. In group 1, 6 patients were readmitted, out of these 4 were managed conservatively, one with double J re-stenting for stent migration and one needed ICTD insertion for pleural effusion. In group 2, five patients were readmitted, out of these 1 needed ICTD insertion for pleural effusion and 4 were conservatively managed. The difference in complication between two group was statistically insignificant.

In our study group 1 and group 2, mean days to return to normal activity was 6.26 ± 1.64 and 4.54 ± 1.23 respectively. The difference in days to return to normal activity of patients between two groups is statistically significant (p<0.0001). Analyses of stent related complications in group 1 showed that 6 (12%) patients developed stent related dysuria, 3 (6%) patients developed urgency and 1 (2%) patient developed haematuria. Group 2 was totally tubeless so there was no stent related complication in group 2.

Overall, results of this study supported the findings that totally tubeless PCNL has less postoperative discomfort, less analgesic requirement, shorter hospital stay and early recovery and no added complications if patients were selected appropriately.

DISCUSSION

Standard PCNL^(6,7) involves placing nephrostomy and DJ stent at the end of the procedure which has undergone several modifications over time including omitting nephrostomy (TubelessPCNL)^(8,9,10), omitting both nephrostomy and DJ stent (Totally tubeless)^(11,12).

This study was performed to compare totally tubeless PCNL and standard PCNL in patients with renal and upper ureteric stones. In this present study statistically insignificant difference between the standardPCNL and totally tubeless PCNL groups were observed for demographic data of the patients. The meanage of patients was 45.72 ± 15.04 years in standardPCNL group and 41.88 ± 15.84 years in Total tubeless PCNL group. In Standard PCNL group 34(68%) patients were males and 16(32%) were female while in Total tubeless PCNL group 33(66 %) were males and 17(34%) were females. Also there was no statistically significant difference between the two groups for stone size, side, and location within the kidney. The mean stone size was 15.26 ± 4.99 mm in

Standard PCNL group and in 16.14 ± 3.93 mm in Total tubeless group. Our observations were similar to studies conducted by Sabaey et al.⁽¹⁴⁾ N. Moosanejad A. et al.⁽¹²⁾ who reported that there was statistically insignificant difference between the two groups for patient demographics and stone characteristics.

The mean operative time was longer in the Standard PCNL group than in the Total tubeless PCNL group in our study. The mean operative time in Standard PCNL and Total tubeless PCNL was 66.60 ± 11.89 versus 63.30 ± 12.31 min, respectively but this difference was statistically insignificant (p -value=0.071). Similar observations were made by Khairy Salem et al.⁽¹⁵⁾ and Sabaey et al.⁽¹⁴⁾ in their studies but Ni S et al.⁽¹⁶⁾ concluded that tubeless PCNL had a reduced operative time as compared to the standard PCNL.

For the mean postoperative drop in haemoglobin, there was no significant difference between the two groups in the present study ($p=0.0763$). The mean haemoglobin fall was 0.85 ± 0.48 g/dl for Standard PCNL versus 0.77 ± 0.37 g/dl for Total tubeless PCNL. Our observations were supported by previous studies done by Sabaey et al.⁽¹⁴⁾, Kara et al.⁽¹⁷⁾ Khairysalem et al.⁽¹⁵⁾

The presence of nephrostomy tube or double J stent is frequently associated with postoperative pain. Pain was assessed at 24 hours after procedure by Visual analog scale. In our study, the mean pain score group was 4.14 ± 1.47 and 5.70 ± 1.16 in totally tubeless PCNL and standard PCNL group respectively, a statistically significant difference between the groups ($P=0.0001$). Similarly lesser postoperative pain was observed by Agrawal et al.⁽¹⁸⁾ and Khairy Salem et al.⁽¹⁵⁾ in their studies.

Postoperative pain management was done by NSAIDS (inj. Diclofenac) in the present study. In our present study, comparison of the postoperative analgesic requirement in the Total tubeless PCNL group was significantly less than that of Standard PCNL group (156 ± 39.63 versus 249 ± 65.07 mg, $p < 0.0001$). This advantage of total tubeless PCNL was also reported in other studies done by Zhong et al.⁽¹⁹⁾, Khairy Salem et al.⁽¹⁵⁾ and sabaey et al.⁽¹⁴⁾. Less postoperative pain and analgesic requirement in total tubeless PCNL group in our study was mainly due to omission of nephrostomy tube and stent which were main cause of pain in standard group.

In the present study we observed statistically insignificant difference between the groups for the stone-free rate, similar observation was noted in other published studies of Ni et al.⁽¹⁶⁾ and Khairy Salem et al.⁽¹⁵⁾ while Bilen et al.⁽²⁰⁾ in their study observed that stone-free rates were 91.6% vs 78.5 % in the tubeless and the standard PCNL groups respectively.

In this present study comparison of two groups statistically insignificant difference for postoperative urinary leak was observed ($p=0.117$). This observation was supported by study done by Sabaey et al.⁽¹⁶⁾. In the Khairy Salem et al.⁽¹⁴⁾ study,

they observed urine leakage in one patient in the Standard PCNL group and five patients in the Total tubeless PCNL group after removal of the ureteric catheter. All patients were managed conservatively and urine leakage settled within 12-24 hours.

In our study postoperative ultrasonography did not show postoperative urinoma and perinephric hematoma in both the groups. Our results are similar to the study of Kara et al.⁽¹⁷⁾ who also did not find any perinephric collection on ultrasonography in totally tubeless PCNL group; however Bilen et al.⁽²⁰⁾ in their study, showed that totally tubeless PCNL is associated with increased complication rate as compared to the standard PCNL.

Hospital stay is an important criterion in comparison of two techniques for the management of same disease. In our study hospital stay was significantly lower in Total tubeless PCNL group as compared to Standard PCNL group. Mean hospital stay in total tubeless PCNL group and Standard PCNL group was 29.22 ± 10.79 and 56.06 ± 16.37 hours respectively and this difference was statistically significant (p value < 0.0001). Similar observations were seen in published study of Khairy Salem et al.⁽¹⁵⁾ in which the mean (range) hospital stay was 1.7 (1–4) days vs 2.8 (3–4) days in the Total tubeless PCNL group and the Standard PCNL respectively. In the study of Kara et al.⁽¹⁷⁾ the mean of hospital stay was 1.5 days vs 3.2 days for Total tubeless PCNL and standard PCNL groups respectively. Similar conclusions of shorter hospital stay in favour of totally tubeless group were observed in the studies of Bilen et al.⁽²⁰⁾ (3.1 versus 4.9 days) and Etemadian et al.⁽²¹⁾ In our study 1(2%) patient was discharged from the hospital within 24 hours in Total tubeless PCNL group. Our results are similar to the study conducted by BM Zeeshan Hameed⁽²²⁾ in which they concluded that ambulatory PCNL is a safe procedure in well informed selective patients. These are the patients with small burden of stone and staying close to the hospital.

In the present study follow-up complications were compared between two groups. In Standard PCNL group no patient developed colic, 4 (8%) developed fever and 2(4%) developed hematuria while in Total tubeless PCNL group, 3(6%) patient developed colic, 4 (8%) patients developed fever, 4(8%) developed haematuria. In Standard PCNL group 6 patients were readmitted, out of these 4 were managed conservatively, one with Double J re-stenting for stent migration and one needed ICTD insertion for pleural effusion. In Total tubeless PCNL group, five patients were readmitted, out of these 1 needed ICTD insertion for pleural effusion and 4 were conservatively managed (2 for fever & 2 for clot colic). The difference in complication between two group was statistically insignificant. Our results are in concordance with the study conducted by Sung Il Yun, et al.⁽²³⁾ who reported that there were no significant differences in postoperative complications, or the stone-free rate between the two groups.

Return to normal activity was described as total number of in-patient and outpatient days from the time of admission to the point in which the patients return to normal life activity such as going to job or college. In our study there was significant difference in the days to return to normal activity. Mean days to return to normal activity was 6.26 ± 1.64 and 4.54 ± 1.23 days in Standard PCNL group and Total tubeless PCNL group respectively. Our results are similar to study conducted by Zhong et al.⁽¹⁹⁾ Seyed Mohammad Kazem Aghamir et al.⁽²⁴⁾

Overall, results of this study again supported the findings that total tubeless PCNL is safe, effective technique and can be done in majority of patients with radiopaque renal and upper ureteric calculus < 3cm. Decision for Total tubeless PCNL should be taken intraoperatively in the absence of intraoperative pelvicalyceal injury, ureteral injury, bleeding, residual stone. Total tubeless PCNL modification of PCNL help in reducing analgesic requirement, hospital stay, morbidity with no added complications.

CONCLUSION

In conclusion both standard PCNL and Total tubeless PCNL are safe, effective and accepted procedures for primary management of renal and upper ureteric calculus. Total tubeless PCNL has favourable results in selected patients if stone burden is less than 3 cm in absence of significant residual stones, pelvicalyceal perforation and bleeding. Total tubeless PCNL has added benefit of decreased postoperative pain, less analgesia requirement, shorter hospitalisation, faster return to normal activities and no need for another procedure for stent removal.

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