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Original Research Article

A PROSPECTIVE RANDOMISED STUDY TO COMPARE THE EFFICACY AND OUTCOME OF TUBELESS PCNL WITH DJ STENT VERSUS EXTERNAL URETERIC CATHETERIZATION

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Abstract

Background: The management of renal calculi has changed dramatically during past two decades, largely due to improvement in Endo-urological armamentarium. Tube-less PCNL has several advantages including a reduced hospital stay, decreased patient discomfort, earlier return to normal activities, and decreased hospital costs. **Materials and Methods:** We have performed a prospective randomised study by comparing the postoperative comfort, complications and outcome of the patients who will undergo Tubeless PCNL with a Double J Stent versus Tubeless PCNL with External Ureteric catheterization from October 2016 to April 2018 and analysed the data of 100 patients who fulfil eligibility criteria. **Results:** There were no significant differences between the two techniques regarding the patient's age, gender, comorbidities, size of calculus, location of calculus, side of calculus, and calyx puncture site in patients. The prolonged operation time of was a result of Double-J stent insertion at the end of the procedure but it was not clinically significant on comparison. **Conclusion:** Tubeless PCNL with an External Ureteric Catheter is as feasible as using Double-J stent in terms of post-operative pain, haemoglobin drop, blood transfusion, shorter hospitalization, return to normal activity and complications.

INTRODUCTION

Nephrolithiasis represents a large portion in the field of urological pathology with a lifetime prevalence of 5-10%.[1] Moreover, kidney stones are a recurrent disorder, with lifetime recurrence risks reported to be as high as 50%.[2] The aetiology, treatment modalities, and morbidities of urinary stone disease are highly complex. The prevalence of this condition is increasing in developed countries, and environmental factors, dietary habits, and metabolic abnormalities have gained importance.[3]

The management of renal calculi has changed dramatically during past two decades, largely due to improvement in Endo-urological armamentarium. Currently, we have to choose from different modalities available for the treatment of renal calculi and many factors need to be considered to determine the optimal treatment option. Important factors include the stone size, location, patient's overall health status, available technology and expertise, besides the socio-economic status of the patient.

The European Association of Urology recommends that Percutaneous Nephrolithotomy (PCNL) should be the primary treatment modality for kidney stones that are larger than 2 cm and for the lower pole even for stones > 1 cm with unfavorable factors for ESWL.[4]

Percutaneous Nephrolithotomy (PCNL) is a minimally invasive procedure to remove stones from the kidney by a small puncture wound through the skin. Advances in surgical technique and technology have enabled the continuous evolution of PCNL, allowing the urologist to remove calculi percutaneously with increasing efficiency. Because the percutaneous approach to stone removal is superior to the open approach in terms of morbidity, convalescence, and cost, PCNL has replaced open surgical removal of large or complex calculi at most institutions.[5-10]

Tube-less PCNL has several advantages including a reduced hospital stay, decreased patient discomfort, earlier return to normal activities, and decreased hospital costs.[11,12] No consensus guidelines have been formulated in selecting patients suitable for tubeless PCNL. Recently, several investigators have tried to extend the inclusion criteria by including

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patients with larger stones (>3 cm), or those having moderate intraoperative bleeding.

We have performed a prospective study in the Department of Urology at our institute by comparing the postoperative comfort, complications and outcome of the patients who will undergo Tubeless PCNL with Double J Stent versus Tubeless PCNL with External Ureteric catheterization.

Table 1: History of the first advancement of Percutaneous Nephrolithotomy

Source	Year	Procedure
Goodwin et al.[5]	1955	First Percutaneous nephrostomy
Fernstrom and Johansson,[6]	1976	First Percutaneous nephrolithotomy
Wickham et al,[7]	1984	First tubeless Percutaneous nephrolithotomy
Valdivia et al,[8]	1987	First supine Percutaneous nephrolithotomy
Helal et al,[9]	1997	First mini-perc

OBJECTIVES

To evaluate and compare the efficacy of Tubeless PCNL using external Ureteric catheterization and double J stenting and to evaluate and compare the outcome of Tubeless PCNL using external Ureteric catheterization and double J stenting.

MATERIALS AND METHODS

This study was carried out at Venkateshwara Kidney Centre, a tertiary health care centre in Karimnagar in the department of genito-urinary surgery. Patients who were attended Urosurgery opd in our hospital during study period from October 2016 to April 2018.Patients who were satisfying the study inclusion criteria, those who were able to follow up, and who were undergone for the tubeless PCNL in our hospital during study period from October 2016 to April 2018.

A Prospective, Randomized, Comparative Study of 100 cases (50 cases of Tubeless PCNL with Double J Stent & 50 cases of Tubeless PCNL with External Ureteric Catheter) during October 2016 to April 2018. Out of all the patients who attended Urosurgery OPD in the study duration, those eligible for Tubeless PCNL were around 400 patients. Out of all eligible cases, about 200 patients underwent Tubeless PCNL in our hospital with Inclusion Criteria of Symptomatic patients with renal stone size > 20mm and Lower pole renal stone size >10mm.The Exclusion Criteria were Presence of significant Residual stones, Multiple access requirement ,Serious intra operative bleeding ,Collecting system perforation, Need for early second-look surgery, Presence of urinary sepsis, Solitary Kidney, Kidney with congenital anomaly, Deranged renal function, Paediatric age group patients, Pregnancy, Analysis was performed on data from patients who were undergone for Tubeless PCNL at our hospital from October 2016 to April 2018.

Patients were evaluated with complete medical history, physical examination, and necessary biochemical and radiological investigations. Preoperative baseline investigations included complete hemogram, renal function tests, serum electrolytes, coagulation profile, chest X-ray and electrocardiogram. Urine routine examination and culture was done in all enrolled patients. The patients with a positive urine culture were treated with appropriate antibiotics until urine culture was sterile. Radiological investigation, including Ultrasonography, X-ray KUB region, and intravenous urogram were done. Non-contrast CT abdomen & Renal DTPA scan were done when needed. Our surgical team experienced in Endourology performed all surgical procedures in both the groups, and informed and written consent was obtained from all the subjects. All Tubeless Percutaneous Nephrolithotomy were performed with the patient in prone position with standard technique using 24F Amplatz was inserted into calyceal system under fluoroscopy guidance. 20 Fr nephroscope was used in all the cases. Swiss lithoclast (Electro Medical Systems, Switzerland) (Pneumatic) was used to fragment the stones. Stone clearance was confirmed with the C-arm and using flexible nephroscope.

After the stone clearance, randomization was done immediately using the closed envelope method. The scrub nurse opened a sealed envelope at random, in which the information about the drainage type was hidden beforehand, and then the patients received the corresponding drainage type. If it was Double-J stent, we removed the open ended Ureteric Catheter, and if not, we ended the procedure directly with the Ureteric catheter in place. Nephrostomy Tube was not kept in any patients. Skin incision was not sutured to monitor postoperative drainage/bleeding if any.

Foleys catheter along with Ureteric catheter (Group A) was removed on postoperative day 1 unless complications arised, such as fever, urinary extravasation and so on. In such cases, they have been maintained until symptomatic improvement. All Patients were kept on intravenous antibiotics and were discharged with DJ stent in situ (Group B) along with oral antibiotic for a week. All patients were followed up at 1st week, 2nd week and 3rd week. Stent related symptoms were noted. Pain scores calculated. Number of days required to return to normal/routine activity was noted. DJ stent removal was done at 3 weeks after surgery under Antibiotic coverage (in Group B).On 3 weeks post operative day, ultrasonography, x-ray KUB and eventually non-contrast CT-scan KUB when necessary were

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performed to check for residual stone. Residual stone fragment <=4mm was considered insignificant.

The information collected includes demographics, stone side, stone location whether pelvic or calyceal, stone size, medical co-morbidities included hypertension and diabetes. Peri-operative characteristics, operation duration, intra-operative blood transfusion noted. Post-operative information such as duration of hospital stay after surgery, pain score (visual analogue scale) on Day 0, 1 and 2, 7, 14, 21st postoperative day, change in hemoglobin and serum creatinine, stent related symptoms and complications were noted (postoperative and also on follow up) and classified by the modified Clavien score for PCNL.

The analysis includes the profiling of patient on different demographic, clinical parameter, stone location whether pelvic or calyceal, stone size, medical co-morbidities (hypertension and diabetes), as well as operative data (calyx puncture, operation duration) and post-operative information (duration of hospital stay after surgery, pain score, complications, change in hemoglobin and serum creatinine, total recovery time). All study data was entered into an electronic data spreadsheet and analyzed using a statistical analysis program with biostatistician assistance. Complications were classified by the modified Clavien score.

Quantitative data was presented in terms of mean and standard deviation. Qualitative/categorical data were presented as absolute numbers and percentages. Chi square test was used for testing of association of qualitative data between both the groups. Pearson correlation coefficient was used to assess the correlation between hemoglobin drop and operating time. Unpaired Student t test was used for two different samples for testing of association of quantitative data between both the groups. P-value less than 0.05 were considered as statistically significant.

RESULTS

Between October 2016 and April 2018, we studied 100 patients with renal calculi who underwent Tubeless Percutaneous Nephrolithotomy in the Department of Urology, at our institute. Among these 100 cases, 50 underwent Tubeless PCNL with external Ureteric catheterization while 50 cases were managed by Tubeless PCNL with Double J Stenting. The following observations were made: The Age distribution of our patients varied from 20 years to 59 years. Mean in Group A (Tubeless PCNL with Ureteric Catheter) was 41.86 years with SD ± 9.50 and mean in Group B (Tubeless PCNL with DJ Stent) was 41.32 years with SD ± 8.98. Both the groups were comparable in age and the difference was not statistically significant (p=0.77). Out of 50 patients in Tubeless PCNL with Ureteric Catheter group, 32 were male and 18 female & in Tubeless PCNL with DJ Stent out of 50 cases, 27 were males & 23 females. Out of total number of patients, 59 were males and 41 were females. Both the groups were comparable in gender and the difference was not statistically significant (p-value = 0.30).08 patients in Tubeless PCNL with Ureteric Catheter group and 03 patients in Tubeless PCNL with DJ Stent group had Diabetes mellitus and both groups were comparable and the difference was not statistically significant (p-value = 0.110)15 patients in Tubeless PCNL with Ureteric Catheter group and 08 patients in Tubeless PCNL with DJ Stent group had Hypertension and both groups were comparable and the difference was not statistically significant (p-value = 0.09).

In the Tubeless PCNL with Ureteric Catheter group, 28 (56%) cases had stones located on the right side and 22(44%) were on the left side. In Tubeless PCNL with DJ Stent group, 28 (56%) cases had stone located on the right side and 22(44%) had on the left side. No case had bilateral stones. The difference in side of PCNL between two groups was not statistically significant (Chi Square Value = 0.00; p-value = 1.00).

In the Tubeless PCNL with Ureteric Catheter group, 14 (28%) cases had stones located in the renal pelvis, 04 (08%) in the upper calyx, 12(24%) in the middle calyx and 20(40%) in the lower calyx. In Tubeless PCNL with DJ Stent group, 19(38%) cases had stones located in the renal pelvis, 05 (10%) in the upper calyx, 12(24%) in the middle calyx and 14(28%) in the lower calyx. No case had bilateral stones. The difference between two groups in stone location was not statistically significant.

The size of stone in our patients varied from 15 mm to 30 mm. Mean in Group A (Tubeless PCNL with Ureteric Catheter) was 20.72 mm with SD ± 3.41 and mean in Group B (Tubeless PCNL with DJ Stent) was 21.80 mm with SD ± 3.79. Both groups were comparable in stone size and the difference was not statistically significant (p=0.096).

Lower calyx puncture was the common route of entry into the pelvicalyceal system (PCS) with 32(64%) & 30(60%) punctures in Tubeless PCNL with Ureteric Catheter & Tubeless PCNL with DJ Stent respectively. Both groups were comparable in calyx puncture and the difference was not statistically significant (p=0.913).

The operative time in our patients varied from 30 min to 75 min. Mean in Group A (Tubeless PCNL with Ureteric Catheter) was 44.32 min with SD ± 7.08 and mean in Group B (Tubeless PCNL with DJ Stent) was 46.20 min with SD ± 8.52. Mean operative time in group A was less than Group B but was not statistically significant (p = 0.233)

Table 2: Site of the stone.

	Tubeless PCNL with Ureteric Catheter (n=50)	Tubeless PCNL with DJ Stent (n=50)	Total
Renal Pelvis			
Yes	14	19	33

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No	36	31	67
Upper Calyx			
Yes	04	05	09
No	46	45	91
Middle Calyx			
Yes	12	12	24
No	38	38	76
Lower Calyx			
Yes	20	14	34
No	30	36	66

Table 3: Size of the stone

Stone Size (mm)	Tubeless PCNL with Ureteric Catheter (n=50)	Tubeless PCNL with DJ Stent (n=50)	Total
10-15	03 (06%)	01 (02%)	04 (04%)
16-20	23 (46%)	17 (34%)	40 (40%)
21-25	19 (38%)	24 (48%)	43 (43%)
26-30	05 (10%)	08 (16%)	13 (13%)

Table 4: Calyx of Puncture

Calyx of Puncture	Tubeless PCNL with Ureteric Catheter (n=50)	Tubeless PCNL with DJ Stent (n=50)	Total
Upper	06 (12%)	07 (14%)	13 (13%)
Middle	12 (24%)	13 (26%)	25 (25%)
Lower	32 (64%)	30 (60%)	62 (62%)

Table 5: Operative Time

Study Parameter	Tubeless PCNL with Ureteric Catheter (50)	Tubeless PCNL with DJ Stent (50)	Mean Difference	t- value	p- value
OT time(min)	44.32±7.08	46.20±8.52	-1.88	-1.199	0.233

DISCUSSION

In 1997, Bellman et al. introduced the concept of Tubeless PCNL.[13] They demonstrated that tubeless PCNL not only decrease the complications but also reduced the adverse events caused by nephrostomy tubes. An internal or external stent was used for draining the upper urinary system postoperatively. Previous studies have found that Tubeless PCNL resulted in less postoperative pain and shorter hospital stay In several reports, tubeless PCNL with DJ Stent have confirmed the safety and efficacy.[13-16] DJ stent is the most common form of internal drainage in the urinary surgery.[17] In 2001, as an external stent, a six Fr ureteral catheter was firstly used for 48 hours in PCNL and demonstrated that this technique in selected patients could reduce postoperative discomfort without increase complications.[18]

This study aimed to compare External Ureteric Catheterization versus Double-J Stent in tubeless PCNL for drainage in patients with kidney stones. One Hundred patients undergoing Tubeless Percutaneous Nephrolithotomy were randomized into two groups, Group A (50 patients): Tubeless PCNL with external Ureteric catheter) and Group B (50 patients): Tubeless PCNL with Double-J stent). In our study, we had patients Age ranging from 20 to 59 years with mean age of 41.86 yrs ± 9.50 in Group A (Tubeless PCNL with Ureteric Catheter) and 41.32 yrs ± 8.98 in Group B (Tubeless PCNL with Double-J Stent). Both groups were comparable in age and the difference was not statistically significant (p=0.770). In Gonulalan U et al 2013,[19] study, the Mean age of 46.8 ± 14.2 in group A and 46.7 ± 13.7 in group B (p=0.96). In Joshi R et al,[20] 2014 study, patients age ranging from 19 to 65 years with the Mean age of 38.28 ± 11.22 in group A and 40.04 ± 14.83 in group B (p=0.638).In our study, 59% were males (in group A 64%, in group B 54%) and 41% were females (in group A 36%, in group B 46%). Both groups were comparable in Gender (p-value = 0.30). In Joshi R et al,[20] 2014 study, 64% were males (in group A 64%, in group B 64%) and 36% were females (in group A 36%, in group B 36%) (p= 1.000).

In our study, Stone size was ranging from 15 mm to 30 mm, with a mean of 20.72 mm with SD ± 3.41 in Group A (Tubeless PCNL with Ureteric Catheter) and mean of 21.80 mm with SD ± 3.79 in Group B (Tubeless PCNL with Double-J Stent). Both groups were comparable in stone size and the difference was not statistically significant (p=0.096). In Joshi R et al,[20] 2014 study, mean of stone size 13.6±2.47 in group A and 12.24±2.52 in group B was present (p>0.05). In Zhou Y et al,[21] 2016 study, mean of stone size 21.80±9.19 in group A and 22.55±8.58 in group B was present (p=0.664). In our study, there were no significant differences between the two techniques regarding the patient's age, gender, comorbidities, size of calculus, location of calculus, side of calculus, and calyx puncture site in patients. In our study, the operative time varied from 30 min to 75 min with mean of 44.32 min ± 7.08 in Group A (Tubeless PCNL with Ureteric Catheter) and mean of 46.20 min ± 8.52 in Group B (Tubeless PCNL with Double-J Stent). Mean operative time in group A was less than Group B but was not statistically significant (p =0.233). The prolonged operation time of group B was a result of Double-J stent insertion at the end of

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the procedure. Most of the studies concluded that there was no significant difference between operative timing of both the groups except in one research paper by Gonulalan U et al,[19] who concluded that Tubeless PCNL with Ureteric catheter takes significantly lower operating time than Tubeless PCNL with DJ Stent ($p<0.001$).

CONCLUSION

Tubeless PCNL with an External Ureteric Catheter is as feasible as using Double-J stent in terms of post-operative pain, haemoglobin drop, blood transfusion, shorter hospitalization, return to normal activity and complications. But, stent-related symptoms because of presence of a Double-J stent and the need for postoperative cystoscopy to remove the Double-J stent and its cost can be avoided with an External Ureteric Catheter. External Ureteric Catheter is as efficacious as Double-J Stent for internal drainage. We believe that a normal Ureter is the best drainage tube. However, a further study with large sample size is required to extrapolate these findings for general population and comparisons of both the methods.

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