

ORIGINAL RESEARCH

A Prospective Randomised Study to Compare the Postoperative Morbidity and Complications of Tubeless PCNL with DJ Stent versus External Ureteric Catheterization

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ABSTRACT

Introduction: In Tubeless PCNL, a Double J Stent can be used for internal drainage with a favorable outcome in selected patients with the advantage of decreased postoperative pain, analgesia requirement, and hospitalization days and on the other way in Tubeless PCNL with External Ureteric Catheterization can be done which is minimally invasive with reduced hospital stay & costs, less requirement of analgesia, less patient discomfort with early recovery to work, no stent related symptoms in follow up and no post operative procedure for removal afterwards. **Materials & Methods:** To evaluate and compare the effect of both stenting techniques, we have done 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. **Observations:** Patients experienced stent related symptoms post-operatively before removing the external Ureteric catheter but Stent related symptoms were significantly lower and significant compared to patient with stent postoperatively. **Conclusion:** External Ureteric Catheter is associated with significantly less post-operative stent related symptoms & complications. Patient with External Ureteric Catheter will not require further cystoscopic procedure for stent removal, so it is patient friendly and cost effective.

Keywords: Tubeless PCNL, External Ureteric Catheter, Double-J stent, Pain score Hospital stay, Complications

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INTRODUCTION

In recent years, further technological modifications like use of miniaturized instruments have undoubtedly expanded the role of PCNL. Mini PCNL refers to use of an access sheath size of 14-20Fr.^[1] Ultramini PCNL, or 'UMP' is a more recent addition, and generally refers to an access sheath size of 11-13Fr^[2]. Micro PCNL refers to use of 4.85Fr (16G) 'all seeing needle' in which renal access and laser stone fragmentation are performed in a single step procedure^[3]. Mini-microperc is a recent modification of micro PCNL using 8F metallic sheath^[4].

Tubeless PCNL is defined as PCNL without postoperative nephrostomy tube placement. In several single-center studies, Tubeless PCNL has reported successful in obese patients, children, recurrent stones, solitary kidneys, deranged renal function, and in staghorn stones requiring multiple access tracts, supracostal puncture, or bilateral simultaneous PCNL^[5-8]. Degree of obstruction, anatomic variation of renal shape and position, and elevated serum creatinine were also not considered contraindications to tubeless PCNL^[9]. Although the placement of a nephrostomy tube has some advantages such as

urinary diversion, haemorrhage control, improved tract recovery, and a tract for secondary operations, the tube may cause pain and early discomfort for the patient^[10,11].

Although a recent review has demonstrated that the tubeless method has many advantages, 75% of urologists still prefer to place a tube to avoid complications^[12]. Wickham et al^[13] in 1984 was the first to report their experience omitting the nephrostomy tube after PCNL, but the concept did not gain acceptance especially after conflicting reports resulting in prolonged hospitalization and pain^[14]. In 1997, Bellman et al. published his results of patients undergoing tubeless PCNL and again challenged the need for requirement of a nephrostomy tube for drainage^[15]. In their series, all patients had an indwelling ureteral stent inserted in addition to an indwelling catheter instead of a nephrostomy tube. Exclusion criteria for this study included an operative time of more than 2 hours, PCNL requiring two or more tracts (the main exclusion criterion), significant perforation of the collecting system, significant residual stone burden, or significant postoperative bleeding. They found no major complications using this approach^[15].

In Tubeless PCNL, a Double J Stent can be used for internal drainage with a favorable outcome in selected patients with the advantage of decreased postoperative pain, analgesia requirement, and hospitalization days. Tubeless PCNL with External Ureteric Catheterization is minimally invasive with reduced hospital stay & costs, less requirement of analgesia, less patient discomfort with early recovery to work, no stent related symptoms in follow up and no post operative procedure for removal afterwards. In our set up we get a good number of patients that undergo Tubeless PCNL with Double J stent for internal drainage. To address this dilemma, 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 a Double J Stent versus Tubeless PCNL with External Ureteric catheterization.

OBJECTIVES

To evaluate and compare the effect of both stenting techniques on post-operative morbidity and hospital stay. To evaluate and compare the stent related symptoms and complications between both the groups.

MATERIALS & 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 attended Urosurgery OPD 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) was done. Out of all 400 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. Patients were evaluated with 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. After the stone clearance, randomization was done immediately using the closed envelope method. 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. Foleys catheter along with Ureteric catheter (Group A) was removed on postoperative day 1 unless complications arised. All Patients were kept on intravenous antibiotics and were discharged with DJ stent in situ (Group B) along with oral antibiotic for a week and Stent related symptoms were noted. Pain scores calculated. DJ stent removal was done at 3 weeks after surgery under Antibiotic coverage (in Group B).

The information collected includes Post-operative information such as duration of hospital stay after surgery, pain score (visual analogue scale on 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.

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.

OBSERVATIONS AND RESULTS

The decrease in hemoglobin after surgery varied from 0.3g% to 1.3 g%. Mean drop in hemoglobin in group B was less than Group A but was not statistically significant ($p = 0.365$). The change in serum creatinine after surgery varied from -0.3 mg% to 0.28 mg%. Mean drop in serum creatinine in group B was more than Group A but was not statistically significant ($p = 0.623$). Mean pain scores in between Group A and B, There was no significant difference between pain scores (VAS) of both the groups at postoperative day 0, 1, 2, 1st week, 2nd week and 3rd week follow up. ($p > 0.05$). The hospital stay in our patients varied from 02 days to 04 days Mean hospital stay time in group A was less than Group B but was not statistically significant ($p = 0.233$). The return to normal/ routine activity of patients varied from 5 days to 10 days. Mean return to normal/ routine activity time in group A was less than Group B but was not statistically significant ($p = 0.233$). In the Tubeless PCNL with Ureteric Catheter group, 01 (02%) cases had residual stone fragments. In Tubeless PCNL with DJ Stent group, 02 (04%) cases had residual stone fragments. The difference seen in presence of residual stone fragments of PCNL between two groups was not statistically significant (Chi Square Value = 0.343; p -value = 0.557). In the Tubeless PCNL with Ureteric Catheter group, 02 (04%) cases had stent related symptoms postoperatively before removing external Ureteric catheter. In Tubeless PCNL with DJ Stent group, 12 (24%) cases had stent related symptoms included frequency, urgency, painful urination, flank pain, suprapubic pain. In 05 (10%) patients the symptoms were severe enough that required early removal of DJ stent. Stent related symptoms were more common in Group B (Tubeless PCNL with DJ Stent) than Group A (Tubeless PCNL with Ureteric Catheter), which was statistically significant (Chi Square Value = 8.305; p -value = 0.003).

Complications: 05 patients in Group A and 03 patients in Group B had postoperative Urine Leakage (Grade 1) which was managed conservatively (Observation). None patients in Group A and 03 patients in Group B had postoperative fever (Grade 1) which was managed conservatively (Observation). 05 patients in Group A and 03 patients in Group B had postoperative Bleeding (Grade 1) which was managed conservatively (Observation). 02 patients in Group A and 03 patients in Group B had postoperative Vomiting (Grade 1) which was managed with Anti-emetic drugs. 04 patients in Group A and 06 patients in Group B had postoperative fever (Grade 2) which was managed with change in the Antibiotics. 02 patients in Group A and 02 patients in Group B had postoperative bleeding (Grade 2) which was managed with Blood Transfusion. No Grade 3, Grade 4, Grade 5 complication was noted in both the groups. There was no statistical significant difference between the incidences of complications (Grade 1, Grade 2) in two groups.

In our study, the decrease in hemoglobin after surgery varied from 0.3g% to 1.3 g%. Mean drop in hemoglobin in group B was less than Group A but was not statistically significant ($p = 0.365$) which was consistent with other studies as shown in Table 1. Drop in hemoglobin was dependent on operative time with correlation coefficient (r) = 0.377; p -value < 0.0001.

In our study, the mean pain score (VAS) on post-operative day 0, 1, 2, 1st week, 2nd week and 3rd week in patients undergoing Tubeless PCNL with Ureteric catheter (Group A) was not statistically significant compared to Tubeless PCNL with DJ Stent (Group B).

Mean hospital stay in group A was less than Group B but was not statistically significant ($p = 0.151$). This was consistent with result showed in other studies.

Table 1: Drop in Hemoglobin

(Hb Drop) (g/dl)	Tubeless PCNL with Ureteric Catheter	PCNL with Double-J Stent	p value
Our study	0.83 ± 0.267	0.78 ± 0.282	0.365
Zhou et al [16]	1.04 ± 0.619	1.15 ± 0.997	0.500
Jiang H et al [17]	0.72 ± 0.48	1.08 ± 0.97	0.190
Gonulalan U et al [18]	1.13 ± 0.68	1.205 ± 0.72	0.150
Gonen M et al [19]	0.21	0.22	0.87

Table 2: Pain Score

(Mean Pain Score) (VAS)	Tubeless PCNL with Ureteric Catheter	PCNL with Double-J Stent	p value
Our study (POD 2)	4.48 ± 1.14	4.30 ± 0.81	0.367
Zhou Y et al (POD 2) [16]	2.80 ± 2.49	2.92 ± 2.07	0.408
Jiang et al (POD 2) [17]	4.6 ± 1.7	4.7 ± 1.9	0.02
Gonulalan U et al (POD 1) [19]	3.54 ± 1.76	3.56 ± 1.84	>0.05

Table 3: Hospital Stay

(Mean hospital stay) (days)	Tubeless PCNL with Ureteric Catheter	PCNL with Double-J Stent	p value
Our study	2.36 ± 0.525	2.52 ± 0.579	0.151
Zhou Y et al ^[16]	5.70 ± 2.72	5.72 ± 2.08	0.961
Jiang et al ^[17]	5.0 ± 0.8	5.2 ± 1.1	<0.001
Gonulalan U et al ^[18]	1.67 ± 1.06	1.58 ± 0.91	>0.05
Gonen M et al ^[19]	1.3	1.17	0.47

DISCUSSION

In our study, time for return to normal activity in group A was less than Group B but was not statistically significant ($p=0.093$). In our study, in the group A (Tubeless PCNL with Ureteric Catheter) 01 (02%) cases had residual stone fragments. In the group B (Tubeless PCNL with DJ Stent) 02 (04%) cases had residual stone fragments. The difference in residual stone fragments of PCNL between two groups was not statistically significant ($p = 0.557$). In Jiang H et al^[17] study, 02(6.7%) patients in group A and 01(3.3%) patients in group B had residual stone fragments which was statistically not significant ($p=0.78$). In our study, 12 (24%) patients in Group B (Tubeless PCNL with DJ stent) experienced stent-related symptoms such as urgency, frequency, painful urination, flank pain and suprapubic pain. In 05 (10%) patients the symptoms were severe enough that required early removal of the DJ stent. In Group A (Tubeless PCNL with Ureteric catheter) 02 (04%) patients experienced stent related symptoms post-operatively before removing the external Ureteric catheter. Stent related symptoms were significantly lower in Group A compared to Group B which was statistically significant ($p=0.003$). Stent-related discomfort should not be taken lightly. Shah et al.^[20] found that 30% of the patients experienced discomfort related to DJ placement. Similarly, 52.1% of the patients had some sort of stent-related symptom in a study by Murat Gonen and associates^[20]. In our study, we did not evaluate the cost of a Double-J stent or an outpatient flexible cystoscopy. Bellman and co-workers^[21] developed a new technique of placing a Double-J stent that allows outpatient removal of the stent through the flank using a stent tether. Using this technique can avoid the cost of cystoscopy; however, stent-related discomforts are not eliminated. This technique needs further assessment in larger series. Zhao and colleagues^[22] demonstrated that patients who received a DJ stent after Tubeless PCNL had significantly lower Health Related Quality of Life using the Wisconsin Stone Quality of Life questionnaire. Similarly, Jiang H et al^[17] also showed that patients with a DJ stent after Tubeless PCNL suffer significantly more irritation symptoms (nocturia, frequency, and urgency), negative emotions (anxiety, annoyance, irritability), and societal dysfunction (lower motivation, less interest in sex, and socializing), compared to the other group (Tubeless PCNL with external Ureteric catheter). This

may be because an indwelling Double-J stent can negatively impact the patient's mind and cause low Health Related Quality of Life. Jiang H et al^[17] study suggested that the most recommended type of drainage after PCNL may be an open ended ureteral catheter, which not only led to comparable higher Health Related Quality of Life but also shorter hospitalization, required less analgesic dosage postoperation, and did not need removal by cystoscopy (removed along with Foley catheter), which can decrease the financial burden, especially in developing countries like India. Hence, it may be deserved to recommend this drainage type for both clinicians and patients.

Complications were graded according to Modified Clavien classification. In our study, 05(10%) patients in Group A and 03(06%) patients in Group B had experienced urinary leak (grade 1), which was treated conservatively with observation in both the groups. In Zhou Y et al study^[16], 04(7.1%) patients in Group A and 05(9.4%) patients in Group B had experienced urinary leak (grade 1), which was treated conservatively with observation in both the groups ($p=0.931$). A successful urinary drainage of kidney after PCNL is important to reduce the rate of post-operative urinary leakage. In our study, 03(06%) patients in Group B had experienced Fever $>38^{\circ}\text{C}$ (grade 1) on post-operative day 0, which was treated conservatively with observation. The risk factors for infection are preoperative urinary tract infection, the presence of infected urinary stones, operation duration and peri-operative blood loss^[23,24]. The rate of postoperative fever was reported 8.9% to 32.1 % by several studies^[23-26]. The single dose or short course antibiotic prophylaxes were suggested for sterile urine^[27]. In our study, 05(10%) patients in Group A and 03(06%) patients in Group B had experienced Bleeding (grade 1), which was treated conservatively with observation in both the groups. 02(04%) patients in Group A and 02(04%) patients in Group B had experienced Bleeding (grade 2), which was treated conservatively with blood transfusion in both the groups. Bleeding is a result of laceration in renal parenchyma in PCNL and nephrostomy tube is placed to avoid this bleeding^[28,29]. The transfusion rates after PCNL were reported with a wide range as 0–17.5 %^[23-26]. The number of calyceal tracts and stone size was reported as risk factors for significant bleeding^[23]. The overall transfusion rate of Gonulalan U et al. study^[18] was 3.1 % and the number of patients with

standard PCNL that required transfusion was significantly higher than the patients with tubeless PCNL. The placement of nephrostomy tube was not enough to avoid the blood transfusion in that study in comparison of tubeless PCNL. The overall transfusion rate of Jiang H et al^[17] study was 3.3 % in group B and no transfusion was required in group A. In our study, 01(02%) patients in Group A had experienced Ureteric colic (grade 3) on post-operative day 7, which was treated with placement of Double-J stent. It was removed after 3 weeks without any complications. In Mouracade P et al study^[30], 01 patient in group A needed urgent placement of a DJ stent because of renal colic early after removal of the ureteral catheter. In our study, 05(10%) patients in Group B had experienced UTI (grade 3), which was consistent with the severe stent related symptoms, which was treated with the early removal of Double-J stent (at 2nd week post-op). The solid organ injuries could be seen in PCNL procedures. Pleural or lung injury is one of these complications that could be seen 9.3 % of patients with supracostal tubeless PCNL^[31]. The injuries of the duodenum, colon and other abdominal organs were seen rarely^[23].

CONCLUSION

External Ureteric Catheter is associated with significantly less post-operative stent related symptoms & complications. Patient with External Ureteric Catheter will not require further cystoscopic procedure for stent removal, so it is patient friendly and cost effective.

So, we recommend the use of External Ureteric Catheter in place of Double-J stent for internal drainage in selected group of patients undergoing Tubeless PCNL to avoid of stent related symptoms mostly due to Mechanical stimulus that comes from the bladder coil, stent displacement with physical activity may impact stent discomfort, trigonal irritation by the distal end of the stent, flank pain is most likely a result of urine reflux towards the kidney.

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