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Original Research Article

Comparison of standard and tubeless percutaneous nephrolithotomy for renal calculi: a prospective randomized control trial

Manu Muraleedharan Kamalakshi[1]*, Vasantharaja Ramasamy[1], Darsan Sadasivan[1], Sunil Raveendran[1], Selvam Paramasivam[2], Venugopal Ganapathy[1]

[1]Department of Urology, Government Medical College, Trivandrum, Kerala, India
[2]Department of Social and Preventive Medicine, Government Medical College, Tiruchirappalli, Tamil Nadu, India

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***Correspondence:**
Dr. Manu Muraleedharan Kamalakshi,
E-mail: drmanumk@gmail.com

ABSTRACT

Background: In the current era of minimally invasive interventions, the mainstay of treatment of renal stones larger than 2 cm is percutaneous nephrolithotomy (PCNL). PCNL underwent various evolutionary changes minimizing morbidity to the patients. We prospectively compared the outcome of tubeless PCNL (without nephrostomy drainage tube) to reduce the pain and discomfort caused by tube with standard PCNL in the treatment of renal stones.
Methods: In this randomized control trial (RCT), we divided patients satisfying the inclusion criteria of consenting for trial, single access puncture, less than 3 stones each less than 3 cm, operative duration of less than 2 hours into two groups, standard PCNL (group 1) and tubeless PCNL (group 2) with 25 patients each. Randomization and group assignment were done after complete clearance of renal stones.
Results: Patient's age, gender, sides of stone and stone size were comparable between two groups (standard versus tubeless PCNL). Postoperative hemoglobin drop, bleeding, pyrexia, urine leak, and blood transfusion requirement did not show a statistically significant difference between the two groups. Analgesic requirement (190 mg versus 80 mg of tramadol), operative duration (49.80 min versus 38.60 min), postoperative pain score (6/10 versus 3.64/10-visual analog scale) and duration of hospital stay (68.48 hours versus 41.12 hours) showed statistically significant difference favoring tubeless PCNL.
Conclusions: Tubeless PCNL may be a safe, acceptable and effective modality of treatment for renal calculi in carefully selected patients comparing standard PCNL resulting in less operative duration, lower postoperative pain, reduced analgesic requirement and shorter hospital stay.

Keywords: Percutaneous nephrolithotomy, Tubeless, PCNL, Randomized control trial, Renal calculi

INTRODUCTION

In 1976, Fernstrom and Johansson first described percutaneous nephrolithotomy (PCNL) which is the universally accepted modality in the treatment of large and complex renal stones. Over a period of time, various changes have occurred in the techniques of PCNL.[1] PCNL was associated with morbidities such as bleeding, pyrexia, incomplete stone removal, pleural injury, and adjacent organ injury.[2] After completion of stone removal, usually, a nephrostomy tube is placed which helps in tamponade of bleeding, drainage of urine, tract recovery, and a guide for second look nephroscopy if needed.[3,4] In various studies, the usage of small caliber nephrostomy tubes were found to be equivalent to large nephrostomy tubes.[5-7] Apart from the above-mentioned

benefits of placing a nephrostomy tube, it often increases early postoperative morbidity like pain and prolonged hospital stay.[8]

Technical evolutions in optics of nephroscope and lithotripters have decreased morbidity after PCNL considerably. The presence and removal of nephrostomy are associated with morbidities such as infection, pain, urine leak, bleeding, and prolonged hospitalization.[9] Bellman et al in 1997 first described "tubeless" PCNL which involved placement of a ureteric stent without nephrostomy.[10] The presence of a double-J stent in tubeless PCNL may be associated with stent-related problems such as frequency, urgency, nocturia, pain, and hematuria.[11] However, the morbidity of the nephrostomy tube after PCNL is much higher compared to the stent-related symptoms of tubeless PCNL which can be managed by medical therapy.

In this randomized control trial (RCT), we evaluated the perioperative outcomes of tubeless PCNL and compared it with standard PCNL. The purpose of our trial was to determine whether tubeless PCNL is safe and less morbid treatment modality for renal stones compared to the standard PCNL with nephrostomy tube.

METHODS

Study population

We conducted this prospective randomized control trial in the Department of Urology, Government medical college, Trivandrum, Kerala, South India during the period of July 2018 to April 2019 (10 months). We enrolled our trial in Clinical Trials Registry-India (CTRI) numbered CTRI/2018/07/015022 followed by Institutional research committee and Human Ethics committee approval prior to the conduct of the study. Informed consent and patient information sheet were explained in detail to the study subjects prior to their enrollment in the trial. Inclusion criteria were patients with less than 3 calculi, less than 3 cm size consenting for the trial, single puncture PCNL, less than 2 hours procedure time with complete stone clearance confirmed by fluoroscopy and endoscopy, without significant bleeding and intact pelvicalyceal system at the end of the stone removal. Exclusion criteria were patients with staghorn renal calculus, renal anatomical abnormalities, coagulopathies, unfit for general anesthesia and active urinary tract infection.

Study procedure

Basic demographic, clinical and radiological details were analyzed for the study population. Preoperatively, all the patients were evaluated with blood and urine routine examinations, renal function studies, urine culture, coagulation profile, and computed tomography (CT) scan. Patients were subjected to thorough preoperative anesthetic check-up and optimized for surgery. All the PCNL were performed by a conventional technique by a single surgeon. Under general anesthesia, in lithotomy position 6 French (F) ureteric catheter was inserted using a cystoscope. Then in the prone position desired calyces were punctured using bull's eye method, under fluoroscopy guidance using an 18 gauge 20 cm two-part echo tip initial puncture needle. Alkens dilator used for tract dilation up to 28 F and pneumatic lithotripter was applied to break the calculi.

Randomization

Randomization was done only for those patients satisfying the inclusion criteria based on the duration of surgery, single puncture tract, intraoperative bleeding, stone burden, intact pelvicalyceal system following surgery, and no residual stones at the end of the procedure. The patients were divided into two groups: Group 1 in which after the procedure, a 20 F nephrostomy tube was inserted into the pelvicalyceal system (standard PCNL); Group 2 in which after the procedure only ureteral stent and no nephrostomy tube was inserted (tubeless PCNL). Based on the previous study by Tefekli et al, comparing postoperative hemoglobin (Hb) drop in g/dl between Tubeless PCNL group and standard PCNL group was taken as the reference for calculating the sample size of this study.[12] As per the calculation, twenty-five patients were included in each group. The randomization allocation was done by the receptionist in the admission section of our OPD (Outpatient department) using random number generator software, and allocation concealment was done by a sequentially numbered opaque‑sealed envelope which was opened at the end of stone removal.

Postoperative period

Patients were monitored in the postoperative period for operative duration in minutes, bleeding-gross hematuria from the nephrostomy in standard PCNL group and gross hematuria in catheterized urine or visible voided hematuria after catheter removal in tubeless PCNL group, postoperative drop in haemoglobin in gm/dl, blood transfusion requirement, postoperative pyrexia, urine leak, postoperative pain assessed 24 hours after surgery by visual analog scale (VAS) which ranges from 0- no pain to 10- maximum intolerable pain, analgesia requirement (in mg- tramadol) and duration of hospital stay.[13] Data collected were used for the study.

Statistical analysis

Data were entered according to the variables onto spreadsheets of Microsoft Office Excel 2010 and the variables were analyzed using standard analytical techniques using the latest version of SPSS software. The associations between study variables were analyzed using

the Chi-square test and Student's t-test. 'p' values <0.05 were considered significant.

RESULTS

Patients and stone characteristics comparing standard PCNL (GROUP 1) and tubeless PCNL (GROUP 2) were shown in table 1. Mean patient ages were 41.96 years group 1 compared to 45.98 years in group 2. Out of 25 patients, 17 were males and 8 were females in group 1. Out of 25 patients, 15 were males and 10 were females in group 2. Out of 25 patients, 12 had the left-sided disease and 13 had the right-sided disease in group 1. Out of 25 patients, 12 had the left-sided disease and 13 had the right-sided disease in group 2. Mean stone size was 2.36 cm in group 1 compared to 2.31 cm in group 2. All the above-mentioned data were comparable between the two groups.

Table 1: Patients and stone characteristics.

Study variable	Group 1 (standard PCNL)	Group 2 (tubeless PCNL)	'p' value *
Number of patients (n)	25	25	-
Age (in years)-mean±SD	44.96±11.43	45.98±12.74	0.309
Sex (male/female)	15/10	17/8	0.556
Side of the stone (right/left)	13/12	13/12	1.000
Size of the stone (in mm)-mean±SD	23.64 ± 4.39	23.16 ± 4.56	0.706

*: 'p' values calculated using Student's t-test for quantitative variables and chi-square test for qualitative variables-values less than 0.05 were taken as significant, SD- standard deviation, PCNL- percutaneous nephrolithotomy.

Table 2: Perioperative outcome data between standard PCNL (group 1) and tubeless PCNL (group 2).

Outcome variable	Group 1 (standard PCNL)	Group 2 (tubeless PCNL)	'p' value *
Number of patients (n)	25	25	-
Operative duration (in minutes)-mean±SD	49.80±9.73	38.60±6.04	<0.0001
Drop in Hemoglobin (in gm/dl)-mean±SD	0.73±0.42	0.76±0.27	0.751
Analgesic requirement (in mg-tramadol)-mean±SD	190±97.89	80±40.82	<0.0001
Postoperative pain (VAS 0-10) -mean±SD	6±0.91	3.64±0.86	<0.0001
Postoperative bleeding (yes or no)	1/24	1/24	1.000
Postoperative pyrexia (yes or no)	1/24	0/25	0.312
Postoperative urine leak (yes or no)	1/24	0/25	0.312
Blood transfusion requirement (yes or no)	1/24	0/25	0.312
Duration of hospital stay (in hours)-mean±SD	68.48±16.86	41.12±6.35	<0.0001

*: 'p' values calculated using Student's t-test for quantitative variables and chi-square test for qualitative variables-values less than 0.05 were taken as significant, SD- standard deviation, PCNL: percutaneous nephrolithotomy, VAS: visual analog scale.

Perioperative data comparing standard PCNL (group 1) and tubeless PCNL (group 2) were shown in table 2. The mean operative time in group 1 was 49.80 minutes compared to 38.60 minutes in group 2. The mean drop in hemoglobin postoperatively was 0.73 g/dl in group 1 compared to 0.76 g/dl in group 2. Postoperative blood transfusion was required in 1 out of 25 patients in group 1 compared to none in group 2. Postoperative pyrexia was seen in 1 out of 25 patients in group 1 compared to none in group 2. The mean analgesic requirement was 190 mg of tramadol in group 1 compared to 80 mg in group 2. The mean postoperative pain scores 24 hours postoperatively was 6 in group 1 compared to 3.64 in group 2. One out of 25 patients in each group had postoperative bleeding. Postoperative urine leak was seen in 1 out of 25 patients in group 1 compared to none in group 2. The mean duration of hospital stay was 68.48 hours in group 1 compared to 41.12 hours in group 2. Postoperative Hemoglobin drop, postoperative bleeding, postoperative pyrexia, post-op urine leak and blood transfusion requirement did not show a statistically significant difference between the two groups. The analgesic requirement, operative duration, postoperative pain score and duration of hospital stay showed a statistically significant difference between two groups ('p' values shown in table 2).

DISCUSSION

With the advancements in the surgical field, minimally invasive procedures like PCNL is the preferred modality of treatment for renal calculi in recent times.[14,15] Though

placing a nephrostomy tube at the end of standard PCNL has many advantages, it still causes significant pain and discomfort for the patient increasing the postoperative morbidity. Two modifications were made in standard PCNL in order to avoid the morbidity caused by large bore nephrostomy tube. They were decreasing the caliber of nephrostomy tube (mini PCNL) and omitting nephrostomy tube with only double J stent placement (tubeless PCNL).[16] Mini PCNL was first reported by Jackman et al with 13-20 F (French) working sheaths in order to decrease renal trauma and tract size. Despite the smaller size nephrostomy tube, most of the morbidity except postoperative pain did not get much altered compared to standard techniques.[17] Mini PCNL is usually preferred to treat only smaller renal calculi. A study by Li et al showed no significant advantage of reducing surgical trauma in mini PCNL compared to standard PCNL.[18]

With the advent of tubeless PCNL in the 1990s, the morbidity of the nephrostomy tube is completely avoided and it gained widespread popularity in recent years.[19] However certain drawbacks like stent-related symptoms and intraoperatively missed residual fragments which needed auxiliary treatment were seen in some tubeless PCNL studies.[20,21] Even though many RCTs were conducted in evaluating the efficacy and safety of tubeless PCNL, it remains as inconclusive evidence because of the quality and quantity of the analyzed RCTs.[19] Moreover, tubeless PCNL are generally not accepted yet in clinical practice, because of the problems faced like obstruction by residual fragments, urine leak and need of second look procedure.[22]

Patient and stone characteristics between the two groups were comparable in our trial (Table 1). We compared parameters like operative duration, post-op hemoglobin drop, blood transfusion requirement, post-op pyrexia, bleeding, urine leak, post-op pain scale, post-op analgesic requirement, duration of hospital stay between standard PCNL and tubeless PCNL groups. The mean operative time in standard PCNL group was 49.80 minutes compared to 38.60 minutes in tubeless PCNL group which was statistically significant similar to study by Sebaey et al (46.9 min and 40.6 min in standard and tubeless mini PCNL respectively) and other previous RCTs.[23-29] Hemoglobin drop postoperatively was 0.73 gm/dl and 0.76 gm/dl in standard and tubeless PCNL respectively which was not significant statistically. Previous studies by Tefekli et al (1.3 gm/dl and 1.7 gm/dl in standard and tubeless PCNL respectively) and other RCTs also showed similar results.[12,23-32] Even though, this result questioned the need for the placement of nephrostomy tube for tamponade reducing blood loss, our randomization in this trial was in patients who did not have significant intraoperative bleeding. Hence we still suggest nephrostomy tube placement in cases with intraoperative bleeding. However, Shoma et al, based on his findings concluded that nephrostomy tube placement did not affect hemoglobin drop and it is the patient's inherent coagulation capacity which stopped bleeding.[33] In our trial, postoperative bleeding as previously defined was seen in one patient in each group. The patient in standard PCNL group required blood transfusion as there was a significant drop in hemoglobin and in tubeless PCNL spontaneous resolution was seen with minimal loss of hemoglobin. None of these observations showed a statistical difference between two groups (Table 2).

Postoperative urine leak and pyrexia were seen in only one patient in the standard PCNL group and none in the tubeless PCNL group showing statistically insignificant results. Regarding postoperative fever, our finding was similar to the study by Aghdas et al, that patient with nephrostomy tube had more incidence of fever.[34] Similar to the analysis by Borges et al, we also did not find any statistical significance for postoperative fever between two groups.[9] In our trial, we had a single patient with fever in standard PCNL group and the same patient had prolonged urine leak more than 48 hours. In a study by Jou et al, residual fragments were found in patient developing postoperative fever but the results were insignificant.[35] As postulated by Borges et al, postoperative edema at the pelviureteric junction, intraoperative lithotripsy trauma were the reasons for obstruction and prolonged urinary leakage.[9] Ansari et al analyzed the risk factors for urine leak and found out factors like, residual stones, complex stones and complex anatomy caused prolonged urine leakage.[36] In our case, the patient had obstruction and urine leak probably due to post-op edema or residual fragment which was invisible or missed intraoperatively. However, both of the complications subsided with a conservative line of management. In contrary to the finding in our study, if urine leak occurs in tubeless PCNL patient, the poor outcome should be expected as relook procedure could not be done and possible additional morbid intervention may be needed. Hence, we suggest a careful selection of patient intraoperatively in decision making regarding placement of nephrostomy tube considering the above-mentioned factors.

Nephrostomy tube related pain is a common urologic symptom in patients undergoing standard PCNL.[37] Various studies showed significant morbidity due to nephrostomy tube placement after PCNL, like discomfort and significant requirement of analgesics.[23-25,28,31,32] Our trial showed statistically significant results of increased mean pain score (6 versus 3.6-standard versus tubeless PCNL) and increased mean analgesic requirements (190 mg versus 80 mg of tramadol-standard versus tubeless PCNL) in standard PCNL compared to tubeless PCNL. A study by Agarwal et al showed findings similar to our study of the mean analgesic requirement (128 mg versus 81.3 mg of tramadol-standard versus tubeless PCNL). Similar results like significantly less analgesic requirement and less pain score by the visual analog scale in tubeless PCNL comparing standard PCNL were seen in various studies.[27,28,30,31] Our results on comparing the mean duration of hospital stay postoperatively showed

significantly lower duration in tubeless PCNL group (68.48 hours versus 41.12 hours-standard versus tubeless PCNL). Our results were similar to a study by Crook et al showing the mean duration of hospital stay of 80.64 and 55.66 hours in standard and tubeless PCNL respectively.[13] Most RCTs done previously showed similar results of shorter hospital stay after tubeless PCNL similar to our study.[12,23-25,27-32] Morbidity associated with nephrostomy tube and time delay due to tube removal procedure after surgery were the reasons for more duration of hospital stay in standard PCNL group.

Analyzing our results, we suggest placement of nephrostomy tube in patients prone to a postoperative obstruction like residual fragments, lithotripter trauma, intraoperative bleeding being significant, deranged renal function, and pelvicalyceal system injury. Tubeless PCNL although showed promising results overall less morbidity in our trial should be preferred only in carefully selected patients with no residual stones, no bleeding or injury, no complex stone or abnormal kidney anatomy to avoid any complications postoperatively.

CONCLUSION

Tubeless PCNL may be a safe, acceptable and effective modality of treatment for renal calculi in carefully selected patients comparing standard PCNL resulting in less operative duration, lower postoperative pain, reduced analgesic requirement and shorter hospital stay. We suggest widespread adoption of tubeless PCNL in patients with uncomplicated intraoperative course owing to its lesser morbidity and early return to normal activity.

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