EFFICACY AND SAFETY OF STANDARD VERSUS TUBELESS PERCUTANEOUS NEPHROLITHOTOMY- A RANDOMIZED CONTROLLED STUDY

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ABSTRACT

BACKGROUND

Nephrolithiasis is a common urological disorder. PCNL is indicated for renal calculi > 2 cm in size. We present a prospective study to assess the efficacy and safety of tubeless PCNL in comparison to standard PCNL.

METHODS

A randomized control trial study was conducted in Sri Rama Chandra Medical Centre, Chennai, over a period of 2 years (i.e., between February 2016 to March 2018). A total of 220 patients were divided equally into two groups and were randomised into: Group A (undergoing tubeless PCNL; n = 110) and Group B (undergoing standard PCNL; n = 110). Factors that were evaluated included operative time, hospital stay, drop in haemoglobin, blood transfusion required, analgesics required, ancillary procedure performed, stone clearance and complications. The qualitative variables were analysed by chi-square test and quantitative variables were analysed by the student's t test. A p-value <0.05 was considered as statistically significant.

RESULTS

There was no statistically significant difference between the two study groups for patient age, gender, stone location, associated stone disorders, and co-morbidities. Majority of the study participants were male i.e., 56.4 % in Group A and 55.5 % in Group B. The mean age in group A was 42.45 ± 14.13 years and in group B was 45.44 ± 12.12 years. There was statistically significant less operative time, less hospital stay, smaller drop in haemoglobin and less analgesic requirement in Group A (p-value < 0.0001) as compared to Group B. There was no significant difference between the study groups with respect to stone clearance, complications, requirement of blood transfusion and ancillary procedures performed.

CONCLUSIONS

The present study proves the advantages of tubeless PCNL. It has significantly less operative time, short hospital stays, less drop-in haemoglobin and less requirement of postoperative analgesic in comparison with standard PCNL. Thus, tubeless PCNL is effective and safe in selected group of individuals.

KEY WORDS

Nephrolithiasis, Nephrostomy Tube, Standard Percutaneous Nephrolithotomy, Tubeless Percutaneous Nephrolithotomy, Ureteral Stent

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BACKGROUND

Nephrolithiasis is one of the most common urological conditions. In fact, current data establishes its prevalence in the United States population at 10.6% for adult male and 7.1 % for adult female.[1] Though historically, urinary calculi had high prevalence in male gender, but recently its incidence rate ratio of adult male to female has come down from 3.4 to 1.3.[2] Urinary calculi is usually a recurring and lifelong disease, forecasting even greater recurrence rates and dreadful clinical outcomes in the later part of life and thus, culminating in significantly higher economic burden.[3] White population are commonly affected than Asians and Afro-Americans. There is also greater prevalence with advancing age.[1]

Various methods for the treatment for nephrolithiasis range from non-invasive to invasive and includes medicinal treatment, extracorporeal shock wave lithotripsy (ESWL), percutaneous nephrolithotomy (PCNL), and open renal surgery.[4,5] PCNL was first demonstrated in 1976 by Fernstrom and Johansson and in the last two decades, it has become a preferred therapy for extracting a large and complex renal stone.[6,7]

Standard PCNL procedure includes placement of a nephrostomy tube at the completion of the procedure and while, some urologists also practice insertion of ureteral stent for internal drainage. Advantages associated with nephrostomy tube includes haemostasis along the tract, avoiding urinary extravasation, and maintain adequate drainage of the kidney, but the tube is also associated with

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disadvantages such as an increased hospital stay and more analgesic requirement. Tubeless PCNL is PCNL without postoperative nephrostomy tube placement. It was in 1997, when Bellman first demonstrated tubeless PCNL. Since then, the urologist has tried to modify this procedure with interest and enthusiasm, leading to its widespread use.[8] The efficacy and safety of this procedure has been reported in several prospective randomized controlled studies, systematic reviews and meta-analysis. These studies have also demonstrated that the length of hospital stay, use of analgesics, pain profiles, and indirectly cost are significantly lower in patients undergoing the tubeless PCNL procedure.[9-16] In the present study, we aimed to prospectively compare the efficacy and safety of the standard and tubeless PCNL, with special focus on feasibility, operative time, postoperative pain, complications and length of hospital stay.

METHODS

A Randomized control trial study total of 220 patients with nephrolithiasis underwent PCNL in our hospital between February 2016 to March 2018. Patients are divided equally into two groups - Group A (110 cases of tubeless PCNL) and Group B (110 cases of standard PCNL). The groups had no differences between operation technique– including dilatation size and type. Sample size was taken for convenience. This 220 Patients were randomized using computer generated random numbers and allocated into two groups into Group A and Group.

Inclusion criteria were stone > 2 cm in size (Who underwent PCNL as primary procedure); single puncture tract; procedure lasting less than 2 hrs.; less than three stones with a diameter < 25 mm; complete extraction of all stones; and no significant bleeding at the end of the procedure. Whereas, exclusion criteria included residual calculi; significant bleeding at the end of procedure and multiple puncture tract.

All patients were evaluated with physical examination, urine analysis, urine culture and sensitivity, complete blood count, renal function test, X-ray KUB, and non-contrast CT. Patients with urinary tract infections (UTI) were treated with antibiotics and operation was performed after sterile urine cultures.

Statistical Analysis

All statistical analysis was performed using SPSS (version 17) for Microsoft Windows. Descriptive statistics were presented as numbers and percentages. The data were expressed as Mean ± SD. Independent sample student t test were used to compare continuous variables between two groups. A chi-squared test was used for comparison categorical variables between two groups. A two-sided p-value < 0.05 was considered statistically significant.

RESULTS

In the present study, there were no drop-outs. Thus, all 110 patients in each group were evaluated. Majority of the study population in both the groups included male gender, with male: female ratio of 1.29:1 and 1.24:1 in Group A and Group B, respectively. There was no statistically significant difference among demographic variables in both the groups (Table 1).

Variables	Group A (n = 110)	Group B (n = 110)	p-Value
Age (Years)	42.45 ± 14.13	45.44 ± 12.12	0.094#
Gender Male (%)	62 (56.4 %)	61 (55.5 %)	
Female (%)	48 (43.6 %)	49 (44.5 %)	0.892$

Table 1. Demographic Variables of Both the Groups

Data expressed as absolute number, percentage and mean ± SD; SD-Standard deviation; # - Unpaired t-test; $ - Chi-square test; p-value < 0.05 was considered as statistically significant.

Variables	Group A (n = 110)	Group B (n = 110)	p-Value
Sr. creatinine (mg/dl)	1.098 ± 0.429	1.020 ± 0.468	0.198#
Laterality			
Left (%)	57 (51.8 %)	61 (55.5 %)	
Right (%)	53 (48.2 %)	49 (44.5%)	0.589$
Co-morbidities			
Hypertension (%)	10 (9.1 %)	14 (12.7 %)	0.387$
Diabetes mellitus (%)	21 (19.1 %)	19 (17.3 %)	0.727$
Associated Stone Disease			
Ureteric stone (%)	9 (8.2 %)	7 (6.4 %)	
Opposite kidney stone (%)	11 (10 %)	18 (16.4 %)	0.353$

Table 2. Preoperative Variables of Both the Groups

Data expressed as absolute number, percentage and mean ± SD; SD-Standard deviation; # - Unpaired t-test; $ - Chi-square test; p-value < 0.05 was considered as statistically significant.

Variables	Group A (n = 110)	Group B (n = 110)	p-Value
OT time (minutes)	62.06 ± 12.89	72.22 ± 17.55	< 0.0001#
Puncture Site			
Inferior calyx (%)	76 (69.1 %)	85 (77.3 %)	
Middle calyx (%)	24 (21.8 %)	13 (11.8 %)	
Superior calyx (%)	10 (9.1 %)	12 (10.9 %)	0.138$

Table 3. Intraoperative Variables of Both the Groups

Data expressed as absolute number, percentage and mean ± SD; SD-Standard deviation; # - Unpaired t-test; $ - Chi-square test; p-value < 0.05 was considered as statistically significant

Variables	Group A (n = 110)	Group B (n = 110)	p-Value
Drop in Hb (gm %)	0.98 ± 0.168	1.187 ± 0.382	< 0.0001#
Analgesic requirement (gm)	236.55 ± 53.294	350.99 ± 55.175	< 0.0001#
Hospital stay (days)	2.78 ± 0.932	3.9 ± 1.292	< 0.0001#
Stone Clearance			
Complete (%)	107 (97.3 %)	105 (95.5 %)	
Incomplete (%)	3 (2.7 %)	5 (4.5 %)	0.471$
Ancillary Procedure			
ESWL (%)	6 (5.5 %)	9 (8.2 %)	
URS (%)	9 (8.2 %)	7 (6.4 %)	
No complications (%)	95 (86.4 %)	94 (85.5 %)	0.652$
Complications			
Bleeding	7 (6.4 %)	5 (4.5 %)	
Urosepsis	9 (8.2 %)	14 (12.7 %)	
No complication	94 (85.5 %)	91 (82.7 %)	0.480$

Table 4. Postoperative Variables of Both the Groups

Data expressed as absolute number, percentage and mean ± SD; SD-Standard deviation; ESWL- Extracorporeal shock wave lithotripsy; URS-Ureteroscopy; # - Unpaired t-test; $ - Chi-square test; p-value < 0.05 was considered as statistically significant.

Preoperative variable in both the study groups are summarised in Table 2. Mean serum creatinine, laterality index, and co-morbidities like hypertension and diabetes mellitus were not significantly different in both the groups.

Intraoperative variables in both the study groups are depicted in Table 3. Mean operation time was higher in Group B and it was found to be statistically significant (p-value < 0.0001). While, inferior calyx was the puncture site in majority of the study population in both the groups, but these puncture sites were not found to be significantly different (p-value = 0.138).

Postoperative variables in both the study groups are mentioned in Table 4. Mean decline in haemoglobin (p-value < 0.0001), mean analgesic requirement (p-value < 0.0001) and mean duration of hospital stay (p-value < 0.0001) were found to be significantly higher in Group B. Majority of the patients had stone clearance i.e., 97.3 % in Group A and 95.5 % in Group B. Bleeding as a complication was observed in 7 patients of Group A and 5 patients of Group B. Whereas, urosepsis was reported in 9 patients of Group A and 14 patients of Group B. But there was no significant difference in the operative complications among the study groups (p-value = 0.480). These complications were managed conservatively. Finally, there was no significant difference between the study groups in ancillary procedures performed (p-value = 0.652). Wherein, 6 patients of Group A and 9 patients of Group B underwent ESWL and 9 patients of Group A and 7 patients of Group B underwent URS.

Surgical Technique

All patients underwent PCNL under general anaesthesia. Patients were placed in lithotomy position and a 6 Fr ureteric catheter was introduced. Contrast was used to identify the collecting system and to select the calyx for puncture.

After prone positioning with adequate padding, posterior calyceal puncture was done under fluoroscopic guidance. Level of puncture was decided as per location of stone to ensure complete clearance.

Puncture was done using 18 G two-part needle and guide-wire was placed within the system. Guide-rod was introduced, and serial coaxial dilatation of tract done with Alkens metal dilator. Amplatz's heath was placed. Using 20.8 Fr Karl Storz nephroscope and Karl Storz pneumatic lithotripter stone fragmentation was done.

After fragments were evacuated, antegrade 6 Fr ureteric stent was placed in group A and skin incision sutured and compression bandage applied. A 20 Fr nephrostomy tube along with 6 Fr ureteric stent was placed in patients coming under group B.

Variables

Preoperative parameters like stone size, stone disease in the opposite kidney and ureter, preoperative serum creatinine, and associated co-morbidities were recorded. Intraoperative parameters like operative time, access tract and the need for blood transfusion were recorded. Patients were followed up in postoperative period with decrease in Hb, need for blood transfusion, need for analgesia, hospital stay, complications and need for ancillary procedure. In group B, post-procedure X-ray KUB was performed before removing the nephrostomy tube on the first postoperative day. In both group, ureteric stent was removed after 14 days.

Thus, stone size, preoperative serum creatinine, operative time, stone clearance rate, length of hospital stay, analgesic requirements, and postoperative complications such as bleeding, infection or ureteral obstruction were recorded and compared.

DISCUSSION

American Urological Association (AUA) recommends PCNL for kidney stones > 2 cm in size. It provides a higher stone-free rate than SWL or URS and is less invasive than open surgery or laparoscopic/ robotic assisted procedures. Moreover, the success rate of PCNL is less dependent on composition, density and location of the stone.[17] Historically, the procedure followed includes leaving a temporary nephrostomy tubes of varying calibre and type in place at the end of PCNL procedures for variety of reasons such as drainage, tamponade of bleeding and to permit second-look procedures.[6,18] Tubeless PCNL wherein only an internal ureteral stent is used, has been claimed to have less morbidity and early recovery when compared to a standard PCNL.[8,9,11,16]

In the present study, there was no statistically significant difference between the study groups in terms of the age and gender of the patients, stone side (i.e., left or right) and location (i.e., ureter or opposite kidney), comorbidities such as hypertension and diabetes mellitus, and serum creatinine; thus minimising their effect on the outcomes of the procedures.

In the present study, majority of patients in both the group were males (56 % in Group A and 55 % in Group B). This finding is in accordance with the previous studies, which reported that male gender has higher prevalence of nephrolithiasis.[1,19,20] In the present study, mean age of patients in group A was 42.45 years and 45.44 years. Various studies have reported similar findings.[21,22] The cause of higher prevalence in middle-age population may be due to more laborious work performed by them relative to others, and thus, resulting in less fluid intake and greater rate of dehydration.[23]

In the present study, comorbidities like hypertension and diabetes mellitus (DM) were reported in 9.1 % and 19.1 % patients in Group A and 12.7 % and 17.3 % patients in Group B, respectively. While, occurrence of uric acid stone shows positive correlation with DM, the evidence for the association between hypertension and nephrolithiasis has been inconsistent. Lower urinary pH due to the effects of insulin resistance on ammoniagenesis has been described as reason for positive correlation between DM and nephrolithiasis.[24]

In the present study, time taken for procedure was statistically more in Group B as compared to Group A (p-value < 0.0001). Contrary to the present study, Nalbant I et al.[11]and Gupta NP et al.[25]reported slightly longer operative time for standard PCNL as compared to tubeless PCNL, but there was no significant difference (p-value > 0.05). While, recent meta-analysis by Xun Y et al.[16] reported that tubeless PCNL was significantly associated with shorter operative time (p-value = 0.012). Thus, supporting the findings of the present study. These differences in operative times cited in literature might be due to the different criteria used to calculate operative time. Moreover, important determinants of total operative time are patient characteristics and surgeon's experience.

In the present study, mean hospital stay and mean amount of analgesic required (Tramadol) was found to be significantly less in patients of Group A compared to Group B (p-value < 0.0001). Similarly, Agarwal MS et al.[18] and Gupta NP et al.[25]demonstrated significantly less mean hospital stay and mean amount of analgesic required in patients with tubeless PCNL as compared to standard PCNL. While, Nalbant I et al.[11] and Sebaey A et al.[26] reported only significantly decreased mean hospital stay and mean amount of analgesic required, respectively in patients with tubeless PCNL as compared to standard PCNL. As tubeless PCNL does not

require use of nephrostomy tube and thus, less postoperative pain and discomfort. Resulting in short hospital stay and less use of analgesics. Moreover, the standard PCNL procedure requires an additional procedure for tube removal, leading to more use of analgesics and further increasing the hospital stay.

Post-operative drop in haemoglobin finds its mention in the literature. To determine the patients who may have had more significant intraoperative bleeding, and thus, may be at greater risk of post-operative bleeding, we used the immediate post-operative drop in haemoglobin. In the present study, mean decrease in haemoglobin was significantly higher in Group B (p-value < 0.0001) as compared to Group A, but there was no significant difference between the study groups for the number of patients who required blood transfusion. Thus, suggesting that in patients with moderate intraoperative bleeding the tubeless PCNL is safe. But, there was no significant difference between tubeless and standard PCNL for mean decrease in haemoglobin and blood transfusion rate as per the studies by Xun Y et al.[16] and Agarwal MS et al.[18] Though the drop in haemoglobin may not be associated with the use of a nephrostomy tube.

In the present study, there was no significant difference in the operative complications like urosepsis and bleeding (p-value = 0.480).Similarly, Isac W et al. reported no significant difference between tubeless and standard PCNL regarding the complications. In the present study, requirement of ancillary procedures (i.e., ESWL and URS) was not statistically significant (p-value = 0.652) between the study groups. Sofikerim Met al.[27] performed only ESWL as ancillary procedures, 8.3% for standard and 4.2% for tubeless groups. In a study by Shah H et al.[28] the majority of ancillary procedures were extra corporeal shock wave lithotripsy (ESWL) (18 in tubed group and 19 in tubeless group).

Moreover, in the present study, there was no significant difference in between both the groups for stone clearance (p-value = 0.471). Amer Tet al.[10] reported no significant difference in stone clearance between tubeless and standard PCNL. With PCNL, at the completion of the procedure, it is sometimes difficult to eliminate the presence of residual stones. Thus, in certain patients, carrying out an additional puncture tract may sometimes be inevitable.

Limitations of the present study includes non-randomised nature of the study (Thus, leading to selection bias), size of stone was not evaluated, and pre- and post-operative pain scores were not calculated.

CONCLUSIONS

Tubeless PCNL is effective and safe alternative to standard PCNL, in a cautiously selected group of patients. When compared to standard PCNL, tubeless PCNL has significantly shorter hospital stay, less operative time, less decrease in haemoglobin, less requirement of analgesics, shorter hospital stay which indirectly leads to reduction of healthcare cost. In the near future, with expertise and further decline in morbidity, tubeless PCNL may become a day-care procedure in a selected group of patients.

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