

Comparative Study between Outcome of Standard and Tubeless Percutaneous Nephrolithotomy (PCNL) at District Level Tertiary Hospitals in Bangladesh

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Abstract:- Renal calculus is one of the commonest problems of the urinary tract. Surgical approach is more effective treatment option to remove it. Among all surgical procedures, Percutaneous Nephrolithotomy (PCNL) has gradually become a preferred option in last two decades for renal calculus that has largely replaced the open approach. Currently, it is the procedure of choice for renal calculus > 2 cm, or those are refractory to ESWL. The crucial step in Standard PCNL is placing a nephrostomy tube. In recent years, it has been reformed as 'Tubeless' PCNL with some modifications in which a Double-J (D-J) stent is placed without any nephrostomy tube for internal drainage. This study was done to compare the outcomes of Standard PCNL and Tubeless PCNL at district level tertiary hospitals in Bangladesh among 46 patients with renal calculus up to 3 cm size. Many authors agree that Tubeless PCNL or its modifications are effective as well as safe. Although, nephrostomy tube is responsible for an increase of post-operative morbidity, in our study, we did not find any statistically significant difference between these two procedures.

Keywords:- Renal Calculus, Percutaneous Nephrolithotomy, ESWL, Nephrostomy Tube, D-J Stent.

I. INTRODUCTION

Renal calculus is one of the commonest problems of urinary tract (Stoller et al). The life-time prevalence is 1 to 15% based on age, gender, race, and geographic location with a peak incidence in 4th to 6th decades of life (Marshall et al). The stone disease occurs 2 to 3 times more in young males than females, though it's declining now. It commonly affects the Whites than then Asians and Afro-Americans (Soucie et al, 1994; Romero et al, 2010). Patient with renal stone may present with loin pain, haematuria, graveluria, associated UTI, urinary obstruction, even acute renal insufficiency in severe case (Lorenz et al).

Surgical treatment is more effective option to remove stone and the goal is maximum stone clearance with minimum morbidity to relieve obstruction, to prevent further stone growth, to eradicate causative organisms and associated infection as well as to preserve renal function depending on number, location, size, and composition of stone, renal anatomy, obesity, body habitus, and infection (Matlaga et al). There are many options for surgical removal of renal stone. Among all procedures, PCNL has gradually become a preferred option in last two decades.

Using a PCN tube of 20 to 26 Fr for internal drainage is considered as a standard procedure following PCNL. The PCN tube drains pelvi-calyceal system, serves as way to tamponade the percutaneous tract, and provides an access to the pelvi-calyceal system if any second look nephroscopy is needed for the residual calculi. But some patients develop complications such as pain, prolonged urinary leak at the PCN site which may prolong the hospital stay (Jones et al). Placing only a D-J stent in place of PCN tube, the "Tubeless PCNL" may overcome these problems (Maheshwari et al).

So, our study was done to compare the post-operative outcomes between Standard PCNL and Tubeless PCNL in terms of operative time, post-operative pain, post-operative drop in Hb%, urinary leakage, peri-renal collection, hospital stay, and return to day-to-day activities.

II. RATIONALE

PCNL is the procedure of choice for stone size > 2 cm, or those are refractory to ESWL. Nephrostomy tube following PCNL is traditionally placed in-situ for adequate haemostasis, drainage, second look, prevention of retro-peritoneal haematoma. Nevertheless, some controversies exist where nephrostomy tube is thought to contribute some post-operative morbidity also. So, our study was done to signify the difference between Standard PCNL and Tubeless PCNL as well as to compare the outcomes between these two procedures.

III. REVIEW OF LITERATURE

PCNL was first developed in 1976s by Fernstorm and Johansson to remove a renal stone as an adjunct to the open surgical management of large renal calculi (Geraghty et al). Based on its high success rate, low morbidity, and low complication rate, it has largely replaced the open approach (Frenstrom et al, 1976; Gupta et al, 2003; Clayman et al, 1984). Now, it is the procedure of choice for removing stone > 2 cm, or those are refractory to ESWL (Shah et al).

Bellman and colleagues (1997) first described Tubeless PCNL with an internal ureteral stent placed for a week or two which is mainly of two types. One is where only D-J stent passed, no nephrostomy tube inserted after completion of procedure. Another one is Totally Tubeless PCNL i.e. neither nephrostomy tube nor D-J stent placed after the procedure (Aghamir et al, 2004). Different studies demonstrate the advantages of Tubeless PCNL regarding postoperative pain, post-operative analgesia requirement, urinary leakage, hospital stay, time to return to day to day activities (Shen et al).

Bellman et al. challenged the need for a nephrostomy at all in their seminal work in 1997. Their study was based on 50 patients who were age-, sex- and procedure-matched. The authors highlighted compelling advantages of the tubeless approach: shorter hospitalization and convalescence reduced analgesic requirements and savings of up to USD 2,000 per case. Since then, there has been a literature base corroborating these outcomes. The technique involved internalizing the renal drainage process (ureteric catheter or JJ stent placement) or alternatively no stent at all (totally tubeless PCNL).

Shah et al. compared the outcome of tubeless PCNL with small-bore nephrostomy drainage after PCNL. In this study, patients undergoing tubeless PCNL experienced significantly less postoperative pain, needed less analgesia, and were discharged 9 hours earlier than patients in the other group. However, 39.4% of patients in the tubeless group had bothersome stent-related symptoms, of which 61.5% needed analgesics and/or antispasmodic agents.

IV. METHODOLOGY

A. Type of the Study: Observational

B. Place of the Study:

1. Department of Urology
AndroCare,
Cumilla, Bangladesh
2. Department of Urology
MAG Osmani Medical College and Hospital Sylhet,
Bangladesh
3. Department of Surgery
Mainamoti Medical College Hospital
Cumilla, Bangladesh
4. Department of Surgery
Haji Asgar Ali Hospital
Norshingdhi, Bangladesh

C. Study Period: September 2020 To August 2023

D. Study Population: 46 Patients With Renal Stone Up To 3 Cm Size

E. Sampling Technique : Purposive Sampling

F. Inclusion Criteria :

1. Stone size up to 3 cm
2. Single tract access
3. Stone refractory or not feasible to ESWL
4. No significant per-operative bleeding
5. No significant calyceal perforation
6. No significant residual stone

G. Exclusion Criteria :

1. Stone size > 3 cm, or Staghorn calculus
2. Multiple tract access
3. Major congenital anomalies of kidney
4. Stone in solitary functioning kidney
5. Significant bleeding or calyceal perforation per-operatively
6. Residual stone

H. Variables :

1. Operating time
2. Post-operative pain (VAS)
3. Post-operative temperature
4. Post-operative drop in Hb%
5. Urine leakage time
6. Peri-renal collection
7. Hospital stay
8. Return to normal day to day activity

I. Study Procedure:

This district level tertiary hospital based prospective observational study was conducted in AndroCare, Cumilla; MAG Osmani Medical College Hospital, Sylhet; Mainamoti Medical College Hospital, Cumilla, and Haji Asgar Ali Hospital, Norshingdhi to compare the outcomes of Standard PCNL and Tubeless PCNL. Patients with renal calculi were evaluated by the detailed history, clinical examination, location and size of stones, pelvi-calyceal dilatation, and all other required pre-operative investigations. Those who met the inclusion criteria were purposively included in this study. After a decision for operation, the whole procedure of the study was explained to each patient, and then asked for consent. Those patients who gave consent were considered as a case of this study.

V. RESULT

Total 46 patients were divided into Group-A (Standard PCNL) and Group-B (Tubeless PCNL), 23 in each group. All data were analyzed using Student's t- test, and the level of significance was 0.05. None of the difference between two groups approached the level of significance.

A. Operating Time:

87.0 % of patients in Group-A required above 90 minutes for operation to be completed whereas only 8.7% of patients in Group-B required above 90 minutes. The difference did not approach the level of significance (P= 0.354).

B. Post-Operative Pain:

In Group-A, 21.7 % patients suffered from severe pain whereas only 8.7 % patients suffered from severe pain in Group-B. In Group-A, 65.2 % and 13 % patients suffered from moderate and mild pain respectively whereas in Group-B, 17.4 % and 73.9 % patients suffered from moderate and mild pain respectively. The difference did not approach the level of significance (P= 0.336).

C. Post-Operative Temperature:

In Group-A, 17.4% patients had post-operative temperature raised by more than 1° whereas in Group-B, only 8.7% patients had post-operative temperature raised by more than 1° postoperatively. 13% patients in each group had post-operative temperature raised by 1°. The difference did not approach the level of significance (P= 0.120).

D. Post-Operative Drop in Hb%:

Post-operative drop in Hb% in 24 hours dropped more than 1 g/dL in 30.4% patients of Group-A and 17.4% patients

of Group-B. The difference did not approach the level of significance (P= 0.244).

E. Urine Leakage Time:

In Group-A, 91.3% patients had continued urine leakage more than 24 hours whereas in Group-B, only 4.3% patients had continued urine leakage more than 24 hours post-operatively. The difference did not approach the level of significance (P= 0.240).

F. Peri-Renal Collection:

None of Group-A and Group-B was found to have any peri-renal collection on Ultrasonographic examination of the kidney post-operatively.

G. Hospital Stay:

In Group-A, 73.9% patients stayed in hospital for more than 3 days whereas in Group-B, only 5% patients stayed in hospital for more than 3 days post-operatively. The difference did not approach the level of significance (P= 0.501).

H. Return to Normal Day to Day Activity:

In Group-A, only 13% patients returned to normal day to day activity within 20 days whereas in Group-B, 73.9% patients returned to normal day to day activity within 20 days post-operatively. The difference did not approach the level of significance (P= 0.317).

Table 1. Comparison of Operating time between two groups (n= 46).

Operating time (minutes)	Group		P value
	Group- A	Group- B	
Below 90	3 (13.0)	21 (91.3)	0.354
Above 90	20 (87.0)	2 (8.7)	
Mean \pm SD	1.87 \pm 0.344	1.09 \pm 0.288	

Table 2. Comparison of Post-operative pain between two groups (n= 46).

Post-operative pain	Group		P value
	Group- A	Group- B	
Mild	3 (13.0)	17 (73.9)	0.336
Moderate	15 (65.3)	4 (17.4)	
Severe	5 (21.7)	2 (8.7)	
Mean \pm SD	2.09 \pm 0.596	1.35 \pm 0.647	

Table 3. Comparison of Post-operative temperature between two groups (n= 46).

Post-operative temperature	Group		P value
	Group- A	Group- B	
Within normal level	16 (69.6)	18 (78.3)	0.120
Raised by 1°	3 (13.0)	3 (13.0)	
Raised by > 1°	4 (17.4)	2 (8.7)	

Post-operative temperature	Group		P value
	Group- A	Group- B	
Mean \pm SD	1.48 \pm 0.790	1.30 \pm 0.635	

Table 4. Comparison of Post-operative drop in Hb% between two groups (n= 46).

Post-operative drop in Hb%	Group		P value
	Group- A	Group- B	
Below 0.5	3 (13.0)	4 (17.4)	0.244
0.5 to 1.0	13 (56.6)	15 (65.2)	
Above 1.0	7 (30.4)	4 (17.4)	
Mean \pm SD	2.17 \pm 0.650	2.0 \pm 0.603	

Table 5. Comparison of Urine leakage time between two groups (n= 46).

Urine leakage time (hours)	Group		P value
	Group- A	Group- B	
< 24	2 (8.7)	22 (95.7)	0.240
> 24	21 (91.3)	1 (4.3)	
Mean \pm SD	1.91 \pm 0.288	1.04 \pm 0.209	

Table 6. Comparison of Hospital stay between two groups (n= 46).

Hospital stay (days)	Group		P value
	Group- A	Group- B	
< 3	6 (26.1)	18 (78.3)	0.501
> 3	17 (73.9)	5 (21.7)	
Mean \pm SD	1.74 \pm 0.449	1.22 \pm 0.422	

Table 7. Comparison of Return to normal day to day activity between two groups (n= 46).

Return to normal day to day activity (days)	Group		P value
	Group- A	Group- B	
Within 20	3 (13.0)	17 (73.9)	0.317
20 to 30	5 (21.8)	4 (17.4)	
> 30	15 (65.2)	2 (8.7)	
Mean \pm SD	2.52 \pm 0.730	1.35 \pm 0.647	

VI. DISCUSSION

This hospital based prospective observational study was conducted in AndroCare, Cumilla; MAG Osmani Medical College Hospital, Sylhet; Mainamoti Medical College Hospital, Cumilla, and Haji Asgar Ali Hospital, Norshingdhi from September 2020 to August 2023.

Total 46 patients with renal calculi underwent Percutaneous Nephrolithotomy (PCNL). PCNL was performed in the absence of multiple tract access, major

congenital anomalies of kidney, and stone in solitary functioning kidney, significant per-operative bleeding or calyceal perforation and residual stone. Group-A patients were managed by PCNL with nephrostomy tube in-situ and Group-B patients were managed by PCNL without keeping a nephrostomy tube. Results of treatment of both groups were compiled and compared.

Operating time, Post-operative pain, Post-operative drop in Hb%, Post-operative temperature, Urine leakage time, Peri-

renal collection, Hospital stay, Return to normal day to day activity were compare as outcome variables.

In this study, large and staghorn calculi were excluded as these may need multiple punctures as well as residual stone burden may exist. The stone size was calculated in centimeter by X-ray KUB (100% film) and USS of KUB region.

The Mean \pm SD of Operating time in Group-A was 1.87 ± 0.344 and Group-B was 1.09 ± 0.288 with no statistical significant difference ($P=0.354$). In a study of Aghamir SM et al 2004, a total of 43 patients underwent tubeless and totally tubeless PCNL where mean operating time did not differ significantly, being 75 minutes in tubeless group and 68 minutes in totally tubeless group.

Post-operative pain in Group-A was 2.09 ± 0.596 and Group-B was 1.35 ± 0.647 with no statistical significant difference ($P=0.336$).

The Mean \pm SD of Post-operative temperature was 1.48 ± 0.790 and 1.30 ± 0.635 in Group-A and Group-B respectively. There was no significant difference with $P=0.120$.

Mean \pm SD of Hb% dropped in 24 hours following operation was 2.17 ± 0.650 in Group-A and 2.0 ± 0.603 in Group-B. No statistical significant difference was observed ($P=0.244$). None of the patient in both groups required blood transfusion. In a study of Shah et al. in 2008, the mean haemoglobin decrease was 0.82 g/dL in tubeless PCNL group and 0.92 g/dL in standard PCNL group with significant difference.

In our study, the Urine leakage time was found 1.91 ± 0.288 hours in Group-A and 1.04 ± 0.209 hours in Group-B. No statistical significance was found ($P=0.240$). Desai et al. in 2004 showed tubeless PCNL had shorter mean urine leakage time than standard PCNL.

No Peri-renal collection was found either in Group-A or Group-B on ultrasonography post-operatively.

Patients undergone tubeless PCNL had a Hospital stay of Mean \pm SD 1.22 ± 0.422 comparing with standard PCNL, Mean \pm SD (1.74 ± 0.449). No statistical significant difference ($P=0.501$) was found. In the largest prospective randomized trial by Agarwal et al., in 202 patients, Average hospital stay in the tubeless group was less than 24 hours (21.8 ± 3.9) and was significantly shorter than that of the standard PCNL group (54.2 ± 5). Tubeless group patients took 5 to 7 days for complete convalescence, whereas standard PCNL patients recovered in 8-10 days. The studies of Preminger et al (1985), Ahmed et al. (2014), Al Kohlany et al. (2005) and Falahatkar et al. (2009) reported mean hospital stay for PCNL was 4, 5, 6.4 ± 4.2 & 3.93 ± 1.76 days and for open surgery was 10, 8.8, 10 ± 4.2 & 5.08 ± 2.42 days respectively.

The mean Return to normal day to day activities found 2.52 ± 0.730 in Group-A and 1.35 ± 0.647 in Group-B.

VII. CONCLUSION

Although nephrostomy tube following PCNL has advantages i.e. adequate haemostasis, adequate drainage, second look operation, prevention of retro-peritoneal haematoma, and some controversies exist where it is thought to contribute some post-operative morbidity also comparing to tubeless PCNL. Nevertheless, our study did not find any significant difference between outcomes of these two procedures that means Tubeless PCNL has no additional benefits over than standard PCNL.

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DECLARATION

I, Dr Nandan Kishur Kar, as a principal author hereby humbly declare that I have had carried out the research work along with other three co-authors entitled,

“Comparative study between outcome of Standard and Tubeless Percutaneous Nephrolithotomy (PCNL) at district level tertiary hospitals in Bangladesh”

No part of this research work has been submitted in any journal, either national or international prior to this date.