ABSTRACT

Percutaneous nephrolithotomy (PCNL) is an effective treatment for large renal calculi and usually a nephrostomy tube is placed in the kidney at the end of procedure to avoid post operative complications. This is to compare the outcome of tubeless PCNL versus tubed PCNL. In a randomized prospective study of sixty-four consecutive patients were enrolled and divided into two groups; A being tubeless group and B being nephrostomy group with 32 patients in each arm divided by quota sampling restricted block method with allocation ratio of 1:1. The mean age in group A was 36.69 ± 13.65 years and in group B was 38.09 ± 13.18 years with no significant p value (p = 0.501). Duration of hospital stay in group A was 3.63 ± 1.04 days and in group B was 6.34 ± 1.71 days with a significant p value (p = 0.001). In group A 31 (96.9%) and in group B 24 (75%) cases were not transfused with blood while 1 (3.1%) and 8 (25%) cases were transfused with blood with a significant p value (p = 0.026). The post operative complications were comparable in between two groups. Therefore tubeless PCNL reduces the hospital stay and blood transfusion rate with no obvious post operative complications.

Key Words: Conventional, Hospital stay, Percutaneous nephrolithotomy (PCNL), Tubeless.

INTRODUCTION

Placement of a nephrostomy catheter after PCNL is considered the standard procedure. The purpose of tube is to tamponade bleeding, aid in renal drainage, prevent urinary extravasation and offer access for the future endoscopic procedures. Despite these apparent advantages nephrostomy tubes have been implicated in causing postoperative discomfort and increasing morbidity, prolonging hospital stay and continued urinary leakage. However, in recent years, with a growing realization of significant postoperative pain and morbidity after PCNL because of nephrostomy tubes, attempts have been made to modify standard PCNL.1, 2

Here in this study, tubeless PCNL is defined by placing an internal drainage with double J stent without external nephrostomy tube and tubed PCNL is defined by placing both internal stent and external nephrostomy tube.

Today, several studies are stating the superiority of tubeless PCNL in terms of less morbidity, lower post operative pain and shorter hospital stay.2-5

The aim of this study was to compare the outcome of tubeless PCNL with conventional percutaneous nephrolithotomy (PCNL) in terms of Post-operative hospital stays and Blood transfusion rate.

MATERIAL AND METHODS

Settings and Study Design: This is the hospital based prospective study conducted in the Department of urology, Chitwan Medical College, Bharatpur, Chitwan, Nepal from Jan 1st to Dec 31st 2013. In a randomized prospective study 64 patients were divided in two groups; group A (n=32) underwent PCNL without tube and group B (n=32) underwent PCNL with tube in prone position with the conventional technique. Demographic, operative data, post operative complications, patients’ satisfaction rate and follow up complications were
recorded and analyzed between two groups.

All the cases of more than 15 years having renal pelvis stone of greater than 2 cm or stones greater than 1 cm in lower pole calyx or all renal stones resistance to extracorporeal shock wave lithotripsy.

**Exclusion Criteria**

1. Patients with preoperative nephrostomy tube,
2. Patients requiring redo surgery,
3. Patients with non renal pain like radiculitis,
4. Patients with coagulative disorder,
5. Patients requiring more than two tracts,
6. Patients with renal anomalies e.g. ectopic, horse shoe kidneys,
7. Patients not willing to enroll in this study,
8. Patients with ASA grade III or more

**Study Protocol**

All the patients subjected for PCNL were admitted in the department of urology of Chitwan Medical College, Bharatpur and were included in the sample. A day prior to surgery, clinical evaluation and physical examination with the following investigations (complete blood count, prothrombine time, urine routine microscopic examination and culture, renal function test, X-ray chest, electrocardiogram, ultrasonography of abdomen and pelvis and intra venous urogram/CT with or without contrast urography were carried out. All patients who met the inclusion criteria were randomized for study.

Randomization was carried out by opening an envelope on the day of surgery by restricted block method with allocation ratio of 1:1. The block size comprises of eight participants of every eight consecutively enrolled participants.

**Distribution of Patients**

Patients were divided into two groups by random number table into Group A (n = 32 patients) for tubeless conventional PCNL and the other group B (n = 32) for tubed conventional PCNL. This operation was performed under general anesthesia or spinal anaesthesia.

**Operative Details**

A written informed consent was taken and explanation of risks and benefits of the procedure and research was given to the patient and/or his/ her attendants. General anesthesia or spinal anaesthesia was given. Retrograde ureteric catheterization and retrograde pyelography was done routinely in all patients in a lithotomy position to delineate the anatomy and to fill the pelvicalyceal system with contrast media (Urografin) to facilitate percutaneous access. A ureteric catheter 6 Fr was left in the renal pelvis, as a point of reference and also if required to refill contrast media at the time of percutaneous access. A 16 /14Fr Foley catheter was passed per urethra and the ureteric catheter was secured with Foley’s catheter. Position of patient was changed to prone. Foam padding was placed under the chest and knees and folded pillows under each foot. Operating site was routinely prepared and draped. Access to pelvicalyceal system was acquired through upper, middle or lower calyceal systems according to stone burden, location and dilatation of the particular calyx.

Initial puncture for PCNL tract was made with a puncture l8guage needle. Puncture was made under image intensifier with all axes of the C-arm at zero and 30 degree. Position of needle was reconfirmed by drainage of urine and with antegrade filling of the collecting system with contrast media. Then a guide wire 0.035 inch size was threaded in through the puncture needle into the pelvicalyceal system. The tract was then gradually dilated first with vascular dilator then by cook dilator up to 24-30fr as required with seldinger technique. Amplatz sheath was slid over the whole set of dilators down to the olive tip dilator as seen with help of image intensifier. Amplatz sheath was confirmed in the required calyx then the dilator set was removed and guide wire was retained through nephroscope. An irrigation system with normal saline as irrigant was connected and the light source (xenon) was also attached. Nephroscopes used was 26 Fr through a 24-30Fr Cook Amplatz sheath. Guide wire was retained till the end of the surgery. Stones were targeted and fragmented with a pneumatic lithoclast with the single and multiple fires and were retrieved out with forceps. At the end of the procedure final search for any residual stones were made by the image intensifier and nephroscope. A 20/24Fr nephrostomy tube was placed only in group B patients. In group A patients no nephrostomy tube was placed. After completion
of the procedure and recovery from anesthesia all patients were shifted to the urology ward and observed for study purpose.

Case sheets of patients, who underwent PCNL through the specified period were studied to evaluate patients’ demographic data, stone characteristics, costal approach, calyceal puncture, duration of surgery, hospital stay, duration of operative procedure, blood transfusion rate peri-operatively, stone free rate, redo operation, complications at the time of operation and post operative complications were noted in both groups of patient. The duration of operation was calculated from start of inserting endoscope and closing of the tract with the suture materials.

In our set up as the patients are reluctant to go home in the first post operative day even though the surgeons requested to discharge, it is defined early discharge as less or equal to 3rd post operative day.

RESULTS

Total of 64 patients treated for renal stones with PCNL were included in this study, they were randomized in two groups. Group A comprising 32 cases of tubeless PCNL, group B comprising of 32 cases with tubed (with post operative nephrostomy tube) PCNL. The mean age in group A was 36.69 years with Standard deviation of 13.63. Similarly, in Group B was 38.09 years with standard deviation of 13.18. There was no significant p value between the groups.

The males were more affected than the female in both the groups with no significant p value as shown in the following table 1.

Table 1: Patients’ demographic data

| Variable   | Tubeless         | Tubed          | P-Value |
|------------|------------------|----------------|---------|
| Age(years) | 36.69±13.63      | 38.09±13.18    | 0.501   |
| Sex        |                  |                |         |
| Male       | 18 (56.2%)       | 22 (68.8%)     | 0.439   |
| Female     | 14 (43.8%)       | 10 (31.2%)     |         |

The hospital stay in group A was 3.63 days with standard deviation of 1.04 and in the group B was 6.34 days with the standard deviation of 1.71 days. The p value was significant (p = 0.001).

As per in our series as early discharge were considered as less or equal to 3d post operative days most of discharge were early in tubeless group as compared to the tubed group with a significant p value as shown in the table 2 (p = 0.001).

Table 2: Duration of Hospital Stay

| Variable         | Tubeless          | Tubed           | P-value |
|------------------|-------------------|-----------------|---------|
| Duration (days)  | 3.63 ± 1.04       | 6.34 ± 1.71     | 0.001   |
| ≤ 3rd POD        | 19 (59.4%)        | 1 (3.1%)        | 0.001   |
| ≥ 4h POD         | 13 (40.6%)        | 31 (96.9%)      |         |

Regarding the blood transfusion rate there was no transfusion in 31(96.9%) patients in group A as compared to group B where 8 (25%) were transfused. The p value was significant (p = 0.026) as shown in the table 3. As haemoglobin changes are one of the important parameter for the bleeding the pre and post operative haemoglobin changes were recorded. The mean pre operative haemoglobin in group A was 12.73 gm% with standard deviation of 1.64 gm%. Similarly, the mean pre-operative haemoglobin in group B was 12.45 gm% with standard deviation of 1.59 gm%. After the operation, 24 hrs haemoglobin were recorded. The post operative haemoglobin in group A was 11.98 gm% with standard deviation of 1.88 gm%. There were no significant changes in p value pre and post operative haemoglobin level changes in both the group (p = 0.5 vs p = 0.096) respectively.

Table 3: Post-operative blood transfusion rate and haemoglobin changes

| Variable         | Tubeless         | Tubed           | P-value |
|------------------|------------------|-----------------|---------|
| Post operative blood transfusion |                  |                 |         |
| No transfusion   | 31 (96.9%)       | 24 (75%)        |         |
| Transfusion      | 1 (3.1%)         | 8 (25%)         |         |
| Haemoglobin (gram%) | 12.73 ± 1.64 | 12.45 ± 1.59    |         |
| Pre operative    |                  |                 |         |
| Post operative   | 11.98 ± 1.92     | 11.18 ± 1.88    |         |
| Duration of operation (minutes) | 62.44 ± 6.07 | 96.31 ± 46.13  | 0.002   |

The duration of operation in tubeless group was 62.44 minutes with standard deviation of 46.07 minutes and in the tubed group was 96.31 minutes with standard deviation of 46.13 minutes. The operation time was lesser in group A as compared to...
considered as less or equal to 3d post operative days. The mean stone size in group A was 3.47 cm with standard deviation of 1.01 cm and in group B was 3.69 cm with standard deviation of 1.42 cm. There was no statistically difference in p value P = 0.888.

The stone was categorized in two groups on the basis of indication of PCNL i.e. 2 cm cut off line. Few of the cases were operated less than 2 cm and these were lower calyceal stone and one of the patient opted for PCNL denying ESWL in group A. Six (18.85%) patients were operated for stone less than 2 cm in group B and all of them given the option of ESWL which they refused. Twenty-eight (87.5%) and 26 (81.2%) were operated in group A & Group B respectively with no significant P value (p = 0.491) as shown in the table 04.

### Table 4: Stones characteristics and laterality

| Variable         | Tubeless       | Tubed          | P- value |
|------------------|----------------|----------------|----------|
| Stone size (cm)  | 3.47 ± 1.01    | 3.69 ± 1.42    | 0.888    |
| < 2cm            | 4 (12.5%)      | 6 (18.85)      |          |
| ≥ 2cm            | 28 (87.5%)     | 26 (81.2%)     | 0.491    |
| Stone number     |                |                |          |
| one stone        | 15 (46.9%)     | 14 (43.8%)     |          |
| two stones       | 7 (21.9%)      | 7 (21.9%)      | 0.96     |
| Multiple stones  | 10 (31.2%)     | 11 (34.4%)     |          |
| Laterality       |                |                |          |
| Right            | 18 (56.2%)     | 16 (50%)       |          |
| Left             | 12 (37.5%)     | 14 (43.8%)     | 0.873    |
| Bilateral        | 2 (6.2%)       | 2 (6.2%)       |          |

The numbers of stones were equally distributed in both of the group as shown in the table 04 with no significant p value. There was predominance of right sided stone in both of the above group with no significant p value (p = 0.96). Two (6.2%) cases were operated bilaterally in each group as shown in the table 04.

Minor perforation of collecting system was defined as laceration of the collecting system with no through to through perforation while major perforation was defined as perforation with obvious fluid leakage in the extraperitoneal cavity.

There were no perforations of collecting system in 28 (87.5%) cases in group A and 16 (50%) in group B respectively. Minor perforations were noted in 4 (12.5%) and 16 (50%) cases in group A and Group B respectively. There was significant p value (p = 0.001).

### Table 5: Distribution of cases by perforation of collecting system, post operative nephrostomy leakage, hematuria and complications.

| Variable                               | Tubeless       | Tubed          | P value |
|----------------------------------------|----------------|----------------|---------|
| Perforation of collecting system       |                |                |         |
| No                                     | 28 (87.5%)     | 16 (50%)       | 0.001   |
| Minor                                  | 4 (12.5%)      | 16 (50%)       |         |
| Post operative nephrostomy leakage     |                |                |         |
| No                                     | 30 (93.8%)     | 16 (50%)       |         |
| Minor                                  | 2 (6.2%)       | 27 (75%)       |         |
Post operative complications

|                      | Tubeless | Tubed | P value |
|----------------------|----------|-------|---------|
| No                   | 31 (96.9%) | 23 (71.9%) | 0.053   |
| Fever                | 1 (3.1%)  | 7 (21.9%)   |         |
| Others               | 0        | 1 (3.1%)    |         |

There were no nephrostomy leakage in 30 (93.8%) and 10 (31.2%) cases in group A and group B respectively. Two (6.2%) cases had leakage in tubeless group and 22 (68.8%) in tubed group with significant p value (p = 0.001) as shown in table 5.

Similarly post operative minor haematuria were seen in 16 (50%) and 27 (84.4%) cases in group A and group B respectively with significant p value (p = 0.003).

In group A no complications were noted in 31 (96.9%) cases and 1 (3.1%) had post operative pyrexia. In group B 23 (71.9%) had no complications and 7 (21.9%) had fever and 1 (3.1%) had urinary tract infections which resolve with the minor treatment. The p value was 0.053 as shown in the table 5.

Table 6: Distribution of cases by Stone free rate, success rate and re-operation

| Variable                      | Tubeless | Tubed | P value |
|-------------------------------|----------|-------|---------|
| Stone free rate               |          |       |         |
| No Stones                     | 32 (100%)| 25 (78.1%) | 0.02    |
| < 4mm                         | 0        | 4 (12.5%) |         |
| > 4mm                         | 0        | 3 (9.4%) |         |
| Stone success rate            |          |       |         |
| Success                       | 32 (100%)| 29 (90.6%) | 0.238   |
| Not success                   | 0        | 3 (9.4%) |         |
| Re-operation                  |          |       |         |
| No                            | 32 (100%)| 29 (90.6%) | 0.238   |
| Yes                           | 0        | 3 (9.4%) |         |

Stone free rate was achieved in 100% cases in group A while 25 (78.1%) in group B with no stones at all. Insignificant stones less than 4 mm were seen in 4 (12.5%) cases in group B. Similarly, significant stones of more than 4 mm were seen in 3 (9.4%) cases. The p value was 0.02. Overall the stone success rate in group B was 90.6% and 100% in group A. But there was no significant p value (p = 0.238).

Three (9.4%) cases were re-operated in group B cases for the significant stones with no significant p value (p = 0.238) as shown in the table 6.

Table 7: Distribution of cases by follow-up complications and removal of Foley’s catheter

| Variable            | Tubeless | Tubed | P value |
|---------------------|----------|-------|---------|
| Follow-up complications |          |       |         |
| No                  | 30 (93.8%)| 29 (87.5%) | 0.53    |
| Yes                 | 2 (6.2%) | 3 (9.4%) |         |
Removal of Foley's catheter (days) | 1.38 ±0.70 | 2.28 ± 0.99 | <0.001

There were no complications in 30 (93.8%) cases in group A and 29 (87.5%) cases during the follow up. Minor complications were seen in 2 (6.2%) cases and 3 (9.4%) in group A and group B cases respectively with no significant p value (p = 0.53) as shown in the table 7.

Mean removal of Foley’s catheter was 1.38 days with standard deviation of 0.70 days in group A and 2.28 days with standard deviation of 0.99 days in group B. There was significant p value association (p = 0.001) as shown in the table 7.

DISCUSSION

Percutaneous nephrolithotomy (PCNL) is considered the most effective treatment and recent modality for large renal calculi. This technique was first used in 1976. PCNL success rate has progressively increased because of the advancement in endoscopic equipments and techniques. The PCNL has the advantages of higher stone clearance and cost effectiveness when compared with other treatment modalities, such as ESWL and open stone removal techniques. Although open surgery has a role in selected cases, apparently PCNL decreases morbidity rates as compared with open surgery. Placement of nephrostomy tube after PCNL is considered the standard procedure. Traditionally a large bore 20-24 Fr nephrostomy tube is used. The advantages of postoperative nephrostomy tube are tamponading bleeding, aiding in renal drainage, preventing urinary extravasation, and offering access for redo-PCNL. However, in recent years, with a growing realization of significant post-PCNL pain and morbidity because of nephrostomy tubes, attempts have been made to modify conventional PCNL(1). To reduce discomfort and tube related morbidity different modifications have been made, like the small sized nephrostomy tube of 10-12 Fr or complete avoiding of tube placement in selected cases.

In 1984, Wickham et al. first published the results of 100 patients who underwent PCNL in whom no ureteral catheter, no stent or no nephrostomy tubes were used. They concluded that, this approach was safe and efficient with shorter hospital stay (<24 hours).

In 1997, Bellman et al. reported the results of 20 patients with small stone burdens who underwent tubeless PCNL. The authors stated that this technique was uncomplicated and had the advantages of less hospitalization time and decreased analgesic requirements.

As firstly described by Wickham et al., another technical variation of tubeless PCNL is totally tubeless approach. They concluded that if the operated kidney was stone free, collecting system was intact and there wasn’t any excessive bleeding, there was no need for nephrostomy drainage. However, in 1986, Winfield et al. published the complications of 2 patients who had undergone a PCNL operation for simple upper tract calculi and early nephrostomy tube removal. They experienced serious hemorrhage and urinary extravasation, urinoma requiring internal stenting, transfusion and prolonged hospitalization. This study was a cornerstone for the consideration of nephrostomy tube drainage should be provided during the first 24 to 48 hours after PCNL.

Today, there are few successful reports of totally tubeless PCNL. They mentioned that the hospitalization time, return to normal activities and analgesia requirements were significantly less in totally tubeless group, when compared with conventional PCNLs.

This approach was applied by Aghamir et al. for patients having renal anomalies like horseshoe kidneys, rotational anomalies and ectopic kidneys. The differences between tubeless and standard PCNL groups in terms of operation time, transfusion rates, complications, retreatment and overall stone free rate were not statistically significant. The hospitalization time, return to normal activities and analgesia requirements
were statistically lower in totally tubeless group.

In a recent study, same group assessed the outcome and safety of the totally tubeless PCNL in patients with renal stones in the upper pole of the kidney and subcostal access. Seventy patients with upper pole renal stones were enrolled in this study. Stone sizes were over 1.5 cm. All the stones were extracted through successful subcostal accesses. They stated that totally tubeless PCNL for the upper pole renal stone via subcostal access was accompanied by decreased hospital stay and analgesics use and a rapid return to normal activity.

These studies suggested that the best drainage of the kidney is when there is normal peristalsis of the ureter. However, this approach has not been accepted worldwide, due to obstruction chance of the ureter with stone fragments or blood clots after stone extraction. Most centers prefer some kind of internal drainage after tubeless procedures.

The modern approach is to make the PCNL a day surgery procedure which would be more convenient and more cost-effective for the patients without compromising safety and efficacy. Husain studied 90 patients by distributing in to three groups;

(i) conventional PCNL with large bore tube,
(ii) with small bore nephrostomy tube and
(iii) tubeless PCNL.

In conventional PCNL duration of hospital stay was 4 to 7 days with mean 5.7 ± 0.75 days, while in tubeless PCNL hospital stay period was reduced to 1 to 4 days with mean post operative hospital stay 3.17 ± 0.75 days. This resembles with my study.

In my study hospital stay was significantly lower in tubeless group and as per prior studies it is believed that the nephrostomy tube reduces the bleeding but in my study it seems contradictory. Both blood transfusion rate and post operative hematuria are more in tubed PCNL group. But a larger sample is advised to come to definite conclusion.

CONCLUSION

Tubeless PCNL is an effective and safe procedure for treatment of renal stones in selected cases. This procedure can even be chosen for patients with previous renal surgery, supracostal approach, multiple tracts, staghorn calculi and upper pole stones. By using this method, shorter hospital stay and less blood transfusion rate can be achieved, when compared with conventional PCNL. I think that these results should encourage urologists for opting tubeless PCNL. In the future, tubeless approach may be more palatable to patients than standard PCNL in terms of less hospital stay, lower analgetics requirement, less operative time, less post operative complications and less blood transfusion rate.

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