Comparing Totally Tubeless and Tubeless Percutaneous Nephrolithotomy with Standard Techniques

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Traditionally, percutaneous nephrolithotomy (PCNL) includes placing a nephrostomy tube and a Double J (DJ) stent to drain the kidney and operative tract following the procedure. However, more recent techniques, such as tubeless or totally tubeless PCNL, eliminate these drainage methods. The objective was to assess the feasibility, safety and effectiveness of performing tubeless or totally tubeless PCNL in comparison to standard PCNL a retrospective analysis was performed on 156 patients who underwent PCNL treatment From September 2022 to September 2023. Of these, 78 patients received traditional nephrostomy PCNL, while 46 patients underwent the tubeless procedure and the remaining 32 received the totally tubeless procedure. The three groups showed no significant differences in preoperative patient characteristics. The operation time, analgesic requirements and hospital stay were lower in the tubeless and totally tubeless PCNL group than in the standard PCNL group ($p<0.05$). No significant differences were found in the mean stone size, stone-free status or the occurrence of major complications. The overall complications (Grade-1, 2 and 3) rate was 14.2% in the standard PCNL group, 8.7% in the tubeless PCNL and 9.4% in the totally tubeless PCNL group. The tubeless and totally tubeless PCNL techniques have proven to be safe and effective, even for patients with incomplete staghorn stones and a moderate pelvic stone burden. These approaches are associated with reduced pain, lower analgesic needs, shorter operative times, and decreased hospital stays, making them more cost- effective and less likely to result in complications, while also improving patient satisfaction. Further research is essential to validate the safety of these techniques, encouraging urologists to adopt them in clinical practice.

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Key words: Percutaneous nephrolithotomy, Tubeless PCNL, Totally tubeless PCNL, Standard PCNL

Introduction

Kidney stones, a prevalent ailment impacting at least 10.0% of individuals, often lead to recurrent occurrences in 70% of affected individuals[1]. Diverse treatment methods, encompassing medicinal approaches, extracorporeal shock wave lithotripsy (ESWL), minimally invasive surgeries including laparoscopic and percutaneous nephrolithotomy (PCNL) and open renal stone surgeries have been explored. Over the past three decades, PCNL has proven to be an efficacious minimally invasive surgery, particularly for larger kidney stones and upper ureter stones. Notably more effective than ESWL for stones over 2 cm[1]. PCNL is now employed for various conditions, including anomalous kidneys, ectopic pelvic kidneys, horseshoe kidneys, malrotated kidneys, as well as in pediatric and morbidly obese patients. Its applications extend to calyceal diverticular calculi, upper calyceal calculi with infundibular stenosis and lower calyx stones of 10 mm or more[2,3,4,5]. In 1986, Winfield's report spurred a urologic community movement towards incorporating nephrostomy drainage into percutaneous stone treatment. This "standard" has been widely embraced, becoming a routine aspect of urologic training, with most urologists now endorsing and reinforcing the idea that percutaneous drainage post-PCNL is essential[6,7].

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Standard PCNL procedure involves four key steps: kidney access, tract dilatation, nephroscopy with stone fragmentation and stone extraction and nephrostomy tube with DJ stent insertion. In 1986, Dickinson et al. first proposed the concept of tubeless PCNL to eliminate the side effects of the nephrostomy tube[3]. Traditionally, nephrostomy catheters were used until 1997, after which tubeless PCNL emerged to reduce complications[8,9]. This tubeless PCNL technique, omitting the nephrostomy tube insertion, has demonstrated benefits in pain reduction and quicker resumption of normal activities[8,9]. A contemporary modification in PCNL is the introduction of totally tubeless PCNL, where neither a nephrostomy tube, nor a double J stent or a ureteral catheter is inserted after procedure[10,11,12,13]. It is believed that a normal peristaltic ureter is the best drainage tube[14]. Addressing concerns like dysuria and pollakiuria associated with stents or ureteral catheters[10], this study investigates whether simultaneous avoiding the insertion of nephrostomy and DJ stents/ ureteral catheters can diminish pain, reduce postoperative complications and shorten hospitalization.

Methods

From September 2022 to September 2023, we conducted a retrospective analysis on 156 patients who underwent PCNL at Mymensingh Medical College Hospital and several Private Hospitals. After obtaining the ethical clearance from the Institutional Review Board of MMC, Bangladesh the study enrolled patients with stone size <5cm, complete stone clearance or clinically insignificant residual fragments (CIRFs) and without significant bleeding or collecting system tear. CIRFs are those residual calculi which are <4 mm in size, asymptomatic, non obstructive and non infectious[15]. Exclusions comprised individuals with a single kidney, two or more accesses, supra costal access, complete staghorn stones, kidneys with congenital anomalies, or patients with urosepsis. Before surgery, the kidney anatomy and renal stone configuration were assessed through preoperative radiology and Imaging evaluations, including ultrasonography, intravenous pyelography (IVP) and non-contrast computed tomography scans. Patients either had a negative urine culture or received preoperative antibiotics based on organism sensitivity. The PCNL procedures were performed under Spinal anaesthesia (Subarachnoid block) with the patient in the prone position. Following ureteric catheterization, access to the target calyx was established under fluoroscopic guidance. After tract dilation and nephroscopic evaluation, a pneumatic lithotripter was employed for stone fragmentation followed by stone extraction. Stone-free status and any clinically significant residual fragments more than 4 mm (cf.CIRFs) were assessed through endoscopic and fluoroscopic evaluations. Operating surgeons took absolute decisions whether the procedure would be standard or tubeless or totally tubeless PCNL based on peroperative events to ensure postoperative utmost safety of the patients. The incision site of the PCNL tract was not closed when tubeless or totally tubeless PCNL was performed, to allow the drainage of fluid and avoid postoperative fever. Patients were categorized into three groups: standard PCNL group (n=78) involved the insertion of a nephrostomy (Fr 24) and retention of a double J stent for at least 7 days. Tubeless PCNL group (n=46) featured no nephrostomy insertion, but a double J ureteral stent was utilized and remained in place for more than 7 days post-procedure. In Totally Tubeless PCNL group (n=32), neither a nephrostomy nor a double J ureteral stent was utilized or the ureteral catheter was removed immediate after or within twelve hours (modified totally tubeless) following completion of PCNL. Modified totally tubeless PCNLs (n=5) were incorporated as totally tubeless PCNL. The mean operative time, intraoperative blood loss, visual analog score for pain, analgesic requirements, postoperative hospital stay in days and perioperative complications as Modified Clavien Grading System for complications were all evaluated. Hematocrit levels were monitored twelve hours post-surgery and subsequently on a daily basis. Intramuscular pethidine HCL on demand was administered for postoperative analgesia. Patient evaluations included kidney ureter bladder (KUB) films and ultrasonography. Those with significant residual fragments were directed to additional procedures such as shock wave lithotripsy (SWL) or ureteroscopy. The decision to remove the nephrostomy in the standard group relied on post operative

radiography, ultrasonography and urine color assessment. Statistical analyses were performed using IBM SPSS Statistics version 22.0 (Armonk, NY, USA), with a significance level set at $p<0.05$ for all tests.

Results

The patients' demographic characteristics among the three study groups are outlined in Tables I. It illustrates both quantitative and qualitative variables. The three groups were compared based on independent variables. The comparison of independent variables among the groups was conducted using ANOVA and sex which is Qualitative data analyzed using Chi-square test for independence. Several variables emerged as statistically significant, indicating notable differences among the three study groups. These significant variables include stone size (p=0.29), anesthesia time (p=0.013), the incidence of blood transfusion (p=0.0138) pain scores (p<0.001), analgesic consumption (p=0.028), and hospital stay durations (p<0.001). The average duration of anesthesia was 154 minutes in the standard group, 141 minutes in the tubeless group and 115 minutes in the totally tubeless group. The standard PCNL group had the longest duration of anesthesia. On the other hand, certain variables did not reach statistical significance in comparison among the three groups. Age (p=0.396), sex distribution (p=0.239), creatinine change (p=0.97), hemoglobin change (p=0.063) were identified as non-significant variables.

Table I: Patients characteristics, quantitative and qualitative variables

Variables	Groups			p value [a]
	Standard	Tubeless	Totally tubeless	
Age (Mean±SD)	47.73±10.56	46.68±12.75	44.53±13.64	0.396
Sex [n (%)]				
Male	50 (32.0)	26 (16.6)	15 (9.60)	0.239[b]
Female	28 (17.9)	20 (12.8)	17 (20.8)	
Stone size (cm) (Mean±SD)	3.13±1.27	2.87±0.78	2.74±0.59	0.29
Complete stone free [n (%)]	66 (84.6)	46 (100.0)	32 (100.0)	-
Clinically stone free [n (%)]	72 (92.3)	46 (100.0)	32 (100.0)	-
Anesthesia time (minute) [Mean±SD]	154±72.0	141±42.8	115±63.5l	0.013
Cr Change (Mean±SD)	0.35±2.72	0.23±2.17	0.14±1.51	0.97
Hb Change (Mean±SD)	1.91±1.23	1.58±1.44	1.46±0.82	0.063
Pain (VAS)[c] Mean±SD)	7.25±1.28	5.75±1.34	4.01±0.86	<0.001
Blood transfusion	16 (20.5)	05 (10.8)	00(00.0)	0.0138
Analgesic (mg) (Mean±SD)	80.76±59.13	50.65±19.97	52.99±97.99	0.028
Hospital stay (Mean±SD)	58.34±15.76	48.13±7.15	35.21±12.77	<0.001

[a]P value calculated by ANOVA test; [b] P value calculated by Chi-square test for independence ; [c] Visual Analog Score.

Frequency of complications induced in the three groups based on the scoring method is presented in Table II. Grade 3a and 3b complications were exclusive to the patient cohort with standard PCNL. Grade 4a, 4b & Grade 5 complications were not observed among the three groups.

Table II: Frequency of Complications in Three Groups [a]

Complications [b]	Groups		
	Standard	Tubeless	Totally tubeless
No Complication	67 (85.8)	42 (91.3)	29 (90.6)
Grade 1			
Fever (>38ºC)	5 (6.4)	1 (02.1)	2 (06.2)
Transient elevation of SCr (>0.5 mg/dl)	1 (1.2)	0 (00.0)	1 (03.1)
Grade 2			
Blood transfusion	16 (20.5)	5 (10.8)	0 (00.0)
Urine leakage <24 hours	00 (00.0)	1 (02.1)	1 (03.1)
Infections requiring additional antibiotics			
Wound infection	02 (02.5)	0 (00.0)	0 (00.0)
Urinary tract infection	02 (02.5)	0 (00.0)	0 (00.0)
Pneumonia	0 (00.0)	0 (00.0)	0 (00.0)
Grade 3a			
Renal hemorrhage requiring angioembolization	-	-	-
Postoperative DJ stent placement for urine leakage	1 (1.2)	0 (00.0)	0 (00.0)
Hemo/pneumothorax requiring chest tube insertion	-	-	-
Retention due to blood clots	-	-	-
Grade 3b			
Ureteric calculus	2 (2.5)	0 (00.0)	0 (00.0)
Collecting system perforation	-	-	-
Infundibular stricture	-	-	-
Urethral stricture	-	-	-
Retained PCN tube requiring removal	-	-	-
Perinephric abscess	-	-	-
Grade 4a			
Neighbouring organ injury	-		-
Myocardial infarction	-	-	-
Acute renal failure	-	-	-
Grade 4b			
Sepsis	-	-	-
Grade 5			
Death	-	-	-

[a]Values expressed as n (%); [b]Grading according to Clavian grading system (partial)

Grade 1 and 2 complications are approximately 1.51 times and 4.12 times higher, respectively, in patients undergoing Standard PCNL compared to those undergoing Tubeless PCNL (Table III). Additionally, both associations are statistically highly significant ($p<0.001$). When comparing Standard PCNL to Totally Tubeless PCNL (Table IV), the odds of Grade 2 complications are approximately 3.76 times higher and this association is also statistically significant ($p<0.001$). However, the odds of Grade 1.

Table III: Comparison of complications between standard PCNL and tubeless PCNL as stratified by the modified Clavien system

Grade[a]	Total (N=156)	Standard PCNL (n=78)	Tubeless PCNL (n=46)	Odd ratio	CI	p value
		n (%)	n (%)			
1	10 (06.4)	06 (03.8)	3 (09.3)	1.51	(2.25, 3.56)	<0.001
2	27 (17.3)	20 (25.6)	01 (03.1)	4.12	(2.21, 8.63)	<0.001
3a	01 (00.6)	01 (01.2)	00 (00.0)	0	-	-
3b	02 (01.2)	02 (02.5)	00 (00.0)	0	-	-

[a]Grade 4a, 4b and 5 complications were not observed.

Complications are about 0.82 times (negative association) higher in patients undergoing Standard PCNL compared to Totally Tubeless PCNL and this difference is not statistically significant (p = 0.07).

Table IV: Comparison of complications between standard PCNL and totally tubeless PCNL as stratified by the modified Clavien system

Grade [a]	Total (N=156)	Standard PCNL (n=78)	Tottaly tubeless PCNL (n=32)	Odd ratio	CI	p value
		n (%)	n (%)			
1	10 (06.4)	06 (03.8)	2 (09.0)	0.82	(0.61, 0.95)	0.07
2	27 (17.3)	20 (25.6)	1 (04.5)	3.76	(2.04, 6.56)	<0.001
3a	01 (00.6)	01 (01.2)	0 (00.0)	0	-	-
3b	02 (01.2)	02 (02.5)	0 (00.0)	0	-	-

[a]Grade 4a, 4b and 5 complications were not observed

Grade 3a and 3b complications were exclusive to the patient cohort with standard PCNL, so the odds of Grade 3 were undefined. Grade 4a, 4b and Grade 5 complications were not observed among the three groups.

Table V: Univariate analysis of predictors of complications

Variables	n	Complications		p value
		Yes	No	
Gender (Male)	91	13	78	0.54
Age (>50 years)	27	07	20	0.78
Hypertension	37	10	27	0.07
Diabetes	22	09	13	0.05
Anesthesia time (> 120 min)	89	13	76	0.02
Standard PCNL	78	29	49	0.69
Tubeless PCNL	46	07	39	1.05
Totally tubeless PCNL	20	04	16	1.53

Table V illustrates a univariate analysis examining different factors influencing complications following PCNL. The results suggest a significant association between an increased complication rate after PCNL with diabetes patients as well as anesthesia time exceeding 120 minutes. However, no significant correlations were found between complications and factors such as gender; age over 50 years, hypertension, or various PCNL procedures.

Discussion

Performing PCNL is complex and may be subjected to change during the procedure. Despite preoperative plans for tubeless/ totally tubeless PCNL, it's implementation is not guaranteed. Ensuring postoperative safety depends on crucial intraoperative decisions. Operating surgeons took absolute decisions whether the procedure would be standard/ tubeless/ totally tubeless PCNL based on several peroperative events: i) Accuracy of calyx dome puncture, establishing a central-axis working channel for minimal postoperative bleeding risk[16], ii) stone clearance status[17], iii) Assess collecting system integrity[18,19], though recent findings support tubeless or totally tubeless PCNL after minor injury or tear[20], iv) Rule out ureteral stenosis, particularly UPJO to prevent postoperative and its consequences and v) heck for excessive bleeding around the working channel, employing a security guide wire and ureteroscopic guidance as necessary. Disintegrate the alignment of PCNL tract by gentle massage and body twisting along with manual compression by at least 5 minutes over tract incision site was mandatory employed in tubeless or totally tubeless PCNL. In this study, there were no significant differences among the three techniques regarding the patients' age, gender, stone size, mean change in hemoglobin, and mean change in creatinine levels. No significant differences in blood transfusion between totally tubeless PCNL and standard PCNL were found other studies[10,11], deferred from this study. Creatinine levels were not influenced by the nephrostomy tube or stent, indicating stable renal function regardless of the drainage technique. Stone-free status for each patient only reflected whether stones were visible on radiographic imaging postoperatively. In Our study, complete stone free rate & Clinically stone free rate were 84.6% and 92.3% comparable stone clearance rate with other studies[7,21]. Length of hospital stay showed a statistical difference in this study, like other studies[22,23,24], differed from Joel E. Abbott et al. due to early discharge policy[7]. Nephrostomy tubes were usually clamped and removed at the bedside within 12 to 24 hours after the procedure. Ureteral stents were kept in situ until the first follow-up visit, which typically occurred 07 to 14 days after the procedure. Previous studies have used various analgesics. Aghamir et al.[25], Shah et al.[26] and Sofer et al.[27] used morphine, diclofenac and pethidine, respectively. N Moosanejad et al.[11], administered diclofenac and pethidine to thier patients. We used pathidine as analgesia, giving an initial dosage 1 mg/kg body weight immediate after completion of procedure at operation theater. Additional anagesic was given after 12 hours after assessing pain score (VAS). Need for analgesics in the totally tubeless and tubeless PCNL group were significantly lower compared with that in the standard PCNL group, which is in accordance with previous studies[10,28,29]. Several studies reported that patients who had surgery with the standard PCNL technique experienced worse pain and required more postoperative narcotic analgesic than patients treated with tubeless and totally tubeless techniques[14,30,31]. In this study, requirements of narcotic analgesic were significantly less than standard PCNL group. Recent reports suggest that tubeless PCNL could be implemented after a minor perforation in the collecting system[32]. There is no perforation of collecting system during procedure in this study. Importantly, there was no statistical difference among the complication profiles when comparing the three PCNL procedures. This indicates tubeless and totally tubeless PCNL can be performed safely and effectively in properly selected patients meeting selection criteria. Our movement toward reducing placement of nephrostomy tubes and internal drainage stents is to improve the patient's postoperative pain and discomfort as demonstrated by other studies[7,10,33]. Thus, by performing PCNL safely with the tubeless and totally tubeless techniques, we can achieve significantly improved cost effectiveness, patient pain profiles and seek to shorten length of hospital stay[7,10,24,26,29,34-37]. Following previous studies reported that hospital stays in tubeless and totally tubeless cases ranged from 0.9 to 3.2[38-44] and from 1.5 to 3.4 days[33,45] respectively and consistent with the result of present study. Only a few studies have reported on prolong hospital stay following tubeless[46,47] and totally tubeless PCNL[33,46,48], may be influenced by their hospital discharge policies. One of the most frequent complaints after PCNL procedures is urine leakage and the pain or discomfort caused by drainage tubes. Reducing the number of drainage tubes used at the end of PCNL can lower the pain levels experienced by patients[7,10]. This, in turn, could potentially shorten hospital stays and reduce the need for pain medication. The second Clinical

Research Office of the Endourological Society study group examined the incidence of urinary tract infection to 13.0% after 24 hours, dissimilar to current study's finding of 1.2%. Following the strict protocol for undergoing PCNL procedures, all patients either had a negative urine culture or received preoperative antibiotics based on organism sensitivity, may lead to lower down urinary tract infection rate. In contrast, Aditya K. Singh et al. observed fever in only 3.1% of cases[48] similar to current study's finding of 5.1%. This study results indicated that grade 2 complications were the most common after PCNL, with a blood transfusion rate of approximately 13.4%. This rate is significantly higher than the 4.0% reported by El-Assmy et al.[41,45] But Tefekli et al. and Aditya K. Singh et al. reported almost similar rates of 10.9% and 8.0% respectively[36,48]. In the standard PCNL group, Grade 3a complications (prolonged urinary leakage) and Grade 3b complications were 1.5 and 3.0 respectively, closely matching with 3.5% (Grade 3a) and almost similar to 3.5% (Grade 3b) of Aditya K. Singh's et al.[48] Grade 4a, 4b, and Grade 5 complications were not observed among the three groups in this study, possibly due to selection bias in choosing the operative procedures. In this study, it was found that patients who underwent Standard PCNL were about 3.5 times more likely to experience Grade 1 complications and 3.1 times more likely to experience Grade 2 complications compared to those who had Tubeless PCNL. Both of these findings were highly statistically significant. When comparing Standard PCNL to Totally Tubeless PCNL, the odds of Grade 2 complications are about 3.3 times higher, which is also statistically significant. However, the likelihood of Grade 1 complications is only slightly lower (0.82 times) in patients undergoing Standard PCNL compared to Totally Tubeless PCNL, and this difference is not statistically significant. We also conducted a univariate analysis on specific factors that seem to influence surgical outcomes, particularly in relation to complication rates. In this study, it was found that diabetes and anesthesia time (>120 minutes) associated with a significantly increased complication rate. Tefekli et al.[36] in their retrospective review concluded that diabetes mellitus and hypertension significantly increase the rate of complications after PCNL. In their study, Moreno-Palacios et al. identified female gender, complex kidney stones, and an operative time longer than 120 minutes as factors linked to severe complications[49]. Aditya K. Singh et al. found that only multiple surgical accesses and a positive preoperative urine culture were associated with a higher rate of complications following different PCNL procedures[48]. However, this study showed no significant correlations were found between complications and factors such as gender; age over 50 years, hypertension, or various PCNL procedures. However, a further prospective study with a larger sample size is required to investigate the effectiveness of these techniques. Limitations of the study include the known inherent flaws of a retrospective study. When evaluating the three drainage techniques individually, the power of the study is suboptimal primarily due to the sample size of totally tubeless patients (n=32) and tubeless patients (n=46). Selection of procedural biasness during operation, may have influence on outcomes, but statistically can't be proved regarding stone size, raise of creatinine level and fall of hemoglobin level postoperatively.

Conclusion

Therefore, performing tubeless and totally tubeless PCNL in appropriately selected patients is safe and effective, with demonstrable benefits in terms of operation time, patient morbidly and hospitalization duration over standard PCNL, thereby reducing treatment cost. Though a significant number of urologists still opt for standard PCNL, findings of this study and previous other studies may influence a shift in PCNL practices toward tubeless and totally tubeless PCNL.

It is essential to conduct prospective randomized control trials to affirm the safety of these approaches, which is crucial to influence a shift in PCNL practices.

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