Safety and Efficacy of Tubeless Percutaneous Nephrolithotomy: A Prospective Randomized Study

Mohamed Zewita [1*], Mahmoud M. Shalaby [2], Atef M. Abdlatif [2], M. Atef Abdalziz [2]

Abstract

Background: Urinary lithiasis, or kidney stone disease, is a common and longstanding health issue characterized by significant morbidity and recurrence. Despite advancements in treatment modalities, managing large or complex renal stones continues to pose challenges. The evolution of surgical techniques, such as percutaneous nephrolithotomy (PCNL), has significantly impacted the management of kidney stones. This study aims to evaluate the safety and efficacy of tubeless PCNL compared to conventional PCNL in patients with renal and upper ureteric stones. Methods: A prospective randomized study was conducted at the Urology and Nephrology University Hospital, Assiut University, Egypt, from September 2016 to September 2019. The study included 60 patients who met the inclusion criteria and were randomly assigned into two groups: Group 1 (conventional PCNL) and Group 2 (tubeless PCNL). Postoperative outcomes, including pain scores, fever, blood loss, urinary leakage, length of hospitalization, need for re-hospitalization, and stone-free rates, were evaluated. Statistical analyses were performed using SPSS version 20.0, with a p-value of less than 0.05 considered statistically significant. Results: A total of 60 patients were included in the final analysis, equally divided into two groups. There were no statistically significant differences between the groups regarding demographic data, stone characteristics, hemoglobin levels, creatinine levels, or blood loss. However, the duration of surgery was significantly longer in the tubeless group (Group 2) compared to the conventional group (Group 1) (P-value = 0.034). Both groups achieved comparable stone-free rates with no significant differences in postoperative complications. Conclusion: Tubeless PCNL is a safe and effective alternative to conventional PCNL for managing renal and ureteral stones, with comparable outcomes in terms of blood loss, creatinine, and hemoglobin levels. The main advantage of tubeless PCNL is the potential for reduced postoperative discomfort and quicker recovery, although it requires a longer operative time. These findings support the use of tubeless PCNL as a viable option in appropriately selected patients, with implications for improving patient outcomes and reducing healthcare costs associated with kidney stone management.

Keywords: Tubeless Percutaneous Nephrolithotomy (PCNL), Renal stones, Postoperative outcomes, Surgical techniques, Kidney stone management

Significance | This study showed the safety and efficacy of tubeless PCNL, showing it as a viable alternative with comparable outcomes to conventional methods.

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Introduction

Urinary lithiasis, commonly known as kidney stone disease, is a longstanding health issue associated with significant morbidity. The estimated prevalence of urinary lithiasis ranges from 2% to 3%, with a peak incidence observed between the third and fourth

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decades of life (Khan et al., 2016). Approximately 10% to 15% of cases require surgical intervention, and the recurrence rate can be as high as 50% without appropriate medical follow-up (Shin et al., 2018). The incidence of urinary lithiasis is notably higher in regions with low socio-economic status and in areas characterized by high temperatures and a warm climate, such as the Middle East (Shin et al., 2018). Globally, the prevalence of kidney stones is estimated to range between 1% and 15%, depending on geographic location, dietary habits, and genetic factors (Romero et al., 2010).

The primary objective in treating renal stones is to achieve maximum stone clearance while minimizing patient morbidity. The choice of treatment modality, including shockwave lithotripsy (SWL), percutaneous nephrolithotomy (PCNL), and retrograde intrarenal surgery (RIRS), depends on multiple factors such as stone size, location, composition, patient health status, and anatomical considerations (Srivastava & Chipde, 2013). The evolution of surgical techniques for treating renal stones has significantly progressed over the decades. Fernström and Johansson performed the first PCNL in 1976, which has since become the preferred procedure for managing large or complex renal calculi (Fernström & Johansson, 1976; Preminger et al., 2005).

Historically, the field of nephrology and urology has seen remarkable advancements. In 1941, Rupel and Brown performed the first nephroscopy using a rigid cystoscope inserted into the kidney during open surgery. Subsequently, in 1955, Willard Goodwin conducted the first antegrade nephrostogram by introducing a needle into the collecting system of a hydronephrotic kidney, leaving behind a nephrostomy tube to drain the kidney (Patel & Nakada, 2015). The milestones continued when, in 1978, Arthur Smith performed the first antegrade stent placement through a percutaneous nephrostomy in a patient with a reimplanted ureter (Patel & Nakada, 2015).

PCNL, a complex and major surgical intervention, necessitates meticulous patient preparation and comprehensive preoperative assessments to ensure optimal outcomes and minimize perioperative risks (Choong & Kumar, 2020). Patient preparation typically involves two principal components: a safety check conducted on the day of surgery by both the surgeon and anesthetist, and a thorough preoperative assessment designed to optimize patient readiness, thereby improving surgical outcomes and reducing perioperative complications (Choong & Kumar, 2020). A detailed medical history and physical examination are essential to validate the necessity of the procedure, accompanied by laboratory tests such as a complete blood count, renal profile, albumin levels, coagulation screen, and blood grouping. These assessments help identify any systemic issues and evaluate the patient's renal function status and the metabolic risk for future stone formation.

The growing understanding of the pathophysiology, risk factors, and advances in surgical techniques have significantly impacted the management of kidney stones. However, the recurrence of urinary lithiasis remains a significant challenge, highlighting the need for continued research and innovation in both surgical and medical management strategies (Romero et al., 2010; Shin et al., 2018; Choong & Kumar, 2020). Future directions include exploring minimally invasive techniques, optimizing patient selection for different treatment modalities, and understanding the molecular and genetic basis of stone formation to develop targeted preventive and therapeutic strategies (Rodgers et al., 2020; Sorokin et al., 2017; Pearle et al., 2014).

Materials and Methods

This prospective randomized study was conducted to assess the safety and efficacy of tubeless percutaneous nephrolithotomy (PNL) in patients treated at the Urology and Nephrology Hospital, Assiut University, Assiut, Egypt. The study evaluated postoperative outcomes, including pain scores, fever, blood loss, urinary leakage, length of hospitalization, need for re-hospitalization, and stone-free rates. The study was carried out over three years, from September 2016 to September 2019, and involved a total of 60 patients.

Ethical Considerations

This prospective randomized study was conducted following the ethical standards set forth by the Declaration of Helsinki and was approved by the Ethics Committee of the Urology and Nephrology Hospital at Assiut University, Assiut, Egypt. The study aimed to assess the safety and efficacy of tubeless percutaneous nephrolithotomy (PNL) in patients, evaluating key postoperative outcomes such as pain scores, fever, blood loss, urinary leakage, length of hospitalization, need for re-hospitalization, and stone-free rates.

All participants were provided with detailed information regarding the study's purpose, procedures, potential risks, and benefits. Informed consent was obtained from all patients prior to their enrollment in the study. The confidentiality and anonymity of the participants were strictly maintained throughout the study period, with patient data securely stored and accessible only to the research team. The study ensured that patients received the standard of care irrespective of their participation, and any adverse events were promptly reported and managed according to institutional protocols.

The study adhered to rigorous standards to minimize potential harm and discomfort to the patients, with all interventions performed by qualified professionals. An independent monitoring committee reviewed the study's progress to ensure patient safety and scientific integrity. Furthermore, participants were free to withdraw from the study at any time without any negative impact on their subsequent medical care.

By implementing these ethical safeguards, the study ensured that the rights, dignity, and well-being of all participants were prioritized, and that the research findings would contribute meaningfully to the advancement of medical knowledge and patient care in the field of urology.

Study Type and Target Population

This is a prospective, randomized, self-controlled hospital-based clinical study. The study population consisted of 60 patients treated at the Urology and Nephrology University Hospital, Assiut University. Patients were recruited from September 2016 to September 2019. The inclusion criteria for patient selection included individuals aged 18 years or older who presented with obstructing renal or upper ureteric stones larger than 2 cm, lower calyceal stones greater than 1 cm, or failure of shockwave lithotripsy. Patients of any body mass index (BMI) were included in the study.

Postoperative Care and Follow-Up

On the day of surgery, all patients were closely monitored for vital signs, including blood pressure, pulse, temperature, and urine output. The color and volume of urine in the catheter were observed to detect any abnormalities, and the abdomen was assessed for laxity and the passage of flatus to monitor gastrointestinal function. In cases where there were suspicious conditions or a lengthy operative time, abdominal ultrasonography was performed to rule out any intra-abdominal collections.

Patients were divided into two groups for postoperative care. For Group A, the nephrostomy tube was opened, and close monitoring was performed. Abdominal ultrasonography was conducted to detect any residual stones. A complete blood count was obtained, with a particular focus on hemoglobin levels and serum creatinine to assess kidney function and detect any possible complications. In Group B, the ureteral catheter was removed if no urinary leakage or hematuria was observed. Similar to Group A, abdominal ultrasonography was performed to check for residual stones, and a complete blood count was conducted with an emphasis on hemoglobin levels and serum creatinine.

For patients in Group A, the nephrostomy tube was removed if no residual stones were detected and there was no need for a second procedure. However, the ureteral catheter was retained. Patients in Group B were discharged if no complications were reported, with instructions for follow-up after two weeks.

In Group A, the ureteric and urethral catheters were removed. Clinical observations were conducted to monitor for signs of urinary leakage, loin pain, and body temperature. Provided no complications were detected, these patients were discharged the following day.

At the time of discharge, several parameters were recorded for all patients to ensure comprehensive postoperative assessment. These included a complete blood picture, both pre- and post-operatively, and serum creatinine levels to evaluate renal function. Pain scores and the total dose of analgesics were also documented. Pain was assessed using the Numerical Rating Pain Scale (NRS), which is a simple and widely used tool ranging from 0 to 10, where 0 indicates no pain and 10 represents the worst pain imaginable. This scale was chosen for its simplicity and applicability to a broad range of patients, including children as young as five years old (Iohom, 2006). Additionally, any postoperative urine leakage, fever, and blood loss were recorded. The stone-free status of the patients was determined using imaging studies to confirm the effectiveness of the procedure.

Statistical Analysis

All statistical analyses were performed using SPSS (Statistical Package for the Social Sciences) version 20.0. A p-value of less than 0.05 was considered statistically significant. The Mann-Whitney U test was employed to compare non-normally distributed numeric samples. The Student's t-test was used for comparing continuous variables, while the Chi-square test and Fisher's exact test were applied for comparing categorical variables.

Results

This prospective study was conducted at the Urology and Nephrology University Hospital, Assiut University, Egypt, between September 2016 and September 2019, initially involving 84 patients who were randomly assigned into two groups of 42 patients each. However, several exclusions occurred due to intraoperative complications or loss to follow-up, resulting in a final cohort of 60 patients, with 30 patients in each group.

Patient Allocation and Exclusions

In Group A, three patients were excluded due to intraoperative bleeding, two had pelvicalyceal system (PCS) perforations, two had anomalous kidneys, and four failed to complete follow-up. Similarly, in Group B, two patients were excluded due to intraoperative bleeding, one had a PCS perforation, three had anomalous kidneys, and six failed to complete follow-up. This left a total of 60 patients equally divided into two groups: Group 1: Conventional percutaneous nephrolithotomy (PCNL) and Group 2: Tubeless PCNL

Baseline Characteristics

As presented in Table 1, there were no statistically significant differences in the demographic data between the two groups. Both groups were comparable in terms of age, gender, body mass index (BMI), and stone characteristics (location, number, and burden). Table 2 further confirms that there were no statistically significant differences between the groups regarding the side of the stones, number of stones, or stone burden (P-value > 0.05).

Perioperative and Postoperative Outcomes

The study showed no statistically significant differences between the two groups in the change of hemoglobin levels pre- and post-

Table 1. Demographic data

Personal data	Conventional n= 30		Tubeless n=30		P-value
	No.	%	No.	%	
Sex:					
Male	24	80.0%	27	90.0%	
Female	6	20.0%	3	10.0%	
Age: (years)					
Mean ± SD	38.70 ± 12.84		44.97 ± 13.23		
Range	20.0-60.0		18.0-65.0		
Weight:					
Mean ± SD	77.83 ± 12.65		77.37 ± 13.73		
Range	55.0-110.0		55.0-110.0		

Table 2. Stone criteria

Clinical data	Conventional n= 30		Tubeless n=30		P-value
Side					
	13	43.3%	15	50.0%	0.605
Left	17	56.7%	15	50%	
No. of stones:					
Single	15	50.0%	14	46.7%	0.796
Multiple	15	50.0%	16	53.3%	
Stone burden					
Mean ± SD		580 ± 162		512 ± 135	0.085
Range		300-900		250-836	

Table 3. Pre and post-operative Hemoglobin level change

	Conventional n=30	Tubeless n=30	P-value
Pre-operative:			
Mean SD	12.98 ±1.10	13.25±1.55	0.40
Range	11.0-15.4	11.3-16.7	
Post-operative:			
Mean SD	11.07±1.21	11.45±1.26	0.239
Range	8.5-13.8	10.0-14.3	

Table 4. Creatinine level

Creatinine level	Conventional n=30	Tubeless n=30	P-value
Pre-operative:			
Mean ± SD	1.05 ± 0.27	1.09 ± 0.16	0.485
Range	0.6-2.3	0.9-1.8	
Post-operative:			
Mean ± SD	1.07 ± 0.35	1.01 ± 0.16	0.395
Range	0.6-2.7	0.6-14	
P-value2	0.693	0.082	

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Table 5. Average blood loss.

ABL(ml)	Conventional n= 30	Tubeless n=30	P value
Mean ±SD	837.47 ± 323.49	761.17 ± 239.92	0.501
Median (Range)	764.5 (287.0-1632.0)	748.0 (366.0-1313.0)	

ABL= [EBV x (Hi-HD]/Hi

EBV calculation: body wt (kg) x average blood volume (ml/kg Where:

EBV=Estimated Blood Volume Hi= initial hemoglobin

Hf= final hemoglobin Average blood volumes Adult Men 75 mL/kg Adult Women 65 mL/kg

Table 6. Intra-operative data

Intra-operative data	Conventional n= 30		Tubeless n=30		P-value
Duration of surgery: (min)					
Mean ± SD	120.50 ± 18.26		133.17 ± 26.21		
Range	90.0-165.0		60.0-180.0		
No. of tract	No.	%	No.	%	
One	25	83.3%	29	96.7%	
Two	5	16.7%	1	3.3%	
Access:					
Sub-costal	28	93.3%	29	96.7%	
Supra-costal	2	6.7%	1	3.3%	

procedure (Table 3) or creatinine levels pre- and post-procedure (Table 4). Similarly, there was no significant difference in average blood loss between the groups (Table 5). However, the duration of surgery was significantly longer in the tubeless group (Group 2) compared to the conventional group (Group 1) (P-value = 0.034) as shown in Table 6. No significant differences were found between the groups concerning the number of tracts or the type of access required.

Surgical Technique

Renal access was performed in the operating room for all patients under general anesthesia, using a standardized technique. The procedure included prone positioning, fluoroscopic guidance, cystoscopy, ureteral catheter insertion, retrograde pyelography, renal puncture, and tract dilation with balloon dilators. A 30-Fr access sheath was inserted, followed by rigid nephroscopy (26F), pneumatic disintegration, and forceps extraction of the stone fragments. A flexible ureteroscope was utilized for stones unreachable by the rigid nephroscope. When necessary, additional access was created following the same principles.

At the conclusion of the procedure, patients were randomly assigned to either receive a nephrostomy tube or undergo closure of the tract without tube placement.

This study demonstrated that both conventional and tubeless PCNL are effective and safe techniques for managing renal and ureteral stones, with comparable outcomes in terms of blood loss, creatinine, and hemoglobin levels. The only significant difference noted was a longer duration of surgery in the tubeless group. These findings suggest that tubeless PCNL can be a viable alternative to conventional PCNL, offering the potential for reduced postoperative discomfort and quicker recovery, without compromising the safety or effectiveness of the procedure.

Discussion

Percutaneous nephrolithotomy (PCNL) is now considered the standard procedure for managing large renal stones (Stables et al., 1978). Since its inception, numerous efforts have been made to refine the technique, with the primary goals of minimizing trauma to the kidney and percutaneous tract and reducing postoperative morbidity and hospital stay. Traditionally, drainage after PCNL has been recommended through the use of a nephrostomy tube for several reasons. These include providing adequate drainage of the pelvicalyceal system (PCS), acting as a tamponade to the fresh percutaneous renal tract, and maintaining access to the renal collecting system should a secondary percutaneous procedure be needed. However, despite these benefits, nephrostomy tubes have been associated with increased postoperative pain and morbidity, particularly when positioned near the ribs (Lojanapiwat et al., 2004).

To improve PCNL outcomes, modifications such as reducing the nephrostomy tube's caliber or eliminating its use altogether have been explored. Kader et al. (2004) reported that the use of a small-diameter nephrostomy tube after PCNL could shorten hospitalization and reduce analgesic requirements, without affecting changes in hemoglobin levels compared to larger-diameter tubes. Bellman et al. (1997) further suggested that placing a nephrostomy tube at the end of a PCNL procedure may not be necessary. In their study of 50 patients, replacing the nephrostomy tube with a double-J stent significantly reduced hospital stay, analgesic requirements, cost, and time to return to normal activities, concluding that tubeless PCNL is a safe procedure with several advantages over the standard nephrostomy tube placement. Consequently, tubeless PCNL has gained popularity in many centers.

In our study, there were no significant differences between the two groups concerning patient age, gender, and body mass index (BMI). This finding aligns with the results reported by Istanbulluoglu et al. (2009), who found no significant differences in stone size, hemoglobin levels, or blood transfusion rates between totally tubeless PCNL and standard PCNL. Similarly, Ibrahim et al. (2017) indicated that patient gender, stone characteristics (configuration, location, and burden), prior renal surgery, and surgical position did not significantly impact PCNL outcomes.

Additionally, Crook et al. (2008) conducted a randomized study involving 50 patients with renal stones, comparing standard PCNL and totally tubeless PCNL. They reported no significant differences between the two groups regarding hemorrhage, infection, or blood transfusion, although the hospitalization time was notably shorter in the totally tubeless PCNL group.

In our study, we blindly randomized 60 patients into two groups: Group 1 underwent standard PCNL with nephrostomy tube drainage and a ureteric catheter fixed to an external urethral catheter, while Group 2 underwent tubeless PCNL, which involved no nephrostomy tube but included a ureteric catheter fixed to an external urethral catheter. The two groups were then compared in terms of blood loss, urinary leakage, need for re-hospitalization, stone-free rates, and changes in creatinine and hemoglobin levels pre- and post-operatively.

The study found no significant differences in postoperative hemoglobin levels, creatinine levels, or blood loss between tubeless and standard percutaneous nephrolithotomy (PCNL) for the treatment of renal and upper ureteral stones, highlighting the potential of tubeless PCNL as a viable option. However, the standard PCNL procedure with a nephrostomy tube should be employed in cases where there is intraoperative uncertainty regarding residual stones, intraoperative hemorrhage, perforation of the pelvicalyceal system (PCS), or suspected complications such as organ injury or hydrothorax.

Conclusion

The study demonstrates that both conventional and tubeless percutaneous nephrolithotomy (PCNL) are effective and safe for managing renal and ureteral stones, with comparable outcomes in terms of blood loss, serum creatinine, and hemoglobin levels. Although the tubeless PCNL group experienced a longer surgical duration, this approach offers potential advantages, such as reduced postoperative discomfort and quicker recovery times. These findings suggest that tubeless PCNL could be a viable alternative to conventional PCNL, particularly for patients who prioritize a shorter hospital stay and reduced postoperative pain. The study underscores the importance of patient selection and individualized treatment strategies to optimize outcomes. Future research should focus on refining tubeless PCNL techniques, exploring minimally invasive alternatives, and investigating the molecular and genetic factors influencing stone formation to improve both surgical and medical management of urinary lithiasis.

Author contributions

M.Z. handled the original draft preparation. M.M.S., A.M.A., and M.A.A. contributed to the review and editing of the manuscript.

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Competing financial interests

The authors have no conflict of interest.

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