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Comparative study between standard percutaneous nephrolithotomy and modified percutaneous nephrolithotomy: Using the shah sheath with suction system

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Abstract
This two-year prospective, randomized, comparative, clinical, interventional study at Al Yarmouk Teaching Hospital's Urology Department aimed to compare the efficacy, operative time, residual stone pieces, need for auxiliary procedures, and complications between standard percutaneous nephrolithotomy (PCNL) using Amplatz sheath and modified PCNL using Shah sheath in kidney stone removal. A total of 84 patients were included, with 46 undergoing conventional PCNL and 38 undergoing Shah Sheath PCNL from September 2020 to September 2022. The average ages for the standard and Shah Sheath groups were 44.2±13.1 and 42.2±13.2 years, respectively. Stone sizes were 29.0±4.4 mm in the standard group and 30.3±4.9 mm in the Shah Sheath group. Single stones were more common than multiple stones, with a ratio of 79.8% to 20.3%. The standard group experienced higher rates of fever, sepsis, and urine leak (15.2%, 4.3%, and 4.3%, respectively), but these differences were not statistically significant (P-Value > 0.05). The conventional technique left residual fragments in 15.2% of patients, compared to only 2.6% in the Shah Sheath group (P-Value = 0.047). Shah Sheath PCNL demonstrated a reduced operational time (OR = 0.93, P-Value < 0.001) and an 85% reduction in remaining fragments (OR = 0.15, P-Value = 0.033). Additionally, the Shah Sheath method decreased the need for auxiliary procedures by 88% compared to standard PCNL, although this difference was not statistically significant (P-value = 0.12). In conclusion, Shah Sheath PCNL is a safe and effective treatment for renal stones, offering a higher stone-free rate, shorter operating time, and lower post-surgical systemic reactivity than traditional PCNL. This modified technique may provide improved outcomes for patients undergoing kidney stone removal.

Keywords: Percutaneous nephrlithotomy, PCNL, Shah Sheath, nephrolithiasis

Introduction
Urolithiasis, the production of urinary stones, is a prevalent and long-standing urologic illness. Most instances are upper urinary tract stones. Upper urinary tract stones have increased recently [1]. Stone formation is caused by intrinsic (patient-related) and extrinsic (environmental) causes. Sex, age, family history, and comorbidities are intrinsic variables, whereas fluid consumption, nutrition, lifestyle, climate, and country of residency are extrinsic. Stone blockage may cause Hydronephrosis, kidney failure, sepsis, and bilateral obstruction. These consequences are dangerous to patients. Stone sickness is likely once a stone forms. 10% of males will create another calcium oxalate stone within a year, and 27-50% will do so within 7-9 years [2]. Each stone creation increases the frequency and decreases the time between relapses. Low- or high-risk patients may produce stones. Patients with many stones, bilateral stones, a family history of stones, gastrointestinal disorders, uric acid stones or gout, chronic urinary tract infections, nephrocalcinosis, solitary kidneys, staghorn calculi, children, and young people are at risk. Kidney stones may cause symptoms or be identified inadvertently during medical investigations. KUB x-ray, ultrasound, intravenous urography, CT urography, and MR urography (used in pregnant women with suspected urolithiasis) may identify stones [3]. Watchful waiting (WW), extracorporeal shock wave lithotripsy (ESWL), flexible ureteroscopy (RIRS), percutaneous nephrolithotomy (PCNL), open surgery, and medication dissolving therapy may cure kidney stones. Pain, infection, and blockage need action.

Stone-induced hematuria seldom requires treatment. Watchful waiting (WW) recognises that not all kidney stones require treatment. Symptoms, stone size, and patient age determine whether to intervene or wait. Renal stone advancement has been inconsistently observed. Some studies show that many kidney stones grow, produce symptoms, or need intervention, while others say that few do. Patients differ in stone growth risk and intervention timing [4, 5]. Non-invasive ESWL treats nephrolithiasis. Focusing external stress waves on the stone fragments it. According to EAU recommendations, ESWL and retrograde intrarenal surgery (RIRS) are first-line treatments for stones less than 2 cm in the renal pelvis or upper/middle calyx. Lower pole stone treatment is still debated. Stone size, placement, content, patient characteristics, and operation execution affect ESWL effectiveness. High-volume centres report 71-89% stone clearance rates for diverse stone sites [6, 7]. ESWL factors like shock wave rate affect stone fragmentation and clearance [8]. Laser and flexible ureteroscopy are successful kidney stone endoscopic treatments. This method uses small-caliber ureteroscopes with active deflecting mechanisms, lasers, and stone removal tools. It works for stones under 2 cm and provides access to much of the collecting system. Flexible ureteroscopy and laser fragmentation work better for tiny stones [9]. For kidney stones above 2 cm, percutaneous nephrolithotomy (PCNL) is recommended. It outperforms ESWL and RIRS in stone-free rates. PCNL is risky and difficult to learn. Technological advances have miniaturised endoscopic tools to minimise intraoperative blood loss, complications, and hospital stay [10, 11]. Mini, minimally invasive, ultra-mini, super-mini, and micro-PCNL have appeared in the literature in recent years [12, 13]. However, a unified definition of miniaturised PCNL (mPCNL) and greater knowledge of when to employ certain instruments are needed [14, 15]. Aim of the study to compare efficacy in extracting the stone fragments, operative time, residual stone pieces & the need for auxiliary procedures and complications in standard PCNL (using the Amplatz sheath), & modified PCNL (using the Shah sheath).

Method

This prospective, randomized, comparative, clinical, interventional study was conducted at Al Yarmouk Teaching Hospital's Urology Department over a two-year period. The study aimed to compare the outcomes of standard percutaneous nephrolithotomy (PCNL) and modified PCNL using the Shah sheath and suction mechanism in patients with renal stones larger than 2 cm. A total of 84 patients were included in the study, with 38 patients undergoing PCNL with the Shah sheath and 46 patients undergoing standard PCNL. Preoperative evaluations were performed, including complete blood tests, renal function tests, serum electrolytes, bleeding profiles, urine analysis, and urine culture. Stone burden was assessed using a computed tomography (CT) scan. All patients provided written informed consent before the operation. Follow-up examinations were conducted using ultrasound and non-contrast CT scans to assess stone clearance. The modified PCNL technique utilizing the Shah sheath involved the use of a specially designed 21 Fr sheath with a suction mechanism and a 19Fr nephroscope. The procedure was performed under general or spinal anesthesia. After obtaining the initial puncture, the sheath assembly was placed using fluoroscopic guidance. The stone was fragmented using a ballistic pneumatic lithotripter, and the pieces were removed through the suction mechanism of the Shah sheath. Direct nephroscopy inspection and fluoroscopy were used to confirm stone clearance. DJ stents and nephrostomy tubes were routinely placed. Statistical analysis was performed using R software packages. Continuous variables were presented as means and standard deviations, while categorical variables were expressed as frequencies and percentages. Welch's t-test, chi-square test, Fisher's exact test, and univariate logistic regression were utilized for data analysis.

Results

Eighty-four cases were included in this comparative interventional study, of which 46 patients were assigned to the standard PCNL group and 38 to the Shah Sheath PCNL group. The mean age was 44.2±13.1and 42.2±13.2 years, for standard and Shah Sheath group, respectively. The proportion of males was 56.5% for the first group and 47% for the second group. Body weight was the quite similar between the two cohorts (P-value = 0.4). In regard to stone characteristics, the mean stone size was 29.0±4.4 and 30.3±4.9 mm (Standard vs. Shah Sheath). Single stone was found in the majority of cases (79.8%) as opposed to multiple stones (20.3%). As shown in (Table 1).

Table 1: Description of Patients" demographics and stone characteristics

Characteristics	Overall, N = 84	Standard PCNL, qN = 46	Shah Sheath PCNL, N = 38	P-Value
Age (years)	43.3±13.1	44.2±13.1	42.2±13.2	0.5
Sex				
Males	44 (52.4%)	26 (56.5%)	18 (47.4%)	0.4
Females	40 (47.6%)	20 (43.5%)	20 (52.6%)	
Laterality				
Right	43 (51.2%)	25 (54.3%)	18 (47.4%)	0.5
Left	41 (48.8%)	21 (45.7%)	20 (52.6%)	
Stone size (mm)	29.6±4.7	29.0±4.4	30.3±4.9	0.2
Multiplicity				
Single	67 (79.8%)	34 (73.9%)	33 (86.8%)	0.14
Multiple	17 (20.2%)	12 (26.1%)	5 (13.2%)	

Mean ± SD, N (%)
Welch Two Sample t-test, Pearson's Chi-squared test, Fisher's exact test

The most common location for renal stones was the lower pole (36.9) followed by the pelvic region (21.4%), and the upper pole (21.4%). As shown in (Figure 1).

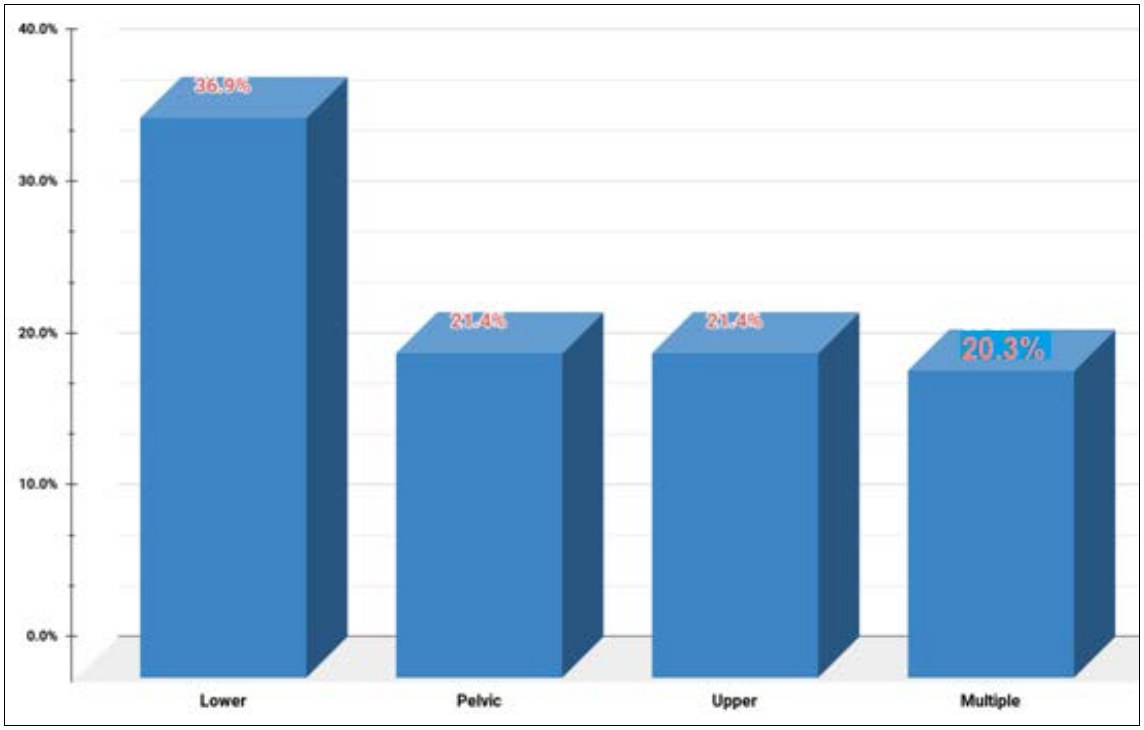

Fig 1: Prevalence of stone size

Regarding operative parameters, the operative time was statically lower in the Shah Sheath group (Mean = 57.4±12.1) when compared to the standard group (74.9±18.1), with a P-value < 0.001. No statistical difference between the two groups was observed in regard to the incidence of operative complications (failure to access, blood transfusion, colonic and pleural injury), as shown in table 2. Though the development of fever, sepsis and urine leak was relatively higher in the standard group (15.2%, 4.3%, and 4.3%, respectively) it was not statically significant (P-value > 0.05). Seven cases (15.2%) had residual fragments after the standard procedure while only one case had similar incident in the Shah Sheath group (P-value = 0.047). Table 2. The need for an auxiliary procedure was also got reduced with the use of Shah Sheath LCNL by 88% as compared to standard PCNL though no statistically significant (P-value = 0.12). As shown in Table 2.

Table 2: Description of operative and post-operative parameters in the two groups

Characteristics	Overall, N = 84	Standard PCNL, N = 46	Shah Sheath PCNL, N = 38	P-Value
Operative parameters				
Operative time (min)	67.0±17.9	74.9±18.1	57.4±12.1	< 0.001
Failure to access	3(3.6%)	2(4.3%)	1(2.6%)	> 0.9
Blood transfusion	5(6.0%)	4(8.7%)	1(2.6%)	0.4
Post-operative parameters				
Fever	10(11.9%)	7(15.2%)	3(7.9%)	0.5
Sepsis	2(2.4%)	2(4.3%)	0(0.0%)	0.5
Urine leak	2(2.4%)	2(4.3%)	0(0.0%)	0.5
Residual fragments	8(9.5%)	7(15.2%)	1(2.6%)	0.047
Need of auxiliary procedure (ESWL)	7(8.3%)	6(13.0%)	1(2.6%)	0.12

Mean ± SD; N (%)
Welch Two Sample t-test, Pearson's Chi-squared test, Fisher's exact test

A univariate logistic regression analysis was conducted, it was found that the use of Shah Sheath procedure significantly reduces the operative time (OR = 0.93, P-value < 0.001). Also, it statistically decreases the likelihood of residual fragments by 85% (OR = 0.15, P-value = 0.033), as shown in Table 3.

Table 3: Odds ratio and their confidence interval for the assessment of the Shah Sheath PCNL procedure

Characteristics	Odds ratio, OR	95% CI	P-Value 1
Age, continuous	0.99	0.96, 1.02	0.5
Operative time, min	0.93	0.90, 0.96	< 0.001
Residual fragments	0.15	0.01, 0.90	0.033
Need of auxiliary procedure (ESWL)	0.18	0.01, 1.12	0.12
Fever	0.48	0.10, 1.86	0.3

OR = Odds Ratio, CI = Confidence Interval

Discussion

Percutaneous nephrolithotomy (PCNL) has become the preferred treatment for renal stones, replacing open surgery due to its safety and effectiveness [16, 17]. Advancements in optics and lasers have led to the development of minimally invasive PCNL techniques, such as mini PCNL (MIP), ultra-mini PCNL (UMP), and micro PCNL. These techniques have shown high success rates with fewer complications compared to conventional PCNL, primarily due to the smaller tract size [18]. The Shah Sheath system, which incorporates suction to assist in the removal of stone fragments, has achieved a stone-free rate of 97.4% in this study [19]. The use of the Shah Sheath system resulted in significantly shorter operative times compared to standard PCNL. The vacuum-assisted sheath allows for rapid suction of small clots and stone fragments, while the grasper used in standard PCNL is slower [20]. Additionally, the Shah Sheath system significantly reduced stone residuals by maintaining a low intrapelvic pressure and providing clear visualization, enabling efficient lithotripsy and fragment removal [21]. Complications such as urine leaks and infections are potential risks associated with PCNL. The Shah Sheath system helps

reduce the occurrence of these complications by maintaining a negative pressure state in the renal pelvis, promoting smooth fluid flow and reducing absorption of infectious fluid, irrigation fluid, perinephric collection, and bacteria/toxin reflux [22]. Preoperative urinary tract infections, high perfusion pressure, prolonged operative times, bacterial toxin absorption, pelvicalyceal system perforation, and poor drainage contribute to increased PCNL complications [23]. Bleeding and the need for blood transfusion were relatively higher in patients undergoing standard PCNL, likely due to the larger sheath size, longer operative times, and greater intra-renal manipulation with the use of stone graspers [24]. In summary, the Shah Sheath system used in modified PCNL offers advantages such as shorter operative times, reduced stone residuals, and lower risks of urine leaks and infections. These benefits can be attributed to the system's suction mechanism, which aids in efficient fragment removal and maintenance of a negative pressure state in the renal pelvis [25].

Conclusion

Both standard PCNL and Shah Sheath PCNL are relatively safe and effective treatment for renal stone patients. In comparison with standard PCNL, Shah Sheath provided significantly higher stone free rate, less operative time and less post-operative systemic reaction.

Conflict of Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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