Percutaneous Nephrolithotomy Using Split Amplatz Sheath: A Randomized Clinical Trial

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Purpose: To compare the outcome of percutaneous nephrolithotomy (PCNL) using split or intact Amplatz sheath.

Materials and Methods: Seventy two patients who underwent PCNL were randomly divided into two groups; PCNL using intact (group 1) and split (group 2) Amplatz sheath. Preoperative data, operative time, largest extracted stone size, fluoroscopy and lithotripsy time, and serum biochemistry tests before and after PCNL were evaluated.

Results: Preoperative features and stone size were not significantly different between the groups. There were no significant differences in complications and postoperative changes in hemoglobin and serum electrolytes. Stone free rate in group 2 (88.1%) was insignificantly higher than group 1 (83.3%) ($p = .05$), but in staghorn stones and stones larger than 1000 mm^2, stone free rate in group 2 was significantly higher than group 1 (82% vs. 72%). The mean extracted stone size in group 2 ($150 \pm 49 mm^2$) was significantly larger than group 1 (40 ± 16 mm^2) ($p < .005$). The mean operative, lithotripsy and fluoroscopy times were significantly longer in group 1.

Conclusion: Using split Amplatz sheath in PCNL facilitates extraction of larger stone fragments which could contribute to shorter fluoroscopy, lithotripsy and operative times.

Keywords: Percutaneous nephrolithotomy; Amplatz sheath; Nephrolithiasis.

INTRODUCTION

Percutaneous nephrolithotomy (PCNL) is the standard procedure for the treatment of stones larger than 2 cm, staghorn calculi, and small stones refractory to shock wave lithotripsy (SWL).[1-3] PCNL has the highest stone-free rate (SFR) among all renal stone treatment options. The SFR after one session of PCNL is more than 80%.[4] Operative time is a key factor correlated with the post-operative and, indirectly with anesthesia-related complications.[5,6] A few studies have investigated factors that influence operative time during percutaneous nephrolithotomy. These studies have shown that a history of open surgery, stone size and surgical experience are correlated with operative time[6,7]. In a study by el-Nahas et al. stone size was found to be a predictive factor for both longer operative time and hospital stay.[8] We hypothesized that extraction of stones in larger fragments may decrease the need for stone fragmentation and consequently, shorten the operative time. Hence, this study was done to compare the perioperative and postoperative outcome of PCNL using split and intact Amplatz sheath.

MATERIALS AND METHODS

Between June and April 2014, 123 patients underwent PCNL in our department. The study was approved by our institutional ethical committee, and informed consent was sought from all patients. All patients who were candidate for PCNL were included except patients with The American Society of Anesthesiologists (ASA) risk class III or more, multiple stones and those requiring supracostal access. Considering study power of 80%, sample size was calculated to be 36 patients in each group. We randomized patients into two groups; in group one PCNL was performed using intact Amplatz sheath, and in group two longitudinally split Amplatz sheath was used. To have a split Amplatz sheath, a conventional Amplatz sheath was simply cut longitudinally in its total length with a surgical knife. The randomization method was simple randomization using table of random numbers. **Figure 1** shows the CONSORT chart of this study. Preoperative evaluation included laboratory tests (complete blood count (CBC), coagulation tests, serum electrolytes, urine analysis and culture) and imaging studies (spiral abdominopelvic computed tomography (CT) scan and/or intravenous urography (IVU). All patients received prophylactic antibiotics preoperatively. Data were collected prospectively by one of the authors blinded to the procedure. Participants and care givers were also blinded to group assignment.

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Table 1. Stones characteristics.

Stone characteristics	Intact group	Split group	Total
Stone location[a]			
Upper calyx	1	1	2
Lower calyx	4	3	7
Pelvis	14	13	27
Pelvis + one calyx	10	13	23
Staghorn	6	7	13
Mean stone size[b] (mm^2)	950 ± 967	1165 ± 1424	1005.7 ± 23

[a]Statistically insignificant difference between the groups. (P = .58)
[b] P = .45

In the lithotomy position and under spinal anesthesia, cystoscopy was performed to insert a 5F ureteral catheter. The position was changed to prone with a support under chest and pelvis. Access to the kidney was obtained under fluoroscopic guidance; the tract was dilated to 30 Fr using Amplatz dilator with single-step dilation technique, and Amplatz sheath (split or intact sheath) was placed. Stone degradation was performed by pneumatic lithotripsy using lithoclast master system (EMS, Switzerland). We did not use flexible nephroscopy for our patients. An 18 Fr nephrostomy tube was inserted at the end of procedure for all patients. All operations were supervised by an attending endourologist. CBC and serum electrolytes were checked on the first postoperative day. Abdominal ultrasonography and plain abdomen X-ray were also performed on the first postoperative day. If there was no significant residual stone, nephrostomy tube was removed. Ureteral catheter was removed when urinary leakage from nephrostomy removal site was less than 100 ml/day. Patients with no residual stone or residual stone < 4 mm were considered stone free. Stone free rate was the primary outcome evaluated in this study. Secondary outcomes included operative time, the largest extracted stone size, fluoroscopy and lithotripsy times, blood tests before and after PCNL, ancillary procedures, hospital stay and complications. For statistical analysis, SPSS ver.21 software was used. Quantitative and categorical variables were tested using student's t-test and chi-square test, respectively.

RESULTS

Seventy two patients (57 men and 15 women) with mean age of 43.45 ± 13.41 years were included in the study. The preoperative characteristics were not significantly different between the two groups. (**Table 1**) The mean body mass index (BMI) was 29.2 ± 5.6 and 28.64 ± 6.1 Kg/m^2 in group one and two, respectively (p = .68). **Table 2** summarizes intra- and

Table 2. Intra- and postoperative data.

Features	Intact group	Split group	*P* value
Operative time (mean ± SD) min	70 ± 22.2	48.33 ± 17.32	.005
Fluoroscopy time (mean ± SD) second	45.8 ± 14.66	25.63 ± 12.8	.005
Extracted stone size (mean ± SD) mm2	40 ± 16	150 ± 49	.005
Preoperative hemoglobin (mean ± SD) g/dl	14.32 ± 1.52	14.1 ± 1.2	.67
Postoperative hemoglobin (mean ± SD) g/dl	11.8 ± 1.56	11.82 ± 2.7	.95
Preoperative Na (mean ± SD) mg/dL	141.7 ± 2.6	141.8 ± 2.6	.14
Postoperative Na (mean ± SD) mg/dL	141.1 ± 2.56	140.08 ± 3.2	.13
Preoperative K (mean ± SD) mg/dL	4.23 ± 0.22	4.34 ± 0.42	.22
Postoperative K (mean ± SD) mg/dL	4.11 ± 0.31	3.95 ± 0.36	.08
Preoperative Cr (mean ± SD) mg/dL	1.11 ± 0.22	1.11 ± 0.27	.9
Postoperative Cr (mean ± SD) mg/dL	1.13 ± 0.27	1.13 ± 0.35	.95
Hospital Stay (mean ± SD) days	3.5 ± 1.5	3.1 ± 1.2	.2
Lithotripsy time (mean ± SD) second	61.9 ± 30.69	38.61±33.58	.003
Access tracts (No. of patients)			.005
1	34	33	
2	2	3	

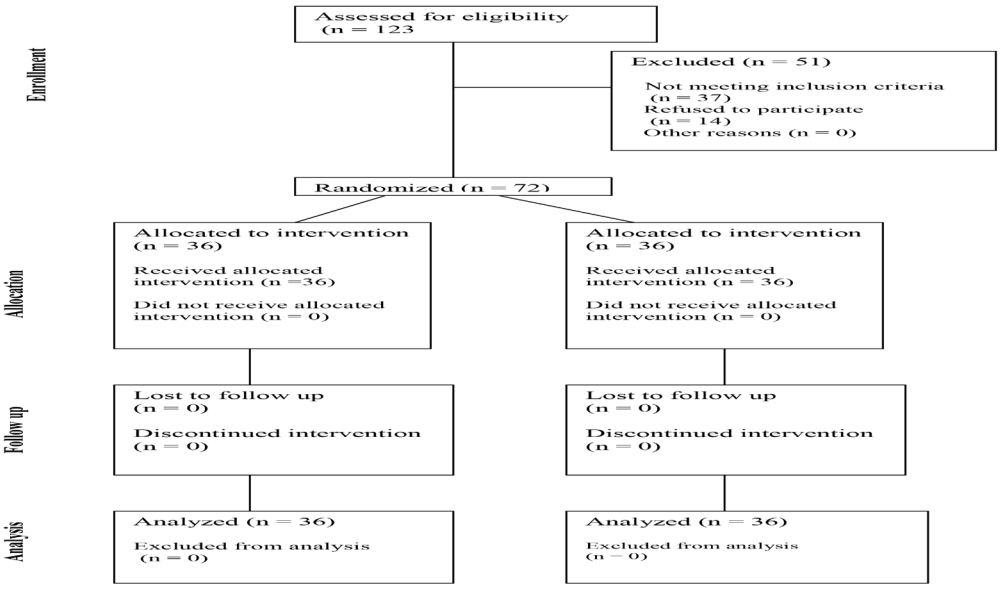

Figure 1. CONSORT chart of the study.

postoperative data. The mean operative, fluoroscopy and lithotripsy times in group one (intact sheath) were significantly longer than group two (split sheath). The mean size of extracted stone fragment in group one was significantly smaller than group two. (**Figure 2**) Hemoglobin change was not significantly different (p = .54) (2.52 ± 1.2 in the split group vs. 2.35 ± 1.07 in intact group). There was no significant difference in mean change of serum sodium (Na), potassium (K), and creatinine between the two groups. (**Table 2**) Stone free rate was not significantly different between the two groups (83.3% vs. 88.1% in groups 1 and 2, respectively) (P = .5). However, in staghorn stones and stones larger than 1000 mm^2, stone free rate in group 1 was significantly lower than group 2 (72% vs. 82%). The need for ancillary procedures was not significantly different between the two groups. SWL was necessary in 6 patients (4 patients in group one and two patients in group two), ureteroscopy in two patients (one patient in each group), and repeat PCNL in two patients (one patient in each group). According to the modified Clavien system, class II complication (blood transfusion) was found in 3 patients in group one and 2 patients in group two (P = .56). Class IIIa complication (double-J stent insertion without general anesthesia because of prolonged urine leakage from nephrostomy removal site) occurred in two patients in group 1 and one patient in group 2. There were no perinephric collection (evaluated by ultrasonography) or major complications (Clavien class IIIb or higher) in our patients.

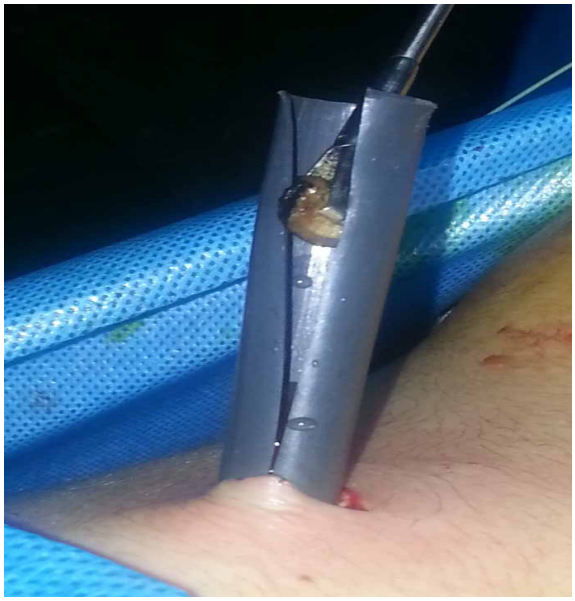

Figure 2. A large stone fragment is extracted from the split Amplatz sheath.

DISCUSSION

Since the first report of PCNL in 1976, its instruments and techniques have evolved. PCNL is currently the standard of care for large renal stones (> 2 cm)[9]. Although PCNL is safe and effective, it is the most costly minimally invasive procedure for renal stone treatment.[10] The cost-effectiveness of PCNL correlates with operative time, stone burden, stone free rate, and major complications.[6] Bleeding is one of the most common complications of PCNL, with an incidence rate of 1-55% in different studies.[11] Operative time is an important factor that correlates with perioperative bleeding and cost-effectiveness of the procedure.[6] A few studies are available about factors affecting operative time of PCNL. Olbert et al. reported on 109 patients who underwent PCNL and found out that stone size correlates with operative time and hospital stay[12]. Akman et al. showed that operative time for stones larger than 1000 mm^2 was three times longer than for stones less than 1000 mm^2. With increasing stone burden, the need for multiple access tracts increases and multiple tracts are correlated with more blood loss and longer hospital stay[6]. Bagrodia et al. found that increasing

stone size affects treatment related costs. Larger stone burden is associated with longer operative time, longer hospital stay, more salvage procedures, and higher cost. They also showed that average operative time slowly decreases with increased experience of surgeon.[10] Some authors have reported that the hydronephrosis grade could affect operative time. They described that a severely hydronephrotic kidney collapses after percutaneous access and detection of stone fragments could be difficult and take longer time.[6,12] Correlation between stone size and operative time could be explained by longer time needed for stone fragmentation and extraction. Since operative time affects complication rate and cost-effectiveness, any attempt to reduce it is of critical importance. Our study compared the outcomes of PCNL using intact and split Amplatz sheath in a randomized clinical trial. It showed that using split Amplatz sheath allows for extracting significantly larger stone fragments which results in decrease of lithotripsy time and number of stone fragments. As the number of stone fragments is reduced, their detection and extraction could be performed easier, faster, and with less need for fluoroscopy. This could also explain higher stone free rate achieved in group 2, particularly for staghorn calculi and stones larger than 1000 mm^2. A technical point of using split sheath was the risk of entrapment of stone fragments in the fascia. To avoid this risk, the fascia should be opened wider. Blood transfusion and mean Hb change was not significantly different between the two groups. There was concern about probable fluid leakage through the split sheath and the risk for electrolyte disturbances. Our findings showed that electrolyte changes were not significantly different between the two groups and none of the patients had perinephric collection on postopearative ultrasonography.

CONCLUSION

Using split Amplatz sheath during PCNL facilitates extraction of larger stone fragments which could contribute to shorter fluoroscopy time, lithotripsy time, and operative time. Operative time is a key factor which correlates with intra- and postoperative complications. It seems that the benefits of using spit Amplatz sheath might be more considerable in large and staghorn stones. This should be confirmed in larger studies with more patients.

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