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Miniaturisation is future of PCNL: Effects of different sizes of Amplatz sheaths on outcomes of Tubeless Miniaturized PCNL in treatment of large renal calculi

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We prospectively evaluated and compared the effects of different sizes of Miniaturized Amplatz sheaths used in tubeless mini-PCNL for treatment of large renal calculi of > 2cm on postoperative outcomes, safety and patient comfort. It is a prospective, randomized & comparative study, including three groups A, B and C, comprising different amplatz sheath sizes of 14, 18 and 22 Fr respectively used during Mini PCNL. All patients admitted between September 2020 to April 2021 with the diagnosis of renal calculi were evaluated for eligibility. A total of 62 patients were enrolled in the study and randomly divided into 3 groups allocated by the programmed software. There were 20 patients in Group A, 21 patients in Group B & 21 patients in Group C. Overall Stone clearance rate was comparable among all groups and it was 95% in Group A, 90.5% in Group B & 85.7% in Group C (p=0.6). Overall Complications rate was 14.5% in total but significantly higher for Group C (p = 0.04). Smaller sheaths resulted in the decreased need for blood transfusion (P= 0.43), less Hb drop (P=0.07), decreased need for postoperative opioid analgesia (P=0.07), less VAS Pain scores (P=0.03) & less duration of hospital stay (P=0.17). Larger size sheaths, on the other hand, had superiority in terms of shorter operating durations (p=0.03).The use of smaller amplatz sheaths is better in terms of stone clearance rate, complications rate & postoperative recovery as compared to their larger counterparts but at the cost of longer operating durations.

Keywords: Amplatz sheaths, PCNL, Renal calculus

INTRODUCTION

In recent times, endourology has taken over the treatment of urolithiasis. Endourology has proven to be better in terms of stone clearance rates and complications rates when compared to open procedures. Endourology is witnessing revolutionizing technological advancements. Owing to these technological advancements, Per-Cutaneous Nephrolithotomy has become a routine and gold standard endourological procedure in the treatment of large & complex renal or proximal ureteral stones (Sheikh JH, 2020). When we look back in history, the first therapeutic percutaneous nephrostomy was performed by Thomas Hillier in 1865, since then continuous efforts are being made to improve the safety and outcome of the procedure by optimizing its technique and gadgets used in it (Bloom DA, 1989). Nowadays, the percutaneous approach can be safely employed even in horseshoe and ectopic kidneys (Purkit B, 2015)

Overall complications rate according to modified Clavien-Dindo system is reported to be 20.5% (Yamaguchi A, 2011) The incidence of bleeding was 9.4% (Kamphuis GM, 2015) However, the occurrence of severe bleeding that may require intervention is around 0.8% (Zeng G, 2021). Therefore, it is necessary to identify those factors that may potentiate the risk of adverse events and take active measures to reduce their frequency rather than take remedial measures. Every step of the procedure is under debate to further minimize the associated morbidity and improve the efficiency of the procedure including patient position, Choice of Calyx for Access, methods of obtaining percutaneous access, Tract dilation methods, different types of dilators, Size of Access sheath to be used, fragmentation modality, and exit strategy (Rastinehad AR, 2009 – Rahman M, 2019). Factors associated with haemorrhage during percutaneous nephrolithotomy include patient characteristics, supracostal puncture, multiple tracts, increase in tract size, tract dilation methods, prolonged operative time, and renal pelvic perforation (Bozzini G, 2020) To reduce the frequency of adverse events, we already tend to use smaller tract sizes and therefore, downsized amplatz sheaths have gained popularity based on assumption that smaller tract sizes would cause less damage to the renal parenchymal tissue

(Karakose A, 2014) Yet there is limited and conflicting data comparing the effects of different miniature-sized Amplatz sheaths on surgical outcomes and safety.

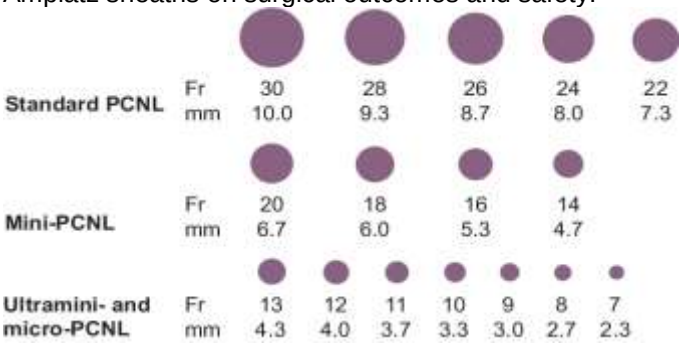

Figure 1: Graphic illustration of the different sizes of amplatz sheaths being used in different types of PCNL for comparison.

So, in this study, we prospectively evaluated and compared the effects of different sizes of Miniaturized Amplatz sheaths in tubeless miniaturized PCNL for large renal calculi of > 2cm on postoperative outcomes, safety and patient comfort. Our Primary end-points included Stone clearance rate, Blood loss, and complications rates classified according to the Clavien-Dindo system. Blood loss was measured in terms of Hemoglobin drop and Need for blood transfusions. Operative time, VAS Pain scores at 24 hrs postoperatively, Need for Opioid analgesics & Duration of hospital stay were secondary endpoints.

MATERIALS AND METHODS

It is a prospective, randomized & comparative study, including three groups A, B and C, comprising different amplatz sheath sizes of 14, 18 and 22 Fr respectively. All patients admitted between September 2020 to April 2021 with the diagnosis of renal calculi were evaluated for eligibility. Inclusion criteria included patients of 18 – 75 years of age, Renal Calculus of > 2cm in size. Patients with active urinary tract infection (positive urine culture), renal malformation, uncorrected coagulopathy, morbid obesity (>40 kg/m2), chronic kidney disease, and pregnant women and patients admitted for second sitting were excluded. A total of 62 patients were enrolled in the study and informed written consent was taken after explaining the study protocol to the patient. The enrolled patients were randomized into three groups using a computer-generated random number & underwent Miniaturised PCNL using allocated Amplatz sheath. The allocation was concealed in a sealed envelope and was revealed by the floor nursing staff to the operating surgeon after induction of anaesthesia. The data collection method was purposive sampling, after getting demographic data the detailed history was taken; presenting complaints, pain status, Lower urinary tract symptoms status, history of previous surgeries were evaluated. Imaging findings were recorded such as Ultrasound KUB, X-ray KUB and CTU or IVU. Preoperative haemoglobin, hematocrit, TLC, urine C/S, Urea, Creatinine, Serum electrolytes were done and recorded. Per-operative parameters such as operative time, fluoroscopy time, iatrogenic complications and Postoperative parameters such as Hematocrit, Hemoglobin, creatinine, TLC, Visual Analogue Scale (VAS) pain scores at 24 hrs postoperatively, need of blood transfusions, development of postoperative fever and duration of hospital stay and catheterization were also recorded. Statistical package of social sciences version 22 was used to enter and analyze the data. Data were analyzed and reported as number and percentage or mean and standard deviation, as appropriate. To evaluate the validity of data results, appropriate tests were performed. P-value <0.05 was considered significant.

Some patients needed pre-stenting with Double J stents to relieve obstruction from outside our hospital or in our hospital. 2 patients in Group A while 6 patients in Group B & C each, already had DJ stents in place at the time of admission (P-value=0.2).

Under general anaesthesia, patients were positioned in dorsal lithotomy position, cystoscope introduced, Ureteral catheter passed over the guidewire onto the respective side under fluoroscopic guidance, contrast injected to highlight the pelvicalyceal system, findings noted under fluoroscopy, Foley's catheter inserted, ureteral catheter secured in place and patient's position then changed to prone. Time consumed during placement of a ureteral catheter in dorsal lithotomy position followed by the change of position to prone was also included in total operative time. Contrast, then, injected again to highlight the pelvicalyceal system and then puncture was performed in the appropriate calyx by triangulation technique using 18 gauge needle, a guidewire was then passed into the pelvicalyceal system. Then tract dilatation was performed with Alken Metallic Telescopic Dilators up to appropriate size. After dilatation, an allocated sized Amplatz Sheath was inserted, nephroscope introduced and stones were fragmented with the help of pneumatic lithotripter in all cases. Stones were collected and sent for FT-IR analysis. At the end of the procedure, a fluoroscopic image was taken to confirm the stone clearance. Amplatz sheath was then removed and hemostasis was secured by applying gentle pressure over the wound which was then closed with the help of vicryl rapid 4/0. No nephrostomy tube was placed and all procedures were Tubeless. Foley's catheter along with the ureteral catheter was left in place for 48hrs (or more in case of severe hematuria). X-ray KUB was done on the 1st postoperative day to confirm stone clearance. All patients were given injection paracetamol 1 gm intravenous 8 hourly as analgesic till postoperative day 2. On postoperative day 2, patients were discharged after removal of Foley's & ureteral catheters (if hematuria had settled) and tablet paracetamol was given 8 hourly. Postoperative pain was evaluated by using VAS pain score at 24 hours. Patients requiring additional rescue analgesics for pain were given

injection nalbuphine 5 mg intravenously. Patients were followed up after 1 month and USG KUB was done to confirm the stone clearance. Complete stone clearance was defined as the absence of calculus on ultrasonography.

RESULTS

In this study, a total of 62 patients were divided into three groups. There were 20 patients in Group A, 21 patients in Group B & 21 patients in Group C. Other patient characteristics and stone related characteristics were all statistically similar among the groups as shown in Table 1.

The overall Stone clearance rate was comparable among all groups but retreatment rates were relatively higher in Group C compared to the other two groups. It was 95% in Group A, 90.5% in Group B & 85.7% in Group C. (P=0.6)

Table 1: Demography and Preoperative variables. (n=62)

Variables		Group A (n=20)	Group B (n=21)	Group C (n=21)	P-value
Gender	Male	13 (65.0%)	14(66.7%)	10 (47.6%)	0.38
	Female	7 (35.0%)	7 (33.3%)	11 (52.4%)	
Age (years)		39.4 ± 12.9	42.7 ± 10.4	42.6 ± 10.6	0.5
BMI		23.2 ± 5.8	29.1 ± 6.6	25.3 ± 4.1	0.2
US stone size		2.8 ± 0.4	2.9 ± 0.6	3.1 ± 0.3	0.08
CT Stone size		2.7 ± 0.1	2.9 ± 0.3	2.6 ± 0.3	0.3
Number of stones	Single	14 (70.0%)	11 (52.4%)	8 (38.1%)	0.05
	Multiple	6 (30.0%)	10 (47.6%)	13 (61.9%)	
Location of stone	Upper calyx	3 (15%)	2 (9.5%)	2 (9.5%)	0.6
	Mid calyx	1 (5%)	0	0	
	Lower calyx	3 (15%)	2 (9.5%)	4 (19%)	
	Pelvis	8 (40%)	13 (61.9%)	10 (47.6%)	
	Partial staghorn	3 (15%)	2 (9.5%)	4 (19 %)	
	Staghorn	2 (10%)	2 (9.5%)	1 (4.8%)	

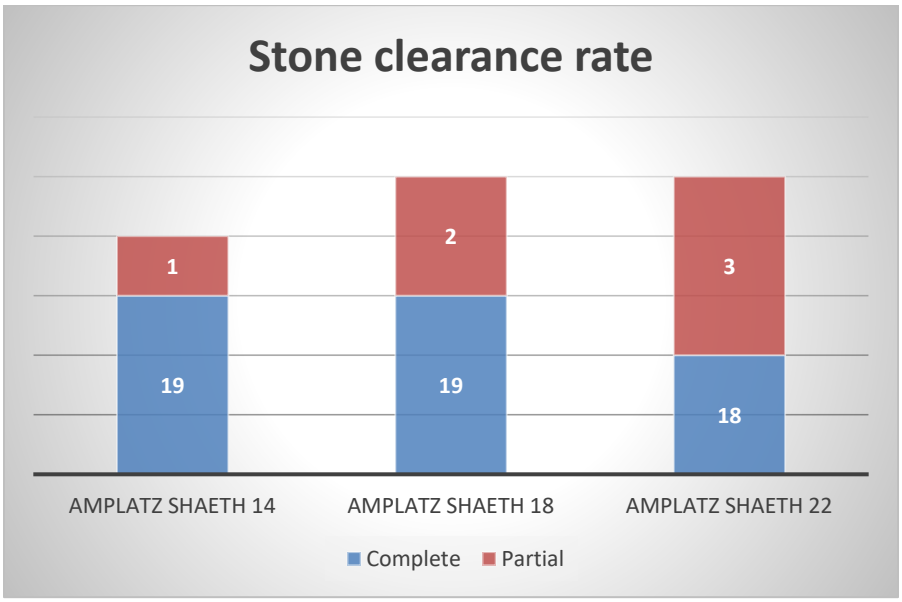

Figure 2: Stone clearance rates. (n=62) (p=0.6)

The distribution of complications among groups & other important operative parameters are compared in table 2.

Table 2: Operative & Post-operative parameters. (n=62)

Variables		Group A (n=20)	Group B (n=21)	Group C (n=21)	P value
Fever		0 (0.0%)	1 (4.8%)	1 (4.8%)	0.28
UTI		0 (0.0%)	0 (0.0%)	2 (9.5%)	
Need of Blood Tx		1 (5.0%)	1 (4.8%)	3 (14.3%)	0.43
Total Operative Time		145.5 ± 36.6	107.7 ± 37.9	90.4 ± 33.3	0.03
Approach	**Supracostal**	3 (15%)	5 (23.8%)	2 (9.5%)	0.5
	Subcostal	17 (85%)	16 (76.1%)	19 (90.5%)	
HB drop		2.4 ± 0.7	3.1 ± 0.3	4.8 ± 1.0	0.07
Pain Vas score		2.3 ± 1.4	2.3 ± 1.4	3.7 ± 3.1	0.03
Post OP Pain	**Mild**	15 (75.0%)	18 (85.7%)	10 (47.6%)	0.002
	Moderate	5 (25.0%)	3 (14.3%)	5 (23.8%)	
	Severe	0 (0.0%)	0 (0.0%)	6 (28.6%)	
Requirement of Post-op Opioid Analgesia		5 (25%)	6 (28.5%)	9 (42.8%)	0.07
Hospital Stay (days)	02 days	19 (95%)	20 (95.2%)	16 (76.1%)	0.17
	03 days	1 (5%)	1 (4.7%)	4 (19%)	

Overall Complications rate was 14.5% in total but significantly higher for Group C, and all were minor & limited to clavien-dindo grades 1 & 2. It was 5% for Group A, 9.5% for Group B & 28.5% for Group C (p = 0.04). Distribution of complications according to the grades is shown in figure 3.

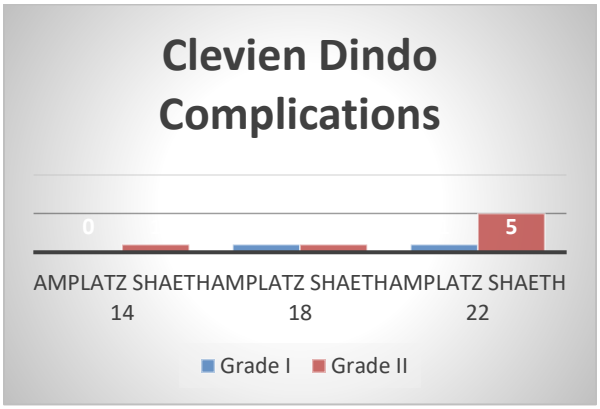

Figure 3: Distribution of complications classified according to Clavien-Dindo System. (n=62)

DISCUSSION

Right now, we are moving through an era of never-ending technological improvements and witnessing continuous modernization of our endoscopic gadgets and that includes miniaturization. In the management of urolithiasis, miniaturization of instruments is thought to help in achieving Stone free status at better patient comfort i.e., postoperative pain, complications rates, duration of hospital stay and blood loss (Singh Ak, 2017). In the case of percutaneous nephrolithotomy, miniaturization of its instruments changes the dynamics of the procedure by having effects on several parameters including the extent of parenchymal damage, intrapelvic pressures, need for nephrostomy tube which may influence other important variables such as Bleeding, Renal impairment, Operative time, postoperative pain or duration of hospital stay etc (Mitropoulos D, 2013) However, the evidence for this in the existing literature is still conflicting. Akito Yamaguchi et al. investigated factors that affect operating times and bleeding complications. The blood loss and blood transfusion rates significantly increased with the increase in tract sizes (p = 0.00016 and <0.0001). This study shows that sheath size, operating

time, stone load, and caseload are predictive factors during PCNL that are associated with bleeding complications or the need for blood transfusion (Thakur A, 2021). Our findings are also supported by Güler et al., who aimed to compare the efficacy of mini PCNL and standard PCNL for renal stones ≥ 2 cm in a Randomized Controlled Trial. The rates of Hb drop and transfusion rates were significantly in favour of mini PCNL. The stone-free rate of the mini PCNL group was relatively better than the standard PCNL group (Zhu W, 2015). In contrast, Zhong et al. had noted that in patients with large staghorn calculi, Hb drop after mini PNL vs Standard PNL was 3.2 vs 3.5 g/dL respectively, and this difference was not statistically significant (Mukherjee S, 2019).

Meanwhile, the use of smaller tracts has been pointed to have disadvantages regarding High Renal Pelvic Pressures (RPP) due to inadequate irrigation outflow (Li XD, 2021). RPP is identified as the important factor in the development of infectious complications due to pyelo-venous backflow & subsequent absorption of endotoxins and bacteria, which may ultimately end up in postoperative fever or sepsis (Cui J, 2021). A reduction in sheath size is also associated with longer Operating times, with a subsequent higher risk of suboptimal RPP for a longer period. Longer duration of procedure is one of the main hindrances in the acceptance of techniques using miniaturized tracts (Sharma G, 2021). Various other factors may also play their role in influencing the duration of the procedure including stone size, anatomy of Pelvi-calyceal system, fragmentation technique or size of percutaneous tract (Zeng G, 2021 – Feng D, 2020). The problem with miniature instruments is that stones are needed to be- broken into very tiny fragments that can then pass through the narrower amplatz sheaths. Zeng et al. compared 18 F & 24 F size tracts in PCNL. The standard PCNL group had a significantly higher Hb drop. The standard PCNL group had shorter duration of procedure, a higher VAS score & significantly longer days of hospital stay. There was no statistically significant difference in the incidence of fever or urosepsis between groups of this study. They concluded that the smaller tract can be a sensible alternative for renal calculi >2cm in size (Jiao B, 2021 – Deng J, 2020). These findings were also replicated in a Meta-analysis published by Zhu et al., who had noted that the Stone Free Rate was not significantly different in mini PNL and Standard PNL groups. Moreover, this meta-analysis also revealed that patients who underwent Mini PNL had less bleeding & Hb drop (p=0.0005), Need of transfusion (p=0.002), less VAS Pain scores (p=0.009), shorter duration of hospital stay (p=0.002), but at the cost of longer duration of procedure (p=0.007). The incidence of Postoperative fever or sepsis was not different between the groups (Jiang P, 2020). In contrast, Ayhan Karaköse and others compared five different sizes of amplatz sheaths but contrary to our study, the operative time was not significantly different (Karakan T, 2017).

The main factor behind the popularity of minimally invasive techniques is the lower patient discomfort scale when measured by Visual Analogue Scale (VAS) pain score, the requirement of analgesics or Duration of hospital stay. In literature, smaller size sheaths are associated with less postoperative pain, the requirement of opiate analgesics and shorter hospital stay presumably due to smaller incisions, smaller tracts, and increased chances of tubeless procedures (Atassi N, 2020). Cheng F. et al. had shown no significant difference in VAS Pain score in mini PNL compared to standard PNL on Post-Operative Day-1 in a Randomized controlled trial (Du C, 2018). In addition, other non-randomized studies have also shown no significant difference in postoperative pain after mini PNL in comparison with standard PNL (Guler A, 2019) In our study, we tried to resolve this issue and further validated that smaller size sheaths are better tolerated by patients in terms of postoperative pain, need for opioid analgesia, duration of hospital stay and postoperative complications rates. In a Systematic Review from the European Association of Urology Urolithiasis Guidelines Panel, Eur Urol (2017), Ruhayel Y, et al., concluded that mini PCNL is as efficacious and safe as standard PCNL for the treatment of renal stones, with a limited risk of significant (Clavien-Dindo grade 2) Complications (Deng J, 2020).

Here in our study, number of supracostal access tracts were comparable in all groups. Number of staghorn calculi, partial staghorn calculi & distribution of calculi in the pelvicalyceal system were comparable among all groups. However, there are more patients with multiple calculi in Group C which may affect the stone clearance rate of the group. The effects of sheath sizes on renal function or other indexes of renal injury have not been evaluated adequately in this study. Another limitation may be a lack of evaluation according to the stone analysis or Hounsfield unit (HU) which can help choose the appropriate size of the sheath. Moreover, the energy modality used for lithotripsy may also play its role & influence the important per-operative parameters but the extent of their effect is not taken into account in this study. Literature shows that type of dilatation during tract formation also has its effects on important postoperative outcomes such as bleeding (Guler A, 2019-Ruhayel Y, 2017). In a general sense, the Anatomy of the Pelvi-calyceal System should also be considered when choosing the appropriate size of instruments. Patients with tiny collecting systems should benefit from the use of downsized instruments. Future research should evaluate such issues. The limited number of patients in each group may be a statistical limitation. So we can surely say that the tendencies would be better revealed by taking a handsome size of the sample with higher numbers on which we are already working (Du C, 2018)

Surgeons should be aware of higher intra-pelvic pressures when using miniaturized instruments. Placement of a ureteral catheter can help in irrigation

Outflow & also allows intermittent flushing. Amplatz sheaths with vacuum suctioning are being developed, so extraction of fragments through the sheath can be facilitated to bring operating time down (Guler A, 2019 – Ruhayel Y, 2017 – Cheng F, 2010). It also hints that we would get to see more miniaturization in near future. Thus, future investigations would need to be carried out on more diverse parameters. More Randomized Controlled Trials (RCTs) with giant sample sizes on a diverse range of populations are required to better understand the efficacy and safety of these improved techniques and gadgets with respect to patient-related factors (Anatomy, postoperative pain, hospital stay), disease-related parameters (stone type, Hounsfield units, number, size & distribution) and procedural parameters (tract size, number of tracts, operative time, supracostal puncture and intrapelvic pressures).

CONCLUSION

The use of miniaturized amplatz sheaths is safe and effective in achieving Stone clearance comparable to that of larger sheaths when treating large renal calculi of >2cm in size. Smaller sheaths resulted in the decreased need for blood transfusion, less Hb drop, less rate of complications, decreased need of postoperative opioid analgesia, less VAS Pain scores, less duration of hospital stay and hence, better post-operative recovery and patient comfort as compared to their larger counterparts. Larger size sheaths, on the other hand, have superiority in terms of shorter operating durations. Miniaturization of PCNL is a safe and necessary evolution of this technique; so endourologists need to develop expertise that would further improvise the outcomes and bring the complications rate down while using even more miniaturized gadgets in the near future as technological advancement goes on.

CONFLICT OF INTEREST

None declared.

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AUTHOR CONTRIBUTIONS

AA: Objective, Manuscript writing
SS: Final approval of manuscript, Surgery
S.SQ: Surgery
JH: Ethical approval, results interpretation
DA: Data collection,
HA: Data analysis, Surgery assistance
NK: Data collection, Surgery assistance
ME: Data collection, Surgery assistance

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