ORIGINAL ARTICLE

Use of Amplatz Sheath in Percutaneous Nephrolithotomy and effect of its various sizes: Randomized Controlled Trial

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ABSTRACT

Background: Nephrostomy tract itself is the most common source of hemorrhage during percutaneous nephrolithotomy, which can be avoided by puncturing through the calyx with minimal angulation between calyceal system and the nephroscope shaft. Smaller the sheath diameter, lesser would be the bleeding. Our objective was to compare mean change in hemoglobin (HB) level in patients undergoing percutaneous nephrolithotomy (PCNL) with 24 versus 30 French Amplatz sheath.

Methods: In this study, 142 patients were randomly divided into Group A undergoing procedure with 24 French Amplatz sheath; and Group B with 30 French sheath. At the end of procedure in both groups, nephrostomy tube was kept for 24 hours. On first post-operative day, patients' HB was checked and compared with pre-operative data, along with blood transfusion rates. SPSS 20 was used for data analysis and p-value < 0.05 was considered significant.

Results: Median age and interquartile range of Group-A and Group-B patients was (40; 18) and (41; 21) years respectively. While stone size of Group-A and Group-B patients reported as (2.0; 0.60) and (2.1; 0.70) cm. The operative time and interquartile ratio of Group-A and Group-B patients was (75; 45) and (85; 45) minutes and we found significant change in HB of Group-A (0.90; 0.80) with Group-B patients (1.90; 0.70) gm/dl respectively [p = 0.000].

Conclusion: It was observed that use of 24 French Amplatz sheath lead to less renal hemorrhage and less hemoglobin drop compared to standard 30 French Amplatz sheath. Thus, small size Amplatz sheath in percutaneous nephrolithotomy may be considered effective and safe option for treatment of renal stones.

Keywords: Percutaneous Nephrolithotomy; Amplatz; Bleeding; Kidney Stones; Hemoglobin.

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INTRODUCTION

Percutaneous nephrolithotomy (PCNL) is the gold standard therapeutic modality for larger renal and proximal ureteric calculi[1,2]. In 1976, Fernstrom and Johansson were the first who described the removal of kidney stones through a nephrostomy tract under radiological guidance[3]. Alken, Marberger, Segura, Wickham and Smith further improved the technique, which later became the standard procedure[4-6]. Indications for PCNL include stone size larger than 2cm and stone in the calyceal diverticulum where extra-corporeal shockwave lithotripsy (ESWL) or the ureteroscopic approach fails to achieve stone clearance[7]. PCNL has significantly reduced the morbidity associated with open surgery for larger renal and proximal ureteric calculi. However, PCNL can result in to significant morbidity, like hemorrhage, sepsis, trauma to surrounding organs, or even loss of renal unit[8]. Although PCNL is well-defined procedure, clinicians are making various changes in the surgical technique to minimize the complications.

Among above complications, hemorrhage is a severe one[9]. Renal bleeding can be managed by placing nephrostomy tube, balloon catheter and lastly angioembolization[10]. Partial or total nephrectomy may be needed if above measures fail to control hemorrhage[10,11]. Stroller and colleagues had reported that 23% of patients undergoing percutaneous nephrolithotomy required blood transfusion for the optimization of hematocrit[12,13]. Increased risk for the hemorrhage depends on presence of stag horn stones, larger stones, multiple tracts formations, solitary kidney and diabetes mellitus[2,9,10]. Karakose and colleagues reported that post-operative hemorrhage was significant in patients in which larger Amplatz sheath was used when compared to smaller one[2]. They retrospectively observed that there was significant intra-operative hemorrhage by dilating tract more than 24 French[14]. In their study's control group, the mean preoperative hemoglobin was 14.2 ±1.6 gm/dl and postoperative one was 10.4±1.8 gm/dl; while in the case group, the preoperative hemoglobin was 13.9±1.8 gm/dl and postoperative one was 12.9±1.7 gm/dl with p value < 0.05[14].

Yamaguchi et al.[15] did a comparison of 5,537 patients in a global study analysis comprising of multiple variables affecting bleeding during PCNL. Univariate analysis showed that probability of bleeding complications was higher with larger sheath size (OR 1.42; p=0.0001). By multivariate analysis, sheath size but not dilation method was predictive of bleeding complications. The study's aim was to observe effects of Amplatz sheath size on post-operative hemorrhage by calculating post-operative hemoglobin drop. Two groups were formed in which 24 and 30 French Amplatz sheath were used respectively.

METHODS

This randomized controlled trial was conducted in Karachi, Pakistan at the Kidney Centre Postgraduate Training Institute. Patients who had PCNL from February 2015 to January 2016 were enrolled in the study. An ethical review board approval was taken (Reference # 46-URO-022015) before commencing the study. The patients were randomized into Group A and Group B by lottery method. PCNL was performed in Group A by using 24 French Amplatz sheath while with standard 30 French Amplatz sheath in Group B. After receiving general anesthesia, cystoscopy followed by ureteric catheterization was done in all patients in lithotomy position and Foley's catheter was placed. Position was changed to prone and renal system was accessed under fluoroscopic guidance. Once access was achieved, guide wire was inserted into the renal system. A 24 French or 30 French Amplatz sheath (according to group randomization) was positioned into the system after serial dilation of tract using Alken's dilators under continuous fluoroscopic vision. Nephroscopy was done and stone was fragmented using pneumatic lithotripter. Foreign body grasper was used for the retrieval of stone fragments. At the end of each procedure, Nephrostomy tube was kept under fluoroscopic guidance and anchored with skin to be removed on second post-operative day. On next day, patients' blood was sent to laboratory for hemoglobin levels and was compared with pre-operative data and recorded on Performa.

All recorded data was checked for normality. Mean and standard deviation was described for continuous variables (pre-operative and post-operative HB) and parametric testing by independent t-test was performed. Data that was not normally distributed (age, stone size, duration of procedure, and change in HB) was described in terms of median and interquartile ratio and was tested using Mann-Whitney test. Categorical variables (gender and stone location and laterality) were described as 'n number' and were compared between both groups applying Chi Square Test. SPSS (Statistical Packages of Social Sciences) version 20 was used for data analysis and p-value < 0.05 was considered statistically significant.

RESULTS

In this study 44 males and 27 female had PCNL in (Group-A); while 46 males and 25 females had PCNL in (Group-B) [p = 0.862] as shown in Figure 1.

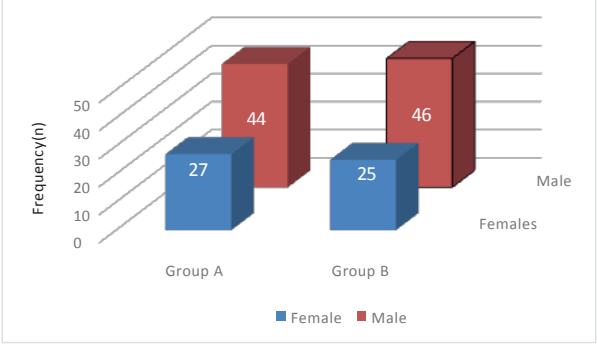

Figure 1: Gender distribution between two groups.

Median age and interquartile range of patients in Group-A (40; 18), was significantly not different from Group-B (41; 21) [p = 0.500] as shown in Table 1. Median stone size and interquartile range of patients in Group-A (2.0; 0.60), was indifferent from Group-B (2.1; 0.70) [p = 0.756] as shown in Table 1.

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Table 1: Demographic and clinical parameters.

Parameters	Analysis	GROUP-A (24 French Amplatz)	GROUP-B (30 French Amplatz)	*p*-Value
Age (years)	Median	40	41	p = 0.500
	Interquartile Range	18	21	
Stone Size (cm)	Median	2.0	2.1	p = 0.756
	Interquartile Range	0.60	0.70	

Median operative time and interquartile ratio of patients in Group-A (75; 45), was also comparative with Group-B (85; 45) [p = 0.192] as shown in Table 2. Mean pre-operative HB and standard deviation of patients in Group-A (12.20 ±1.82), was significantly not different from Group-B (11.83 ± 1.86) [p = 0.292] as shown in Table 2. Mean post-operative HB and standard deviation of patients in Group-A (13.02 ±1.78), was significantly not different from Group-B (13.95 ±1.92) [p = 0.221] as shown in Table 2. Median Change in HB and interquartile ratio of patients in Group-A (0.90; 0.80), was significantly different from Group-B (1.90; 0.70) [p = 0.000] as shown in Table 2.

Table 2: Investigative and Surgical Parameters.

Parameters	Analysis	GROUP-A (24) French Amplatz)	GROUP-B (30) French Amplatz)	*p*-Value
Operative Time (minutes)	Median	75	85	0.192
	Interquartile Range	45	45	
Pre-operative Hemoglobin (gm/dl)	Mean	13.02	13.95	0.221
	Standard Deviation	1.78	1.92	
Post-operative Hemoglobin (gm/dl)	Mean	12.20	11.83	0.292
	Standard Deviation	1.82	1.76	
Change in Hemoglobin (gm/dl)	Median	0.90	1.90	0.000
	Interquartile Range	0.80	0.70	

DISCUSSION

Median and interquartile ratio of change in HB in patients of Group-A (smaller sheath diameter) was significantly less than Group-B in our study, despite similar operative times [p = 0.000]. Kidney stones are a major worldwide health problem[16]. Pakistan lies in Afro-Asian stone Belt (stretching from Philippines, Indonesia, Thailand, India, and Iran and to the Egypt) which has been reported to be high incidence for urolithiasis[17]. Approximately 12% of the population suffers from urinary stone disease in their lifetime and recurrence rate approaches 50%[18]. In Pakistan, stone disease constitutes major workload in adult and pediatricpopulation[19].

PCNL is an established intervention used to treat patients with complex urolithiasis[20]. Moreover, PCNL has a success rate of more than 90% at the cost of complication rates greater than 10%[21]. The most commonly fearful complication following percutaneous renal surgery is renal parenchymal hemorrhage.

Hemorrhage can occur intra-operatively or during early or late postoperative period. Although in routine, small blood vessels are injured during the procedures, rarely cause significant hemorrhage, still necessitating a blood transfusion. Karlin et al.[22] reported that patients undergoing PCNL needed rescue procedures like angiography and embolization for uncontrolled bleeding in 0.8% of cases. It is vital for urologists to develop safe surgical techniques to minimize intraoperative bleeding associated with PCNL because of the risks associated with blood transfusions, consisting of transfusion reactions and infectious diseases. Only few studies pertaining to this subject are available to analyze which are mentioned forth.

Our results were supported by study by Ayhan Karakose[23] who found that use of small caliber Amplatz sheath in PCNL procedure demonstrated reduced hemorrhage, renal functional impairment, and postoperative pain. In his study, he stratified patients in to two groups, one having PCNL with 22 French Amplatz while the other group with 30 French. In group 1 and group 2 (30F), mean stone diameter of patients were 38.47 ± 11.51 mm and 37.69 ± 12.33 mm, respectively. Preoperative and postoperative hemoglobin levels were 14.52 ± 1.5 g/dL and 13.51 ± 1.4 g/dL, respectively in group 1; and 14.23 ± 1.6 g/dL and 10.73 ± 1.7 g/dL, respectively in group 2. In terms of mean operative time, there was significant difference noted between both groups (p = .023), as well as hemorrhage requiring blood transfusion (p = .023) and hospital stay (p = .034).

A very recent study by Thirugnanasambandam[24], 20 patients was operated by PCNL using different sized Amplatz sheath matching the fluoroscopic size of renal calyces. During the study, 28Fr (n=20), 26 Fr (n=6), 24 Fr (n=4), and 22 Fr (n=3) Amplatz sheaths were used for indicated number of patients. The mean pre and postoperative HB levels in all 20 patients was 12.2±0.8 g/dL and 11.8±0.6 g/dL, respectively (p> 0.30). He concluded that smaller size Amplatz sheaths reduce bleeding, renal impairment rates, and postoperative discomfort when compared to larger sized-Amplatz sheaths. In contrast to our study's objectives, a study reported by Cormio et al. showed that nephrostomy tube size and bleeding are not related (instead of Amplatz sheath)[25]. Patients who received a large caliber nephrostomy tube (>18 French) versus small caliber one (<18 French), had a significantly lower rate of HB reduction (3.0 *vs*. 4.3 g/dl; p < 0.001), overall complications (15.8 *vs*. 21.4 %; p < 0.001) and a trend toward a lower rate of fever (9.1 *vs*. 10.7 %)[26].

We think that despite of being a minimally invasive procedure, PCNL is still invasive to the kidney. Our study demonstrated that using a small diameter Amplatz sheath poses less damage to the kidney and results in reduced hemorrhage and renal functional impairment. Though our study lacks objective evaluation of postoperative pain status in patients, we still noticed that using a smaller caliber Amplatz sheath reduced postoperative pain in patients.

Prominent limitation of the study was the use of nephrostomy tube in all patients, which could lead to a tamponade effect upon the tract wall and might have altered the hemodynamics and coagulation mechanisms. In future studies, this bias can be neutralized by doing all cases tubeless so that true potential of using small caliber Amplatz sheath can be observed in controlling tract bleeding. Furthermore, need of more such future studies with even greater sample size, will improve further the results of studies and ultimately the level of evidence for future guidelines.

To best of our knowledge, no prospective study has been published internationally or locally with such variable. This study may provide current baseline data regarding this particular issue. If favorable results are found then it can shape the international guidelines stating that smaller Amplatz size should be used during percutaneous nephrolithotomy in order to decrease incidence of above-mentioned complications.

CONCLUSION

Innovation in techniques of percutaneous renal surgery has reduced the morbidity associated with these procedures. Using smaller size Amplatz (24) sheath in PCNL is an effective and a safe method for treatment of renal stones with possible brief hospital stay without increased adverse effects. Future prospective trials are required for using different sizes of Amplatz sheath to improve outcomes.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

ETHICS APPROVAL

The ethical committee of the Kidney Centre provided the ethics approval with Reference number: 64-URO-022018 dated on February 2018.

PATIENT CONSENT

Detailed informed consents were obtained from all the patients.

AUTHORS' CONTRIBUTION

Surgical practices were performed by SM, FY and AS. The research concept was given by SM and research design was proposed by AS. Data collection and processing was done by FY, AS, SH, WH and SK. Analysis

and interpretation was done by AS while literature search was performed by AS, FY and SM. The scientific writing was done by AS.

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