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COMPARISON OF OUTCOMES OF ONE STEP DILATATION VERSUS METALLIC TELESCOPIC DILATATION IN PERCUTANEOUS NEPHROLITHOTOMY

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Abstract:
Objectives: To compare the outcomes of one step dilatation versus metallic telescopic dilatation in PCNL.
Materials and Methods: Following approval from the ethical committee of The Kidney Centre Post graduate training Institute, this study was conducted within the Department of Urology from January 2022 to September 2022. A total of 90 patients were enrolled. Participants were randomized into two groups using lottery method: Group A underwent dilatation using the one-step dilatation method, while Group B underwent dilatation using metallic telescopic dilatation. A predesigned questionnaire was used to collect the data.
Results: The mean age of group A patients and group B patients were 39.36±10.0 and 37.60±11.3 respectively. The mean size of the stone was 3.15±0.69 cm in Group A and 3.41±0.70 cm in Group B with an insignificant p-value of 0.09. The stone free rate was 39(86.7%) and 32(71.1%) in group A and Group B respectively with an insignificant p-value of 0.07. There was a statistically significant difference between both groups regarding the tract creation time (2.28±0.47 and 4.01±0.65) and Fluoroscopic Exposure Time (65.37±17.9 seconds and 122.0±23.8 seconds) revealing a significant p-value of <0.001.
Conclusion: The study concludes that one step dilatation is more effective as compared to metallic telescopic dilatation for patients undergoing nephrolithotomy in terms of blood loss, improved renal function, tract creation time, and fluoroscopy exposure time without any effect on stone free rate.

Key words: One step dilatation, metallic telescopic dilatation, Percutaneous Nephrolithotomy

INTRODUCTION:

Percutaneous Nephrolithotomy (PCNL) is a surgical procedure used to treat large or complex kidney stones (renal calculi) that cannot be effectively treated with other methods such as extracorporeal shock wave lithotripsy (ESWL) or retrograde intra-renal surgery (RIRS).[(1)] Access tract creation is one of the most crucial step in PCNL.[(2, 3)] Dilatation involves expanding the percutaneous tract to

allow for the insertion of endoscopic instruments to remove kidney stones. At present, there are three methods available for creating an access tract: high-pressure balloon dilation, Amplatz serial fascial dilation, and Alken telescopic metal dilation. Two techniques for serial dilation include Amplatz fascial dilation and telescopic metal dilation. The drawbacks associated with these techniques include their time-consuming nature and the requirement for extended exposure to X-rays.[4, 5)]

Metal telescopic dilation (MTD) is cost-effective due to its reusability, and it sustains a tamponade effect throughout the dilatation process. On the other hand, the balloon dilator offers the advantages of shorter dilatation time and reduced fluoroscopy time, but it tends to be expensive, particularly in developing countries.[6-9)] Each method comes with its own set of pros and cons. Frattini introduced a novel approach known as "one-shot dilatation" (OSD), where tract dilatation is accomplished using a single Amplatz dilator (30F) over a central Alken rod. This technique combines the advantages of previous dilation methods into a single, integrated approach.[10, 11)] Subsequently, various researchers documented the effectiveness and safety of this technique, even in patients with a history of prior open kidney surgery. The approach demonstrated significantly reduced access time, diminished X-ray exposure, and lower blood loss compared to the serial dilator method.[12, 13)]
This study aims to investigate and compare the results of two different methods of dilatation used in the context of Percutaneous Nephrolithotomy (PCNL).

Objective:
To compare the outcomes of one step dilatation versus metallic telescopic dilatation in PCNL.

MATERIALS AND METHODS:

Study Design: Randomized Controlled Trial (RCT).

Study setting: Department of Urology, The Kidney Centre Post graduate training Institute, Karachi, Pakistan.

Duration of the study: This study was conducted between January 2022 to September 2022.

Inclusion Criteria:
- Individuals diagnosed with renal calculi (kidney stones) that require intervention through Percutaneous Nephrolithotomy (PCNL).
- Individuals with renal stones >2cm.
- Patients of 18-50 years of age.
- Both male and female patients.

Exclusion Criteria:
- Refusal to consent
- Pregnant women.
- Patients having bilateral stones
- Hydronephrosis on NCCT
- Uncorrected coagulopathies
- Previous renal surgery
- Congenital renal anomalies
- Previous intercostal (supracostal) access
- Uncontrolled Diabetes Mellitus
- Uncontrolled hypertension

Methods:

Upon obtaining approval from the ethical committee of The Kidney Centre Post graduate training Institute (Reference No. 119-URO-042021-062021), this study was undertaken within the department of Urology from January 2022 to September 2022. The patients admitted for percutaneous nephrolithotomy in the Kidney Centre Postgraduate Training Institute, Karachi were enrolled for this study. Patients meeting our selection criteria were selected by non-probability consecutive sampling method. A total of 90 patients fulfilling the inclusion criteria were enrolled. The participants were randomized using lottery method into two groups. Group A underwent dilatation using the one-step dilatation method, while Group B underwent dilatation using metallic telescopic dilatation. The process of gathering baseline data included a comprehensive review of the patient's medical and surgical history, a physical examination, and several laboratory and radiologic tests. These included abdominal plain film (which included kidney, ureter, and bladder radiographs [KUB]), abdominal ultrasonography, non-contrast kidney, ureter, and bladder computed tomography (NCCT), urine analysis, urine culture with sensitivity and culture testing, serum urea, creatinine and electrolytes (UCE) and complete blood count (CBC). Hemoglobin and serum creatinine levels were also carried out 24 hours post-operatively. For the stone size, we measured the stone's longest diameter from NCCT. X-ray KUB was done at 4 weeks post-operatively in case of radio-opaque stones and ultrasound KUB in case radio-lucent stones to assess stone free rate. Residual fragments < 2mm were considered to be stone free. Data were gathered using predesigned questionnaires. SPSS Version 25 was used for statistical analysis.

RESULTS:

The mean age of all the enrolled patients was 38.48±10.7 years. The mean age of group A patients and group B patients were 39.36±10.0 and 37.60±11.3 respectively with insignificant p-value of 0.44. In this study 48 (53.3%) patients were male and 42 (46.7%) were female (table 1).

The mean size of the stone was 3.15±0.69 cm in Group A and 3.41±0.70 cm in Group B with an insignificant p-value of 0.09.

Out of total enrolled patients in Group A and Group B 9(20.0%) and 1(24.4%) were smokers, 12(26.7%) and 10(22.2%) were suffering from HTN, 8(17.8%) and 6(13.3%) were suffering from DM, 4(8.9%) and 6(13.3%) had IHD respectively.

The stone free rate was 39(86.7%) and 32(71.1%) in group A and Group B respectively with an insignificant p-value of 0.07.

The tract creation time was found statistically significant between both groups 2.28±0.47 and 4.01±0.65 with significant p-value of <0.001.

The Fluoroscopic Exposure Time was 65.37±17.9 and 122.0±23.8 seconds with significant p-value of <0.001 in both groups (table 2).

The mean pre-op Hb in both groups were 14.69±0.81 mg/dl and 14.73±0.81 mg/dl with p-value of 0.78 and post-op Hb were 13.63±.84 mg/dl and 13.31±.83 mg/dl with a p-value of 0.07 in Group A and Group B respectively.

The mean pre-op Creatinine in both groups was 0.84±0.82 mg/dl and 0.84±0.08 mg/dl respectively with p-value of 0.73 and post-op Creatinine was 0.81±0.8 mg/dl and 0.93±0.84 mg/dl in Group A and Group B respectively with a p-value of <0.001 (table 3).

Decrease in Hemoglobin level was significantly higher in Group-B patients as compared to Group-A patients. i.e. (1.05 g/dl vs. 1.42 g/dl, p-value<0.001) and similar trend was seen for creatinine level. i.e. (0.03 mg/dl vs. 0.09 mg/dl, p-value<0.001). Mean difference in Hb and Creatinine in both groups is given in table 4.

Duration of procedure was 89.71 ± 35.05 vs 97.02 ± 42.2 minutes with p-value of 0.37.

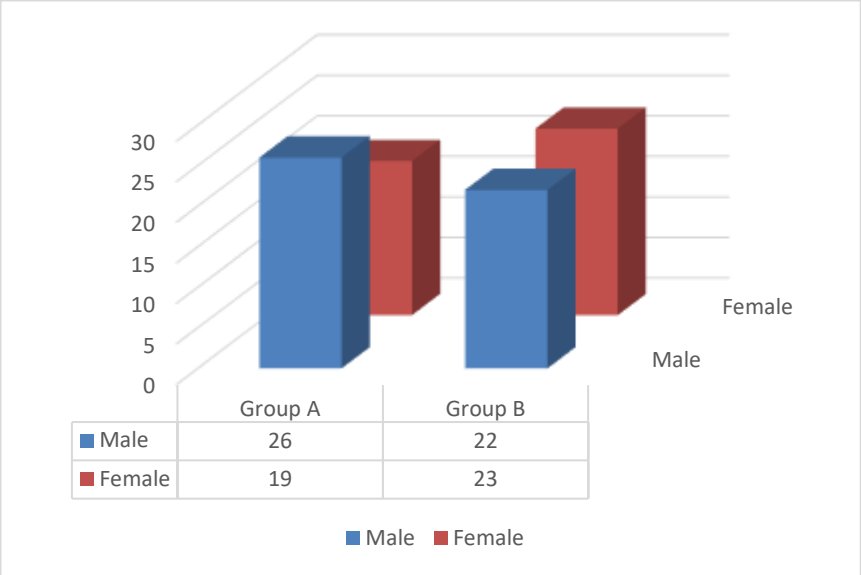

Fig 1: Graph showing distribution of patients based on gender in both groups.

Table 1: Baseline characteristics of the one-shot dilation and the metallic telescopic dilatation groups *(n=90)*

Variables	Groups		P-value
	Group A	Group B	
Age (years)	39.36±10.0	37.60±11.3	0.44
Gender			
Male	26(57.8%)	22(48.9%)	
Female	19(42.2%)	23(51.1)	0.39
Smoking	9(20.0%)	1(24.4%)	0.61
HTN	12(26.7%)	10(22.2%)	0.62
DM	8(17.8%)	6(13.3%)	0.56
IHD	4(8.9%)	6(13.3%)	0.52
Side			
Right	24(53.3%)	23(51.1%)	0.83
Left	21(46.7%)	22(48.9%)	
Stone Size (cm)	3.15±0.69	3.41±0.70	0.09

Table 2: Primary outcome measures

Variable	Group A	Group B	P-value
Tract Creation Time (minutes)	2.28±0.47	4.01±0.65	<0.001
Duration of Procedure (minutes)	89.71±35.05	97.02±42.2	0.37
Stone free rate	39(86.7%)	32(71.1%)	0.07
Fluoroscopic Exposure Time (seconds)	65.37±17.9	122.0±23.8	<0.001

TABLE 3 Comparison of pre-op and post-op Hemoglobin and serum creatinine in both groups

Variables	Groups		P-value
	Group A	Group B	
Pre-operative Hb	14.69±0.81	14.73±0.81	0.78
Post-operative Hb	13.63±.84	13.31±.83	0.07
Pre-operative Creatinine	0.84±0.82	0.84±0.08	0.73
Post-operative Creatinine	0.81±0.8	0.93±0.84	<0.001

Table 4: Comparison of mean decrease in Hemoglobin and Creatinine in both groups.

Groups	**Decrease in**	**Mean**±SD	**P-value**
Group A	Hemoglobin	1.05±1.76	<0.001
Group B	Hemoglobin	1.42±0.22	
Group A	Serum Creatinine	0.03±0.01	<0.001
Group B	Serum Creatinine	0.09±.01	

Discussion:

The aim of the present study was to compare the outcomes associated with two different techniques of renal access dilation during Percutaneous Nephrolithotomy (PCNL). The primary focus is on assessing the effectiveness and safety of one-step dilatation as compared to metallic telescopic dilatation. Many research studies have compared the one-shot dilation and the telescopic metal dilation techniques. Most of these studies found that the one-shot dilation method works well.[14, 15] It not only is effective but also helps reduce the time it takes to access the kidney and lowers the exposure time to x-rays during the procedure.[16-20] Additionally, none of the six randomized controlled trials identified significant differences in success rates and stone-free rates between the one-shot dilation and serial dilation techniques.[20] In the present study, we found the Fluoroscopic Exposure Time 65.37±17.9 seconds in group A and 122.0±23.8 seconds in group B is statistically significant with p-value of <0.001. Trisakul Y documented fluoroscopy durations in the range of 60 to 130 seconds, with an average of 90 seconds, for 60 patients undergoing standard PCNL with the fascial dilation technique. [21] Notably, this study stated time was in the above given range. In contrast to our study findings Amirhassani et al.[18] recorded a mean fluoroscopic time of 41.2 ± 17 seconds in one step dilation and 48.4 ± 15 seconds in telescopic metal dilation. In one-step dilatation method the exposure time was less than the exposure time in metallic telescopic dilatation.

In the present study we have found statistically significant difference in tract creation time between both groups, with values of 2.28±0.47 minutes and 4.01±0.65 minutes, yielding a p-value of <0.001. In a study conducted in China it was observed that, one step group had a significantly shorter mean tract creation time (1.9 ± 0.5 vs 4.5 ± 0.8 min, p-value< 0.001) compared to the sequential group without any difference of stone-free rate (86.4% vs 85.9%, p-value = 0.6145) between both the groups.[28] Similar finding were noted by a study conducted in Nepal.[15] Therefore, one-step dilatation reduces the redundancy associated with serial metallic telescopic dilatation without compromising the outcomes.

In the present study we have found the stone free rate in 39(86.7%) and 32(71.1%) in group A and Group B respectively with an insignificant p-value of 0.07. When comparing these findings with other studies conducted in Thailand, Trisakul Y reported a 67% stone-free rate in 2020 for standard PCNL with the fascial dilation technique.[21] In the case of standard PCNL with metallic dilation, Amornratananont et al. [22] reported a stone-free rate of 54.8% in 2019, while Ahmadmusa N reported a stone-free rate of 74.6% in 2020.[23] Xiong J et al, reported stone free rate of (86.4% vs 85.9%, p-value = 0.6145) between one step group and sequential group.[28] These results indicate variations in stone-free rates among different studies and highlight the importance stone size and complexity rather than tract creation technique for stone free rates in Percutaneous Nephrolithotomy (PCNL).

The results of the current study also highlighted a noteworthy change in hemoglobin and serum creatinine post-operatively. In this study, decrease in hemoglobin level was significantly higher in Group-B patients as compared to Group-A patients. i.e. (1.05 vs. 1.42 g/dl, p-value<0.001). This decrease may be attributed to factors such as longer tract creation time, surgical blood loss or alterations in fluid balance during the procedure. We found a similar trend for decrease in post-operative serum creatinine levels. i.e. (0.03 vs. 0.09 mg/dl, p-value<0.001). In an international study it was found that one step dilation group had a lower postoperative hemoglobin decline than sequential group (0.81 vs. 2.03 g/dl, respectively; p < 0.001). Similarly, postoperative serum creatinine levels (0.93 ± 0.29 vs. 1.13 ± 0.4 mg/dl; p = 0.039) were also significantly less in one step

group.[27] Creatinine is a key indicator of kidney function, and a decrease in its levels could imply improved renal clearance or function following the surgical intervention.[(25)] Our study finding was supported by the study conducted by Khaled Mohyelden et al.[(11)] An another study conducted by Dr. Ganesh Bhakta Acharya et al[(15)] stated that no difference was observed in the procedural success rate between groups A and B (96% v 94% respectively, p=0.64).
From these results, the One Step dilation proves to be straightforward and convenient technique, without the need for any specialized equipment. It facilitates reduced access and fluoroscopic time, consequently lowering the potential risk of x-ray exposure for both the surgical team and the patient. Numerous techniques have been developed thus far to mitigate x-ray exposure, and the one-shot dilation technique is just one among them.[(22, 26)]

Study Limitations: The primary limitation of this study is its relatively small sample size, which may impact its generalization and wider implications of its outcomes. A larger-scale multicentric study would yield more robust and widely applicable results into the comparison of One Step Dilatation versus the Metallic Telescopic Dilation during PCNL.

Conclusion: Results of this study demonstrate that one step dilatation is more effective as compared to metallic telescopic dilatation for patients undergoing nephrolithotomy in terms of blood loss, improved renal function, tract creation time, and fluoroscopy exposure time without any effect on stone free rate.

Conflicts of Interest: The authors declare no conflicts of interest.

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