Single-step dilatation in percutaneous nephrolithotomy, its safety and efficacy: A prospective, single-center study

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Abstract Background: Percutaneous nephrolithotomy (PCNL) is gold standard technique for the treatment of renal calculi larger than 2 cm or complex renal calculi. Establishment of nephrostomy tract is the important step during PCNL. Hence, this study was conducted to evaluate the effectiveness of single-step dilatation in patients with renal calculi undergoing PCNL.

Methods: This is a prospective, single-center study conducted between August 2014 and December 2017. Patient who underwent PCNL using single-step dilatation between the study period were included in the study. Demographic details, stone characteristics, operative time dilatation time, radiation exposure time, rate of complication and blood transfusion were recorded. Data was analyzed and reported using summary statistics. **Results:** A total of 332 patients were enrolled in this study. The mean (SD) age was 42.46 (15.53) years and 181 (54.52%) patients were male. Overall, stone clearance rate was 92%. The mean (SD) operative time was 62.74 (29.61) minutes, tract dilatation time was 2.18 (1.05) minutes, and the radiation exposure time was 12.68 (6.45) seconds. Blood transfusion was required in 12(3.6%) patients. No major complications were reported during post-operative period.

Conclusion: Single-step dilatation technique is safe, economical and feasible technique with added advantage of lesser time of dilatation, lesser radiation exposure and lesser chance of blood transfusion.

Keywords: Calyceal access, complications, dilatation, percutaneous nephrolithotomy, renal calculi

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INTRODUCTION

Percutaneous nephrolithotomy (PCNL) is a minimal invasive gold standard technique first established in 1976 by Fernstrom and Johansson^[1] for the treatment of renal calculi larger than 2 cm in diameter, multiple calculi, staghorn calculi, or large lower calyceal calculi.^[2,3] This technique has proved to be associated with higher success and lower complication rate. The steps for the establishment of nephrostomy tract are the most vital

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during PCNL, which is followed by fragmentation of calculus and placement of nephrostomy.

Dilatation of the nephrostomy tract is conventionally done using three techniques – balloon dilator, serial Alken metal telescope dilators, and semi-rigid Amplatz fascial dilatator.^[4,5] Although conventional single-step dilatation includes use of balloon dilator as safe method, it is associated with higher cost.^[4,6] Metal telescopic

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dilation is time-consuming and increases the risk of radiation exposure; however, serial Amplatz dilatation has disadvantage of more blood loss during exchange process.^[5]

To overcome these challenges, single-step dilatation of the tract with desired Amplatz dilator (24–30 Fr) is described. This reduces the time of dilatation and radiation exposure and also gives good tamponade effect, which causes lesser blood loss, and overall making it economical. Few studies have been reported about single-step dilatation as one of the safe methods of dilatation.^[5,7-9] The main objective of the study is to evaluate safety and efficacy of single-step dilatation during PCNL in patients with renal calculi.

METHODS

Study design

This was a prospective, single-center study conducted between August 2014 and December 2017. Patients of either sex, aged >15 years with renal calculus of size >2 cm and/or multiple renal calculi who underwent PCNL with single-step dilatation at our tertiary care hospital were included in the study. The decision of PCNL was based on clinical judgment and was not prespecified by the study protocol. Patients with bleeding disorders, uncontrolled urinary tract infection, or pregnant women were excluded from the study. The surgical procedure was carried out by a team of experienced urologists comprising two surgeons with similar experience and one senior urologist.

The study protocol was reviewed and approved by the institutional ethics committee (IEC). The study was conducted in accordance with the approved protocol, International Conference on Harmonization Good Clinical Practice guidelines, and Declaration of Helsinki 2013. Each study participant provided written informed consent (assent where applicable along with parent's consent) before participation in the study.

Demographic details, stone characteristics (preoperative computed tomography [CT] scan of kidney ureter bladder region), total operative time, mean time of tract dilatation, radiation exposure time, rate of complications, and blood transfusions were also recorded for analysis. Patients were evaluated with modified Clavien grading system for perioperative and postoperative complications.

Standard surgical technique

Preoperatively, patient undergoes complete blood count, renal function test, and coagulation profile. The PCNL is performed with patient in prone position under general anesthesia. First, the patient is placed in lithotomy position, cystoscopy is done, and 5 Fr ureteric catheter is inserted and fixed to transurethral Foleys catheter. The patient is then repositioned to prone position and pelvicalyceal system is delineated by retrograde injection of contrast material. The 18G PCNL access needle is used to puncture the desired calyx under fluoroscopic/c-arm guidance and guide wire is passed into calyx/pelvis/ureter. An 8–10Fr Alken needle dilator is used for initial dilatation of tract for introduction of guide rod.

Single-step dilatation

Single-step dilatation was done by slowly advancing the Amplatz dilator (24–30 Fr) of desired size under c-arm guidance/fluoroscopy, same diameter access sheath was glided over the dilator. Similar technique was followed if the patient required second or multiple punctures in a complex stone. A 20 Fr rigid nephroscope was used for the procedure and ballistic lithotripter was used for fragmentation of stones. At the end of procedure DJ stent or a nephrostomy tube was inserted.

Statistical analysis

There was no formal sample size calculation used for this study. All statistical analysis was performed using SPSS (version 16.0, Chicago, Illinois, USA). The data obtained were tabulated, analyzed and presented using descriptive statistics, means (standard deviations), or as number (percentages).

RESULTS

Overall, 332 participates were enrolled. Demographic details and stone characteristics are summarized in Table 1. The mean (standard deviation [SD]) age was 42.46 (15.53) years and ranged from 16 to 81 years. Of the total 332 patients, 181 (54.52%) were male and 151 (45.48%) were female. Five patients had horseshoe kidney. A total of 12 (3.61%) patients had undergone previous open surgery (pyeloplasty, pyelolithotomy). 136 (41.96%) patients had Guy's stone score (GSS) II.

Table 1: Demographics	and stone	characteristics	(<i>n</i> =332)
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Parameters	Value
Age (years), mean (SD)	42.46 (15.53)
Sex	
Male	181 (54.52)
Female	151 (45.48)
Renal abnormalities	
Horseshoe kidney	5 (1.51)
Previous open surgery	12 (3.61)
Stone type (GSS)	
GSSI	88 (26.51)
GSS II	136 (41.96)
GSS III	67 (20.18)
GSS IV	41 (12.35)

Data presented as n (%), unless otherwise specifies. GSS: Guy stone score, SD: Standard deviation

Table 2: Sum	mary of	observations	(<i>n</i> =332)	
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Parameters	Value
Total operation time (min), mean (SD)	62.74 (29.61)
Tract dilatation time (min), mean (SD)	2.18 (1.05)
Total radiation exposure (s), mean (SD)	12.68 (6.45)
Hospital stay, median (range)	4 (2-22)
Operation side	, , , , , , , , , , , , , , , , , , ,
Right	184 (55.42)
Left	148 (44.58)
Number of punctures	
1	233 (70.18)
2	81 (24.40)
3	18 (5.42)
Access method	
Triangulation	148 (44.58)
Bull's eye	184 (55.42)
Postoperative drainage	
Nephrostomy tube	286 (74.10)
Tubeless	46 (13.86)
Blood transfusion	12 (3.61)
Complications (modified Clavien classification) (%)	69 (20.7)
Grade 1 (%)	32 (9.63)
Grade 2 (%)	27 (8.13)
Grade 3a (%)	8 (2.40)
Grade 3b (%)	1 (0.03)
Grade 4	0
Grade 5	0

Data presented as n (%), unless otherwise specifies. SD: Standard deviation

The stone clearance rate was 92%. The mean (SD) operative time was 62.74 (29.61) min (range: 22-160 min), tract dilatation time was 2.18 (1.05) min, and the radiation (fluoroscopy) time was 12.68 (6.45) s. Multiple tracts were required in 99 (29.82%) patients; however, in 233 (70.18%) patients, calculus was cleared with single puncture. The median (range) hospital stay was 4 (2-22) days; there were 121 (36.45%) patients who were discharged within 3 days; and 184 (55.42%) patients were discharged between 3 and 10 days. A total of 184 patients were operated on the right side and 148 were operated on left. The PCNL needle access was done using triangulation technique in 148 (44.58%) and by Bull's eye technique in 184 (55.42%) of patients. Overall, 286 (74.10%) patients needed nephrostomy tube in postoperative period. In 46 (13.86%) patients, "nephrostomy-free" or "tubeless" PCNL was done. The Perioperative details are listed in Table 2.

There were no deaths reported during this study. None of the patients had any major complications during postoperative period. 27 (8.13%) patients had residual fragments \geq 5 mm, these patients were followed up for 3 months, and 12 patients required ESWL. Blood transfusion was required in 12 (3.6%) patients, all of whom either had staghorn calculus or GSS IV calculus requiring multiple puncture. None of the patients required postoperative embolization. Complications were seen in

69 (20.7%) patients. It was divided according to Clavien classification into grade 1, 2, 3a, and 3b, which was observed in 32 (9.63%), 27 (8.13%), 8 (2.4%), 1 (0.30%) patients respectively. None of the patients had grade 4 and 5 complications.

DISCUSSION

PCNL has remained the treatment of choice for renal calculi of larger than 2 cm since its introduction in 1976 for extracting renal calculi through percutaneous nephrostomy under radiological control.^[1] The PCNL has gone through various modifications and changes and still evolving. Several types of dilators have been introduced; few of them have stood the test of time. Dr. Kurt Amplatz introduced serial fascial dilators, and later Dr. Alkem developed co-axial sequential telescoping metal dilators. Earlier, Dr. Wickam described serial dilatation of tract up to 26 Fr over several procedures. Now, single-step dilatation technique has been introduced, which shortens the operative time and radiation exposure, also associated with lower incidence of blood loss and related complications. Although balloon dilatation is considered relatively a safe and effective method, it is not routinely used due to its high cost.

In 2001, Frattini et al. proposed single-step dilatation for nephrostomy access. Their study included a total of 78 patients who underwent PCNL from June 1998 to July 1999 and divided into three groups based on tract dilation technique - Alken telescoping dilators, balloon, or single-step. Authors concluded that single-step was feasible in majority of patients and was associated with significantly reduced radiation exposure and cost.^[10] In a study by Amjadi et al., 31 patients with the history of open surgery for renal calculi who underwent single-step dilatation for PCNL showed that stone-free rates and complication rates were comparable in both telescopic procedure and single-step procedure groups; however, fluoroscopy time was significantly shorter than that of the telescopic procedure which reduced from 81 to 27 s.^[11] In another recent study by Suelozgen et al., a total of 932 patients who underwent PCNL using single-step dilation technique were included in the study and had mean fluoroscopy time of 139 s with mean total operative time of 66 min and 82.9% stone clearance rate. These results demonstrated that single-step dilation could be used as an effective and safe alternative dilation.^[7]

In the present study, the mean operative time was 62.74 min, the mean fluoroscopy time of 12.68 s, and total tract dilatation time was 2.18 min with stone clearance rate of 92.7% which are comparable with the literature.

Complications associated with PCNL range between 20% and 83%.^[12] Kidney being a vascular organ, bleeding is one of the major complications during PCNL. Lesser amount of bleeding rarely requires any intervention or transfusions, but severe amount of bleeding always raises the alarm and requires transfusion which is reported around 2%–7% patients.^[12] In the present study, only 12 of 332 patients (3.61%) required postoperative blood transfusion; most of whom had complex anatomy or staghorn calculus requiring multiple punctures. These results are on lower side compared with previous results, possibly due to good tamponade effect during single-step dilatation and due to good success rate of dilatation preventing multiple manipulations. None of our patients required angioembolization or died due to bleeding.

There are continuous efforts to reduce the radiological exposure to the operating personnel or team. Be it using an ultrasound-guided puncture or by using still images rather than continuous fluoroscopy during tract creation or the use of single-step dilatation of access tract. With any of these techniques, significant reduction in the radiation burden can be achieved.

Use of a balloon dilator is said to be the gold standard, but it is associated with significant expenses, especially in hospitals in the developing part of the world. Use of single-step Amplatz dilator reduces this burden and costs are further lowered by the reusability of these dilators after proper disinfection.

Authors acknowledge following limitations of the study. First is nonavailability of comparison with other standard dilatation techniques which are regularly used. This could have helped to compare outcomes of single-step dilatation. Second, this was a single-center study and may not represent all the centers.

CONCLUSION

Single-step dilatation technique with Amplatz dilators can be used as a safe, effective, economical method of dilatation to gain pelvicalyceal access during PCNL. It also reduces the operative time along with radiation exposure to the theater personnel.

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Conflicts of interest

There are no conflicts of interest.

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