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Original Article

Surgery Section

Single vs Serial Dilatation of Access Tract in Percutaneous Nephrolithotomy: A Randomised Control Study on its Feasibility and Effects in Management of Renal Calculi

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ABSTRACT

Introduction: Percutaneous Nephrolithotomy (PCNL) is the recommended treatment for renal calculi. The tract dilatation method has a significant effect on the surgical outcome. One-Shot Dilatation (OSD) involves dilatation using the dilator and Amplatz of desired size, while Serial Dilatation (SD) involves increasing the dilator size progressively upto the desired size.

Aim: To compare the success and complication rates of SD techniques and OSD technique using Amplatz dilators.

Materials and Methods: This was a randomised control study, conducted in a tertiary care centre of Bharati Hospital, Pune, Maharashtra, India, from March 2020 to December 2021. A non probability sampling technique was followed and hundred consecutive patients of renal calculus were included in the study. The patients were then randomly allocated using random number table to undergo PCNL via a One shot Dilatation (OSD-group I) or Serial Dilatation (SD-group II) of access tract. After the initial work-up, the patients underwent PCNL, tract dilated as per the group enrolled. The two groups were then compared for patient demographics, stone characteristics (size, number, location), dilatation type, access time, tract size, access quality, bleeding at entry, operative time, radiation time, postoperative analgesic requirement, tube or tubeless procedure, time for removal of the nephrostomy tube and double 'J' stent placement. The statistical inference was obtained by Analysis of Variance (ANOVA), Kruskall-Wallis t-test, Fisher's-exact test or Chi-square test. Significance was said when p-value <0.05. The analysis was performed on p-value.

Results: In the patients from group I, there was lesser blood loss (Haemoglobin drop 0.89 vs 1.34 gm/dL), clot at entry (6% vs 28%), and radiation exposure (60.9 sec vs 94.1 sec) as compared to group II patients. This was also reflected in reduced mean operative time (46.2 min vs 57.1 min) and lesser duration of hospital stay (3 vs 4 days) among group I patients.

Conclusion: The OSD was found to be superior to SD using Amplatz dilatation in PCNL in terms of having reduced blood loss and reduced exposure to radiation for the patient.

Keywords: Access tracts, Amplatz, Dilatation methods

INTRODUCTION

Percutaneous Nephrolithotomy (PCNL) is a safe and minimally invasive procedure with a high success rate in stone clearance [1,2]. Two most critical steps in PCNL are, gaining access to the pelvicalyceal system and the dilatation of the access tract. These two steps correlate with the success and the complications of the procedure [3]. Usually access and dilatation are done under fluoroscopic guidance [4,5,6]. The use of fluoroscopy bears a risk of radiation exposure to the patient and the surgical team, hence minimising the duration of radiation exposure is important.

The OSD technique was first described by Travis DG et al., [7]. Where, after dilatation with 6 Fr, they skipped to 25-30 Fr dilatation. Later, Frattini A et al., in a study of 26 patients, dilated up to 30 Fr with OSD technique [8]. This technique also has the advantage of quick creation of the access tract [9,10]. After achieving successful access to the tract, fascial dilatation is done. In one shot dilatation technique, the guide rod is inserted over the guide wire and the tract dilator of desired size is threaded over it. After completion of tract dilatation, the Amplatz Sheath is threaded over the dilator. The guide rod dilator assembly is then removed, the tract is kept patent vis the amplatz and the guide wire.

Whereas in the SD technique, after fascial dilatation, the guide rod is passed and tract dilators are passed sequentially, gradually dilating the tract upto the desired size. The Amplatz sheath is then passed over the final dilator and the guide rod dilator assembly is removed to maintain the tract patent via the Amplatz sheath and guide wire. This method has been associated with more blood loss due to repeated insertion and removal of the dilators, causing loss of tamponade effect during the exchange of the dilators.

A meta-analysis by Li Y et al., found that the SD technique was more time consuming. Due to repeated movement of dilators under fluoroscopy guidance, the exposure to radiation was higher. This also meant more trauma to kidney tissue, as compared to single shot dilatation [11].

This study compares the success and complication rates of SD techniques and OSD technique using Amplatz dilators. The primary outcomes measured were mean Haemoglobin (Hb) change, encountering clot upon entry and access time (duration of radiation exposure). The secondary outcomes were duration of surgery, and the length of hospital stay.

MATERIALS AND METHODS

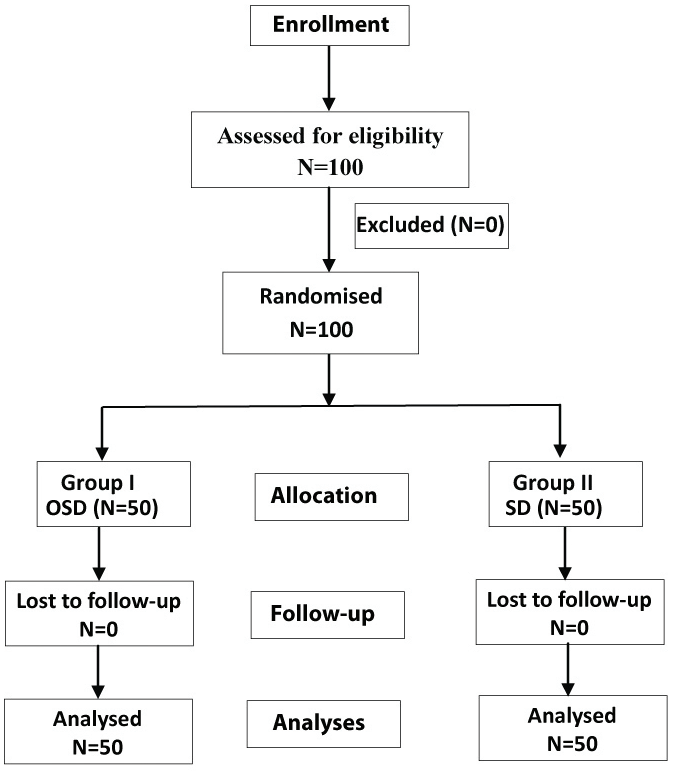
This randomised control study was conducted in a tertiary care center, Bharati Hospital in Pune, Maharasthra, India, from March 2020 to December 2021. All the patients undergoing PCNL in the Department of Urology at Bharati Hospital and Research Centre were included in the study. The study was performed after obtaining clearance from the Institutional Ethical Board (BVDUMC/IEC/03).

Inclusion criteria: All patients undergoing PCNL in the hospital, within the study period were included.

Exclusion criteria: Patients requiring multiple access tracts, urosepsis, uncorrected coagulopathy were excluded.

Study Procedure

A non probability sampling technique was followed. Hundred consecutive patients of renal calculus were included after obtaining their informed consents. The patients were then randomly allocated using random number table, to undergo PCNL via a OSD or SD of access tract. The patients who underwent OSD were classified as group I, and those who underwent SD were classified as group II [Table/Fig-1].



[Table/Fig-1]: CONSORT flowchart.

All enrolled participants were evaluated clinically, biochemically, and radiologically as per the set proforma of the study. This included a thorough clinical checkup and investigations like a complete blood count, coagulation profile, blood sugar and urea/creatinine. Urine analysis with routine examination and culture sensitivity was done in all the patients. X-ray, ultrasonography and a computerised tomography of Kidney Ureter and Bladder region (KUB) were done in every patient.

The PCNL was done either in general or spinal anesthesia. After lithotomy, a 6 Fr ureteral catheter was introduced over a 0.035-inch guidewire into the ureter and kidney. A per urethral catheter was kept. After turning the patient prone, the surgical field was prepared and draped. The desired calyx was punctured under fluoroscopy after retrograde pyelography under fluoroscopic control with an 18-gauge trocar needle. A 0.035-inch guidewire was introduced into the pelvicalyceal system. Over the guidewire, a fascial dilator of 8 Fr was passed, followed by a guide rod.

In group I patients, undergoing OSD technique, over the guide rod, the Amplatz dilator of the desired size was introduced to widen the tract. The Amplatz access sheath was passed over the dilator into the desired calyx. The dilator guide rod assembly was removed. The guidewire was left in the sheath to serve as a safety wire. In group II patients, who underwent SD technique, the Amplatz dilators were sequentially passed over the guide rod until the desired dilatation size was reached. The Amplatz sheath was introduced, and the guide rod dilator assembly was removed leaving the safety guide wire in-situ. Nephroscopy was done, stones were fragmented using a pneumatic lithoclast or Holmium YAG laser. After removal of the stones, 5/26 Double J stent (DJ stent) was placed in the ureter in an antegrade fashion. The decision of the postoperative placement of a nephrostomy was left to the discretion of the surgeon.

The two groups were then compared for patient demographics, stone characteristics (size, number and location), dilatation type, access time, tract size, access quality, bleeding at entry, operative time, radiation time, postoperative analgesic requirement, tube or tubeless procedure, time of removal the nephrostomy tube and double 'J' stent placement. The radiation exposure time was defined as the active fluoroscopy time between the insertion of an 18-gauge needle and the placement of the Amplatz sheath. Operative time was calculated from the time of achieving puncture to the pelvicalyceal system to the insertion of nephrostomy tube. Lastly, preoperative and postoperative haematology and biochemistry was compared, and transfusions, if needed, were documented.

The X-ray KUB was done on the first Postoperative Day (POD) and a decision to remove the nephrostomy tube was made based on the stone clearance and the color of the urine draining from the nephrostomy tube.

STATISTICAL ANALYSIS

All the data was noted down in a pre-designed study proforma. Qualitative data represented in the form of frequency and percentage. The statistical inference was obtained by ANOVA, Kruskall-Wallis t-test, Fisher's-exact test or Chi-square test as per the parameters to be compared. Significance was said when p-value <0.05. The analysis was performed on p-value.

RESULTS

There were 50 patients in group I who underwent tract dilatation by OSD technique, and 50 patients in group II who underwent tract dilatation by SD technique. The mean age of the patients was 41.2 years. The patient population consisted of 61 males, and 39 females. There was no significant difference in the stone burden and the laterality of the stone [Table/Fig-2].

Parameters	Group I	Group II	p-value
Mean age (years)	41.16	45.34	0.215
Gender (female/male)	19/31	20/30	0.84
Laterality (right/left)	25/25	23/27	0.841
Mean stone size (mm^2)	28.82	30.24	0.57

[Table/Fig-2]: Comparison of patients demographic data.

Among the patients enrolled in the study, majority had a lower calyceal access. There was a significantly lower rate of clot at entry, access time in group I as compared to group II. This difference was also seen across the mean operative time and the overall all hospital stay (p-value <0.05) [Table/Fig-3].

In the postoperative period, there was a significantly lesser drop in Hb in group I as compared to group II. While the stone free rates in group I were 100%, the clearance rates in group II were 96%. There was a similar rate of transfusion in both the groups. There was a higher requirement of analgesics in the group II patients, but this was not statistically significant. Among the other findings were that the patients in group I 42% (n=21) were able to become ureteral stent free by the 14^{th} POD, while only 72% of group II patients were able to become DJ stent free by 14^{th} POD. There was also a significant difference in indwelling urethral catheter time among the study groups. This difference was also seen in the mean duration of postoperative hospitalisation which was lesser in group I as compared to group II [Table/Fig-3]. There was no statistically significant difference between both the groups with respect to tract size and access quality.

Variables	Group I	Group II	p-value
Access site			
Upper calyx	2	0	0.433
Middle calyx	8	7	
Lower calyx	40	43	
Clot at entry (yes/no)	3/47	14/28	0.006
Mean Hb change* (g/dL)	0.892	1.34	0.037
Access time (seconds)**	60.9 (30.9)	94.1 (32.04)	<0.001
Mean length of hospital stay (days)	3	4	0.042
Mean operative time (minutes)	46.2	57.1	0.032
Stone free rate	100%	96%	0.495
Transfusion required	1	1	1.0
Analgesic requirement 3 doses	46	48	1.0
Stent removal on POD 14	21	36	0.001
Foleys removal on POD 2	38	39	0.045

[Table/Fig-3]: Comparison of intraoperative and postoperative data.
*Calculated by repeating the postoperative Hb on the first postoperative day, and calculating the difference; **The duration of use of the fluoroscopy machine was recorded; p-value <0.05 considered significant

DISCUSSION

The One-Shot Dilatation (OSD) technique was first described by Travis DG et al., [7] and later by Frattini A et al., [8] OSD technique has the advantage of quick creation of the access tract and has been proven to be faster, safer and a cost-effective technique. The SD technique is time consuming, causes more blood loss and runs the risk of moving the kidney.

In PCNL, the access and the dilatation affect the success of the procedure as well as the complications from it. The access is made with the guidance of ultrasound or fluoroscopy. Fluoroscopy though most commonly used, poses a risk of radiation exposure, hence the shortest time is necessary.

Dilatation that is done under fluoroscopic guidance, warrants confirming each dilator under fluoroscopy. This leads to exposure to more radiation in the SD method than the OSD method [12] Nour HH et al., [13] found shorter operation time and radiation exposure in the OSD group. However, they found no difference in the complication rates and surgical outcome. In a retrospective study by Aydemir H and Halis F, they found no significant difference in total fluoroscopy time and the duration of the surgery [14]. They attribute this to the various other parameters besides the dilatation technique.

The PCNL as a procedure is prone to complications. de la Rosette J et al., [15] in their prospective analysis of 5800 cases found a low-grade complication (grade 1 and grade 2) in 16.4%, and grade 3a and grade 3b complications in 3.6%. They found 79.5% patients had an uneventful recovery, while 0.5% patients had severe complications [16]. Aydemir H and Halis F [14], reports 9.8% patients requiring intraoperative and postoperative transfusion. Pneumothorax occurred in two patients in the SD group and one patient in the OSD group. Selective embolisation was needed in two patients, who were secondary cases, from the OSD group. They attribute this to the fragile vascular walls from inflammation and neovascularisation following previous renal intervention [17].

The presence of staghorn calculi, in previously intervened kidneys poses as an additional risk factor for bleeding. In this study, grade 1 complication occurred in one patient from the OSD group and one patient in the SD group, warranting transfusions. Postoperative fever was seen in one patient from the OSD group and no patients from the SD group. The remaining patients had a smooth recovery. There was no significant difference in the complication rate among the study groups. These findings are consistent with the findings of Süelözgen T et al, who also found no difference between the study groups concerning bleeding complications [16].

The OSD technique was first described by Travis DG et al., [7]. Where, after dilatation with 6 Fr, they skipped to 25-30 Fr dilatation. Frattini A et al., in a study of 26 patients, dilated up to 30 Fr with OSD technique [8]. This technique also has the advantage of quick creation of the access tract Li Y et al., also reported a low complication rate, lower drop in haemoglobin and a shorter duration of exposure to radiation [11]. Dehong C et al., also corroborated significantly lower blood loss in patients undergoing OSD access tract creation [18]. Conversely, Amirhassani S et al., found no significant difference in blood loss, stone free rate and complications between the OSD and SD methods [19]. Our study revealed a smaller drop in haemoglobin in the OSD group than the SD group. Authors additionally found significantly lesser clots in the in the pelvicalyceal system in the OSD group than the SD group.

The duration of hospital stay in our study group was shorter in the OSD group than the SD group. This finding is consistent with the study by Aydemir H and Halis F [11], where they found a higher incidence of postoperative pneumonia and urinary tract infection, requiring prolonged antibiotics. Likewise, Srivastava A et al., [20] found a longer duration of stay in the SD group than the OSD group.

Limitation(s)

The study was limited by its small sample size.

CONCLUSION(S)

Reviewing the literature and correlating the results with our study, the authors found OSD to be superior to serial Amplatz dilatation in PCNL in terms of having reduced blood loss, reduced exposure to radiation for the patient and surgeon team and was also associated with a shorter duration of postoperative hospital stay.

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