

A Comparative Study between Serial Tract Dilatation and One-shot Single Step Tract Dilatation during Percutaneous Nephrolithotomy

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Abstract

Original Research Article

Introduction and background: Since advent, percutaneous nephrolithotomy (PCNL) remains one of the primary armamentarium of surgical management of stone disease. Tract dilatation in PCNL can be done either by serial dilatation or by ‘one-shot’ single step method. This study intends to find out the feasibility of ‘one-shot’ single step tract dilatation. **Materials and method:** Total 188 patients’s undergone PCNL meeting inclusion and exclusion criteria were randomized into two groups from January, 2017 to December, 2018. Group A (serial tract dilatation) and group B (one-shot single step dilatation) included 112 and 76 patients respectively. Length of time of dilatation of tract, X-Ray exposure time, total operative time and perioperative blood transfusion were noted. Any complications were kept into account in both groups. **Result:** Epidemiological profile of the patients and stone characteristics were equivalent between group A and group B. Mean operative time, mean access tract dilatation time, mean total fluoroscopy time and mean postoperative hospital stay were significantly less in group B. Stone free rate, requirement of blood transfusion, post operative pain score and complications rate were similar between both groups. **Discussion and conclusion:** Single step dilatation of PCNL tract is a safe, time saving and effective technique. Judicious application of this procedure in expert hand demonstrates high stone free rate following PCNL.

Key words: Serial Tract Dilatation, One-shot Single Step Tract Dilatation, Percutaneous Nephrolithotomy.

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INTRODUCTION

Among various surgical options for management of renal stone, percutaneous nephrolithotomy (PCNL) has emerged significantly over the last few decades and is considered ‘gold standard’ treatment option [1, 2]. Since its introduction in 1976, PCNL is in a constant state of evolution [3, 4].

One of the basic and fundamental aspects during PCNL is access tract dilatation after initial puncture of the desired calyx. There are several dilatation methods like Amplatz polyurethane serial dilators (ASDs), Alken metallic telescopic dilators and pneumatic balloon dilators. There are two techniques of tract dilatation, firstly the serial tract dilatation using Alken and Amplatz dilators and secondly, ‘one shot’ single step tract dilatation. Controversy exists regarding the optimal dilatation method. Previously, serial dilatation with the Alken and Amplatz dilators were done but improved technologies have introduced a single step dilatation by balloon dilators which are,

however, expensive and disposable after single use. In an effort to further simplify single-step dilation of the renal access tract, a technique is passage of the final semirigid plastic Amplatz dilator without prior dilation by the smaller dilators, termed as “one shot” dilatation in the study. Studies have shown that access tract dilation time, X-ray exposure time, stone free rate, blood loss and other complications are comparable in all the methods.

This study is done to assess the single step dilation of the nephrostomy tract with a 24/26/28 Fr Amplatz dilator compared with Amplatz serial dilatation technique in terms of feasibility i.e., procedural success rate, patient safety and also in terms of total operation time, decrease in hemoglobin percentage, length of post-operative hospital stay and incidence of complications.

MATERIALS AND METHODS

This study has been done at Calcutta National Medical College, Kolkata from January, 2017 to December, 2018. Total 188 patients, who were operated for PCNL, were randomized into 112 patients operated by serial step dilatation with sequential Amplatz dilators and other 76 patients operated by ‘One shot’ dilatation by the single final Amplatz dilator. Patients with history of ipsilateral renal surgery (open or minimal invasive) are also included in the study. The exclusion criteria for the study are:

- Cases where more than one tracts were created (as haemorrhage and other complications would be more in these).
- Cases where redo operations were done, where in a single sitting the stone has not been cleared completely or where case had to be abandoned due to bleeding).
- Cases where any other concomitant surgery, like endopyelotomy or ureterolithotomy were done.

Institutional ethical committee clearance was taken in January 2014 for conduction of the study. A prospective demographic database was created for included patients and informed consent was taken from all patients after purpose of the study was explained to them.

PCNL was done according to standard norms. By random selection of the operating surgeon, either a serial step dilatation by Amplatz dilators of size 18, 20, 22, 24, 26, 28, 30 Fr respectively or a single step “one shot” dilatation with the 24/ 26/28 Fr Amplatz dilator (any one, according to the stone size) was done. The patients in whom serial dilatation was done were designated as “Group A” and in whom “one shot” dilatation was done were designated as “Group B”.

Length of time of dilatation of tract, X-Ray exposure time, total operative time and perioperative blood transfusion were noted. Blood examination for

hemoglobin and packed cell volume was sent on morning of postoperative Day 1. Patients were asked about pain and charted on a Visual Analogue Scale on morning of postoperative Day 1. Post procedural plain X ray was done on Day 2 to document stone retention. Any complications like urine leak, sepsis, pneumothorax, reactionary or secondary haemorrhage, etc were kept into account in both groups. Any requirement of angioembolisation/ nephrectomy was documented.

STATISTICAL ANALYSIS

The continuous variables were analysed using parametric (student’s t-test) statistical methods. Categorical variables were analysed using the Fisher’s exact test, the modification of Pearson chi square test. Data were expressed as mean ± standard deviation. A p value of < 0.05 was considered significant. Data were analysed with the statistical package for the social science (SPSS Inc, Chicago, Illinois, USA) version 15.0 with the help of *Graphpad™* statistical calculator software.

RESULTS

Total 188 patients, meeting inclusion and exclusion criteria, were included in the study for comparison of the two methods of tract dilatation. Of these, 112 patients underwent serial tract dilatation and entitled as Group A and 76 patients underwent “one shot” tract dilatation and termed as Group B.

The demographic profile depicting age, gender, stone laterality, stone size and previous ipsilateral open or minimally invasive urological procedures are depicted in Table 1. The location of stones and punctured calyces are also shown in Table 1. The average size (mode) of maximum diameter of final Amplatz sheath used in Group A was 28 Fr and the average size of the Amplatz dilator used in Group B was 26 Fr.

Table-1: Demographic profiles of two groups

	Group A	Group B
Age in years [mean (range)]	42.08 (11-76)	41.92 (14-78)
Gender [male/ female]	64/48	39/37
Stone laterality [left/ right]	52/60	39/37
Stone size (cm) [mean (range)]	2.72 (1.2-3.8)	2.18 (1.3-3.5)
Previous ipsilateral renal procedures	18	14
Stone locations	Pelvis	20
	Upper calyx	5
	Middle calyx	12
	Lower calyx	27
	Staghorn/multiple calyx	6
	Diverticular	6
Puncture sites	Upper calyx	11
	Middle calyx	24
	Lower calyx	41

Mean of operative time, access tract dilatation time, total fluoroscopy time and postoperative hospital stay were measured in the two groups as detailed in

Table 2. Group B ranked better than Group A in those parameters, which when measured by unpaired student's t test, came to be statistically significant.

Table-2: Differences in time durations of intra and post operative variables in two groups

	Group A	Group B	p-value
Mean operative time [minutes (range)]	88.9 (35-180)	75.2 (30- 120)	0.0101
Mean access tract dilatation time [minutes (range)]	6.28 (2- 12)	4.79 (2- 7)	<0.0001
Mean total fluoroscopy time [minutes (range)]	6.41 (3-13)	5.14 (2.5-8)	<0.0001
Mean postoperative hospital stay[days (range)]	4.64 (2- 10)	4.12 (2- 8)	0.0044

Procedural success rate was next calculated taking into account the redo cases excluded from the study where cases were temporarily cancelled due to excessive bleeding or excessive time requirement. 19 out of total 131(112+19) cases (14.5%) in serial dilatation group and 15 out of 91(76+15) cases (16.48%) in "one shot" group had to undergo redo procedures which, however, when examined statistically by Fisher's exact test as visualised in Table

3, the p value was 1.000 which is statistically insignificant. Stone free rate (no stone in X-ray), blood transfusion rate, decrease in percentage of haemoglobin and hematocrit value rate (between the preoperative and postoperative Day1) and pain score measured by visual analogue scale (on postoperative Day 1) were also measured and compared between the two groups and all differences were found to be statistically insignificant (Table 3).

Table-3: Differences in peri-operative outcomes among two groups

	Group A	Group B	p value
Procedural success rate (%)	85.5	83.52	1.000
Stone free rate (%)	85.71	85.52	1.000
Blood transfusion receive rate (%)	16.96	11.84	0.4063
Decrease in Hb% [gm/dl (range)]	2.173 (0.9- 3.8)	1.875 (0.7- 3.4)	0.1006
Decrease in PCV [% (range)]	8.425(1.8-13.5)	7.565 (0.8-10.8)	0.0762
VAS Pain score [mean(range)]	4.1 (3-6)	4 (3- 5)	0.3444

The postoperative complications were documented in both the groups (Table 4), but this

difference is not statistically significant (p value – 0.31).

Table-4: Post-operative complications in two groups

	Group A	Group B
Postoperative complications	Fever/sepsis	3
	Hemorrhage	3
	Persistent urine leakage	2
	Tract site infection	13
	Hydro/pneumothorax	0
	Nephrectomy, death	0

DISCUSSION

The dilation of the nephrostomy tract is one of the most fundamental steps of PCNL and is usually performed by three dilation methods:

- Semirigid polyurethane serial dilators (Amplatz) over an 8F ureteric catheter or Alken guide-rod (AD)
- Metal telescopic dilators (Alken telescopic dilators: ATD)
- Pneumatic balloon dilators (BD)

Each dilation method has advantages and disadvantages and there have been many attempts and modifications to obtain the best results with minimal

kidney damage. There are also several studies dealing with some indigenous ways of single step dilatation [5-8]. In the early days of PCNL, the Alken telescopic metal dilators and the Amplatz sequential polyurethane dilators were used, which is still now very much in common practice [9]. But their incremental nature can be a problem especially in terms of prolongation of access time, radiation exposure; possibility of tract displacement and with each passage of the dilator, injury to collecting system can result. There is risk of bleeding when a sequential dilator is removed to allow placement of the larger one, because tract is left open, and there is no sheath in place to tamponade bleeding. BD, introduced in the late years of the twentieth century, has been generally regarded as the most modern and safe technique [10, 11].

Handa *et al.* [12] showed superiority of BD over ATD by decreasing incidence of haemorrhage, blood transfusion, and morbidity, as well as providing a shorter surgery time and recovery period. Safak *et al.* [10] did a comparative study between Balloon and Amplatz dilatation and found that mean operative time and tract formation times for the balloon dilation group and the Amplatz dilation group were 106.8 +/- 41.4 and 11.2 +/- 3.0, and 116.4 +/- 23.7 and 16.3 +/- 2.4 min, respectively. 13.7% patients had significant bleeding and required blood transfusion in the balloon dilation group, whereas 16.6% patients had significant bleeding in the Amplatz dilation group. Collecting system perforation was seen in 11.6% patients in balloon dilation group and in 16.6% patients during sequential Amplatz dilation.

However, Burak Özçift *et al.* [13] did a comparative study between BD and AD and found that there was no statistically significant difference in the operative time (97.9 ± 45.3 minutes in balloon group vs. 98.5 ± 43.4 minutes in Amplatz group; p=0.43), decrease in hematocrit values (6.30±2.60 vs. 6.45±2.64; p=0.68), blood transfusion rate (15.6% vs. 16.7%; p=0.84) or treatment success rate (78.9% vs. 79.2%; p=0.96) between the groups.

Gonen *et al.* [14] comparing AD and BD showed that there were no statistically significant differences in operative time (85.7 ± 43.2 v 86.3 ± 41.2 minutes; P = 0.42), preoperative hemoglobin concentration (14.1 ± 1.1 v 13.8 ± 1.4 mg/dL; P = .153), postoperative hemoglobin concentration (11.6 ± 1.7 v 11.2 ± 1.5 mg/dL; p = .601), blood transfusion rate (18.6% v 21.3%; P = .687) and failure rate between the two groups. Joel *et al.* [15] found no significant difference of ATD and BD on blood loss. Michel *et al.* [16] demonstrated BD had decreased operative times, blood loss, and exposure to fluoroscopy. Davidoff *et al.* [17] revealed Amplatz dilatation had higher incidence of bleeding episodes relative to BD. Kukreja *et al.* [18] compared AD, ATD and BD and reported lesser blood loss with AD relative to other dilators without any statistically significant difference.

The Clinical Research Office of the Endourological Society (CROES) had published in 2011 the outcomes of a study related to PCNL performed in 5803 patients from 96 centres worldwide [19]. Observational analyses demonstrated that lower bleeding (9.4 vs. 6.7%), transfusion rates (7 vs. 4.9%) and procedural failure rate were detected in Amplatz dilatation than in BD. However, frequent use of BD in management of larger staghorn stones, and operations performed in different medical centres with various indications were limitations of this study.

Thus there is a constant debate regarding balloon dilatation in comparison to Alken/Amplatz

dilatation. Although the balloon dilation system has advantages, such as the short dilatation and fluoroscopy time, tamponading of the tract, application of radial forces only and no risk of forward perforation [20], its routine application has been limited because of its relatively high cost especially in centres with limited resources [16]. To improve dilation results and also cost effectiveness, some authors [17, 21] proposed single-increment dilation and demonstrated its safety and feasibility.

Frattini and colleagues [22 in 2001, first described the “one shot” dilation (OSD) technique introducing the final Amplatz dilator over the guide-rod. They compared the results between ATD, BD and OSD and showed that mean (standard deviation [SD]) total radiation exposure with telescopic, balloon, and one-shot dilation was 310 (216), 179 (90) and 262 (173) seconds, respectively and found a reduction in the fluoroscopy time during the dilation procedure from 60 to 35 and 20 seconds in the ATD, the BD, and the OSD group, respectively. However, they did not recommend OSD in cases where previous open surgery has been done.

Ziaee *et al.* [23] in 2007, tried to find the outcomes of OSD in 100 consecutive patients with and without a history of ipsilateral open stone surgery. There was no difference in the procedural success rate between both groups (93.5% v 92.6%, respectively) and found mean time of radiation exposure during access being 0.63 ± 0.71 minutes and access tract dilatation time of 6.07 ± 4.37 min with no impact of open previous surgery.

Amjadi and colleagues [24] in 2008 studied results of ATD versus OSD in 31 patients who were previously operated with open renal procedures and found reduced tract dilation fluoroscopy time from 81 ± 53 seconds in ATD group to 27 ± 15 seconds in OSD group, tract dilatation time from 10.47 ± 2.97 min for ATD to 5.72 ± 1.75 min for OSD and had equal hematologic safety profile in both.

Falahatkar *et al.* [25] did a comparative study in 2009 among 214 patients of ATD versus OSD and found that there is no difference in access tract dilatation time, fluoroscopy time, procedural success rate or complications.

Harrech *et al.* [26] in 2014, did a study on OSD in modified supine position for PCNL done in over 300 cases and observed that tract dilation fluoroscopy time was 25 ± 17 seconds, total radiation exposure 142 ± 54 seconds, mean operative time 54.8 minutes (25-137), mean access time 2.1 minutes (0.7-6.2), success rate of access 97.81%, mean haemoglobin decrease of 1.17 ± 0.84 gm/dl and blood transfusions rate of 1.25%.

Hosseini *et al.* [27] did a comparative study in 2014 among preschool children between OSD and ATD and found mean \pm standard deviation of access and fluoroscopy time in both groups were 7.3 ± 1.2 min vs. 5.9 ± 1.5 min ($p > 0.05$) and 70.0 ± 8.9 s vs. 22.0 ± 5.6 s ($p < 0.001$), for ATD and OSD group, respectively. They concluded that percutaneous tract dilation by the one-stage method is safe, effective and associated with considerably less radiation exposure in preschool children.

Nour *et al.* [28] published their report in 2014 about similar comparative study and found that there was no significant difference in stone-free rates and blood loss between the groups, but operative duration (124.9 minutes to 100.9 minutes) and fluoroscopy exposure time (11.8 minutes to 10.5 minutes) was statistically significantly longer when using the ATD than OSD group.

Yutao Li *et al.* [29] published a meta-analysis in 2013 comparing OSD and gradual dilatation technique and determined favourable results for OSD in terms of successful dilation rate (96.09 vs. 100 %), access time and X-ray exposure time, blood loss and transfusion rate. Another meta-analysis by Cao Dehong *et al.* [30] compared the four common tract dilatation techniques and stated that OSD technique should be considered for most PCNLs. Their inference was OSD can significantly decrease tract dilatation fluoroscopy time and lower the haemoglobin decrease compared with MTD. There were no significant differences in stone free and blood transfusion rates between the two groups. According to their meta-analysis, OSD did not lead to more haemorrhages and so was clearly proven to be more effective and safer than MTD, even in patients with previous open renal surgery.

In the present study, which compared between “one shot” Amplatz dilatation and serial Amplatz dilatation, it was found that “one shot” Amplatz dilatation is statistically significantly favourable in terms of operation time, X ray exposure time, time to create access tract and postoperative hospital stay. There is, also, less blood loss thereby leading to less blood transfusion and decrement in haemoglobin and hematocrit when “one shot” tract dilatation has been done. However, comparing statistically, there is no significant difference in terms of stone free rate, decrease in Hb%, decrease in PCV, perioperative blood transfusion, postoperative pain score, procedural success rate and postoperative complications. It is clearly evident that these parameters are in accordance to all present international studies. We found that, in cases of failure, one shot dilatation did not jeopardize application of other dilation techniques and overall PCNL, even in those patients with a history of renal surgery.

After searching extensively in electronic literature database, it can be said that this study to

compare the results between Amplatz serial dilatation and Amplatz single step dilatation has not been done very often in the past and this study is one of only a handful few literary evidences documented.

CONCLUSION

PCNL plays an integral role in managing complex and large upper tract renal calculi. The single-step “one shot” Amplatz dilatation is a time saving procedure, being safe, subjectively economical and an effective technique to gain renal access.

This study shows that “one shot” Amplatz dilatation is better than serial step Amplatz dilatation as it requires less time in terms of access tract creation, X ray exposure, operation time and post-operative hospital stay. Although there is less perioperative blood transfusion requirement and decrease in hemoglobin and hematocrit values for “one-shot” dilatation than serial step dilatation method, but the differences are not statistically significant. Both the methods are similar in terms of stone free rate, postoperative pain score, procedural success rate and postoperative complications.

This study demonstrates that “one shot” Amplatz dilatation is applicable in almost every adult patient, previous open renal surgery, staghorn calculi, to almost every calyx, even calyceal diverticulum. In experienced hands, this technique can be effective to approach even “difficult calices” in a timely manner with less radiation exposure and with a low rate of guide-wire displacement and false passage creation. Further analysis and comparative studies are necessary to confirm the results.

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