

# A prospective randomized study comparing the four tract dilation methods of percutaneous nephrolithotomy

Alok Srivastava<sup>1</sup> · Sanjeet Singh<sup>1</sup> · Ishwar Ram Dhayal<sup>1</sup> · Priyanka Rai<sup>2</sup>

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## Abstract

**Objective** To compare the one-shot dilation (OSD) technique with three other dilation techniques namely telescopic Alken, fascial Amplatz and balloon dilation (BD) in terms of safety efficacy and cost effectiveness.

**Methods** During a 3½ year enrollment period, 480 patients who required PCNL surgery were equally randomized into four groups. All the cases were assessed preoperatively, intraoperatively as well as postoperatively till a period of 3 months. Access time, X-ray exposure time, hemoglobin drop, complications, success rate, etc., were all assessed and recorded.

**Results** Similar preoperative characteristics were observed in all the four study arms. X-ray exposure time during dilation was significantly reduced for both OSD and BD when compared to sequential Amplatz and telescopic Alken dilation (Group ALD = 62.1 + 13, Group AMD = 67.0 + 10, Group OSD = 36.8 + 7, Group BD = 38.1 + 6,  $p$  value = 0.01, post hoc:  $G4 = G3 < G2 = G1$ ). There was no significant difference between the access time, hemoglobin drop, complication and success rates among the groups. BD was the most expensive dilation method when compared to the other three dilation techniques.

**Conclusion** All the four methods of dilation are equally safe and effective but both OSD and BD are

advantageous in terms of lesser fluoroscopy time during dilation. OSD is much cheaper option when compared to BD, and therefore with more experience, it can become the preferable dilation method, especially in the developing countries.

**Keywords** One-shot dilation · Fluoroscopy time · Cost effective

## Introduction

Percutaneous nephrolithotomy (PCNL) is currently the procedure of choice for treating large renal stones, multiple stones, staghorn, large calyceal and certain diverticular stones [1, 2]. Over the last three decades, it has become a common and well-tolerated procedure. Although tract creation and dilatation is the prime fundamental step of PCNL, fluoroscopy is a major part of this step. There are mainly four different methods to achieve dilation such as incremental fascial Amplatz dilator, telescopic Alken type, balloon dilators or a “one-shot” method consisting of a single dilation of the tract with a 26 or 28 F Amplatz dilator [3]. X-ray exposure during PCNL depends on many factors like access time, complexity of the case, including stone size, multiplicity, configuration and location in addition to the number of tracts. Minimizing X-ray exposure is of prime importance during PCNL, and therefore balloon dilation is nowadays being considered as one of the methods to do that as it helps in reducing the X-ray exposure time during renal access. One-shot technique, which is similar in principle to balloon dilation, can offer us the same advantage, but there are only a few studies in the literature [4, 5] supporting the use and cost effectiveness of this technique. In our study, we therefore compared the one-shot technique of

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Sanjeet Singh and Ishwar Ram Dhayal contributed equally.

✉ Alok Srivastava  
dralokpriyanka@gmail.com

<sup>1</sup> Department of Urology and Renal Transplant, Dr.RMLIMS, Vibhuti Khand, Gomti Nagar, Lucknow 226010, India

<sup>2</sup> Department of Surgery, B.R.D. Medical College, Gorakhpur, India

renal dilation with the rest of the three techniques as mentioned above.

## Methods

A total of 480 patients who required PCNL surgery at our institute were enrolled in a single-center prospective randomized controlled trial between October 2012 and April 2016. The cases were equally randomized into four groups (120 patients in each study arm) and named group ALD or group 1, group AMD or group 2, group OSD or group 3 and group BD or group 4 according to the proposed method of tract dilation, namely Alken telescopic, Amplatz serial dilation, one-shot dilation and balloon dilation, respectively. The trial was approved by the local ethics and research scientific committee. A written consent was taken by all the patients after explaining the details of the procedure. Sealed envelopes equally nominating one of the four dilation techniques were used for the randomization process. All the procedures were done by three urologists with vast experience in the field of endourology. None of these urologists was in the learning curve either with regard to PCNL or with the four tract dilation alternatives. Exclusion criteria were age <18 years, BMI >30, any bleeding disorder and severe cardiopulmonary disease. Demographic characteristics, location, size of the stone, access time, fluoroscopy time [number of seconds for which c-arm was used (foot on paddle) from the insertion of guide wire to placement of Amplatz sheath], pre- and postoperative hemoglobin level, success rate, transfusion rate, complication(s), hospital stay, nephrostomy removal time, etc., were analyzed for all the four groups. In each group, after puncture of the collecting system was performed under fluoroscopic guidance, a guide wire was inserted. In group 1, the tract was dilated by the insertion of polyurethane 8 and 10 F dilators by the insertion of the Alken guide and of dilators from 12 to 27 F, and then a 28 F dilator was passed and a 30 F Amplatz sheath (AS) was advanced over it. In group 2, the technique was similar till the insertion of the Alken guide, following which sequential dilation was done with Amplatz dilators usually till 28 F and then the 30 F AS was passed over the last dilator. In group 3, after the introduction of the Alken guide a 28 F, Amplatz was passed through directly followed by the passage of a 30 F AS. For BD after insertion of the 10 F dilator (30 F, length 55 cm, balloon length 15 cm; Cook, Spencer, IN, USA) the balloon dilator was passed over the guide wire and inflated up to 12–15 atmospheric pressure. Full inflation of the balloon throughout its length was confirmed in each case by using contrast medium for inflation. After 30 s, a 30 F sheath was passed over the inflated balloon. The balloon was then evacuated and removed. Fragmentation and stone removal

were accomplished in all patients using pneumatic or ultrasound energy and retrieval graspers through 22-F, 24-F, or 26-F nephroscopes. A holmium laser and nitinol basket catheter were used through flexible nephroscopes whenever required. Stone clearance was determined by a combination of fluoroscopy and rigid or flexible nephroscopy at the end of the procedure and postoperatively by imaging (X-ray KUB, ultrasound and computed tomography whenever required). Although a 18 F nephrostomy tube along with a 5 F ureteric catheter was placed and fixed in majority of the cases, a double-J stent was deployed and left for 4 weeks in cases with significant perforation of the collecting system, suspected ureteral obstruction due to edema and stone fragment migration into the ureter. Repeat PCNL was performed through the same tracks or new ones, if there were significant residual particles identified with KUB or US. A successful outcome was defined when at 3 months the patients were rendered stone free or had residual fragments smaller than 4 mm after PCNL with or without adjuvant treatments.

Statistical analysis was performed using SPSS 21 (Chicago, Ill., USA) software, and one-way balanced analysis of variance (ANOVA) test, *t* test and Chi-square test were applied. The difference was considered significant, if *p* value was <0.05. Post hoc analysis (Tukey's range test) was used in conjunction with ANOVA to find the means that were significantly different from each other. The primary end point was to test the null hypothesis that the perioperative and follow-up features were similar in all the four groups. With a sample size of 120 patients in each treatment arm and a confidence level of at least 95 %, the trial was determined to have a 89 % power to reject the null hypothesis.

## Results

A total of 480 patients were equally randomized into four groups. One patient in group AMD and two patients from group BD were lost to follow-up after the procedure, so their results were not included in the final analysis. The preoperative assessment revealed resembling characteristics among all the four groups (Table 1). There were more number of patients with history of open surgery in group AMD and OSD (19.32 and 18.33 %) when compared to group ALD and BD (15.83 and 15.25 %), although this difference was not statistically significant (*p* value = 0.06). Stone burden and complexity were also similar in all the arms. Staghorn stones were seen in 25.2, 27.5, 28.33 and 27.96 % in group ALD, AMD, OSD and BD, respectively. Statistical analysis showed that the fluoroscopy time in group OSD and BD was similar, but it was significantly less to the time consumed in group ALD and AMD (*p* value = 0.01, post

**Table 1** Demographic variables

Variables	Group 1 (n = 120)	Group 2 (n = 119)	Group 3 (n = 120)	Group 4 (n = 118)	p value
Age	40.1 ± 11.4	41.2 ± 12.9	38.9 ± 12.8	42.1 ± 11.2	0.08
Male/female	62/58	60/59	59/61	59/59	0.68
Laterality right/left	55/65	59/60	56/64	56/62	0.23
Previous open surgery	19	23	22	18	0.06
Previous					
PCNL	6	3	3	4	0.10
TUL	3	3	1	2	0.45
ESWL	1	2	4	2	0.07
BMI (kg/m <sup>2</sup> )	24.3 ± .4	25.1 ± .8	24.9 ± .2	23.9 ± .8	0.57
Hydronephrosis					
Nil	6	6	5	5	0.67
Mild	75	70	77	72	0.11
Moderate	25	26	24	26	0.58
Severe	14	18	14	16	0.76
Stone size (mm <sup>2</sup> )	29.7 ± 5.2	30.1 ± 4.7	30.5 ± 3.9	31.1 ± 4.0	0.67
Stone burden and site					
Staghorn	33	30	34	33	0.55
Partial staghorn	25	27	24	27	0.67
Calyceal	18	17	20	18	0.12
Pelvic	22	20	21	22	0.65
Upper ureter	9	9	8	7	0.29
Multiple	13	16	13	11	0.09

**Table 2** Important intra- and postoperative findings

Variables	Group 1	Group 2	Group 3	Group 4	p value	Post hoc analysis
Mean access time (min)	7.1 ± 1.1	7.0 ± 2.1	6.3 ± 1.9	6.2 ± 2.1	0.05	G1 = G2 = G3 = G4
Mean fluoroscopy time for dilation (sec)	62.1 ± 13	67.0 ± 10	36.8 ± 7	38.1 ± 6	0.01	G4 = G3 < G2 = G1
Failure of access	0	0	1	1	0.22	
No. of access						
One tract	91	97	93	98	0.54	
Two or more	29	22	27	19	0.08	
Overshooting/perforation	0	1	2	1	0.33	
Drop in hemoglobin (g/dL)	1.1 ± 0.7	1.6 ± 0.8	0.9 ± 0.7	0.9 ± 0.1	0.07	G1 = G2 = G3 = G4
Transfusion rate (%)	4.1	4.2	3.3	3.4	0.09	
Time to nephrostomy removal	1.74 ± 1.1	1.75 ± 0.76	1.45 ± 0.11	1.69 ± .54	0.11	G1 = G2 = G3 = G4
Auxiliary procedures (%)	15.94	16.23	19.51	16.11	0.06	
Stone free (%)	84	82	84	83	0.76	
Complications (%)	22.1	20.2	20.4	21.1	0.33	
Hospital days	3.1 ± 1.6	3.5 ± 1.1	2.7 ± 2.1	2.9 ± 1.9	0.10	G1 = G2 = G3 = G4
Cost (INR)	31.1 ± 2.3 K	33.3 ± 6.9	34.1 ± 8.7	45.1 ± 5.2	0.001	G4 > G3 = G2 = G1

hoc: G4 = G3 < G2 = G1). Access time was less in both group OSD and BD when compared to that in group ALD and AMD, but was on the verge of statistical significance ( $p$  value = 0.05; Table 2).

The drop in hemoglobin was not significantly different among all the groups, and five patients each in group

ALD and AMD and four each in group OSD and BD received blood transfusion. Four patients in group ALD, AMD and BD and five in group OSD underwent relook PCNL for residual stones. Two patients in group OSD and one in group ALD had URS as an auxiliary procedure for migrated ureteric stones. Two patients each in group ALD,

AMD and OSD and one in group BD had a double-J stent insertion under local anesthesia for prolonged postoperative urinary leakage from the puncture site. There were nine cases of postoperative urinary tract infection (two each in group ALD, AMD and OSD and three in group BD), and all were managed well with appropriate antibiotics. No other complication such as pleural, visceral and vascular injury occurred in the study.

The rate of over dilation/collecting system perforation was 0.84, 1.6 and 0.85 %, respectively, in group AMD, OSD and BD with no statistical difference among all the four groups. Access dilation failed in two cases of the study with one case each belonging to group OSD and BD. BD by far was the most costly method of dilation, and there was little difference of cost between the rest of the three dilation techniques (post hoc: Group 4 > Group 3 = Group 2 = Group 1).

## Discussion

The prime step of any PCNL is tract creation and dilation, and it invariably requires fluoroscopy. Considering the fact that urolithiasis is a recurrent disease and very often patients require more than one procedure in their lifetime, reducing X-ray exposure is of utmost importance for both the patient and the treating urologist. Reducing X-ray exposure is a challenge during PCNL, and therefore several attempts have been made in recent years to minimize this hazardous factor. Balloon dilation (BD) is one such measure which significantly reduces exposure time, but its high cost is a major drawback, especially in the developing countries [6, 7]. This point is also highlighted in our series where its use increased the cost of treatment by approximately one-third (Table 2). Although one-shot or single-step dilation was also invented for the same purpose, it is much more cheaper than BD. Till now, there are not many randomized controlled trials which favor OSD [5, 8–11]. To our knowledge, our study is the first randomized trial comparing OSD with all the main dilation methods. Falahatkar and Amrihassani et al. [8, 11] in their studies compared OSD with telescopic dilators and reported significantly reduced X-ray exposure time for one-shot technique ( $p$  value 0.003 and 0.03, respectively). They also found no significant difference for the complication, blood transfusion and success rates between the two study arms. Frattini et al. [5] in his study of 78 patients comparing OSD with both BD and telescopic dilation reported equal morbidity with all three techniques with the smallest X-ray exposure and cost with the one-shot procedure. Although this in accordance with our study where both OSD and BD had shorter exposure times as well as less access time, the latter difference was not statistically significant. There were two cases

of failed dilatation in the whole study, one belonging to group OSD and BD, respectively. All the two patients had history of open pyelolithotomy with the patient in group AMD being operated on the same side thrice. We usually choose an access site away from the previous scar, and therefore the patients with history of open surgery in all the four groups could be managed without difficulty. Although in the failed cases we had no choice, but to go through the previous scar site and ultimately we had to use the gradual Amplatz dilation for both the cases. Some previous studies reported a higher failure rate for PCNL in patients who had prior history of open surgery [12, 13]. Frattini et al. [5] stated that their OSD technique although successful was a contraindication in such type of patients. Lojanapivat et al. and Basiri et al. [14, 15] reported that no difference in efficacy and morbidity of PCNL was seen between patients with and those without a history of open nephrolithotomy. According to the former, Amplatz serial dilation worked well in such cases. Like the above studies, Amjadi et al. [16] found their one-shot technique to be as effective as the telescopic dilation technique in previously operated patients. They reported equivalent success rate and complication rate for both the techniques with the former having the advantage of lesser X-ray exposure time. The success of OSD as a dilation technique was also seen in the randomized controlled trial by Amrihassani et al. [11], but their study did not have patients ( $n = 100$ ) with history of nephrolithotomy. Overall there were four cases of overshooting/perforation, one each for group AMD and BD and two for group OSD. Those in group AMD, BD and one from OSD group had a similar history of ipsilateral open surgery, and they had minor pelvic perforations due to overshooting during dilation. The other one in group OSD had a compact system with a staghorn stone. All of them could be managed by placing a double-J stent at the end of the procedure. In all these cases again, we had to go through the previous surgical site, and therefore the increased radial force required for dilation could be the cause of this complication. Nevertheless, we postulate that both OSD and BD are effective measures of dilation even in patients with history of open surgery although precaution has to be taken when the access site has to be through the same surgical scar. In such cases, it would be prudent for the urologist to use the sequential dilation method instead of OSD or BD.

Although the stone-free rates were similar for all the four groups, more number of auxiliary procedures were required in group OSD to achieve stone-free status. This could be probably because despite randomization more number of complex cases were allotted to group 3. The transfusion rate in many large series of PCNL varies between 2 and 10 %. In our series, the transfusions rate was similar for OSD and BD (3.3 and 3.4 %), but was slightly more for the telescopic and serial Amplatz dilator groups

(4.1 and 4.2 %). Similar results were reported in the meta-analysis of Li et al. [17] where the blood transfusion rate was slightly lower for the one-shot technique when compared with gradual dilation, but without statistical significance ( $p = 0.42$ ). Other critical parameters like number of access tracts, complication rate, hospitalization days and time to nephrostomy removal were same in all the arms of our study.

We acknowledge the fact that there are a few limitations in our study. The first one being that our's is a single-center trial with a limited number of patients. A large multicenter randomized trial will definitely be more informative. Second, there is no standard method to calculate the X-ray exposure time so the definition varies from center to center.

Despite the above-mentioned limitations, our study is able to highlight that OSD is as safe and effective as the rest of the dilation techniques. Although it is equally effective in patients with prior history of open pyelolithotomy, we must be extra precautionous when the access site is same as that of the previous surgery scar. Along with BD it carries the advantage of lesser radiation exposure albeit at a much cheaper cost when compared to BD. This fact becomes more important when we consider that urolithiasis is a recurrent disease and many patients undergo multiple procedures throughout their lifetime.

With more and more experience, the technique of OSD can become the preferable method of dilation as it is beneficial for both the surgeon and the patient. This holds true in developing nations where cost is a big issue and BD continues to be an expensive technique.

## Conclusion

All the four dilation techniques are equally safe and effective, but both one-shot dilation and balloon dilation need significantly less fluoroscopy time for tract dilation and are therefore beneficial for both the patient and the surgeon. In future with growing experience OSD, being a much cheaper option as compared to BD, can become the preferable dilation technique, especially in developing countries.

**Author's contribution** Protocol development, data analysis and manuscript writing were done by Srivastava A. Singh S contributed to protocol development, data collection and data analysis. Dhayal I helped in protocol development and data analysis. Data collection and manuscript writing were done by Rai P.

## Compliance with ethical standards

**Conflict of interest** None.

**Informed consent** It was obtained from all individual participants of the study.

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