

Feasibility of one-shot dilation access in the pediatric age group

Alok Srivastava,¹ Krishna Kumar Yadav,² Anjana Singh,³ Anoop Kumar Srivastava,⁴ Sanjeet Kumar Singh¹

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ABSTRACT

Objective To compare sequential fascial dilation (SFD) versus one-shot dilation (OSD) in the pediatric patients undergoing percutaneous nephrolithotomy.

Methods The present study is an observational study. The study subjects were divided into two groups. In group 1, renal dilation was done using the SFD and in group 2, renal dilation was done using the OSD. The amount of time exposed to radiation during access to pelvicalyceal system was estimated. Complications, stone free rates, ancillary procedures for residual stones and hospital stay were compared. Modified Clavien-Dindo classification was used for grading the complications.

Results Radiation exposure and operative time were less in OSD group (95% confidence interval (CI) 3.068 to 14.072, and 2.565 to 12.435, $p < 0.005$). The mean drop of hematocrit was statistically less significant in OSD group ($p = 0.032$). In both groups, complications, stone free rate and hospital stay were statistically insignificant.

Conclusions OSD is feasible in the children with reduced radiation exposure and shorter operative time. The outcome was similar to SFD.

INTRODUCTION

The treatment of choice for treating all forms of kidney stones in adults is percutaneous nephrolithotomy (PCNL).^{1,2} Woodside *et al* published the first pediatric series evaluating the use of PCNL in 1985.³ PCNL was previously reserved as a secondary technique in children who had failed extracorporeal shock wave lithotripsy (ESWL) or as part of sandwich therapy with ESWL after it was accepted as a safe and effective therapy in children.⁴

Tract creation, dilation and fluoroscopy are the fundamental steps of PCNL. There are primarily four techniques for dilation. These are fascial Amplatz dilator, telescopic Alken type dilator, balloon dilator and 'one-shot dilation' (OSD) techniques. In OSD, the tract was dilated directly by using a 26 F or 28 F Amplatz dilator.⁵ The amount of radiation a patient is exposed during PCNL is determined by access time, case complexity, and the number of tracts. Because children are three to five times more prone to have radiation-induced morbidity and mortality, it is essential to reduce radiation exposure. Nowadays,

Key messages

What is already known about this subject?

- ▶ There are two methods of dilation in percutaneous nephrolithotomy (PCNL), namely one-shot dilation (OSD) and sequential fascial dilation (SFD), which are comparable in terms of results and complications in adults.
- ▶ Children are three to five times more prone to have radiation-induced morbidity and mortality.
- ▶ There are fewer studies of pediatric age groups on OSD.

What are the new findings?

- ▶ OSD is feasible, safe, and well tolerated in the pediatric population.
- ▶ OSD had reduced radiation and shorter operative time in comparison with SFD.
- ▶ The drop of hematocrit was less in OSD in comparison with SFD.

How might it impact on clinical practice in the foreseeable future?

- ▶ If repeated studies suggest the same findings, it would be better to adopt OSD as the procedure of choice for dilation during PCNL in children with shorter duration of the surgery along with less exposure of the radiation to the children as well as the operative team.

balloon dilation and OSD are considered as the methods of choice to reduce radiation exposure during renal access in the adults. Therefore, a procedure that is either more effective or equally effective but with low radiation exposure is needed, especially in the pediatric population.

In this study, we compared the safety and efficacy of OSD with the sequential fascial dilation (SFD) in PCNL among pediatric patients for operative and radiation exposure time, along with preventing a dilator exchange that could result in increased blood loss.

METHODS

This is a prospective, observational study done from July 2015 to June 2020 at Dr RML Institute of Medical Sciences, Lucknow, a tertiary



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¹Urology, Dr Ram Manohar Lohia Institute of Medical Sciences, Lucknow, India

²Pediatrics, Dr Ram Manohar Lohia Institute of Medical Sciences, Lucknow, Uttar Pradesh, India

³Department of Pathology, Mayo Institute of Medical Sciences, Barabanki, Uttar Pradesh, India

⁴Radiotherapy, Dr Ram Manohar Lohia Institute of Medical Sciences, Lucknow, India

Correspondence to

Dr Sanjeet Kumar Singh; sanjeetsingh1982@yahoo.in

care teaching hospital. We planned to study the duration of radiation exposure in two surgical steps during PCNL, namely OSD and SFD. We decided to conduct a pilot study with 50 patients in each group. Included were children of age 5–16 years, referred with already diagnosed renal urolithiasis by X-ray Kidney, Ureter and Bladder (KUB), intravenous pyelography (IVP) or non contrast computerized tomography (NCCT) of KUB, and fulfilling indications for PCNL. Indications for PCNL were one or more of (1) stone size ≥ 2 cm, (2) partial and complete staghorn stones, (3) stone in lower pole of >1.0 cm. The children fulfilling the inclusion criteria were recruited prospectively. The first eligible patient was allotted for group 1 (OSD) and next for group 2 (SFD) consecutively until each group had 50 patients.

After explaining the procedure in detail, all of the patients' parents or legal guardians signed a written informed consent form. The procedures of all recruited subjects in the present study were done by two urologists having extensive experience. None was on the learning curve for PCNL or either of the two tract dilation techniques. Subjects with previous renal surgery, uncorrected coagulopathy, ectopic kidney, diverticular stones, chronic kidney disease, malrotated kidneys and skeletal deformity were excluded. Data were recorded and analyzed for demographic variables, location, side, size and composition of the stones along with hemogram, radiation exposure time (total fluoroscopy time in seconds for which c-arm was used (foot on the paddle) from the insertion of a guidewire to the placement of sheath), operative time, rate of stone clearance, duration of hospital stay and complications. Institutional ethical clearance was taken before start of the recruitment of the subjects in the study.

Operative technique

Under general anesthesia, a 6 Fr ureteric catheter was inserted in lithotomy position. This catheter was used for opacification and distension of the pelvicalyceal system by injecting contrast. After ureteral catheterization, the PCNL was done in prone position. After getting ingress to the pelvicalyceal system through a sheathed needle (two-part trocar needle, M/S Cook Medical), the stylet was removed and a guide wire (150 cm Nitinol Terumo hydrophilic guidewire M) was inserted. The tract in both groups was initially dilated by using 8 F and 10 F polyurethane dilators and then Alken guide was inserted. Further, tract dilation in group 1 (SFD) was done by using Amplatz dilators (M/S Cook Medical Amplatz Renal Dilators) sequentially with increasing size of dilators by 2 F each time up to 24 F and then passing 26 F sheath or smaller over the last dilator. In group 2 (OSD), further tract dilation was achieved by using Amplatz dilator of 24 F or 26 F size directly without doing it sequentially. Stone fragmentation was done by ultrasonic and ballistic device (M/S Shockpulse-SE, Olympus). Stone fragments were evacuated by using forceps.

Stone clearance confirmation was done by fluoroscopy and rigid (Richard Wolf nephroscope) or flexible (Cysto-NephroFiberscope, CYF-5, Olympus) nephroscopy in perioperative period while X-ray KUB or NCCT KUB (if the stone was radiolucent) in postoperative period. A 10 F or 12 F suction catheter was placed in place of nephrostomy tube in all cases for drainage under gravity. DJ stent of appropriate size according to age (generally age in years +10 is the size of stent) was put when there was intercostal/supracostal puncture, pelvic perforation and impacted upper ureteric stone. Relook PCNL was performed on 3rd postoperative day through the same track or new one for significant residual stone fragments. Patients with considerable intraoperative bleeding and pelvicalyceal system breach had their nephrostomy tube removed on 3rd postoperative day while the rest of the patients got it removed on 2nd postoperative day. A successful outcome was considered if there was no residual stone or fragments <4 mm at the end of 3 months post-PCNL irrespective of adjuvant treatments. Modified Clavien-Dindo classification was used for grading the complications. In grade I, requirement of analgesics and antipyretics; in grade II number of blood transfusions, the need for higher antibiotics, and need for tranexamic acid; in grade III DJ stenting, stent repositioning, perinephric abscess, intercostal tube drainage for hydrothorax/pneumothorax, urethral stricture and retention of urine due to blood clot were considered.

Statistical analysis

The data were collected using a predesigned questionnaire and subsequently were entered in Microsoft Excel. For normally distributed data, proportions were given as percentages, and continuous data were provided as mean \pm SD. An unpaired Student's t-test was used for comparing differences between continuous normally distributed data. The X^2 test was used to analyze the proportions. A 95% confidence interval (CI) was calculated for the differences for means and proportions. A p value of less than 0.05 was considered significant.

RESULT

We screened 110 patients with indication of PCNL. We excluded 10 patients with various exclusion criteria, such as previous renal surgery (3), uncorrected coagulopathy (1), ectopic kidney (1), diverticular stones (1), chronic kidney disease (2), malrotated kidneys (1), and skeletal deformity (1). Stone and demographic profiles of the patients were comparable as shown in [table 1](#). The tract dilation was done successfully in every case. The stone removal was done through the single tract in all cases. The mean operative time, time of radiation exposure, success and failure rate along with hospital stay are given in [table 2](#). Radiation exposure time, mean operative time and drop in hematocrit were statistically less significant in OSD group. Among the additional treatment, PCNL, ESWL and ureteroscopic lithotripsy (URSL) were done

Table 1 Demographic profile of the patients

Patients' profile		Group 1 (SFD)	Group 2 (OSD)	95% CI	P value
Age (y)		10±3	9.8±4	-1.186 to 1.586	0.779
Sex (M/F)		29/21 (58%/42%)	28/22 (56%/44%)	-0.174 to 0.214	0.436
Stone size in cm (length/width)		3.2±1.1/2.2±0.8	3.7±1/2.5±0.9	-0.912 to -0.088/-0.634 to 0.034	0.035/0.117
Stone location	Pelvic	16 (32%)	15 (30%)		0.987
	Calyceal	7 (14%)	7 (14%)		
	Pelvic + calyceal	9 (18%)	10 (20%)		
	Staghorn	10 (20%)	11 (22%)		
	Upper ureteric	8 (16%)	7 (14%)		
Side (right/left)		27/23 (54%/46%)	29/21 (58%/42%)	-0.234 to 0.154	0.585
Stone composition	Calcium oxalate	44 (88%)	45 (90%)		0.993
	Struvite	1 (2%)	1 (2%)		
	Apatite	1 (2%)	1 (2%)		
	Uric acid	1 (2%)	1 (2%)		
	Mixed	3 (6%)	2 (4%)		
Body mass index		23.5±4.8	22.8±3.9	-1.014 to 2.414	0.474
Preoperative	Hemoglobin	12.5±1.68	12.9±1.72	-1.066 to 0.266	0.293
	Hematocrit	38.9±3.89	38.1±3.52	-0.654 to 2.254	0.335
Serum creatinine		1±0.3	1.1±0.2	-0.2 to -0.0	0.053

CI, confidence interval; OSD, one-shot dilation; SFD, sequential fascial dilation.

for the residual stone fragments after the first PCNL. DJ insertion was done in two patients of OSD group (intercostal puncture =1, impacted upper ureteric stone =1) and three patients in SFD group (intercostal puncture =1, impacted upper ureteric stone =1, pelvic perforation =1). Relook PCNL was successfully done through old tract with the flexible cystonephroscope. [Table 2](#) shows the complications according to the modified Clavien-Dindo classification.

DISCUSSION

Stone incidence is 4.3% in children.⁶ The strategies for diagnosis, therapy, and follow-up are vastly different from those used in adults. The incidence of stones is increasing in the pediatric patients. This may be due to an increasing sedentary lifestyle, increased fast food consumption, obesity and increased direct and indirect salt intake.⁷

Underlying metabolic and anatomical disorders are the main concerns in children with stone disease. Other concerns in the developing kidney are operative trauma, high recurrence rate, exposure to radiation during procedure and need for retreatment.⁸ Radiation exposure to the surgical team and children is a serious concern. For the first time, Frattini *et al* reported the one-shot approach as a unique method for PCNL to reduce radiation exposure in adults.⁹

Like other minimally invasive techniques, PCNL is evolving. Renal dilation is one of the most key steps during PCNL. PCNL technique and equipment advancements have improved patient outcomes.^{5 10 11} Many

publications have claimed that dilation up to 26 Fr does not result in substantial morbidity in children. Based on renal scarring alone, it has been proven in animal models that employing a small access has no benefit.¹²

There is radiation exposure during PCNL. It is difficult to decrease radiation exposure. To limit radiation exposure, using a single semirigid dilator, often known as 'one-shot', is a good alternative to routine SFD (Amplatz). The findings of this study clearly demonstrated that the OSD is feasible and successful along with reduced radiation exposure.^{5 13-18} Hosseini *et al* studied preschool children (<6 years) and showed that fluoroscopy duration was considerably shorter in OSD group. This study also stated that the OSD technique is safe and successful in preschool children.¹⁹

Rather than using total fluoroscopy time in the present study, we used tract dilation fluoroscopy time because it is a good indicator of the pace of dilation, as the total time is affected by the time spent on the puncture of the pelvicalyceal system, insertion of the guidewire and the search for residual stones after fragmentation and removal.

Bleeding is an important complication, especially in vulnerable populations, such as children. Bleeding can depend on sheath size, stone burden, number of tracts and operative time. Kukreja *et al* found that the calyx used during intrarenal access had no effect on the development of complications; however, the dilation technique had an effect on bleeding.²⁰ In various studies, bleeding requiring transfusion reported between 0.4% and 24%.^{21 22} In the present study, we found it was 3.0%. This difference could have been attributed to experience

Table 2 Clinical characteristics and outcome of the patients

Parameters			Group 1 (SFD)	Group 2 (OSD)	95% CI	P value
Radiation exposure time (s)			47.69±13	39.12±15	3.068 to 14.072	0.003
Mean operative time (min)			78±14	70.5±11	2.565 to 12.435	0.004
Perioperative	Hemoglobin (g/L)		110±15.8	110±13.1	-0.569 to 0.569	1
	Hematocrit		37.11±2.45	36.9±1.97	-0.661 to 0.081	0.637
Mean drop	Hemoglobin		2.1±1.08	1.6±1.4	0.01 to 0.99	0.50
	Hematocrit		2.1±1.44	1.44±1.6	0.063 to 1.257	0.032
Hospital stays (d)			4±1.9	3.2±1.8	0.075 to 1.525	0.80
Success rate after first PCNL			44 (88%)	45 (90%)	-0.143 to 0.103	0.749
Overall success rate			47 (94%)	46 (92%)	-0.08 to 0.12	0.829
Additional treatment	PCNL		2	3		
	ESWL		3	2		
	URSL		1	-		
	DJ stenting		3	2		
Complications as per modified Clavien-Dindo classification	Grade 1	Fever*	3 (6%)	2 (4%)	-0.066 to 0.146	0.611
		Urine leak after PCN removal†	2 (4%)	1 (2%)		
		Total	5 (10%)	3 (6%)		
	Grade 2	UTI‡	3 (6%)	2 (4%)	-0.077 to 0.157	0.648
		Blood transfusion§	2 (4%)	1 (2%)		
		Postoperative pneumonia¶	1 (2%)	1 (2%)		
		Total	6 (12%)	4 (8%)		
	Grade 3	Hydrothorax**	1 (2%)	1 (2%)	-0.055 to 0.055	1
		Total	1 (2%)	1 (2%)		
	Total complications		12 (24%)	8 (16%)	-7.84 to 23.45	0.319

*Managed by antipyretics.

†Managed by compression bandage.

‡Managed by change of antibiotics.

§Managed by blood transfusion.

¶Managed by antibiotics.

**Managed by intercostal tube placement.

CI, confidence interval; ESWL, extracorporeal shock wave lithotripsy; OSD, one-shot dilation; PCN, Percutaneous Nephrostomy; PCNL, percutaneous nephrolithotomy; SFD, sequential fascial dilation; URSL, Ureteroscopic lithotripsy; UTI, Urinary Tract Infection.

of the surgeon, tract dilation method and number of tracts. The frequency of bleeding requiring transfusion was similar between OSD and SFD groups.

Daw *et al* studied children less than 6 years of age prospectively. They found that Miniperc was comparable with standard PCNL in terms of requirement of blood transfusion. However, operative time was significantly higher, and stone free rate was lower with stone more than two or stone size ≥ 3 cm in Miniperc group.²³ These differences may have been attributed to smaller size of tract, reduced intraoperative field visibility and the requirement of more time to break into smaller fragments and extract. Meta-analyses showed comparable results between MiniPCNL versus standard PCNL regarding fever, urinary tract perforation, leakage and needing blood transfusion.^{24 25} Similar findings have

also been reported by other researchers.^{9 10 13 15 16} Presently, PCNL is being performed through smaller tract size, such as Miniperc/MiniPCNL (11–20 Fr) and Microperc/MicroPCNL (4.8 Fr) to reduce blood loss and other complications. Our results showed that the OSD did not cause more complications, including bleeding, than SFD. Telescopic, balloon, and OSD had similar hematologic safety profiles in a clinical research by Frattini *et al*. Similarly, telescopic and OSD had similar complication rates in a randomized study by Falahatkar *et al*.^{9 10 19 26–28}

The strength of the present pilot study is the sufficient number of patients in both comparable groups for confounding factors. The limitation of the present study is that there was no long-term follow-up for renal scarring after the PCNL. It would have been better if the present study was done as a randomized controlled trial.

In conclusion, the OSD is feasible, safe and well tolerated in the pediatric age group. In addition to comparable complications, this method also provides reduced radiation exposure for children as well as operating surgeons and nursing teams along with shorter operative time.

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