An Open Label Study to Evaluate The Safety and Efficacy of Percutaneous Nephrolithotomy in Children Aged 2-14 Years

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ABSTRACT

Introduction: Increasing incidence of renal calculi, associated complexities due to metabolism, congenital and anatomic abnormalities compelled the medical fraternity to adopt an effective mode of treatment in pediatric population In addition, high recurrence rate in this population makes the treatment more challenging. So this study was conducted to evaluate the safety and efficacy of pediatric percutaneous nephrolithotomy (PCNL) among children aged 2-14 years.

Material and methods: In this six year study, 80 patients aged 2 - 14 years diagnosed to have renal calculi with > 1cm calculi were included. Those with anatomic abnormalities of the kidney (horseshoe kidney/malrotated kidney), complex stag horn stones, stones of < 1cm, deranged renal functions and bleeding disorders were included. PCNL was performed using a selective calyx by peripheral puncture using conventional PCNL in 50 kidneys and Mini-PCNL in 40 kidneys under the guidance of C-arm with mean operating time of 50 minutes. All cases were followed up with mean follow-up period of 3-12weeks.

Results: The mean stone burden was 28mm (10mm-35mm). 90 kidneys (38 right, 32 left sided,10 Bilateral) were Complete clearance was achieved in 88 out 90 PCNLs. Post-operative complications were noted in 11PCNLs in which hthree presented with bleeding and 8 presented with fever. Only 2 PCNLs had the residual calculi in whom complete clearance was achieved by additional procedure ie. ESWL.

Conclusion: PCNL is safe and effective treatment for paediatric renal calculi, Associated with less morbidity and shorter hospital stay. PCNL associated with increased stone free rates irrespective of stone composition.Mini PCNL is preferable in children especially those with low BMI, children under 10years and children with stone burden less than 1.5cms.

Keywords: Renal Calculi, Percutaneous Nephrolithotomy, Mini PCNL, Extracorporeal Shock Wave Lithotripsy, Urinary Tract Infection.

INTRODUCTION

Increasing incidence of renal calculi, associated complexities due to metabolism, congenital and anatomic abnormalities compelled the medical fraternity to adopt an effective mode of treatment in pediatric population In addition, high recurrence rate in this population makes the treatment goal elusive.^{1,2} Treatment aims at total clearance without any residual fragments of calculi along with pain management, eradication of the causative micro-organisms, relief of any obstruction, appropriate and adequate management of urinary tract infection (UTI).³ Correction of any underlying metabolic or anatomical abnormalities is also crucial in the prevention of recurrence and in preservingrenal function in this population.^{4,5}

Surgical treatment has drifted from open surgeries to endoscopic surgeries for renal calculi even in children which have proved not only effective but also safe.^{1,2,3,4} Significant development

in the recent past including PCNL, extracorporeal shock wave lithotripsy (ESWL) have changed the management and resulted in better treatment outcome of renal calculi extensively⁵ Hence, open surgeries are now considered rarely. Selection of a suitable procedure is crucial in pediatric population as the aim is to achieve a good therapeutic success rate with minimal/no damage to the renal tissue. Hence, minimally invasive methods have replaced open procedures in the management of urolithiasis, with the first successful cases of pediatric PCNL and ESWL reported in 1984 and 1986, respectively.⁶⁻⁸

PCNL has been identified globally as a safe procedure associated with appreciable greater success rate along with lesser major associated surgical complications⁶ and proved to be suitable, safe and effective in all age groups including pediatric cases of renal calculi,7,8 replacing open surgeries in many cases.9 It's utility in staghorn and multiple renal stones have promoted it to be the alternative monotherapy in these patients.¹⁰ Increasing evidences supporting the safety, efficacy of PCNL and effective stone clearance in pediatric patients,¹¹ led more urologists adopting this procedure in the management of renal calculi. This procedure is found to be safe in children with anomalous kidney.¹² PCNL has been advocated as a procedure which can be performed on any patient with renal calculi, without any contraindication, without adding any extra risk. Advantage of absence or minimal postoperative complications too has contributed to its popularity.¹³ Further improvisation of instruments and techniques have resulted in miniperc and ultraperc, which have also found to be safe and effective with lesser frequency and severity of complications.^{14,15} However, therapeutic success, recurrence and complications depend on the technique adopted and experience of the urologist. Available reports are from developed countries and there is paucity of data from the developing and underdeveloped countries. Few reports are available from Asia and only countable reports are available from India.¹⁶ which have proved it safe in Indian children. Hence, we conducted this study in our tertiary care referral centre, to assess the efficacy and safety of percutaneous nephrolithotomy (PCNL) in pediatric patients.

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MATERIAL AND METHODS

This study was conducted by the Department of Urology, Nizam's institute of medical sciences, Hyderabad, India for a period of 06 years (Jan 2010- Apr 2016) after obtaining Institutional ethics committee's approval. This was both retrospective and prospective study in children with renal calculi. Prospective pediatric patients were screened after obtaining written informed consent from parents.

A total of 90 PCNL's have been performed among 80 children during the study period with 10 children having bilateral renal calculi for which bilateral PCNL has been done. Children with renal calculi with > 1cm calculi were included while those with anatomic abnormalities of the kidney (horseshoe kidney / malrotated kidney), complex staghorn stones, stones of < 1 cm, deranged renal functions and bleeding disorders were excluded. Children who met the selection criteria were subjected to further evaluation which included clinical and laboratory investigations. Renal functions, urine culture and intravenous pyelography were done for all enrolled patients. All underwent PCNL procedure¹⁷ under general anesthesia after they were considered fit for the procedure. Postoperatively, Hemoglobin (gms%) was estimated in all patients 12 hours after the procedure. Follow-up kidney ureter bladder (KUB) radiograph and Ultrasound was done in all cases to check stone clearance.

Three French (Fr) open end catheter was passed cystoscopically under fluoroscopic guidance upto renal pelvis in patients positioned in lithotomy position. Patient was then put in prone position. Under fluoroscopic guidance, pelvi-calyceal system was punctured (sub-costal approach) using 23 Fr spinal needle. The glide wire was passed through spinal needle into pelvicalyceal system. The tract was dilated using dilators over the glide wire. A PCNL sheath of variable diameter was used for both Conventional, Miniperc PCNL PCNL of smallest size used being 21 Fr (miniperc PCNL) to the largest of 30 Fr (conventional PCNL) was introduced over dilator into pelvicalyceal system under fluoroscopic guidance. A nephroscope was then introduced through PCNL Sheath for conventional and uretroscope was used for miniperc. Pneumatic lithoclast was used to break the stones and three-prong grasper was used to extract the stone fragments.

For patients with bilateral disease a two step planned PCNL¹⁸ was done with interval of 3-4 weeks. Antegrade DJ stenting was done in all these cases. Nephrostomy tube was placed in all patients and removed on the second postoperative day. DJ stent was removed during follow-up on 3rd-4th week of procedure. Statistical Analysis

Data was captured on Microsoft Excel worksheets (Microsoft 2007+) and analysed manually. Analysed data was expressed as frequency, mean±SD, median, and range. Descriptive statistics was used to describe the results. Tables and figures were used where required.

RESULTS

Ninety (38 right, 32 left sided, 10 bilateral) PCNL procedures were done on 80 patients (boys = 45, girls =35).

Mean age±SD of patients was 9.4±2.80 years, youngest was 02 Years and oldest was of 14 years. Median age was 09 years. Age and gender distribution among study population is given in Table 1. Of 10 patients who had bilateral calculi, seven were boys.

Unilateral renal calculi were noted in 70 (87.5%) patients, of which, 38 (54%) were on right and 32 (46%) on left side. Mean stone size was 28.05±6.60mm (range16.mm - 46mm). Fifty patients had stone in middle calyx (Figure 1).

PCNL was performed by a team of urologists, who had hands on experience of > 5 years in this surgery. Average time taken was 50 mins (30-70 minutes) to perform the procedure.

Access into the pelvi-calyceal system was established through puncture of middle calyx, lower calyx and upper calyx in 50 (55%), 32 (36%) and 8(9%) kidneys, respectively. Conventional PCNL was performed on 50 (56%) kidneys while Miniperc PCNL on 40 (44%).

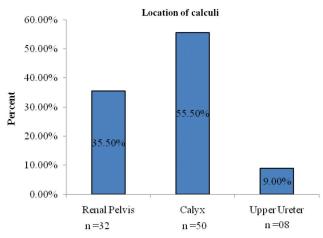
Of 38 right sided (girls=22, boys =16) stones, single puncture required for 33 patients; mean stone size in these was 27.79 ± 6.52 mm. Of 32 left sided (boys =22, girls=10) stones, 25 required single puncture; mean size was 28 ± 6.63 mm. There was no difference in minimum and maximum stone size (min 16mm, max 46 mm). There was no statistically significant difference in the mean size of stone compared to sides. Totally, PCNL was performed with single puncture in 68 (85.0%, boys =40, girls 28) while twelve (15.0%, girls =07, boys =05) required double punctures. Of 12 PCNLs that required double punctures, PCNLs were done by using miniperc for both punctures and in five PCNLs both one conventional and one miniperc punctures were used.

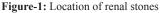
Complete clearance was achieved in 78 (86.66%) patients; residual calculi (<10mm) was seen in two; these patients underwent ESWL prior to the removal of DJ stent.

Of 80 patients, eight (10.0%) developed fever postoperatively, which was treated with appropriate broad spectrum intravenous antibiotics. Post operative bleeding was seen in three patients for who underwent conventional PCNL and required timely blood transfusion.

Ten patients had bilateral renal calculi. Two step procedures

Age (in yrs)	Boys	Girls	Total
	n (%)	n (%)	n (%)
0-5	05 (6.25)	02 (2.5)	7 (8.75)
6-10	22 (27.5)	18 (22.5)	40 (50.0)
11-14	18 (22.5)	15 (18.75)	33 (41.25)
Total	45 (56.25)	35 (43.75)	80 (100.0)
Table-1: Age and Gender distribution among study population			





were performed in these patients. Mean time taken for procedure was 50minutes (30-70minutes).

Patients were discharged with mean hospital stay of 4days. All cases were followed up for 3-12 weeks. There was no report of any untoward event during the follow-up period.

DISCUSSION:

Availability of improvised techniques in procedures adopted for renal calculi has restricted the use of open surgery particularly in Pediatric patients, for selected cases with complications and anatomical abnormalities. Moreover, high rate of recurrence in children¹⁶⁻¹ makes repeated open surgery not a feasible option. Short wave lithotripsy (SWL) is considered as the treatment of choice for symptomatic upper urinary tract calculi in children but not a preferred option in patients with large stone burden, owing to higher rates of failure and the risk of remnants of significant stone fragments in the pelvicalyceal system (PCS). Moreover, anatrophicnephrolithotomy for complex branched calculi has been shown to cause upto 6-16% deterioration in renal function after surgery.9 Therefore, PCNL with proven advantages, can be advocated as a suitable treatment option for children with significant stone burden, to avoid numerous SWL sessions under anesthesia and the risks associated with repeated open surgery.10,11

First series of case report of pediatric PCNL was in 1985 by Woodside et al⁸ after a decade of its description. Pediatric surgeons had their reservation regarding performing PCNL in Children. There was an apprehension due to fear of parenchymal damage, exposure to radiation and risk of major complications. Dawabaet al.12 proved minimal scarring and no significant loss of function with pediatric PCNL. Availability of expertise, improvised instruments in terms of small caliber, advances in energy sources and no of tracts that can be placed along with an additional advantage of direct visualization of stone and its fragments, have made PCNL as the first choice of treatment for renal calculi in children. Apart from this, good therapeutic outcome minimizes the need for recurrent hospital visits.13 Now PCNL is the choice of treatment in renal calculi, and routinely followed in our institution, thus we performed this procedure in our patients. We adopted subcostal approach as supracostal approach is associated with more complications.^{13,14}

We opted to perform conventional PCNL (56%) and Miniperc PCNL (44%) based on our experience there have been reports of good success rate. without any increase in associated complications have been reported with bigger/adult size instruments in children.¹⁵ we were successful with single puncture in 85.0% patients; very few patients (n=12, 15.0%) required double punctures.

We performed 90 PCNL procedures on 80 children with mean age of 9.4 years which was similar to previous studies.¹⁴⁻¹⁷ though a slight higher age of 10.1 and 10.8 years was reported.^{18,2} Samad et al¹⁶ had younger patients in their study with mean age of 6.5 years While Caione P et al have reported high of 13.4 years.³

Unilateral renal calculi were detected in 87.5% patients; stone in middle calyx was detected in 55.5% patients.

Mean stone size was 28mm in our study, which was comparable to that reported by other authors (18-27mm);¹⁴⁻¹⁷ Veeratterapillay R et al¹⁹ have noted slight variation with range of 5-40mm.¹⁹ Romanowsky I et al reported higher stone size of 45.9mm in

their patients.4

Increased operative time of > 1 hour during PCNL procedure has been associated with increased oxidative stress.⁵ Hence, it is in the best interest of the patient to restrict the operative time within 1 hour. Operative time depends on stone size, location and other renal complications such as hydronephrosis; less time is taken by the experienced surgeon.^{6,24} Mean time taken for surgery in our study was 50 minutes by our surgeons, which is well within the recommended time. Samd et al have reported mean duration in their study as 69-115 min.¹⁶

We achieved complete clearance in 86.66% PCNLs. Residual calculi (<10mm) was seen in two PCNLs; these patients underwent ESWL prior to the removal of DJ stent. Veeratterapillay R et al have achieved 84% success rate with initial PCN while 83.9% and 80.0% was reported by Kapoor R et al²³ and Romanowsky I et al,²¹ respectively. reported 80% clearance rate. Samad et al¹⁶ have reported success rate of 90-100%. The stone free rate of 90%, achieved by Desai et.al.¹⁴ Combined with ESWL 100% clearance was achieved in the remaining assuring PCNL in treatment of pediatric renal calculi safe and less morbid.

It is a common belief among surgeons that usage of small caliber scopes makes the procedure more successful; making multiple tracts does not significantly increase intraoperative or postoperative complications in miniperc PCNL. In our study, 12 PCNL (13.33%) procedures required double punctures and 3.33% (3/90) required > 2 punctures. Miniperc was performed in these 12 patients who required double punctures. We had to perform both conventional and miniperc punctures in five patients.

Studies have documented that few patients may require bilateral PCNLs, though number is less. We performed in 10 patients, Synchronous procedure on both kidneys cant be done in fear of blood loss, loss / impairment of function and increased operation time only selected cases we do synchronous procedure even in adults here as the population studied are pediatric group we opted for staged procedure. We feel that staging the procedure and selecting patients is very important to reduce caliber of percutaneous tract in children with nondilated collecting system. Use of small caliber instruments for larger stones decreases the chances of injury avoiding torque forces while manipulating the instruments.

Average stay has been short in our study, which was four days. Nasirov FR et al⁹ have reported 5.9 days (2-31 days), but in their study, mean age was 34.4 yrs.

Complication rate associated with pediatric PCNL varies between 5-10%.^{12,21} Higher rate of 30.3% has been reported by Mousavi-Bahar SH et al²⁵ which included severe complications renal parenchymal and duct injury, colon perforation, damage to major vessels, pneumothorax and hemothorax.⁷ Fever has been reported as common post operative complication which was seen in 10.0% patients in our study. Various studies have reported it to be $3.03^{19} - 12.90\%^{23}$ Lower rate was reported by Mousavi-Bahar SH (1%).

Bleeding, development/exacerbation of urinary tract infection, perinephric collections are expected postoperative complication.^{8,18} Bleeding, a common complication of any surgery, can occur in this method also, prevention and management of which depends on surgeon's skill.

This complication becomes a critical issue if it occurs intraoperatively; apart from causing immediate after effects, it can result in residual stones.⁶ Providing good postoperative care can limit further complications.

PCNL was safe and effective in our patients and we recommend this to be considered as first choice of treatment in pediatric patients with renal calculi. Though successful with single punctures, few required double punctures. Stone clearance rate was comparable to the available data. Careful evaluation, selection of patients, skill of surgeons and good postoperative nursing care contribute towards the success of the procedure. MiniPCNL is preferable in children < 10 years, with low BMI and stone burden < 1.5cms.

CONCLUSION

PCNL is safe and effective treatment for paediatric renal calculi. It is associated with less morbidity and shorter hospital stay. PCNL is associated with increased stone free rates irrespective of stone size. This procedure yields good therapeutic outcome, results in better clearance rate. Proper patient selection, careful evaluation, skill of surgeons and good postoperative nursing care contribute towards the success of the procedure and reduces the complications.

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