

FACTORS AFFECTING THE COMPLICATION RATES OF PEDIATRIC PERCUTANEOUS NEPHROLITHOTOMY USING THE MODIFIED CLAVIEN CLASSIFICATION SYSTEM



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ABSTRACT

Background

Percutaneous nephrolithotomy (PCNL) is effective and safe in children, with a high success rate and a low rate of major complications. The significant factors identified should be considered by clinicians to decrease associated complication rates.

Objectives

To evaluate factors affecting the complications using the modified Clavien scoring system (MCCS) in children undergoing PCNL.

Patients and Methods

We performed prospective data analysis of 109 consecutive patients under the age of 17 years who underwent PCNL from September 2009 to January 2018. Stone complexity was determined according to certified Guy's stone score (GSS). All PCNL procedures performed by a single experienced urologist under general anaesthesia and fluoroscopic guidance in a prone position. Complications recorded according to the MCCS.

Results

The study comprises 109 patients who underwent 115 PCNL (six patients had bilateral PCNL), (65 boys and 44 girls), with a mean (range) age 6.57 ± 4.51 (1-17) years and mean (range) stone burden was 2.341 ± 1.105 (0.6-6) cm. The Stone-free rate after PCNL monotherapy was 93%, which heightened to 96.5% after shock wave lithotripsy. Thirty-nine children (33.9%) had operative complications; 95% were minor, Clavien grade I in 19 (16.5%) patients, grade II in 18 (15.7%) patients, all were managed conservatively, while two (1.7%) patients have Grade IIIb Complications requiring surgical intervention. The Degree of hydronephrosis (moderate and severe), GSS, and operation duration were significantly associated with perioperative complications ($P < 0.05$).

Conclusions

PCNL in children is effective and safe for handling simple as well as complex renal calculi. Assignment of the modified Clavien classification to all possible PCNL complications is a reproducible system for the improvement in reporting of detail perioperative complications. The distinguishing factors should be considered to reduce associated complication rates.

Keywords: *Renal stone, Pediatric percutaneous nephrolithotomy, Stone-free rate, Modified Clavien classification system.*

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INTRODUCTION

Paediatric Urolithiasis is a prevalent problem in developing countries, and the incidence of pediatric Urolithiasis is on rising in all age groups worldwide. It is frequently associated with urinary tract infection, anatomical and metabolic abnormalities, together with climate and dietary factors (1-4).

Moreover, with the miniaturization of equipment, the reliability of pediatric PCNL has greatly increased (5-8) and PCNL is now the preferable procedure in children necessitating surgical intervention and causing no longer anatomical or functional renal damage irrespective of age or size of instruments (9-11).

Stone –free rates in recent studies were $\geq 90\%$ in children of all age groups using different sizes of instruments (5, 9, 12,13), despite the high success rates, PCNL is a highly invasive operation and the deliberate complication is a considerable concern. The global reported complication rate in children, varied from 12.9% to 30.4% (7, 9, 12, 17-20), fever and blood transfusion being the most common complications differing from zero to 31% and 23.9% respectively (5-8, 12, 13, 17, 20).

Most of the studies classified PCNL complications as major or minor, with the primary focus on postoperative fever, blood transfusion or urinary leakage necessitating intervention. To defeat the problem of under-reporting and to implement a recognized comprehensive podium for comparisons, the Clinical Research Office of Endourological Society (CROES) PCNL Study Group has recently assigned specific Clavien scores to each potential complication of PCNL, to enhance the consistency of reporting detrimental outcomes (21,22).

Our objective was to evaluate factors affecting the complications using the template of the modified Clavien scoring system (MCCS) in children undergoing PCNL.

PATIENTS AND METHODS

We performed prospective data analysis of 109 consecutive patients under the age of 17 years who underwent 115 PCNL (six were bilateral), from September 2009 to January 2018.

Preoperative evaluations included history, examination, urinalysis, urine culture, renal function tests, complete blood count, coagulation profile, abdominal ultrasonography, plain X-ray, intravenous urography (IVU). NCCT (non-contrast computerized tomography

was performed only when indicated especially in previously operated (open renal stone surgery) cases to evaluate the relation of the colon and surrounding structures to the kidney, and in complex renal calculi where more than one tract may be needed.

The stone burden measured by multiplying the two largest dimensions on preoperative radiography and the stone complexity were classified according to Guy's stone score (appendix 1).

All PCNLs were performed under general anaesthesia, using prophylactic intravenous antibiotics. A four or five Fr ureteral catheter inserted in the lithotomy position, for opacification of the pelvicalyceal system, patients turned on to prone position and under fluoroscopy guidance, percutaneous access was established. Tract formation was performed by serial coaxial dilatation using Alken dilators, afterwards, in using Amplatz sheaths, their chosen sizes were based on the degree of hydronephrosis observed at fluoroscopy after contrast injection, and stone size, calyx anatomy, and surgeon's preference were additional factors in deciding the appropriate Amplatz sheath size.

A 17 French Karl-Storz slender nephroscope without external sheath used for all cases reinforced as necessary using a flexible cystoscope (15 Fr). Pneumatic lithotripter used for the disintegration of the stones. To reach calyces inaccessible through rigid nephroscope a flexible cystoscope serves as a flexible nephroscope used to examine and remove stones. In cases of multiple or migratory calyceal stones, to avoid another tract, an initial puncture (IP) needle was introduced in calyx containing stone and stone was flushed out with saline irrigation. The stone-free status is confirmed using both fluoroscopy and endoscopic examination with flexible nephroscopy. Number and location of access points, blood loss, hospitalization times, stone burden (according to Guy score) (see appendices 1) (23), stone clearance, and complications (according to the modified Clavien classification) were recorded by a senior and resident urologist (see appendices 2) (21). On completion of the procedure, a Foley catheter is placed in the bladder, 14-16 Fr nephrostomy tube was left in situ in all cases and DJS inserted in most of the cases at the beginning of the series later on inserted in selected patients who had infected stones, pelvicalyceal injury, and extravasations. On the first post-operative day, KUB was done to verify the absence of stones, and when the urine was clear, nephrostomy and urethral catheter were removed, and the patient was discharged

home when there is (was) no urine leakage or fever. Success was defined if stones are removed without the need for the auxiliary procedure.

The first follow-up evaluation was performed 10–14 days after the operation (at the time scheduled for double-J stent removal). Subsequent evaluations were performed if the patient had residual fragments at 6 weeks and 3 months post-operation (chance of spontaneous clearance of the stones fragments) with renal ultrasonography supplemented with abdominal radiographs of KUB, if necessary. The overall SFR was calculated at 3 months post-operation.

Data were analyzed using the Statistical Package for Social Sciences (SPSS, version 19). Chi-square test of association used to compare proportions. When the expected count of more than 20% of the cells of the table was less than 5, Fisher's exact test was used. The Student's t-test used to compare the means of the two groups. A p-value of ≤ 0.05 considered statistically significant. Univariate analyses performed to detect any significant association between each of the dependent and independent variables. The 95% confident interval was calculated.

RESULTS

One hundred and nine patients underwent 115 PCNL (six patients had bilateral PCNL), (65 boys and 44 girls), with a mean (range) age 6.57 ± 4.51 (1-17) years and mean (range) stone size was 2.341 ± 1.105 (0.6-6) cm. Patient demographics and preoperative variables are summarized in table 1. The assigning of the stones according to the GSS was 40% grade I, 46% grade II, 7 % grade III, and 7% grade IV.

Comprehensive operative variables and outcomes outlined in table 2. DJs inserted in 89 children (77.4%) and these were removed under brief anaesthesia three weeks after surgery. Complete stone clearance was achieved in 107 kidneys (93%), while eight (7%) had residual stones. Eventual stone clearance was obtained in 111 units with a success rate of 96.5% after SWL.

Complications of PCNL include fever and blood transfusion. Bleeding that does not require blood transfusion is Grade I. If there was a need for blood transfusion, it is Grade II. The same grade is for transient urine leakage after removal of the nephrostomy tube. Fourteen of our cases were Grade I according to the Clavien score.

Twenty-five (21.72%) procedures have perioperative complications and most of them (92%) were minor and all managed conservatively. The overall complication rate after elucidating the complications according to the modified-Clavien score increased to 39(33.9%) and all forgotten complications were of grade I. The assigning of complications was grade I in 19(16.5%) patients, grade II in 18(15.7%) patients, and grade IIIb2 in two (1.7%) patients, comprehensive details of complications according to MCCS outlined in (Table 3).

Different age groups found to be not correlated significantly with Complications as shown in figure 1 ($p=0.65$).

The degree of hydronephrosis (moderate and severe), GSS and operation duration, were positively correlated with complications ($P < 0.05$). While the Patient's age, stone complexity, DJ stenting, tract numbers, and tract diameter were found to be not significantly associated with complications (Table 4).

One patient developed extravasation of irrigation fluids, detected intraoperatively at the end of the procedure once the patient turns back to supine position huge abdominal distention noted, immediate ultrasonography done reveal large amount of free fluid within the peritoneal cavity, exploration, and drainage was done, three-day nephrostomy left and kept in hospital for four days.

The patient with colonic injury was a 12- year old boy with a single pelviureteric junction stone (20mm in diameter) with moderate hydronephrosis. On the first postoperative day, he developed fever and tachycardia, with abdominal pain and tenderness. CT scan showed air inside and outside the kidney with fluid. The nephrostomy tube was located inside the colon, as it has gone through-and-through. There was fecal peritonitis. The colostomy performed and closed two months later.

Table 1. Preoperative characteristics of patients.

Parameters	
No. of renal units (patients), n (%)	115 (109)
Male/female, n (%)	65/44 (60/40)
Side: left/right, n (%)	57/58 (50.4/49.6)
Means±SD (range) age, years	6.57±4.51 (1-17)
Mean ±SD (range) stone size, cm	2.341±1.105 (0.6-6)
Previous stone related surgery, n (%)	43(37.0)
PNL	7(6.1)
URS	2(1.7)
ESWL	16(13.9)
Open	18 (15.7)
Cystolithotomy	2(1.7)
Pyelolithotomy	14(12.2)
Pyeloplasty	2(1.7)
Stone complexity and location, n (%)	
Single	48(41.7)
Renal pelvic	36(31.3)
middle calyx	7(6.1)
Inferior calyx	5(4.3)
Multiple (multiple calices or pelvic + calyces)	51 (44.3)
Staghorn	16(14)
Partial staghorn	8(7)
Complete staghorn	8(7)
Degree of hydronephrosis	
No hydronephrosis	12 (10.4)
Mild hydronephrosis	52 (45.2)
Moderate hydronephrosis	49 (42.6)
Severe hydronephrosis	2 (1.7)
GSS, n (%)	
I	46(40)
II	53(46)
III	8(7)
IV	8(7)

Table 2. Operative and postoperative data.

Parameters	N (%)
No. and site of punctures, n (%)	
One puncture	109 (94.7)
Lower pole	107 (93)
Supracostal puncture	2 (1.7)
Two punctures	6 (5.1)
Lower pole + middle pole	2 (1.7)
Lower pole + upper pole	2 (1.7)
Lower pole +supra costal puncture	2 (1.7)
Mean ± SD (range) tract size	24.452±1.607 (20-26)
20 Fr	4 (3.47%)
22 Fr	22 (19.13%)
24 Fr	38 (33.04%)
26 Fr	51 (44.34%)
Mean ± SD (range) operative duration, min	54.57±18.43 (40-80)
Mean ± SD (range) drop in hemoglobin, g%	1.34±0.53 (0.40-3.00)
Mean ± SD (range) hospital stay, days	2.25±1.016 (1-10)
JJ stent, n (%)	89 (77.4)
Operative and postoperative complication, n (%)	
Hematuria/bleeding	9 (7.8)
Blood transfusion	4 (3.5)
Extravasation	1 (0.86)
Fever	14 (12.2)
Sepsis	0 (0)
Pleural injury	0 (0)
Colon injury	1 (0.86)
Mortality	0 (0)
Stone clearance (PCNL – single session), n (%)	
Complete clearance	107(93)
Residual	8 (7)
Ancillary procedures, n (%)	
ESWL	4(3.5)
Relook PCNL	0(0)
Final clearance, n (%)	
Cleared	111(96.5)
Residual	4(3.5)

*The indication for blood transfusion was clinical (vital signs) or when haemoglobin cut of a point becomes 8 gm or below.

Table 3. Complications according to the Modified Clavien classification system.

Grade	n (%)
Grade I Deviation from the normal postoperative course without the need for intervention.	19 (16.5)
-Transient urine leakage (<12 h) from puncture site managed by watchful waiting	14 (12.2)
-Transient hematuria/bleeding managed using i.v. fluid or nephrostomy clamping or skin compression/pressure dressing without the need for blood transfusion	5 (4.3)
Grade II Minor complications requiring pharmacological intervention, including blood transfusion and total parenteral nutrition.	18 (15.7)
-Bleeding requiring a blood transfusion	4 (3.5)
-Postoperative fever (>38.0°C) managed with antibiotics in the ward	14 (12.2)
Grade IIIa Complications requiring surgical, endoscopic or radiological intervention, but self-limited, without general anaesthesia	0
Grade IIIb Complications requiring surgical, endoscopic radiological intervention, but self-limited, with general anaesthesia	2 (1.7)
-Extravasation around the tract requiring surgery under GA.	1 (0.87)
-Colon perforation managed by colostomy under GA.	1 (0.87)
Grade IVa Life-threatening complications requiring intensive care unit management; single organ dysfunction, including dialysis	0
Grade IVb Life-threatening complications requiring intensive care unit management; multiorgan dysfunction	0
Grade V Death resulting from complications	0
Number of kidneys with complications	39 (33.9)
Minor complications (grade 1 + 2)	37 (32.2)
Major complications (grade 3 + 4)	2 (1.7)

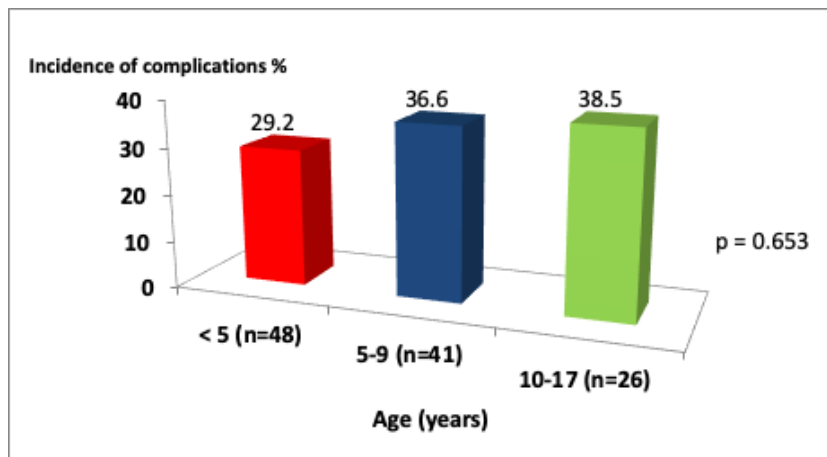


Figure 1. Incidence of complication in deferent age groups.

Table 4. Predictors of complications.

Variables	Total procedures, N	With complications n (%) unless noted otherwise	Without complications n (%) unless noted otherwise	P-value
Gender				
Male	69	19 (27.5)	50 (72.5)	0.077
Female	46	20 (43.5)	26 (56.5)	
Age, years				
< 5	48	14 (29.2)	34 (70.8)	0.653
5-9	41	15 (36.6)	26 (63.4)	
10-17	26	10 (38.5)	16 (61.5)	
Family history of renal stone				
Previous stone related surgery	2	0(0)	2(100)	0.548 *
PNL				
URS	7	3(42.9)	4(57.1)	0.688 *
ESWL	2	2(100)	0(0)	0.113 *
Open	16	8(50)	8(50)	0.143
Cystolithotomy				
Pyelolithotomy	2	0(0)	2(100)	0.229 *
Pyeloplasty	14	8(57.1)	6(42.9)	
No of stone				
1	2	0(0)	2(100)	0.708 *
2	30	8 (26.7)	22 (73.3)	
3	15	5 (33.3)	10 (66.7)	
4	4	2 (50)	2 (50)	
Side of stone				
Right	58	24 (41.4)	34 (58.6)	0.088
left	57	15 (26.3)	42 (73.7)	
Anatomy				
Normal	113	39 (34.5)	74 (65.5)	0.548 *
Malrotated kidney	2	0 (0)	2(100)	
Degree of HN				
No HN	12	6 (50)	6 (50)	< 0.001 *
Mild HN	52	6 (11.5)	46 (88.5)	
Moderate HN	49	27 (55.1)	22 (44.9)	
Sever HN	2	0 (0)	2 (100)	
Stone complexity				
Single pelvis	36	13(36.1)	23(63.9)	0.052 *
Single middle calyx	7	2(28.6)	5(71.4)	
Single lower calyx	5	1(20)	4(80)	
Multiple (multiple calices or pelvic + calyces)	51	17 (33.3)	34 (66.7)	
Complete Staghorn stone	8	6(75)	2(25)	
Partial Staghorn stone	8	0(0)	8(100)	
GSS				
I	46	16 (34.8)	30 (65.2)	0.016 *
II	53	17 (32.1)	36 (67.9)	
III	8	0 (0)	8 (100)	
IV	8	6 (75)	2 (25)	

*Derived from Fisher's Exact Test, * * Derived from T-test

Table 4 (continued). Predictors of complications.

Variables	Total procedures, N	With complications n (%) unless noted otherwise	Without complications n (%) unless noted otherwise	P-value
No. of punctures				
1	109	35 (32.1)	74 (67.9)	0.178 *
2	6	4 (66.7)	2 (33.3)	
Tract dilatation (Fr)				
20	4	2 (50)	2 (50)	
22	22	4 (18.2)	18 (81.8)	0.311 *
24	38	14 (36.8)	24 (63.2)	
26	51	19 (37.3)	32 (62.7)	
DJ stent				
Without Dj stent	26	6 (23.1)	20 (76.9)	0.185
With Dj stent	89	33 (37.1)	56 (62.9)	
Operation duration, min		67.53±11.57	51.57±10.43	< 0.001
Hemoglobin drop		1.60 ± 0.55	1.18 ± 0.46	< 0.001
Prolonged nephrostomy	6	6 (100)	0 (0)	0.001 *
Mean ±SD Hospital stay, days		2.92±1.30	1.91±0.59	< 0.001 * *
Stone clearance				
Clearance	107	35 (32.7)	72 (67.3)	0.441 *
Residual	8	4 (50)	4 (50)	
Ancillary procedure				
ESWL	4	3 (75)	1 (25)	0.018

*Derived from Fisher's Exact Test, * * Derived from T-test

DISCUSSION

The existence of correlated metabolic and anatomical anomalies in 20–40% of children with Urolithiasis discriminate them from adults, making them more amenable to stone recurrence⁽²⁴⁾. Hence, a minimally invasive procedure, with a high success rate and minimal morbidity, is desirable in children. SWL is safe and effective, maintaining its status as the preferred approach for treating upper-tract calculi up to 1.5 cm in size; however, its efficacy falls with increasing stone size/multiplicity^(25, 26). With the growing skill of urologists and refinements in instrumentation and technology, PCNL has become a well-established basic treatment in pediatric cases⁽¹⁾.

Our results show that pediatric PCNL is a safe treatment procedure with a valuable stone clearance rates (93%) after a single session of PCNL, rising to 96.5% after additional procedures (SWL) with overall complications rate of 21.72% and most complications are inconsequential in magnitude. This compares favourably with published series over the past two decades^(8-10, 13, 18-20, 27-37). The previous series have shown that PCNL performed safely in children with stone clearance rates of 58–93% and complication rates

of 0–30%. The largest pediatric multi-institutional retrospective analysis reported by Önal et al⁽³⁸⁾ who disclosed 1205 PCNLs on pediatric patients with a mean age of 8.8 years, in which 95.6% of cases were ended using a single tract with an overall clearance rate of 81.6% and a complication rate of 27.7%. Nouralizadehet al.⁽⁹⁾ reported a 10% complication rate for patients with a mean age of 3.1 years (lowest in series), with an average stone burden of >30mm. Aron et al.⁽³²⁾ used multiple tracts and obtained a stone clearance rate of 89% with no reported complications.

The complication rate in the current study was (21.72%), and with the application of MCCS, due to more precise notification of complications, the number of complications increased significantly to (33.9%). However, 94.9% of the total complications were Clavien score I, and II which were managed conservatively.

There are only limited studies in the literature using the modified Clavien Classification system to report PCNL complications in children^(5, 36- 39). Our results were favourably compared to them (Table 5).

Table 5. Using the modified Clavien classification system to report PCNL complications in children.

Authors	No. renal units	Overall complication (%)	Grade I n (%)	Grade II n(%)	Grade III		Grade IV		Grade V n(%)
					IIIa n (%)	IIIb n (%)	IVa n (%)	IVb n (%)	
Ozden et al. ⁵	100	42	15(15)	19(19)	4(4)	-	-	-	-
Guven et al. ³⁹	140	29.1	17(12.1)	4(2.9)	11(7.9)	7(5)	-	-	-
Goyal et al. ³⁶	158	39.2	39(24.7)	26(16.5)	4(2.5)	5(3.2)	1(0.6)	0	0
Önal et al ³⁷	1205	27.7	180(14.2)	45(3.8)		13(0.9)	2(0.2)		1(0)
Present study	115	33.6	19(16.5)	18(15.7)	0	2(1.7)	0	0	0

Through assessing different factors influencing complications, we found that the degree of hydronephrosis, stone burden (GSS), and operation duration were cardinaly correlated with complications ($P < 0.05$). At the same time patient's age, stone complexity, tract size, number of punctures, and DJ stenting were found to be fundamentally not correlated with complications. Önal et al ⁽³⁸⁾ revealed that stone history, positive urine culture, operative time, length of hospitalization, treatment success, punctured calyx and location of the stone significantly affected the complication rates, Goyal *et al.*⁽³⁶⁾ found that stone size, GSS, tract size, number of the puncture and operation duration were significantly associated with complications ($P < 0.05$). Ozden *et al.* ⁽⁵⁾ found a stone burden and operation duration to be the only independent factors affecting complications on binary logistic regression analysis. While Zerenet *al.* ⁽¹²⁾ and Desai *et al.* ⁽¹³⁾ found that stone burden, operation duration, number and size of tracts to be significant predictors affecting blood transfusion.

Modified Clavien classification system is of value for documentation of all complications that would otherwise have been missed if the classification were not used. On the other hand, there was no problem in "management" since the underreported complications were minor, easily noticeable and appropriately manageable without the need for the Clavien score. The modified Clavien classification system detected all complications caused by PCNL except possible damage of the renal parenchyma with subsequent renal scarring.

Limitations of this study were: It was a single center study and included the tract sizes 20Fr and above.

In conclusions, PCNL in children is effective and safe for handling simple as well as complex renal calculi. Assignment of the modified Clavien classification to all possible PCNL complications is a reproducible system for the improvement in reporting of detail perioperative complications. The distinguishing factors should be considered to reduce associated complication rates.

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Appendix 1: Modified Clavien classification system

Grade I	Any deviation from the normal postoperative course without the need for treatment.
Grade II	Requiring pharmacological treatment with drugs Blood transfusions and total parenteral nutrition are also included.
Grade III	Requiring surgical, endoscopic or radiological intervention.
Grade IIIa	Intervention not under general anesthesia.
Grade IIIb	Intervention under general anesthesia.
Grade IV	Grade IV Life-threatening complication requiring IC/ICU management.
Grade IVa	Single organ dysfunction (including dialysis).
Grade IVb	Multiorgan dysfunction.
Grade V	Death of a patient.

Appendix 2: Guy's stone score

Grade I	A solitary stone in the mid/lower pole with simple anatomy Or A solitary stone in the pelvis with simple anatomy
Grade II	A solitary stone in the upper pole with simple anatomy Or Multiple stones in a patient with simple anatomy Or Any solitary stone in a patient with abnormal anatomy
Grade III	Multiple stones in a patient with abnormal anatomy Or Stones in a calyceal diverticulum Or Partial staghorn calculus
Grade IV	Staghorn calculus Any stone in a patient with Spina Bifida or Spinal Injury