

Evaluation of the Learning Curve for Percutaneous Nephrolithotomy

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Purpose: To determine the number of percutaneous nephrolithotomy (PCNL) operations which are required to achieve competence or excellence.

Materials and Methods: One hundred and five consecutive PCNL operations performed by a fellow in endourology, with no previous experience in performing solo PCNL, were studied. Operation duration, stone extraction percent, stone-free rate, number of access, tubeless cases, and complications were studied in sequential groups of 15 patients as the surgeon gained experience.

Results: Operation duration decreased from the mean of 95.4 minutes in the first to 15th patients to 78.3 minutes in the 31st to 45th patients, and then remained unchanged. Minor complications were only observed in the first to 45th patients. Stone extraction percent increased from the mean of 88.3% in the first to 15th patients to 99.3% in 91st to 105th patients. Percentage of patients with no residual fragments decreased from 53% in the first to 15th patients to 6.7% in the 91st to 105th patients. No statistically significant differences were observed in estimated blood loss or transfusion rate between sequential groups of subjects.

Conclusion: An improvement in operation duration was observed, and absence of complications was achieved after 45 cases. The improvement in stone clearance was observed up to the last subjects. Competence and excellence were achieved after 45 and 105 operations, respectively.

Keywords: percutaneous nephrolithotomy, percutaneous nephrostomy, clinical competence

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INTRODUCTION

Since introduction in 1976, percutaneous nephrolithotomy (PCNL) has revolutionized the stone surgery and has widely practiced all over the world. Many modifications in this technique were later introduced that have made its learning process rather complicated and difficult.⁽¹⁾ As PCNL is currently considered as the treatment of choice for managing large renal stones,⁽²⁻⁴⁾ every urologist should be able to perform this procedure.

Nevertheless, very few data are available to reach a sound conclusion for devising a training program.^(1,5-6)

To precisely prepare a training program for PCNL, its learning curve should be determined. Learning curve is a theoretical concept that draws a surgeon's performance against time axis.^(1,5) The point at which no further improvement is observed,⁽⁵⁾ or the point at which the slope of the line changes,⁽⁷⁾ has been

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suggested as the point of competence or learning, respectively. Few studies have been performed to investigate PCNL learning curve,^(1,5) in which operation duration and radiology screening time were employed to determine the curve.^(5,8) As suggested before, these markers are not the best indicators of clinical performance^(1,5,8) and there is still no consensus regarding the best practical clinical surrogate markers of performance in PCNL operations.⁽¹⁾ We studied PCNL learning curve of a surgeon using different indicators of performance.

MATERIALS AND METHODS

One hundred and five consecutive PCNL operations for removal of large renal stones performed by a single surgeon were studied prospectively. The surgeon was a graduated urologist who was trained for fellowship in endourology and had no previous experience of performing solo PCNL. He had experience in performing other endourology procedures like ureteroscopy, transureteral lithotripsy, and percutaneous ultrasound-guided nephrostomy.

Shahid Labbafinejad Medical Center is a busy tertiary referral hospital with an average of three PCNL operations on each working day. In our department, urology fellows first observe 30 operations, then, scrub as first aid in another 30 operations with a senior fellow, and thereafter, they perform PCNL while the senior fellow is scrubbed as first aid and interferes in case of any problem for another 30 operations. After the previous three steps, the fellow is allowed to perform solo PCNL unsupervised and asks for help if required. The studied PCNL operations were this latter group of unsupervised operations.

The operation was performed as the standard procedure. Briefly, after general anesthesia, a 5 or 6F ureteral catheter was inserted and fixed to a Foley catheter. Then, the patient was placed in a prone position with special care of pressure points. The desired calyx was punctured under the guidance of fluoroscopy and guidewire was inserted. The preferred contrast medium was air, but if it was helpless, a contrast medium would be injected. The dilation was performed with Amplatz dilators in one shot manner in

most of the patients and when it was impossible (mostly in patients with previous flank surgery and severe fibrosis), dilation was performed by serial metallic dilators. After Amplatz sheath insertion, nephroscopy was performed and stones were fragmented by pneumatic lithotripter (Litho Crack, Sp. Swiss-Germany) and removed.

If the operation was straightforward with no significant bleeding, residual stone, and pelvicaliceal injury and if the ureteral catheter was in the pelvis, the procedure was terminated without nephrostomy insertion (tubeless PCNL). In other subjects, a 16F nephrostomy tube was placed. In tubeless cases, the ureteral catheter was removed after 48 hours and patients were discharged. In other cases, Foley and ureteral catheters were removed the day after the surgery. Nephrostomy tube was clamped 48 hours after the surgery and removed after 24 hours if no leakage or fever existed. In proximal ureteral stones, solitary kidneys, and patients with uremia, a double-J ureteral catheter was routinely inserted.

In operations with supracostal or intercostal access, a chest x-ray was taken after the surgery. Patients were followed up with kidney, ureter, bladder (KUB) x-ray or ultrasonography the day after the operation, and any detectable residual stones were considered significant.⁽⁹⁾

A total of 105 consecutive patients were divided into 7 groups, 15 subjects each. The operation duration, estimated blood loss (EBL), transfusion rate, minor and major complications, stone-free rate (SFR), stone extraction percent (SEP), tubeless rate, number of access, and hospital stay were compared among various groups. Estimated blood loss was calculated using the following formula: $EBL = (Hct \text{ before op} - Hct \text{ after op} / Hct \text{ before op}) \times (\text{weight} \times 85)$. Stone extraction percent was determined by following formula: $1 - (\text{stone surface at the end of the operation by fluoroscopy} / \text{stone surface before operation})$. Stone surface was calculated as the product of maximal height and width of the stone.⁽¹⁰⁾ Stone-free patient was defined as a patient with no observable residual fragment in the postoperative KUB x-ray. Major and minor pelvicaliceal system injuries were defined as the rupture of the kidney pelvis and small injuries/tears of the pelvicaliceal

system during the operation observed through a nephroscope, respectively.

Statistical analysis was carried out using the SPSS software (the Statistical Package for the Social Science, version 16.0, SPSS Inc, Chicago, Illinois, USA). Categorical data across groups were compared by Chi-square test and continuous variables were compared by one-way analysis of variance (ANOVA). In order to remove the confounding effect of stone size on the stone extraction percent, a multiple linear regression model was employed, in which in the first block stone size was entered into the model and then, patient's sequence number was introduced. Statistical significance was considered with the two-sided *P* value of less than .05.

RESULTS

Demographic data are presented in Table 1. The operative data are shown in Tables 1 and 2.

The operation duration was calculated for patients with a single access, excluding patients who had two-access points, because they were not equally distributed in different patients' groups. The operation time decreased from the mean of 95.4 minutes for the first to 15th patients to 84.0 minutes for 16th to 30th patients, and thereafter, further decreased to 78.3 minutes for the 31st to 45th patients. Afterward, little fluctuations were observed in the mean operation time in the next groups. This pattern, however, was not statistically significant (Figure 1).

Stone extraction percent increased from the mean of 88.3% for the first 15 patients to 93.7% for 16th to 30th patients, and followed by, slow increase

Table 1. Demographic characteristics and operative data.

Characteristics	
Sex (male/female)	66/39
Age, year (mean ± SD)	44.4 ± 14.8
Body weight, kg (mean ± SD)	76.3 ± 17.2
Previous renal surgery, %	24 (23)
Number of opaque stones, %	80 (76)
Side (Left/Right)	65/40
Solitary kidney, %	7 (7)
Stone location, n (%)	
Upper calyx	4 (4)
Middle calyx	6 (6)
Lower calyx	83 (79)
Multiple calices	12 (11)
Approach, n (%)	
Subcostal	94 (89)
Intercostal	3 (3)
Supracostal	1 (1)
Multiple	7 (7)
Number of access, (%)	
One	93 (89)
Two	12 (11)

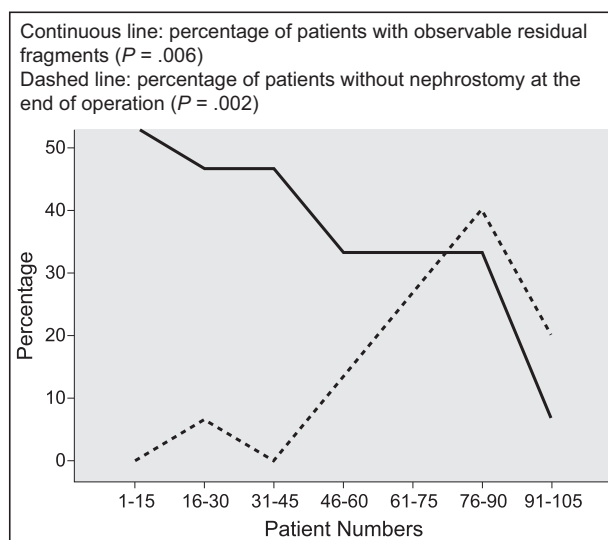


Figure 1. Percentage of patients with observable residual fragments and percentage of tubeless subjects

Table 2. Operative and postoperative data according to patients' groups.

Characteristics	Patients order, mean ± SD or N (%)							<i>P</i>
	1 to 15	16 to 30	31 to 45	46 to 60	61 to 75	76 to 90	91 to 105	
Estimated blood loss, mL	328 ± 195	268 ± 244	412 ± 228	245 ± 126	422 ± 312	293 ± 193	301 ± 180	NS
Operation duration, minutes [§]	99.3 ± 26.9	84.0 ± 18.5	78.3 ± 17.0	80.7 ± 23.4	89.0 ± 21.4	81.0 ± 19.7	87.7 ± 19.7	NS
Stone size > 5cm [†]	10 (67)	10 (67)	13 (87)	7 (47)	4 (27)	6 (40)	4 (27)	.005
2-access-PCNL cases	3 (20)	0 (0)	0 (0)	1 (7)	3 (20)	3 (20)	2 (13)	NS
Minor injury [‡]	1 (7)	1 (7)	6 (40)	0 (0)	0 (0)	0 (0)	0 (0)	.001
Hospitalization, Days	4.1 ± 1.3	3.3 ± 1.0	3.5 ± 1.2	3.6 ± 1.3	2.7 ± 0.6	2.8 ± 0.9	3.3 ± 1.5	.03

*Chi-square for linear by linear association.

[§]Calculated for one-access operations.

[†]Any observable residual stone fragment in postoperative day kidney, ureter, bladder x-ray or ultrasonography.

[‡]Includes small injuries of the minor and major calyces observed during the operation by nephroscope.

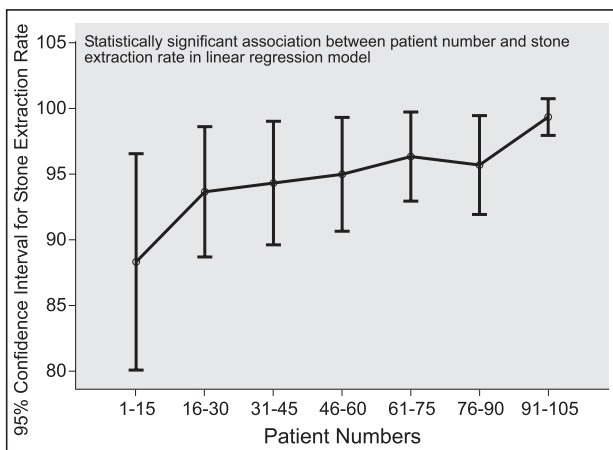


Figure 2. Stone extraction percentage in sequential groups of patients.

to 95.7% for 76th to 90th patients and afterward, significant increase occurred up to 99.3% for the 91st to 105th patients ($P = .04$).

Considering patients with residual stones as depicted in Table 2, a downward trend was observed from 53% for the first 15 patients up to 6.7% (1 patient) for the 91st to 105th patients ($P = .006$).

All minor pelvicaliceal system injuries occurred in the first 45 patients ($P = .001$), which were managed conservatively by keeping nephrostomy tube for a longer duration. No pelvicaliceal system injuries were recorded after the first 45 patients (Table 2). No major complications were observed in any patient. Tubeless rate increased from no patient (0%) in the first 15 patients up to 30% in the 76th to 105th patients ($P = .002$).

For internal control, we studied the stone size in various patients' groups. The percentage of large stones (> 5cm) increased from 67% in the 1st to 15th patients to 87% in 31st to 45th patients. This corresponds to a part of the learning curve where continuous improvement was observed in SEP, operation duration, and residual fragments. Then, we observed increasing ability of the surgeon to perform the operation despite increasing burden of the stones.

The linear regression model revealed that after including stone size in the model, patients' sequence number was still a statistically significant predictor of stone extraction rate ($P = .004$). The odds ratio for increase in stone extraction rate

with the next patient was 1.09 (95% Confidence Interval: 1.03 to 1.15). No significant differences were observed in transfusion rate or EBL among patients' groups.

DISCUSSION

Stone surgery is a frequent practice in urology.^(1,11) For training programs in urology, it is important to know the number of operations that makes a urology resident competent.⁽⁸⁾ The length of training period is no longer an appropriate criterion for judging the competency,⁽⁸⁾ as the number of operations vary greatly between teaching centers.⁽¹¹⁾ This is the reason why it is important to determine PCNL learning curve.

Defining PCNL learning curve has another major advantage. Percutaneous nephrolithotomy has a steep learning curve that has made many urologists reluctant to perform this operation.^(5,12-14) Watterson and colleagues, reported that only 11% of urologists obtained the access themselves and many relied on a radiologist for this step of the procedure⁽¹⁵⁾ that is the most difficult and important part of the operation.^(1,2,8,9) It has been shown that stone clearance rates are better and complications are less when the access is obtained by a urologist.⁽¹⁵⁾ Therefore, by defining the learning curve and providing enough operations for training urologists, they will be more inclined to perform this operation after graduation and become involved in all steps of the operation.⁽¹⁶⁾

Learning curve is a diagram that depicts a surgeon's ability against time.⁽⁵⁾ This idea was first noted in laparoscopic surgery for cholelithiasis,⁽¹⁷⁻²¹⁾ and in urology is mostly studied in cancer surgery.^(1,5) A few studies have been completed on PCNL learning curve. A number of 60 operations have been suggested to gain competence, and over 115 operations to achieve excellence. Nonetheless and as suggested before, the reduction of the operation duration demonstrates the surgeon's familiarity with the technique, tools, and the aspects of puncturing target calyx more than the whole operation, and its reduction provides an estimate of the ability to perform the operation. Furthermore, screening time reduction reflects an intricate part of the operation consisting of identifying and

puncturing target calyx.⁽⁸⁾ These markers have been considered more as a financial aspect of the operation than competency.⁽⁹⁾

The most important clinical aspects of competency are stone clearance and operation complications.^(1,5,8) Nevertheless, it has been suggested that clearance rate varies and depends on many factors, including stone composition, stone size, access type and numbers, and the number of involved calyces.⁽³⁾ It has also been stated that the clearance rate depends more on the supervising surgeon's experience than the operating surgeon.⁽⁸⁾ In a study by Tanriverdi and associates, stone clearance rate did not show any significant changes in sequential groups of patients. The authors concluded that a surgeon can meet this goal very soon in his first few patients' operation.⁽⁵⁾

In this study, SEP has been calculated as a relevant clinical end point. The more complete is the removal of a stone with the smaller size of the residuals, the less ancillary procedures will be needed.⁽²²⁻²⁴⁾ Furthermore, we evaluated the number of patients without any residual stone fragments (SFR).⁽⁹⁾ As shown in Figure 1, better results are observed with more operations, and this improvement is observable until the 105th patient, where the SEP and SFR are very acceptable (99.3% and 93.3%, respectively).

Although alteration in operation duration was not statistically significant, but showed an observable pattern of decrease from the 1st to 15th patients to the 31st to 45th patients. After little fluctuations in 46th to 90th patients, a small increase in operation duration was noticed in the 91st to 105th patients. This small increase could be attributed to the surgeon's interest in removing the residual fragments totally and making the patient stone-free after acquiring basic competence in the procedure (Figure 1).

Minor complications were observed only in the first 45 patients, which mostly occurred in the 31st to 45th patients (Table 2). No further complications were observed in 46th to 105th patients. Increased transfusion (not statistically significant) and complications rate in the 31st to 45th patients could be attributed to a higher

percent of large stones, the presence of two patients with solitary kidneys with staghorn renal calculi, and the previous history of open stone surgery.

Considering decrease in operation duration and the absence of complications as a measure of competency, a surgeon would be able to reach this goal after 45 operations. If we consider acceptable stone extraction percent and residual rate as a measure of gaining excellence, a surgeon can approach this target after 105 operations as suggested before.⁽¹⁾

Following limitations should be considered for this study: 1) This study reflects the learning curve of a single surgeon. There are also some published articles on the learning curves of other surgical procedures by a single surgeon.⁽²⁵⁻²⁸⁾ Nevertheless, there is interpersonal variations among learning curves of different surgeons based on their skills and expertise.⁽⁷⁾ 2) The protocol of this study had minor differences with some previously published articles. In this study, we did not include the 30 operations that the surgeon was the principal surgeon and had aid of a supervising fellow scrubbed as the first aid. The reason was that the supervising fellow was easily involved in the operation in case of any trouble for the beginner surgeon. Our beginner surgeon was a graduated urologist with the previous experience in endourology procedures. The results may be different for a urology resident. 3) The center in which this study was performed is a crowded referral center with a large volume of patients undergoing PCNL each day. The results for centers with fewer patients may be different. 4) The best imaging for residual stones after PCNL is computed tomography scan. We could not employ it in this study, as it is not a routine follow-up evaluation measure in our center.

CONCLUSION

A surgeon without previous experience in solo PCNL reaches a plateau in operation duration and will be free from complications after 45 operations. Improvement in stone clearance rate and stone extraction percent continues to be observed up to the 105th operation.

CONFLICT OF INTEREST

None declared.

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