Original Article

Comparison of percutaneous nephrolithotomy complications according to the modified clavien classification during and after the learning curve

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Abstract. The aim of the study was to compare the percutaneous nephrolithotomy (PCNL) complications according to the modified clavien classification during and after the learning curve.

In our study, PCNL procedures were applied to 275 patients between May 2010 and June 2014. The complications were retrospectively compared according to the Modified Clavien Classification during and after the learning curve. The first 50 cases were defined as the learning curve and referred to as Group-1 and the following cases as Group-2.

We performed 294 PCNL applications on a total of 275 patients. The average duration of surgery was 120 (65-230 min.-max.) minutes and 80.2 (20-140 min.-max.) minutes in Group-1 and in Group-2, respectively ($p<0.05$). When complications, following PCNL, were evaluated according to the modified Clavien classification, grade I, II, IIIa, IIIb, IVa, IVb, and V complications were observed in 12 (15%), 54 (67.5%), 10 (12.5%), 4 (5%), 0 (0%), 0 (0%), and 0 (0%) patients of group 1, respectively. When group 2 was evaluated, grade I, II, IIIa, IIIb, IVa, IVb, and V complications were observed in 24 (12.4%), 132 (68.4%), 30 (15.5%), 6 (3.1%), 1 (0.5%), 1 (0.5%), and 0 (0%) patients, respectively. Grade-5 complication was not observed in any of our patients.

The Modified Clavien Classification may be useful for the comparison of PCNL complications during and after the learning curve for reporting outcomes.

Key words: Percutaneous nephrolithotomy, Modified-Clavien, Complications, learning curve

1. Introduction

Percutaneous nephrolithotomy (PCNL) operations are routinely applied to lower pole stones larger than 1.5cm and to calcyceal stones larger than 2cm (1). Complications can be eminently observed in these procedures, similar to all surgical methods. The reporting of these complications should be routine in surgical interventions (2). It is necessary to standardize the developing complications as accurate as possible to evaluate the surgical methodology and to compare it with other surgical approaches. Clavien et al. (3) discussed the surgical operations in four stages in 1992 (3). This classification did not gain wide acceptance, since it classified the complications occuring only after the surgery (4).

Dindo et al. (5) proposed a modified classification in 2004. Tefekli et al. (6) used the Modified Clavien Classification first in describing the complications of the PCNL series. Thereafter, PCNL complications are similarly classified according to the Clavien Classification in the multi-centre study (CROES) of the World Endo-urology Society (7).

After the CROES study, it has been recommended that the use of the Modified Clavien Classification should be a standard approach for classifying the post-PCNL complications. Since 2012, it has also been advised that this classification should be applied

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to evaluate the PCNL-complications in the Urinary System Stone Diseases-Follow-up Manual of the European Association of Urology (8).

2. Materials and methods

In our study, 294 PCNL procedures applied to 275 patients between May 2010 and June 2014 were analyzed. The complications were retrospectively compared according to the Modified Clavien Classification (Table 1) during and after the learning curve. The first 50 cases were defined as the learning curve and referred to as Group-1 and the following cases as Group-2. Routine preoperative techniques were applied to all cases. The cases were investigated with computerized tomography (CT) and intravenous urography (IVU) for diagnostic purposes.

The stones were classified as simple stones (isolated renal pelvis stone, isolated calyx stone) or complex stones (complete or partial staghorn stones, multi-calyceal stones, calyceal stones accompanied with renal pelvis stones). Operations were performed for stones greater than 1.5cm in the lower calyx and for stones greater than 2cm in other calyces. Also operations were performed smaller 1.5cm stones which were in calyx diverticulum. The operations were performed after the urine cultures became sterile. Antibiotic prophylaxis was started one hour before the operation with 1 gram of Ceftriaxone. The antibiotherapy was continued intravenously at a dosage of 2x1gr for two days if it was necessary. The procedure was started under general anesthesia after the catheter (open tip ureter catheter with a size of 4 or 5 french) was inserted into the ureter by a cystoscopy in the lithotomy position. The operations were performed by a group which included two surgeons.

Thereafter, the prone position was given to the patients. In this position, the stone-containing kidney was localized under the C-arm fluoroscopy (SireMobil Compact, Siemens). The collective system anatomy was revealed with the retrograde pyelography and access to the desired calyx group was performed via an 18G percutaneous access needle (18G percutaneous access needle, Microvasive) with the help of a Multiplanar C-arm fluoroscopy.

Guide wire (Sensor guide wire, Microvasive) was positioned from the needle into the collective system. Dilatation to a width of 30F was provided through the guide wire by filliform dilators, and an Amplatz working sheath was inserted thereafter. The stone breaking procedure was accomplished with a 26F rigid nephroscope (Storz, Germany), pneumatic lithotripter (Vibrolith-Elmed, Ankara, Turkey) and with a laser lithotripter (Wolf, Germany). After the purgation of stones was achieved, an anterograde pyelography was performed to evaluate the calyceal integrity and passage to the ureter. Thereafter, a 14F nephrostomy tube was inserted into the renal pelvis.

Table 1. Meaning of the different grades among the modified Clavien System and its example in PCNL surgery (5)

Grade 1: Any deviation from the normal postoperative course without the need for pharmacologic treatment or surgical, endoscopic, and radiologic interventions. Allowed therapeutic regimens are drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside. (Fever, Transient elevation of serum creatinine)
Grade 2: Complications requiring pharmacologic treatment with drugs other than such allowed for grade 1 complications. Blood transfusions and total parenteral nutrition are also included. (Blood transfusion, Urine leakage < 12 h, Infections requiring additional antibiotics (instead of prophylactics), Wound infection, Urinary tract infection, Pneumonia)
Grade 3: Complications requiring surgical, endoscopic, or radiologic intervention.
Grade 3a: Intervention not under general anesthesia (Double-J stent placement for urine leakage > 24 h, Double-J stent placement for UPJ and pelvis injury, Urinoma, Pneumothorax, Retention and colic due to blood clots
Grade 3b: Intervention under general anesthesia (Ureter-bladder stone, Calyx neck stricture, UPJ obstruction, AV fistula, Perirenal hematoma needing intervention, Perinephritic abscess, Perioperative bleeding requiring quitting the operation)
Grade 4: Life-threatening complications (including central nervous system complications) requiring intensive care unit stay
Grade 4a: Single organ dysfunction (including dialysis) (Neighboring organ injury, Myocardial infarction, Nephrectomy, Lung failure)
Grade 4b: Multiorgan dysfunction (Urosepsis)
Grade 5: Death of the patient

Complete blood count and serum biochemistry analyses (creatinine, urea, AST, ALT) were performed on all patients at the early postoperative period. The patients were evaluated with direct urinary system graphy performed on the first postoperative day. Patients with clinically unimportant (<4mm) stones and the stone-free patients were accepted as "successful" cases. A double J-catheter was inserted to the patients if a prolonged (>24-48 hours) urine leakage was observed. Urine culture specimens were sent to the laboratory for culture in patients who had fever during their postoperative follow-up. Antibiotherapy was started according to the antibiogram results.

The patients were re-evaluated with direct urinary system graphy and ultrasonography (USG) 3 months after the operation. If necessary, the patients were also evaluated with non-contrast CT imaging. The peroperative (bleeding, organ injury), postoperative early period (bleeding, fever, enuresis, dj-stent application), postoperative late period at the 3rd month (fistula, upper-narrowing, non-functional) complications were investigated and compared according to the Modified Clavien Classification.

Statistical Analyses

Z Test for two-proportion was applied to the study groups for the statistical evaluation. Data regarding age and duration of the operation were demonstrated as mean±standard deviation. Statistical analysis was performed by using SPSS (SPSS Inc., Chicago, IL, USA, Version 17.0). Probability values <0.05 were considered as significant.

3. Results

Bilateral stones were present in 19 of the total of 275 patients. PCNL was performed on a total of 294 units. Bilateral stones were present in 5 of the first 50 patients and in 14 of the remaining 225 patients. (The patient characteristics are given in table 2).

The average preparation time for the surgery was 45 (30-65 min.-max.) minutes and 30 (18-45 min.-max.) minutes for Group-1 and Group-2, respectively. The average duration of surgery was 120 (65-230 min.-max.) minutes and 80.2 (20-140 min.-max.) minutes in Group-1 and in Group-2, respectively ($p<0.05$). The average time for the removing the nephrostomy tube was 3.1 (2-7 min.-max.) and 2.7 (1-4 min.-max.) minutes in Group-1 and Group-2, respectively ($p<0.05$). Single percutaneous access was sufficient for all cases.

When complications, following PCNL, were evalauted according to the Modified Clavien Grade-1, it was seen as 12 and as 24 complications in Group 1, and Group 2, respectively. When the data were evaluated according to the Grade-2, 54 complications were seen in Group1 and 132 complications were seen in Group 2. When the Group-1 was evaluated according to the Grade 3A, a double-J catheter

Table 2. Patient characteristics

Variables	Group 1 (n:50)	Group 2 (n:225)
No. of patients		
Mean age±SD (range).	41.1±11.18 (14-77)	44.3±12.11 (16-81)
Mean follow-up (days) (range)	4±0.9 (2-14)	2.3±0.7 (1-5)
Male:female	37:13 (74%:26%)	157:68 (69.8%:30.2%)
Stone location (%)		
Staghorn Stone	14 (28%)	82 (36.4%)
Renal pelvis	20 (40%)	70 (31.1%)
Lower Renal calyx	14 (28%)	56 (24.9%)
Upper Renal calyx	1 (2%)	15 (6.7 %)
Calix diverticulum	1 (2%)	2 (0.9%)
Mean stone burden (range)	540±41.1 mm²(90-1200)	660±25.5 mm²(88-1800)
Laterality		
Right (%)	25 (50%)	110 (48.9%)
Left (%)	20 (40%)	101 (44.9%)
Bilateral stone (%)	5 (10%)	14 (6.2%)
Preop positive urine culture	9 (18%)	27 (12%)
Prior ESWL (%)	5 (10%)	41 (18.2%)
Prior open surgery	3 (6%)	33 (14.6%)

ESWL: Extracorporeal shock wave lithotripsy, a: Surface area (length x height)

was inserted to 8 (16%) patients, who had urine leakage lasting for more than 24-48 hours after retraction of the nephrostomy tube. Six of these had complex stones and 2 had pelvis stones. In Group-2, a double-J catheter had been inserted into 22 (9.7%) patients. Fifteen patients had complex stones, 3 had renal pelvis stones and 3 had upper calyx stones. To one patient with a complex stone, a dj stent and percutaneous drain was applied due to perirenal urinoma developing 1 week after the operation. The complications in Group-1 were observed at a significantly higher rate than Group-2 according to grade 1(p:0.037) and grade 2 (p<0.001).

In Group-1, open surgery was applied to 4 patients due to inability of access and to 2 patients due to bleeding. In Group-2, open surgery was applied to one patient with pelvis+lower calyx stone due to inability of access. 1 patient had undergone open surgery due to bleeding. The stones were cleared, the bleeding control was obtained and nephrectomy was not required. In one patient, an arteriovenous fistula was encountered. This patient was classified as Grade 3B. In one patient, colon injury (Grade 4a) and in another one, urosepsis (Grade 4b) were observed. These were the patients in Group-2. Grade-5 complication was not observed in any of our patients. In totally 80 complications were seen in Group 1 and 193 complications in Group 2. (Results of our two groups were given in Table-3 and compared in Table 4).

Table 3. Comparison of Group 1 and Group 2 patients according to complications

Grade	Group 1 (n:50)	Group 2 (n:225)
Grade 1		
Fever	10 (12.5%)	15 (7.8%)
Transient elevation of serum creatinine	2 (2.5%)	9 (4.7%)
Grade 2		
Blood transfusion	20 (25%)	37(19.2%)
Urine leakage <12 h	19 (23.75%)	52(26.9%)
Infections requiring additional antibiotics (instead of prophylactics)	11 (13.75%)	23(11.9%)
Wound infection	1 (1.25%)	5 (2.6%)
Urinary tract infection	3 (3.75%)	11 (5.7%)
Pneumonia	0 (0%)	4 (2.1%)
Grade 3a		
Double-J stent placement for urine leakage >24 -48 h	8 (10 %)	22 (11.4%)
Double-J stent placement for UPJ and pelvis injury	0	0
Urinoma	0	1 (0.5%)
Pneumothorax	0	0
Retention and colic due to blood clots	2 (2.5%)	7 (3.6%)
Grade 3b		
Ureter-bladder stone	2 (2.5%)	4 (2.1%)
Calyx neck stricture	0	0
UPJ obstruction	0	0
AV fistula	0	1 (0.5%)
Perirenal hematoma needing intervention	0	0
Perinephritic abscess	0	0
Perioperative bleeding requiring quitting the operation	2(2.5%)	1(0.5%)
Grade 4a		
Neighboring organ injury	0	1(0.5%)
Myocardial infarction	0	0
Nephrectomy	0	0
Lung failure	0	0
Grade 4b		
Urosepsis	0	1(0.5%)
Grade 5	0	0
Total	80	193

UPJ = ureteropelvic junction; AV = arteriovenous.

Table 4. Comparison of complications between Group 1 and Group 2 according to the modified clavien system classification

Grade	Total (n=275)	Group 1 (n=50)	Group 2 (n= 225)	p-value
I	36	12	24	0.037*
II	188	54	132	0.001*
IIIa	40	10	30	0.274
IIIb	10	4	6	0.181
IVa	1	0	1	0.316
IVb	1	0	1	0.316
V	0	0	0	0.99

*P<0.05 is considered as significant.

When all cases were evaluated on their follow-up, it was found that 60.2% (n=177) of the cases were cleared of their stones, 32.9% (n=97) had clinically unimportant stones and the operation was unsuccessful in 6.8% of the cases (n=20). As additional treatment, Re-PCNL was applied to 8 cases, ESWL was applied to 5 cases and Retrograde Intrarenal Surgery (RIRS) was applied to 7 patients.

4. Discussion

Modified Clavien Classification was previously used in the classification of open surgical interventions in Urology (9,10). Thereafter, it was modified for endo-urological operations (6,11,12). Right after that, it was used for the evaluation of the complications of laparoscopic and robot-guided laparoscopic surgical interventions (13). The complications should be standardized to evaluate the effectiveness and the cost-efficacy of the particular surgical method and to compare it with other surgical approaches. The Clavien-Dindo Classification is especially advised for the evaluation of PCNL applications, albeit not accepted as a definite standard as yet.

We also believe that standardization is necessary to compare the complications and to determine the cost-efficacy of different surgical procedures and to compare different centers applying the same surgical procedure. In our study, we retrospectively evaluated our cases according to the Clavien-Dindo Classification before and after the learning curve. Thereby, we demonstrated a new application area for the Modified Clavien Classification. Complication rates of up to 83% can be encountered during and after PCNL applications (14). Extravasation (7.2%), blood transfusion (11.2–17.5%) and fever (21.0–32.1%) are the most frequent complications. Comorbidity (renal failure, diabetes, gross obesity, pulmonary diseases) increases the complication risks (14).

Investigations performed according to the Modified Clavien Classification have revealed bleeding, fever and urine leakage as the most frequent complications (7). Also in our study results are the same. While Mandal et al. (15) encountered 245 complications in 116 renal units among 278 PCNL applications, we encountered 273 complications among 294 PCNL applications.

Also Shin et al. (11) reported 297 complications in 282 cases among 698 patients. According to the Modified Clavien Classification, 88 (12.6%), 145 (20.8%), 31 (4.4%), 5 (0.7%), 6 (0.9%), 4 (0.6%) and 3 (0.4%) of these occured as Grade-1, 2, 3a, 3b, 4a, 4b and 5 complications, respectively. The most frequently observed complications were urine leakage (15.2%), transient fever above 38°C (11%) and blood transfusion (6.9%).

The majority of the post-PCNL complications are minor (6,11,12,15). In our study, too, minor complications comprised the majority of the complications. Blood transfusion, fever and urine extravasation were the most frequently encountered complications in parallel to the existing literature. The complications in Group-1 were observed at a significantly higher rate than Group-2 according to grade 1($p<0.05$) and grade 2 ($p<0.05$). Since the learning curve was not separately demonstrated in the current literature, we had no chance to compare our learning curve with other groups. When we considered our complications, we observed that the complications decreased with increasing number of patients and subsequently enhanced surgical experience.

Post-PCNL bleeding rates requiring embolization have been reported to occur at rates between 0.8% and 1.4% in the literature (16-18). Kukreja et al. (19) demonstrated that the stone size did not significantly influence the bleeding, yet increased the transfusion rates. In our study we didn't do embolization. In Group-1, open surgery was performed on 4 (8%) patients due to inability of access and on 2 (4%) patients due to bleeding. In Group-2, open surgery was applied

only to one (0.4%) patient with renal pelvis+lower calyx stone due to inability of access. Open surgery was applied to one (0.4%) patient due to bleeding. The stones were cleared, bleeding control was achieved and no nephrectomy was performed. Arteriovenous fistula was observed in one case in Group-2 and this patient was classified as Grade-3B. It was determined in the literature that Grade-2 and 3a complications were significantly higher in patients with complex stones (6). In our study too, Grade-2 and 3a complications in both Group-1 and Group-2 were higher in patients with complex stones and it was determined that this fact was related to the prolonged surgical period.

Sepsis (0.3–4.7%), colonic (0.2–0.8%) and pleural (0.0–3.1%) injuries are rarely encountered complications (14). In our study, colonic injury (Grade 4a) was seen in one patient, which healed with the conservative approach. In the literature too, it has been observed that the conservative approach is advised according to the follow-up (20). In one patient, urosepsis (Grade 4b) was observed. This was the patient in Group-2. Long surgical periods and high ASA-risk are related with serious complications (21). It was revealed that the patient who developed A-V fistula had a high ASA-risk and that the case who developed sepsis was a patient with a positive urine culture. The reason for us to encounter an A-V fistula, colonic injury and urosepsis in Group-2 may be related to the higher number of patients in this group.

Shin et al. (11) observed all Grade 4b and 5 complications in patients with staghorn stones. In our study, a Grade-5 complication was not observed, and only one Grade-4b complication was encountered. This case had a lower calyx stone and a previous history of pyelolithotomy. In the literature, it has also been revealed that the types of complications increase with increasing number of cases (7). The reason for us not encountering a Grade-5 complication may be related to the low number of our cases.

The rate of additional treatment requirement after PCNL has been given as approximately 10% in the literature (22). The result of our cases (6.8%) who had undergone additional treatment was observed similar to literature.

5. Conclusion

One center may apply the Modified Clavien Classification for the comparison of complications during and after the learning curve. We observed that with increasing experience, the complication rates decline and success rates become higher.

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