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Stone Disease

Classification of Percutaneous Nephrolithotomy Complications Using the Modified Clavien Grading System: Looking for a Standard☆

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Abstract

Objectives: A classification (modified Clavien system) has been proposed to grade perioperative complications. We reviewed our experience with percutaneous nephrolithotomy (PNL), grading the complications according to this new classification.

Methods: A total of 811 PNLs were performed between 2003 and 2006, and charts were retrospectively reviewed focusing on complications observed. According to the modified Clavien classification system, perioperative complications were stratified into five grades. Grade 1 defined all events that, if left untreated, would have a spontaneous resolution or needed a simple bedside intervention. Grade 2 complications required specific medication, including antibiotics and blood transfusion. Grade 3 complications necessitated surgical, endoscopic, or radiologic intervention (3a without general anesthesia, 3b under general anesthesia). Neighboring organ injuries and organ failures were classified as grade 4, and death was considered a grade 5 complication. Kidney stones treated with PNL were also classified as simple and complex and complication rates were compared.

Results: A total of 255 perioperative complications were observed in 237 (29.2%) patients. There were 33 grade 1 (4%), 132 grade 2 (16.3%), 54 grade 3a (6.6%), 23 grade 3b (2.8%), 9 grade 4a (1.1%), and 3 grade 4b (0.3%) complications, and 1 death (0.1%). Most complications were related to bleeding and urine leakage. Grade 2 and 3a complications were significantly more common in patients with complex renal stones.

Conclusions: A graded classification scheme for reporting the complications of PNL may be useful for monitoring and reporting outcomes. However, minor modifications concerning auxiliary treatments are needed and further studies are awaited.

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1. Introduction

High success rates exceeding 90% are being reported with percutaneous nephrolithotomy (PNL) and modifications have further decreased the morbidity while maintaining efficacy [1–3]. However, complications after or during PNL may occur with an overall complication rate of up to 83%, including urinary extravasation (7.2%), bleeding necessitating transfusion (11.2–17.5%), and postoperative fever (21–32.1%), whereas major complications, such as septicemia (0.3–4.7%) and colonic (0.2–0.8%) or pleural injury (0.0–3.1%) are rare [4]. Comorbidities such as renal insufficiency, diabetes, morbid obesity, or cardiopulmonary diseases increase the risk of complications [5].

Although results from several large series on PNL from outstanding centers are reported in the literature, there is still no consensus on how to define complications and stratify them by severity. This hampers comparison of outcome data and generates difficulties in informing patients about PNL complications [1,6,7]. Several structured classifications of surgical complications exist in the literature, but none of them has been validated prospectively and their reproducibility is questionable [8–11]. A new classification (modified Clavien system) has been proposed to grade perioperative complications of general surgery and has been validated in a cohort of 6336 patients [12]. The same classification system has recently been used by urologists to grade perioperative complications following laparoscopic radical prostatectomy, laparoscopic live donor nephrectomy, and retroperitoneoscopy [13–15].

Herein, we review our experience with PNL, to grade perioperative complications according to this new classification.

2. Patients and methods

Between 2003 and 2006, 811 PNL procedures were performed at our institution. Patient data, which was entered and maintained prospectively in our PNL registry, was evaluated in this study.

Preoperative complete blood count, serum creatinine, platelet count, bleeding and coagulation profile, and urine cultures were obtained from all patients. The use of anticoagulant drugs was stopped at least 1 wk before the operation. Radiologic evaluation included intravenous urography (IVU) and urinary tract ultrasonography, with the addition of noncontrast computed tomography (CT) in selected cases. The stone burden was determined by radiographic studies, and stones were basically classified as simple (isolated renal pelvis or isolated caliceal stones) or complex (partial or complete staghorn stones, renal pelvis stones accompanying caliceal stones), regardless of their size [16].

Each patient underwent PNL beginning with cystoscopy and insertion of a ureteral catheter, as previously described elsewhere [17]. Briefly, patients were then placed prone and percutaneous access was obtained by the attending urologist (A.T.) at a single setting using C-armed fluoroscopy. Following proper caliceal puncture, the tract was dilated with high-pressure balloon dilator (Nephromax™, Boston Scientific) and a 30F Amplatz sheath was placed. Nephroscopy was performed with a rigid, 26F nephroscope. Additional tracts were created, when indicated, in the same session. Stone clearance and the integrity of the collecting system were confirmed intraoperatively by fluoroscopy and antegrade nephrostography. A 14F nephrostomy tube was placed into the renal pelvis or the involved calyx at the conclusion of majority of cases.

Antibiotic prophylaxis was maintained by quinolones. The first dose (500 mg ciprofloxacin) was administered intravenously when anesthesia was initiated, and the second dose was given 12 h later. The patients were then given oral ciprofloxacin until their nephrostomy tubes were removed, unless their postoperative urine culture revealed significant colony-forming units of uropathogens, which were treated accordingly. A fever of $\geq$38 °C was considered significant [18].

On postoperative day 1, the Foley and ureteral catheters were removed, if the urine was not hematuric. A plain film of the kidneys, ureters, and bladder was obtained. In patients who were rendered stone free or in those with no clinically significant residual fragments, the nephrostomy tube was removed on postoperative day 2 after antegrade nephrostography showing ureteral drainage down to the bladder. A double-J catheter was considered if urine drainage from the tract persisted for >24–48 h after the removal of the nephrostomy tube. The nephrostomy tube was left in place if a second PNL session due to residual stones was planned. Re-PNL, ureteroscopy, and shock wave lithotripsy (SWL) were considered as accessory treatment alternatives when indicated.

Serum creatinine levels and blood counts were obtained in all patients postoperatively. All patients were seen 3 mo postoperatively. The PNL procedure was considered successful if the patient was either free of stones or had any CIRFs, defined as <4 mm, nonobstructive, noninfectious, and asymptomatic residual fragments [17].

Mean age, stone size, success rate, and need for auxiliary procedures were documented. The modified Clavien grading system was used for evaluating perioperative and postoperative complications of PNL [12]. According to the modified Clavien classification system, perioperative complications were stratified into five grades (Table 1). Grade 1 defined any deviation from the normal postoperative course without the need for pharmacologic treatment or surgical, endoscopic, and radiologic interventions. In this grade, allowed therapeutic regimens are drugs as antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside. Grade 2 was defined as complications requiring pharmacologic treatment with drugs other than those allowed for grade 1 complications such as blood transfusions. Infections requiring additional

Table 1 – Classification of surgical complications according to the modified Clavien system [12]

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.
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.
Grade 3: Complications requiring surgical, endoscopic, or radiologic intervention. **Grade 3a:** Intervention not under general anesthesia **Grade 3b:** Intervention under general anesthesia
Grade 4: Life-threatening complications (including central nervous system complications) requiring intensive care unit stay **Grade 4a:** Single organ dysfunction (including dialysis) **Grade 4b:** Multiorgan dysfunction
Grade 5: Death of the patient

antibiotics instead of prophylactics were also classified as grade 2. Grade 3 was considered to be complications requiring surgical, endoscopic, or radiologic intervention; grade 3a was intervention not under general anesthesia, whereas 3b was under general anesthesia. Urine leakage from the flank for <12 h was considered as a grade 2 complication because it necessitated prolonged hospitalization. Prolonged urine leakage that necessitated endoscopic double-J stent placement was considered a grade 3 complication. Life-threatening complications (including central nervous system complications) requiring stay in the intensive care unit were accepted as grade 4. There were two subgroups of grade 4: 4a single organ dysfunction (including dialysis) and 4b multiorgan dysfunction. Death of a patient was considered as a grade 5 complication.

Complication rates of simple and complex stones were compared using the χ^2 and Fisher exact tests. Odd ratios were calculated and statistical determinations were within the 95% confidence interval (CI). All p values were 2-tailed, and $p < 0.05$ was considered statistically significant. Data were expressed as mean + standard deviation. The data were entered into an Excel™ (Microsoft, Redmond, WA) database and analyzed with an SPSS™ (SPSS version 13.0, Chicago, IL) statistical software package.

3. Results

Descriptive data of the cohort and the overall postoperative outcome are summarized in Table 2. At the 3-mo follow-up, an overall success rate of 91%, including CIRFs observed in 19.7%, was achieved. Auxiliary treatment alternatives, including SWL in 85, re-PNL in 22, and ureterorenoscopy (URS) in 7 patients, were performed in a total of 114 (14%) patients. Success rate for simple stones was 97% and 85% for complex stones.

Table 2 – Descriptive data of patients undergoing percutaneous nephrolithotomy and their overall surgical outcome

Mean age: 42.7 ± 14.5 yr (range: 11–80 yr) Male/Female: 457/354 Mean stone burden: 7.8 ± 3.7 cm^2 (range: 1.5–30 cm^2)
Classification of stones: Simple: 52.1% (n = 422) Complex: 47.9% (n = 389)
Mean operation time: 57.9 ± 22.5 min (range: 20–180 min)
Mean percutaneous access no.: 1.6 ± 0.5 (range: 1–5) Single access: 72.3% (n = 586) 2 accesses: 20.0% (n = 163) 3 accesses: 5.7% (n = 46) 4 accesses: 0.9% (n = 8) 5 accesses: 0.4% (n = 4)
Location of percutaneous access Subcostal access: 90% (n = 729) 11th–12th intercostal access: 9.9% (n = 81) 10th–11th intercostal access: 0.1% (n = 1)
Overall postoperative outcome: Mean urethral catheterization time: 1.04 ± 0.2 d (range: 1–3 d) Mean duration with nephrostomy tube: 2.8 ± 0.4 d (range: 1–7 d) Mean hospital stay: 2.7 ± 0.7 d (range: 1–15 d)
Overall success at postoperative month 3: 91% (n = 738)

A total of 255 complications were encountered in 237 (29%) patients. Grade 1 complications were recorded in 4%, grade 2 in 16.3%, grade 3a in 6.6%, grade 3b in 2.8%, grade 4a in 1.1%, and 4b in 0.3% (Table 3). The mortality rate (grade 5 complication) was 0.1%. The occurrence of complications in patients with simple and complex stones is shown in Table 4. Grade 2 and 3a complications were significantly more common in patients with complex stones ($p < 0.05$). Patients with complex stones were 3.3 times more likely to exhibit grade 2 complications and 1.7 times more likely to have grade 3a complications (Table 4).

The most common complication in the grade 1 group was fever requiring antipyretics in 23 cases (3%). As grade 2 complications, 91 patients (11%) required blood transfusion and 31 (4%) had urine leakage <12 h. Infections necessitating additional antibiotics other than prophylactics were also classified as grade 2 complications (Table 3). Double-J ureteral stent application due to urine leakage persisting >24 h (4%) was the most common complication in the grade 3a group. As grade 4a complications, 4 patients (0.4%) underwent nephrectomy. The reasons were renal function loss in one patient with a simple stone and in the complex stone group, two patients had arteriovenous fistulas that could not be managed by radiologic intervention and nonfunctioning kidney due to ureteropelvic junction obstruction in one. One

Table 3 – Complications of percutaneous nephrolithotomy classified according the modified Clavien system

	TOTAL (n = 811)
Grade 1	33 (4%)
Fever	23 (2.8%)
Transient elevation of serum creatinine	10 (1.2%)
Grade 2	132 (16.3%)
Blood transfusion	89 (10.9%)
Urine leakage <12 h	31 (4%)
Infections requiring additional antibiotics (instead of prophylactics)	
Wound infection	4 (0.4%)
Urinary tract infection	7 (0.8%)
Pneumonia	1 (0.1%)
Grade 3a	54 (6.6%)
Double-J stent placement for urine leakage >24 h	38 (4.6%)
Double-J stent placement for UPJ and pelvis injury	9 (1.1%)
Urinoma	1 (0.1%)
Pneumothorax	3 (0.3%)
Retention and colic due to blood clots	3 (0.3%)
Grade 3b	23 (2.8%)
Ureter-bladder stone	14 (2%)
Calyx neck stricture	1 (0.1%)
UPJ obstruction	2 (0.2%)
AV fistula	2 (0.2%)
Perirenal hematoma needing intervention	1 (0.1%)
Perinephritic abscess	1 (0.1%)
Perioperative bleeding requiring quitting the operation	2 (0.2%)
Grade 4a	9 (1.1%)
Neighboring organ injury	3 (0.3%)
Myocardial infarction	1 (0.1%)
Nephrectomy	4 (0.4%)
Lung failure	1 (0.1%)
Grade 4b	
Urosepsis	3 (0.3%)
Grade 5	1 (0.1%)

UPJ = ureteropelvic junction; AV = arteriovenous.

patient (0.1%) with preoperative respiratory system problems was lost on postoperative day 2 because of sepsis.

4. Discussion

Despite high success rates, major concerns in percutaneous renal surgery involve serious complications such as blood loss, adjacent organ injuries, and life-threatening infections [5,7,17–20]. Stratifying complications of PNL as major and minor ones, Lee et al reported major complications (ie, death, bleeding necessitating intervention, significant infection, urinary tract injury, and injuries to adjacent organs) in 6% of patients and minor complications (ie, postoperative fever, bleeding necessitating transfusion, extravasation, tube dislodgment, pneumonia, prolonged urine drainage from the flank, etc) in >50% of patients undergoing PNL [7]. However, terms such as major and minor are not standardized and, therefore, an informative comparison of complications is difficult.

For a valuable quality assessment, relevant data on outcome must be obtained in a standardized and reproducible manner to allow comparison among different centers, among different therapies, and within a center over time [12]. Objective and reliable outcome data are increasingly requested by patients and payers (government and private insurance) to assess quality and costs of health care. Moreover, health policy makers point out that the availability of comparative data on an individual hospital's and physician's performance represents a powerful market force, which may contribute to limit the costs of health care while improving quality [12]. However, case mix and case selection have a great impact on the occurrence of complications. In the present series, overall complication rate, namely, blood transfusion rate, is obviously high due to the fact that the mean stone burden was great and a significant number of patients had complex stones. Therefore, case mix must be considered when reporting and comparing complications.

In 1992, Clavien et al proposed general principles to classify complications of surgery, and recently the same group modified this classification focusing on life-threatening complications and long-term disability [21]. They also validated their classification in a survey consisting of 6336 patients and concluded that this new grading system appeared to be reliable and represented a compelling tool for quality assessment in surgery to be used in all parts of the world [12].

This new modified complication classification has recently been used by urologists to report the outcomes of laparoscopic radical prostatectomy, laparoscopic live donor nephrectomy, retroperitoneoscopy, and other urologic laparoscopic procedures [13–15,22]. To our knowledge, the present study is the first to report perioperative complications of PNL using the modified Clavien grading system. Our results showed that grade II complications were the most commonly observed ones after PNL. Bleeding necessitating blood transfusion was the most common individual complication, observed in 11% of cases. Transfusion rates can be regarded to be higher but this can be explained by the elevated frequency of complex stones necessitating multiple percutaneous accesses, although the rate of other complications correlated well with the

Table 4 – Comparison of complications, classified according to the modified Clavien system, between simple and complex stones

	TOTAL (n = 811)	Simple (n = 422)	Complex (n = 389)	p	OR	95%CI
Grade 1	33 (4%)	14	19	>0.1	0.6	0.3–1.2
Grade 2	132 (16.3%)	37	95	**<0.001**	**3.3**	2.2–4.9
Grade 3a	54 (6.6%)	21	33	**<0.05**	**1.7**	0.95–2.9
Grade 3b	23 (2.8%)	9	14	>0.1	0.5	0.2–1.19
Grade 4a	9 (1.1%)	5	4	>0.1	NA	NA
Grade 4b	3 (0.3%)	2	1	>0.1	NA	NA
Grade 5	1 (0.1%)	1	0	>0.1	NA	NA

OR = odds ratio; CI = confidence interval; NA = not applicable.

previously published series [4,6,7,23–25]. Blood transfusion was indicated in 4% of patients with simple renal stones and in 18.5% of patients with complex renal stones, the majority of which were managed by multiple punctures. Our personal experience indicates that performing additional punctures for residual stones, despite the risk of bleeding, was more commonly accepted by our patients, who generally did not prefer to undergo auxiliary treatments.

The lower incidence of grade 1 complications could be biased by the retrospective nature of the present study because some of the minor, self-limited complications, such as early nephrostomy tube dislodgment, which is quite frequent especially in obese patients, and transient paralytic ileus were not recorded.

Segura et al found the rate of major complications as 3.2% in their series [6]. If we redesign their complications according to modified Clavien grading system, perioperative bleeding that required halting the operation, which was observed in 6 patients (0.6%), can be classified as a grade 3b complication, because a second session PNL procedure is generally indicated. Furthermore, 6 cases (0.6%) in their series developed arteriovenous fistula that was managed by embolization (grade 3b), whereas nephrectomy was performed in one patient due to hemorrhage that could not be managed conservatively [6]. In the present series, perioperative bleeding necessitating blood transfusion (grade 2 complication) was observed in 89 (10.9%) patients, whereas the operation had to be terminated due to severe bleeding (grade 3b complication) in two additional patients, who were scheduled to undergo a second PNL session. Postoperative bleeding was observed in three other patients, in whom arteriovenous fistula (grade 3b complication) and perirenal hematoma (grade 3b complication) were diagnosed.

In their study, Lee et al reported the complications of percutaneous nephrolithotripsy (PCNL) in 582 patients [7]. Major complications were hemorrhage requiring exploration in 6 patients (1%; grade 3b), septicemia in 2 (0.3%; grade 4a), pneumothorax in 17 (2.9%; grade 3a), urinoma formation in 2 (0.3%; grade 3a), pelvis laceration in 5 (0.9%; grade 3a), ureter avulsion in 1 (0.2%; grade 3b), and ureteral stricture formation in 5 (0.9%; grade 3b); 2 patients (0.3%) died (grade 5). The most common minor complication was fever observed in 22%, and this is grade 1 according to the modified Clavien classification [8]. Blood transfusion was required in 11.2% (grade 2), extravasation was evident in 7.2% (grade 3a), early displacement of nephrostomy tube was observed in 5.8% (grade 1), paralytic ileus was observed in 2.6% (grade 1), and urine leakage from the track >1 wk was encountered in 1.5% (grade 3a) [7,12].

A complication rate of 50.8% was noted in a recent study, with the most common complication being transient fever in 27.6% [26]. However, only 2.8% of our patients experienced fever postoperatively. This contrast can be explained by the fact that prophylactic antibiotics were used in all patients in our series. Furthermore, fever accompanied several other complications such as infections requiring additional antibiotics, urinoma, perinephritic abscess, and urosepsis as summarized in Table 3, as well as a side effect of blood transfusion. Therefore, fever alone, responding well to antipyretics, was classified as grade 1 and observed in 2.8%. Otherwise, elevated body temperature was actually evident in a higher number of patients in our series.

In fact, complications stratified as grade 1 and 2 in the present series, can be considered as minor, and grade 3, 4, and 5as major according to other classification systems. However, the modified Clavien system is more objective and reproducible, representing a compelling tool for quality assessment. In a previous complication classification system, complications were stratified into four grades according their severity [21]. Grade 1 included minor risk events not requiring therapy. Grade 2 complications were defined as potentially life-threatening complications with the need for intervention or a hospital stay longer than twice the

median hospitalization for the same procedure. Grade 3 complications were defined as complications leading to lasting disability or organ failure, and finally a grade 4 complication indicated death [21]. In the present classification, grade 1 complications have been divided into two grades, and grade 2 is now defined as grade 3, and grade 3 as grade 4. Therefore, the new grade 1 complications do not generally prolong hospital stay and do not add significantly to the related expenses. However, the new grade 2 complications prolong hospitalization and significantly increase the morbidity.

In the original paper by Dindo and Clavien, the use of prophylactics is not classified as grade 2 but as grade 1. The use of prophylactics was considered as a part of the procedure. Furthermore, fever not responding to antipyretics and necessitating additional antibiotics other than prophylactics was considered as a grade 2 complication [12]. We routinely used perioperative prophylactic antibiotics, and patients with postoperative fever classified as grade 1 were already using antibiotics.

In the present study, we further compared complications rates, classified according to the modified Clavien system, in patients with simple and complex stones. Grade 2 and grade 3a complications were 3.3 and 1.7 times more common in patients with complex stones. This statistical difference can be attributed to the facts that the stone burden was greater and that multiple accesses were more commonly indicated in this subgroup.

We postulate that more significant complications graded as 3b and 4 are quite rare and are related to anatomic as well as technical factors and coexisting medical disorders. Therefore, these complications may be encountered in similar rates in patients with simple and complex stones.

However, we admit that there are some weak points when using the modified Clavien grading system in classifying complications of PNL. First of all, it is not clear how to grade the presence of clinically significant or insignificant residual fragments because they cannot be defined as complications but rather as failures, increasing the morbidity. Therefore, we did not include them in the present classification. There are also controversies in grading auxiliary treatments, such as re-PNL, SWL treatment, and ureteroscopy because they are not real complications but part of the stone management. A total of 14% of patients in the present series underwent auxiliary treatments. Because re-PNL and ureteroscopy required general anesthesia, they may be classified as grade 3b. Besides this, SWL treatment may be considered as a grade 3a complication because it is generally not done under general anesthesia in our country. In the present study, 14 patients presented with stones in the ureter or bladder postoperatively and were managed endoscopically. The majority of these stones were residual fragments that changed their location postoperatively, but some of them were the ones that migrated to the ureter and were overlooked during PNL procedure. Therefore, it is highly crucial to screen the ureter as well as the bladder with contrast agent at the end of the PNL procedure. Placement of double-J urethral stent due to urine leakage or preceding SWL treatment also represents a controversy in our opinion. Although rarely encountered, grading of long-term complications such as secondary ureteropelvic junction and infundibular obstruction is also controversial. In the present study, secondary ureteropelvic junction obstruction resulted in renal function loss, which indicated nephrectomy, and this was considered as grade 4a. On the other hand, secondary ureteropelvic junction and infundibular obstructions managed endoscopically were graded as grade 3b.

5. Conclusions

The modified classification presented in this report is the first of its kind for the PNL procedure. A graded classification scheme for reporting the complications of PNL may be useful for monitoring and reporting outcomes. It is also helpful in informing patients. The broad implementation of this classification may facilitate the evaluation and comparison of surgical outcomes among different surgeons and centers. However, minor modifications, especially concerning auxiliary treatments, are needed and further studies are awaited for the development of an accepted classification system applicable to all urologic procedures.

Conflicts of interest

The authors have nothing to disclose.

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