



Applicability of the Clavien–Dindo grading system for assessing the postoperative complications of endoscopic surgery for nephrolithiasis: a critical review

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ABSTRACT

Objective: Adaptation of the Clavien–Dindo classification for assessing the severity of complications following the endoscopic treatment of nephrolithiasis and evaluation of its versatility and objectivity.

Material and methods: We retrospectively reviewed the medical records of 1027 patients who presented stones located in upper urinary tract (597 males, 58.1% and 430 females, 41.9%), mean age 38.9±15.6 (range, 4 to 84) years. The age ranged from 4 to 15 years in 46 (4.5%) of the patients. The mean size of the stones was 30.3±0.6 (range, 3 to 150) mm. Percutaneous nephrolithotomy (PNL) and ureteroscopy (URS) were performed by three experienced surgeons, PNL with the patients in the prone position. Fragmentation of stones was carried out using a pneumatic lithotripter. The outcomes were compared using Fisher's exact test and Student's t-test. The Clavien–Dindo grading system was used.

Results: We observed 195 (19.0%) patients who presented a total of 250 complications during the postoperative period. Additional interventions have been performed to eliminate 74 complications: 41 under general anesthesia and 33 without it. "Stone free status" was reached in 879 (85.6%) patients. Postoperative complications were assessed using Clavien grading system: Grade I for 64 complications (6.2%); Grade II for 111 (10.8%); Grade IIIa for 33 (3.2%); Grade IIIb for 39 (3.8%); Grade IVa for 3 (0.3%); Grade IVb for 0; and Grade V for 0.

Conclusion: There is no ideal classification system for assessing the severity of surgical complications. The Clavien–Dindo classification can be adapted to assess the severity of postoperative complications following endoscopic procedures for nephrolithiasis if certain corrections are made.

Key words: Clavien–Dindo classification; complication; endoscopic treatment of nephrolithiasis.

Introduction

While treating patients with nephrolithiasis, urologists currently use various methods of intervention, such as extracorporeal shock wave lithotripsy (ESWL), endoscopic methods of removing stones, and open surgery.^[1-3] The usage rates of these methods in the treatment of nephrolithiasis differ between countries, depending on the availability of hospital equipment, the development of methodology, the experience of the surgeons, and the wishes of the patient. In the Republican Specialized Center of Urology (RSCU, Tashkent, Uzbekistan), endourological procedures predominate among the various treatment methods for nephrolithiasis; therefore, up to 70% of patients with staghorn or multiple stones

undergo endoscopic treatments.^[4] However, it should be noted that these interventions often lead to life-threatening complications, even when performed by experienced surgeons. Because the complication rate is not necessarily an indicator of the severity, complications should be evaluated with respect to both their quantitative and qualitative features and compared to both the degree of severity and their response to additional therapeutic measures aimed to eliminate them.

According to Martin et al.,^[5] the objective assessment of surgical treatments should be guided by 10 criteria. In our opinion, one of the most important criteria is to assess the severity of complications, which allows an ordering of these complications according to Clavien–

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Dindo classification. Developed in 1992 by Clavien et al.^[6] as a classification of surgical complications, the criteria were subsequently improved in 2004 and have been successfully approved in 10 surgical centers in various countries. Furthermore, they have been recommended by the European Association of Urology (2012) to evaluate surgical complications.^[7,8]

Including the intraoperative complications in this system in an attempt to update and change it can lead to an incorrect assessment of the results.^[9,10]

However, the practical use of the Clavien-Dindo classification to assess complications suffers from a lack of universality. We have attempted to adapt it to the particular complications that can follow endoscopic surgery for nephrolithiasis, and we have set the following objectives:

- (1) To develop criteria for the postoperative complications of endoscopic surgery of nephrolithiasis based on the classification of Clavien-Dindo, using retrospective data obtained from observed postoperative complications;
- (2) To evaluate the utility of the Clavien-Dindo classification in the assessment of postoperative complications of the endoscopic treatment of nephrolithiasis using the developed complication criteria;
- (3) To evaluate the degree of objectivity of the Clavien-Dindo classification for grading the postoperative complications of endoscopic treatment of nephrolithiasis and evaluating the surgical procedures performed in the RSCU.

Material and methods

The case histories of 1027 patients (597 men, 58.1% and 430 women, 41.9%), with ages ranging from 4 to 84 (38.9±15.6) years, who presented stones located in the upper urinary tract and who underwent endoscopic surgery at the RSCU from 2008 to 2010 were studied. The patients were distributed into two groups: 446 (43.4%) patients with simple stones (single and localized in a calyx, a pelvis, or an ureter) and 581 (56.6%) patients with complex stones (two or more, irrespective of their sizes and locations, staghorn stones, and staghorn stones in combination with a single or multiple stones). The stones were located only in the pyelocaliceal system (PCS) in 765 (74.5%) of the patients, in the PCS and ureter in 262 (25.5%) of the patients, and only in the ureter in 202 (19.7%) of the patients.

The average size of the stones in the 1027 patients was 30.3±0.6 (range, 3 to 150) mm; therefore, the size of the

stones that were restricted to the ureter was 14.4±0.5 (range, 3 to 55) mm (Table 1).

The interventions were performed by three experienced urologists who each have more than 20 years of work experience.

The duration of the follow-up was 3 months.

The postoperative complications were evaluated according to the classification of Clavien-Dindo^[7], Table 2.

Statistical analysis

The outcomes were compared using Fisher's exact test and Student's t-test. The descriptive statistics were calculated, and data processing was performed using Microsoft Office Excel 2007, StatSoft Statistica 8.0, and statistical formulas.

Results

Of the 1027 cases examined, 948 stones were removed via percutaneous access with the patient in the prone position, and the remaining 79 cases involved transurethral access. Interventions were performed through 2 access points in 77 cases, through 3 access points in 14 cases, and through 4 access points in 2 cases. The PC accesses were performed by a urologist. It is important to note that 152 of the patients had previously installed nephrostomic tubes due to acute pyelonephritis that was present before the stone surgery.

To assess the nature of the complications and to categorize them according to their severity, we must clearly distinguish between the normal and complicated postoperative courses. We found no clear examples in the literature of the criteria of normal and complicated postoperative courses following the endoscopic treatment of nephrolithiasis. Those authors used the Clavien-Dindo classification without focusing their attention on it.^[11-14] We have taken the first step in identifying and agreeing on the criteria of a standard-uncomplicated postoperative period (Table 3).

Furthermore, we have developed criteria for complications of the postoperative period (Table 4). In developing the criteria for these complications, we considered the degree of severity in terms of each of the 5 grades of the Clavien-Dindo system. At the same time, this work once again demonstrates that there is no perfect and universal classification of surgical complications that would have encompassed the complications of all types of surgeries. However, the Clavien-Dindo classification is the most widely recognized

Table 1. Distribution of the patients with respect to the stone type and the initial stone diameter

No	Type	Number of patients	Initial stone diameter (mm)	SE (SD) m (σ)
1.	Simple stones	446	18.2	0.4 (8.1)
2.	Complex stones	581	39.6	0.8 (20.4)
Within the complex stones:				
a.	Two or more stones (multiple stones)	384	34.5	0.8 (16.6)
b.	Staghorn stones and staghorn stones in combination with a single or multiple stones	197	49.4	1.7 (23.4)
Total:		1027	30.3	0.6 (19.4)
p<0.01 between all groups				

Table 2. Classification of the surgical complications according to the modified Clavien-Dindo system

Grade	Cases
I	Any deviations from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. The allowed therapeutic regimens include antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections that were opened at the bedside.
II	Complications that require pharmacological treatment with drugs other than those allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.
III	Complications that require surgical, endoscopic or radiological interventions.
IIIa	Interventions not under general anesthesia.
IIIb	Interventions under general anesthesia.
IV	Life-threatening complications (including central nervous system complications) that require treatment in the intensive care unit.
IVa	Single organ dysfunction (including dialysis).
IVb	Multiorgan dysfunction.
V	Death of the patient.

as being adaptable to various types of surgical complications.^[11,12,14] In our view, it was particularly challenging to delineate between grades I and II and define the border between them based on the growth of their severity. We realize that these complications may differ between the various types of interventions at various centers.

Therefore, the analysis revealed 180 (17.5%) patients who presented 235 examples of a complicated postoperative course. In 140 patients, we observed one complication, 2 complications in 27 patients, 3 complications in 11 patients, and 4 complications in 2 patients. To address 59 of the complications, additional interventions were performed: 33 of these interventions were performed without anesthesia and 26 were performed under general anesthesia.

As a result of the analysis, we categorized 235 postoperative complications according to the Clavien-Dindo classification, as follows in Table 5.

Discussion

There were 235 postoperative complications observed in 180 (17.5%) patients, each with a different character. The most common complications could be categorized as grade I and II, with infectious-inflammatory processes in 116 (11.3%) of the patients and hematuria in 49 (4.8%) of the patients, 7 (0.7%) of whom needed a blood transfusion. To treat the 59 complications that were classified as grades III and IV, additional interventions were required. The severity of the complications depended both on their early recognition and on the adequacy and timeliness of their elimination. In this regard, the experience of the nursing staff who assist the doctor in caring for the patient has been invaluable.

Considering an example of the postoperative period for pyelonephritis, it is possible to demonstrate the advantages of the Clavien-Dindo classification. There were 115 (11.2%) cases

Table 3. Criteria of a standard-uncomplicated postoperative period following endoscopic surgery for nephrolithiasis

- Insignificant (moderate) staining of the urine with blood along the nephrostomy, ureteral or urethral catheter that does not lead to the formation of blood clots, as well as an impairment of the drainage that does not require additional fluid (more than 1 liter), diuretic therapy and hemostatics;
- An increase in the body temperature of the patient up to 37.9°C without chills, within 48 hours or less, that does not require antipyretic or infusion therapy (more than 1 liter).
- Locating the intraoperative placement of the ureteral or urethral catheters from 12 hours to 7 days (under the direction of the surgeon), without the development of infectious and inflammatory processes and additional interventions;
- A single session of routine antegrade pyelography before removing the drainage;
- Clinically insignificant residual stones;
- Clinically significant residual stones at any location after surgery for complex stones.

of postoperative pyelonephritis considered during the analyzed time period. According to the classification, the patients were distributed in the following manner: 95 cases of grade II, 8 of grade IIIa, 10 of grade IIIb, and 2 of grade IVa. This classification has demonstrated not only the frequency of pyelonephritis but also, importantly, its severity; in addition, it required additional procedures and interventions that were necessary to treat the complications.

Based on these data, we felt it was necessary to note the disadvantages of classification, comparing our positions with other authors.^[7,10-14,17,18] The criteria listed in Table 4 were determined by us in 2011. During the implementation of this classification in clinical practice, the severity of a few of the complications was not commensurate with the meaning of the paragraph analysis of their doubt. Previously, we assumed that it would be difficult to distinguish between the relatively minor complications in grades I and II g. The creators of the original Clavien-Dindo classification proposed that the need for a blood transfusion should be attributed to grade II (Table 2). Based on the minimally invasive endoscopic techniques used in urology, in our view, the need for a blood transfusion after endoscopic procedures for nephrolithiasis, even in the absence of additional interventions, must be attributed as a grade III complication. The severity and significance of the bleeding differs from other complications that are considered to be grade II (Table 4). Additionally, it is no less dangerous than a replacement nephrostomy without anesthesia, which is referred to as grade IIIa.

Regardless, a blood transfusion should not be considered to be the only method of treatment but should instead be seen as a serious and dangerous intervention for the patient. In our opinion, according to the classification system, this complication should be compared with the necessity of additional intervention without general anesthesia, i.e., with grade IIIa complications (?) (Table 4).

Seven (0.7%) cases among our patients needed blood transfusions during the postoperative period and were therefore assigned to grade IIIb, encompassing the referred patients who underwent additional open and endoscopic interventions under general anesthesia.

Terrible postoperative infectious complications, such as urosepsis showing varying degrees of severity and systemic inflammatory response syndrome (SIRS), severe sepsis, septic shock and refractory shock syndrome (multiorgan dysfunction) should also be considered.^[19,20] Authors have suggested that the classification of surgical complications attributed to grade IVb should involve multiple organ failure, without specifying other forms (Table 2). In the RSCU, the patients who present sepsis and SIRS go on to be treated in the Department of Urology, and the patients with other forms of sepsis are treated in the intensive care unit. Accordingly, we have included in the SIRS group the grade II complications, severe sepsis was attributed to grade IVa, septic shock and refractory shock with multiple organ failure were attributed to grade IVb.

Finally, the question of whether residual stones, which are a specific consequence of the endoscopic treatment of nephrolithiasis, should be considered as a complication remains controversial. The creators of the Clavien-Dindo classification did not consider this issue, as they developed the classification based on complications for all types of surgery. Urologists must decide either to consider residual stones along with other complications or to define them separately from other complications. Tefekli et al.^[14] recognized the complications of PNL using a classification that considered only the residual ureteral and bladder stones that migrated during intervention and required further intervention during the postoperative period. In fact, according to the logic of classification, they were right. However, in our opinion, the vast experience of urologists in the endoscopic treatment of nephrolithiasis allows us to raise the level on quality. For complex

Table 4. Criteria of postoperative complications after endoscopic surgery for nephrolithiasis

Grade	Cases
I	<p>Hematuria through the nephrostomic tube or during self-urination that requires additional infusion therapy (more than 1 liter) and/or the use of diuretics;</p> <p>Fever above 38°C that remains elevated for less than 24 h and that requires the use of antipyretics or another therapy;</p> <p>Loss of the nephrostomic tube, not due to any intervention but requiring further observation;</p> <p>Urine leakage around the tube up to 48 h, with adequate functioning of the drainage;</p> <p>Transient elevation of the serum creatinine.</p>
II	<p>Infectious and inflammatory processes in the urinary tract that require additional antibiotic therapy (other than prophylactic) (acute pyelonephritis, acute prostatitis, acute urethritis, or acute cystitis), including when infusion-detoxification therapy prolongs the hospital stay of the patient;</p> <p>The need for analgesics within 48 hours of the operation or later, in connection with a previous intervention;</p> <p>Inadequate drainage of the kidney cavities that can be eliminated without further intervention but requires extra care and drugs other than those included in grade I;</p> <p>Urine leakage around the tube that lasts longer than 48 h and can be eliminated without further intervention but requires additional follow-up and the use of drugs beyond those included in grade I;</p> <p>The absence of a ureteral passage, leading to prolonged nephrostomy drainage in the kidney and the need for additional therapy;</p> <p>Any additional drug therapy that results in an exacerbation of the chronic comorbidities or transferred anesthesia (pneumonia, pleuritis, chronic bronchitis, repeated vomiting, prolonged headache, etc.);</p> <p>The treatment of wound infections (a rare occurrence after endoscopic interventions);</p> <p>Parenteral nutrition.</p>
IIIa	<p>Parenchymal bleeding combined with tamponade of the PCS* or the bladder, leading to the removal of blood clots (without general anesthesia);</p> <p>Replacement of the nephrostomic drainage, regardless of the cause (inadequate drainage of the cavities of the kidneys, loss of drainage, urine leakage around the tube, or a urinoma);</p> <p>Implementation of therapeutic and diagnostic FNAB** of the kidney^[15,16] (e.g., a patient with acute pyelonephritis is categorized as grade II, but if he underwent a FNAB, the patient qualifies for IIIa);</p> <p>Installation of a ureteral stent (due to prolonged swelling of the mucous ureter because of damage to the pelvis and UPJ***);</p> <p>Setting a double-J stent due to getting wet with urine;</p> <p>Puncture of the pleural cavity with or without draining (caused by pneumothorax, hemothorax, or hydrothorax);</p> <p>X-ray radiological interventions (except routine antegrade pyeloureterography before removing the drainage);</p> <p>Obstruction and renal colic due to blood clots;</p> <p>Blood transfusions (?).</p>
IIIb	<p>PC nephrostomy or renephrostomy (drainage loss, bleeding, or the development of a urinoma);</p> <p>Ureterscopy;</p> <p>Nephroscopy;</p> <p>Open intervention (due to a postoperative ureteral stricture or parenchymal bleeding);</p> <p>Arteriovenous fistula;</p> <p>Perirenal abscesses;</p> <p>Any other intervention under general anesthesia;</p> <p>Clinically significant residual stones after surgery for simple stones and additional interventions (?).</p>
IVa	<p>Dysfunction of one organ that developed after the intervention (kidney, lungs, liver, heart (heart attack), CNS**** (stroke)) that requires treatment in the intensive care unit;</p> <p>Monitoring during the postoperative period due to damage to a neighboring organ;</p> <p>Nephrectomy;</p> <p>Hemodialysis due to newly acquired renal failure;</p> <p>Urosepsis: severe sepsis (?).</p>
IVb	<p>Urosepsis: septic shock and refractory shock syndrome (multiorgan dysfunction) (?).</p>
V	<p>Death of the patient.</p> <p>Chronic renal failure during the intermittent phase. During the postoperative period: a forced session or sessions of hemodialysis (grade IIIa).</p>

*PCS: Pyelocaliceal system; **FNAB: Fine-needle aspiration biopsy^[15,16]; ***UPJ: Ureteropelvic junction; ****CNS: Central nervous system; (?): interpretation provided in the discussion

Table 5. Postoperative complications after endoscopic surgery of nephrolithiasis at the RSCU according to the Clavien-Dindo grading system

Grade	Cases
I 64 (6.2%)	42 cases who presented a hematuria on the nephrostomic tube or during micturition, requiring additional infusion and/or diuretics; 19 cases of a one-day fever above 38°C that required antipyretics; 3 cases of the drainage falling out, without the need for an additional intervention but with the need for observation.
II 111 (10.8%)	96 cases involving an exacerbation of the infectious and inflammatory processes in the urinary tract (95 cases of acute pyelonephritis and 1 case of acute prostatitis) that demanded an additional antibiotic, infusion and detoxification therapy and prolonged the hospital stay; 3 cases involving inadequate drainage of the cavities of the kidney combined with a subfebrile condition that lasted longer than 2 days and was eliminated without the need for additional intervention but did require additional therapy; 1 case of urine leakage from a fistula by a drainage that persisted for over 2 days and required an additional period of observation but no additional intervention; 11 cases involving a failure of the permeability of the ureter that resulted in a prolonged drainage of the kidney and the need for additional therapy.
IIIa 33 (3.2%)	1 case of renal hemorrhage with the development of a tamponade of the bladder, which required the removal of the blood clots from the bladder using a urethral catheter; 8 cases of acute pyelonephritis; in 7 of these patients, regression occurred only after achieving an adequate drainage of the PCS of the kidney by replacing the nephrostomic drainage, and the other patient underwent FNAB of the kidney; 19 cases involving the replacement of a nephrostomic drainage due to the inadequacy of a drainage of PCS of a kidney (n=10), a partial fall of the drainage (n=4) and urine blotting from a fistula by a drainage and the development of a urinoma (n=5); 5 cases involving the placement of a stent due to damage of the permeability of the ureter.
IIIb 24 (2.3%)	3 cases involving an open intervention (1 was a resection of a postoperative stricture of a PUJ, and the other 2 involved a lumbotomy due to the presence of parenchymal bleeding); 1 patient underwent ureteroscopy; 20 cases involved PC nephrostomies due to a loss of a drainage (n=10), bleeding (n=7) and the development of a urinoma (n=3).
IVa 3 (0.3%):	1 case of nephrectomy; 1 application of hemodialysis due to renal failure. 1 case of urosepsis: severe sepsis was observed.
IVb	not observed.
V	not observed.

stones, particularly staghorn stones, the interventions are often multistage, and additional surgery for residual stones should be considered as a stage of treatment rather than as complication. However, all of the clinically significant residual stones after surgery that were due to simple stones must be considered to be complications and organized based on the methods used to eliminate them. We analyzed these complications in our patients and identified 26 (5.8%) cases (Table 6).

The stones were clinically significant in 15 of these 26 patients, and to eliminate them, additional interventions were performed after the main procedure under general anesthesia, 2-Percutaneous nephrolithotomy (PNL) and 13-Extracorporeal shockwave lithotripsy (ESWL). According to the concept of classification, we propose to include these cases in grade IIIb. Although these procedures due to residual stones went smoothly, they could also lead to other undesirable complications. In

the remaining 11 cases, the residual stones are regarded as clinically insignificant. Therefore, the overall view of the systematic complications, including the residual stones, is as follows: 250 complications in 195 patients (19.0%), 64 of which were grade I (6.2%), 111 were grade II (10.8%), 33 were grade IIIa (3.2%), 39 were grade IIIb (3.8%), 3 were grade IVa (0.3%), 0 were grade IVb, and 0 were grade V.

In conclusion, the classification of surgical complications by Clavien-Dindo is not universal but is comfortable and adaptable. It should be integrated into clinical practice using certain corrections, which will allow for an objective assessment of the severity of complications after endoscopic surgery for nephrolithiasis.

A blood transfusion in the absence of additional surgical interventions must be attributed to grade IIIa.

Table 6. Frequency of residual stones according to the dependence on their quantity and complexity

Nº	Type of stones	Number of patients	Quantity of the residual stones	Frequency of the residual stones (%)
1.	Simple stones	446	26	5.8
2.	Complex stones	581	122	20.9
	Within the complex stones:			
a.	Two or more stones	384	63	16.4
b.	Staghorn stones and staghorn stones in combination with a single or multiple stones	197	59	29.9
	Total	1027	148	14.4
p<0.01 between all groups				

Clinically significant residual stones after endoscopic surgery for simple stones should be considered to be a complication and attributed to grade III, depending on whether additional interventions are applied using the anesthesia of choice.

Severe sepsis should be categorized as grade IVa, and septic shock and refractory shock as IVb.

The rate of complications for endoscopic surgery for nephrolithiasis at the RSCU was 19.0%: 70% of these complications were relatively light (i.e., grades I-II), and the remaining 30% were recognized as grade III-IV, as additional invasive interventions and intensive care were required to treat them.

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