

## ASSESSMENT OF POSTOPERATIVE COMPLICATIONS OF TRANSURETHRAL CONTACT PYELOCALICOLITHOTRIpsy IN PATIENTS WITH HIGH-DENSITY STONES ACCORDING TO THE CLAVIEN–DINDO CLASSIFICATION

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Improving the effectiveness of treatment of urolithiasis is a topical issue in modern urology. Despite a large number of studies on this problem, there is currently no unified algorithm for assessing postoperative complications of removal of calculi of the renal cavity system by transurethral access.

**Purpose of the study:** based on a retrospective analysis to adapt the classification of postoperative complications according to Clavien–Dindo from 2004 to describe the complications of transurethral contact pyelocalicolithotripsy.

**Materials and methods.** A retrospective analysis of the results of surgical treatment of 211 patients with kidney stones with a density of 960 HU to 1840 HU was performed. Ultrasonic energy was used for lithotripsy. Criteria for the normal course of the postoperative period in patients have been formulated.

**Results.** The number of postoperative complications was calculated. The obtained data are distributed according to the corresponding gradations of the adapted Clavien–Dindo classification.

**Conclusion.** The improved Clavien–Dindo classification, taking into account the adaptation, can be used as an up-to-date, accessible and logical template for assessing the postoperative complications of transurethral contact pyelocalicolithotripsy.

**Keywords:** urolithiasis; transurethral contact pyelocalicolithotripsy; Clavien–Dindo classification.

## ОЦЕНКА ПОСЛЕОПЕРАЦИОННЫХ ОСЛОЖНЕНИЙ ТРАНСУРЕТРАЛЬНОЙ КОНТАКТНОЙ ПИЕЛОКАЛИКОЛИТОТРИПСИИ У ПАЦИЕНТОВ С КАМНЯМИ ВЫСОКОЙ ПЛОТНОСТИ ПО КЛАССИФИКАЦИИ CLAVIEN – DINDO

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Повышение эффективности лечения пациентов с мочекаменной болезнью является актуальным вопросом современной урологии. Несмотря на большое число исследований по данной проблеме, в настоящее время отсутствует единый алгоритм оценки послеоперационных осложнений удаления конкрементов полостной системы почки трансуретральным доступом.

**Цель исследования:** на основании ретроспективного анализа адаптировать классификацию послеоперационных осложнений по Clavien – Dindo 2004 г. для описания осложнений трансуретральной контактной пиелокаликототрипсии.

**Материалы и методы.** Проведен ретроспективный анализ результатов хирургического лечения 211 пациентов с камнями в почках плотностью от 960 HU до 1840 HU. Для литотрипсии использовалась ультразвуковая энергия. Сформулированы критерии нормального течения послеоперационного периода.

**Результаты.** Подсчитано количество послеоперационных осложнений. Полученные данные распределены по соответствующим градам адаптированной классификации Clavien – Dindo.

**Заключение.** Усовершенствованная классификация Clavien – Dindo с учетом адаптации может быть использована в качестве актуального, доступного и логичного шаблона для оценки послеоперационных осложнений трансуретральной контактной пиелокаликотрипсии.

⊗ **Ключевые слова:** мочекаменная болезнь; трансуретральная контактная пиелокаликотрипсия; классификации Clavien – Dindo.

## INTRODUCTION

Kidney stone disease (KSD), or urolithiasis, is one of the world's most common diseases. It is usually diagnosed at the ages of 20 to 65 years old, accompanied by a decrease in the quality of life, and often leads to loss of earning capacity and the development of severe complications [1–3]. The annual incidence of urolithiasis in Europe is more than 2000 people per one million population [4]. KSD requires emergency hospitalization in about 70% of urological patients [1, 5, 6].

Indications for surgical calculi removal include prolonged pain, lack of effect from drug treatment, significant urine outflow reduction leading to impaired renal function, secondary infection, and multiple and/or large kidney stones over 1.5 cm [1, 7]. Over the past decade, the proportion of open surgical interventions has decreased significantly. This decrease is associated with the active introduction of minimally invasive technologies for treating KSD, including high-density calculi [8, 9]. These methods also include contact lithotripsy and various modifications, which provide patients complete relief from calculi, including dendriform and multiple calculi [7, 10, 11]. In this regard, most urologists recognize their minimally invasiveness and efficacy as the main advantages of endoscopic therapies over open surgical interventions. Advanced endoscopic technologies enable fragmenting calculi of different composition and structure to obtain the desired result during the first procedure. Over time, this field has become the gold standard treatment method of KSD, presented in the clinical guidelines of the European Association of Urology and the Russian Society of Urology [2, 12].

Contact retrograde lithotripsy is an endoscopic method for renal calculi removal that is widely used in clinical practice. Its important advantage is its low injury rate. This method enables achieving stone dispersion, making it available for further litho-extraction while avoiding migration [11]. This lithotripsy method's advantages enable its use in urethro-renal

pyeloscopy and fragment calculi, most often in the pelvis and the middle calyces group [13, 14].

Improving the quality of medical care remains an essential task in many fields of medicine, including urology. KSD treatment effectiveness is associated with a decrease in postoperative complications. However, the lack of a standardized postoperative complications classification in the urolithiasis treatment complicates the analysis of surgical intervention results. Most researchers agree that it is necessary to systematize endoscopic methods' complications of urolithiasis in terms of severity, considering the subsequent therapeutic measures to eliminate them. In practice, a quantitative assessment of complications is widespread; the current stage of the endoscopic solution of the KSD problem requires assessing the complications qualitatively.

In 1992, Clavien et al. proposed a standardized system for grading surgical treatment (T92) complications, with the need for repeated interventions as the main criterion. Complications were divided into four grades and included five levels. In 2004, Dindo et al. proposed modifying the T92 system using five degrees of complications and containing seven levels [15] (Table 1). The modified system, known as the Clavien–Dindo classification, proved to be the most convenient for practical use. It indicated whether the complication led to an intervention under general anesthesia, transfer to the intensive care unit or organ dysfunction. It was based on the type of therapy required to treat complications. This system is widely used in many fields of medicine, but especially in general surgery and urology [16]. This classification is simple, convenient, reproducible, and is used in various medical institutions worldwide [17, 18, 19]. Its use in urology for assessing surgical activities results is also becoming more widespread [20].

*This study aims* to adapt the existing Clavien–Dindo classification of 2004 to assess the postoperative complications of transurethral contact pyelocalicolithotripsy (TUCPCL).

Table 1 / Таблица 1

**Classification of surgical complications according to the modified Clavien – Dindo system (2004)****Усовершенствованная классификация хирургических осложнений по Clavien – Dindo (2004)**

Degree	Criteria
I	Any deviations from the norm in the postoperative period do not require surgical, endoscopic, or radiological intervention. Only conservative therapy is performed using antiemetics, antipyretics, analgesics, diuretics, electrolyte administration, physiotherapy, or treatment of a wound infection that opened in a hospital.
II	Complications requiring an expansion of the volume of drug therapy (except for those indicated for complications of degree I), blood transfusion, and total parenteral nutrition.
III	Complications requiring surgical, endoscopic, or radiological intervention:
IIIa	• interventions without general anesthesia;
IIIb	• interventions with general anesthesia.
IV	Life-threatening complications (including the central nervous system) requiring the patient's stay in an intensive care unit:
IVa	• insufficiency of one organ (including dialysis);
IVb	• multiorgan failure.
V	Lethal outcome.

**MATERIALS AND METHODS**

A retrospective analysis of surgical treatment results of 211 patients with unilateral kidney stones having a density of 960 to 1840 Hounsfield units (HU) was performed. Patients were hospitalized from 2016 to 2020 in the clinical bases of the Department of Urology, Mechnikov North-Western State Medical University. Of these, 171 (81%) and 40 (19%) patients were hospitalized on a scheduled and urgent order basis, respectively. There were 122 (58%) men and 89 (42%) women. The patients' ages ranged from 20 to 69 years and averaged 44 years.

Laboratory tests (complete blood count, biochemical blood test, common urine analysis, bacteriological urine examination), ultrasound and X-ray examinations of the kidneys and urinary tract, dual-energy computed tomography (DECT) with densitometry were performed on all patients in the preoperative period.

Hospitalized patients with KSD complained predominantly of pain in the lumbar region, most often in the area of a compromised kidney. Dyspeptic symptoms such as nausea and vomiting, and dysuria, gross hematuria, fever, and arterial hypertension were also frequent complaints. Twenty-four patients (11% of the total number of patients) did not indicate the presence

of pain but noted other clinical symptoms of nephrolithiasis. Plain radiography revealed X-ray-positive urine calculi in 205 (97%) patients, whereas DECT detected them in 6 (3%) patients. All patients underwent an ultrasound examination, and calculi were revealed in all cases. The kidney's anatomical and morphological parameters (size, contours, parenchyma thickness, cavity system changes, the state of nearby structures) and the density and structure of calculi were determined using radiation diagnostic methods.

According to the DECT data, all patients had a confirmed, single renal calculus. Their size ranged from 10 to 24 mm, with a density from 960 to 1840 HU. The calculi's quantitative distribution based on location in the cavity system is presented in Table 2. In 120 (57%) patients, calculi were localized in the right kidney. In 91 (43%) patients, they were revealed in the left kidney. At the same time, calculi were located in the pelvis on the right in 47 (22%) patients, in the pelvis on the left in 38 (18%) patients, in the calices on the right in 73 (35%) patients, and the calices on the left in 53 (25%) patients (Table 2).

TUCPCL was performed on all patients. For lithotripsy, ultrasonic energy was used, generated by a device manufactured by EMS SA Swiss LithoClast Master. After the end of the surgery, a ureteral stent

Table 2 / Таблица 2

**Localization of calculi in the kidney in patients with urolithiasis (n = 211)****Локализация конкрементов в почке у пациентов с уролитиазом (n = 211)**

Calculus localization	Side		Total (n)
	right (n, %)	left (n, %)	
Upper calix	32 (15)	23 (11)	55
Medium calix	41 (20)	30 (14)	71
Renal pelvis	47 (22)	38 (18)	85
Total	120 (57)	91 (43)	211

was placed in the patients. The risk of complications during anesthetic support was calculated by assessing the patient's objective status, approved by the American Society of Anesthesiologists (ASA). Complications in the postoperative period were assessed according to the Clavien–Dindo classification adopted in 2004.

## RESULTS

The results of the intervention performed showed the high efficiency of TUCPCL. The data obtained demonstrated that the destruction of stones and the passage of fragments within one week after TUCPCL was noted in all patients. In 200 (94.8%) cases, positive results were achieved after one surgical intervention, and in 11 (5.2%) patients, positive results were achieved after two surgeries.

When analyzing the results of surgical interventions, close attention was paid to postoperative complications since the study aimed to systematize complications according to the Clavien–Dindo system. We had to divide the postoperative period into uncomplicated and complicated periods to adapt the classification (Table 3).

The following criteria for an uncomplicated postoperative period were selected:

- presence of a urethral catheter for no more than 24 hours, in rare cases no more than two days;
- absence or minor traces of blood in the urine through the Foley urethral catheter for no more than two days;
- absence of high body temperature or subfebrile body temperature for no more than two days;
- confirmation of the correct location of the inserted ureteral stent;
- absence of an infectious and inflammatory process in the urinary tract.

At the same time, there should have been no indications for additional surgical interventions to relieve complications that arose. It is not possible to formulate a difficult course without determining the normal course of the postoperative period.

The next stage was analyzing complications and their distribution with adaptation according to the Clavien–Dindo classification grades.

Various complications were noted in 36 (17%) of 211 patients operated. A total of 59 complications were

Table 3 / Таблица 3

### Criteria for postoperative complications in transurethral contact pyelocalicolithotripsy adapted to the classification of Clavien–Dindo

#### Критерии послеоперационных осложнений при трансуретральной контактной пиелокаликотрипсии по адаптированной классификации Clavien–Dindo

Degree	Criteria
I	Increased body temperature to febrile levels, requiring antipyretic drugs or other additional therapy. Pain in the projection of the organ operated, lasting no more than two days.
II	Increased body temperature to hyperpyretic values, requiring antipyretic drugs or other additional therapy. The use of additional antibacterial therapy in connection with the infectious and inflammatory process in the urinary tract (acute cystitis, acute urethritis, acute prostatitis, acute pyelonephritis), parenteral administration of drugs for detoxification therapy, which increases the duration of the patient's stay in hospital. Intake of painkillers for 48 hours or longer, associated with surgical intervention, unsatisfactory drainage of the renal cavity system, which can be eliminated by using appropriate drugs (except for drugs listed in degree I), avoiding additional interventions. The use of any other medications required in the event of an exacerbation of concomitant diseases, and associated with anesthetic support (headache, frequent and persistent nausea with vomiting, pleurisy, pneumonia, bronchitis, etc.). The need for parenteral nutrition.
IIIa	Gross hematuria requiring additional infusion therapy (more than 1.5 liters) and/or the intake of diuretics and hemostatic agents. Tamponade of the bladder resulting from bleeding from the upper urinary system, and subsequent relief of the complication by flushing and irrigation without general anesthesia.
IIIb	Ureteroscopy. Any causes that can be resolved by replacement of the ureteral stent (poor drainage of the kidney, displacement or prolapse of the ureteral stent). Any interventions with general anesthesia.
IVa	Mono-organ failure after surgery (myocardial infarction, acute cerebrovascular accident, lesion with liver, lung, or kidney failure) requiring intensive therapy. Follow-up in the postoperative period due to organ damage. Nephrectomy. Hemodialysis sessions due to advanced renal failure.
IVb	Sepsis, septic shock, multiple organ failure, disseminated intravascular coagulation, thrombohemorrhagic syndrome, need to stay in the resuscitation and intensive care unit.
V	Lethal outcome.

registered so that 19 (9%) patients had one complication, two complications were registered in 12 (6%) patients, three complications were noted in four (2%) patients, and one patient had four different complications. A greater number of complications (34, 58%) were treated conservatively without surgery. The elimination of 25 (42%) complications required manipulation without anesthesia in 14 (23%) patients and under general anesthesia in 11 (19%) patients.

The indwelling Foley urethral catheter was removed in 160 (76%) patients after 24 hours. In eight (4%) patients due to concomitant diseases, such as benign prostatic hyperplasia, the urinary catheter was removed on day 7. The replacement of catheters was performed on days 3–4 to prevent the development of infectious and inflammatory processes.

Body temperature deviations from normal values were recorded in the postoperative period in 22 (10%) patients (subfebrile in 12 (6%), febrile in seven (3%), and pyretic in three (1%) cases). The rise in body temperature lasted from several hours to six days after the surgery, on average about 36 hours. Eight patients required antipyretics. The maximum body temperature of 40.2 °C was in one patient, and the fever developed probably due to an exacerbation of chronic pyelonephritis.

Complications due to gross hematuria were noted in four (2%) patients. Except for one patient, all cases were stopped with hemostatic therapy. One patient with an initially low hemoglobin content (82 g/l) and preserved gross hematuria in the postoperative stage

(decrease in hemoglobin level to 71 g/l) required transfusion of one dose of fresh frozen erythrocyte concentrate in a volume of 300 ml with additional infusion therapy in a volume of up to 1.5 l. Gross hematuria was successfully arrested, and on day 2, the hemoglobin level was 84 g/l. After discharge, a consultation with a hematologist was recommended. No patient needed open surgery. In one case, bladder tamponade caused by gross hematuria was detected. It required washing the bladder with an isotonic solution with the Foley urinary catheter's reinstallation.

One of the most frequent complications in the postoperative stage was an exacerbation of pyelonephritis (in 24 (11%) patients), which was successfully treated conservatively in all cases. We believe that this complication's primary cause was the presence of a ureteral stent or nephrostomy drainage installed during the preoperative stage.

Stent (migration) dislocation was registered in nine (4%) patients, which required stent reinstallation under general anesthesia. In seven (3%) patients, chronic pyelonephritis exacerbation was noted before the stent position correction. In two cases, the stent migration was insignificant and did not lead to urodynamics impairment from the upper urinary tract.

According to the adapted Clavien–Dindo classification, the retrospective analysis revealed 59 cases of postoperative complications distributed according to the degree of complication (Table 4).

Table 4 / Таблица 4

#### The distribution of postoperative complications according to transurethral contact pyelocalicolithotripsy adapted to the classification of Clavien–Dindo

#### Распределение послеоперационных осложнений трансуретральной контактной пиелокаликолитотрипсии согласно адаптированной классификации Clavien–Dindo

Degree	Criteria
I	In 8 (4%) patients with concomitant diagnoses, a Foley urinary catheter was installed for three to seven days. 12 (6%) cases of increased body temperature from normal values (subfebrile in 12 (6%) and febrile in seven (3%) patients).
II	In 24 (11%) patients, exacerbation of chronic pyelonephritis was detected, which was arrested by the intake of antibiotic therapy. Three cases (1%) of increased temperature to pyretic values (40.2°C), which was relieved by using antibacterial and antipyretic therapy. In two (1%) cases, the stent migration was insignificant and did not lead to impairment of urodynamics from the upper urinary tract.
IIIa	Four cases of gross hematuria which was stopped by using hemostatic therapy. In one case, bladder tamponade was detected with subsequent irrigation of the bladder.
IIIb	Seven (3%) patients required stent correction under general anesthesia. In one (1%) case, there was a need for transfusion of one dose of erythrocyte concentrate in a volume of 300 ml with additional infusion therapy in a volume of up to 1.5 liters.
IVa	Not detected
IVb	Not detected
V	Not detected

## DISCUSSION

In many urology areas, there are still no adapted postoperative complications classifications that depend on surgical intervention options. This gap causes difficulty in interpreting surgical complications and assessing the quality of the surgery performed. Although many urologists argue that their subjective judgment is an appropriate guide for determining the degree of postoperative complication, it is still worth recognizing that the surgeon's subjective opinion is unreliable in many situations since it does not have objective criteria and largely depends on the clinician's experience [21]. Second, the probability of complications of endoscopic interventions depends on the operator's level of skill, the quality of training in the procedure performed, and the presence of patient comorbidities and risk factors [22].

The improvements of endoscopic techniques and equipment have shifted the focus on the critical aspects of poor surgical outcomes. They are now increasingly associated with the practical skills of the operating doctor. Based on such changes, the classifications developed in the past decades are now considered unadaptable but sometimes outdated.

Analysis of the data in the literature reveals that randomized controlled trials with a high level of evidence are relatively rare, despite the great interest of the world urological community (more than 230 published articles according to PubMed during the last five years as of September 2020). This limitation naturally leads to a small number of recommendations for their use in clinical practice regarding the criteria for postoperative complications.

## CONCLUSION

A standardized surgical complications classification and grading system are essential for interpreting the results of surgical interventions and their comparison between various medical centers and individual surgeons. In recent years, several works have been published, which aimed to create, adapt, and standardize the criteria for postoperative complications indicating the importance of studying this subject. Particular attention should be paid to the correct use of the generally accepted Clavien–Dindo classification system since it has not been validated for grading postoperative complications depending on the type of surgery. As the adapted classification was used by the usual approach without considering the surgery peculiarities and postoperative com-

plications associated with treating the underlying disease, many authors interpreted them unreliably. Urologists have significantly changed their attitudes toward using standardized criteria to describe complications, with an exponential increase in the number of articles that present the Clavien–Dindo classification. There is an urgent need for a universal description of urological interventions complications, which is useful for providing medical care to urological patients and conducting research.

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