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COMPLICATIONS OF EXTRACORPOREAL SHOCK -WAVE LITHOTRIPSY AND THEIR SYSTEMATIZATION

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ABSTRACT

The aim of study was to study the effectiveness of extracorporeal shock-wave lithotripsy and assess its post-procedural complications.

Materials and methods. The results of treatment of 200 patients with urolithiasis who were admitted to the Republican Specialized Scientific-Practical Medical Center of Urology in the period 2019-2020 that have been exposed to ESWL because of upper urinary tract (UT) stone(s) prospectively were analyzed. The mean patients' age was 39.7 ± 14.7, BMI - 25.5 ± 4.8 (kg / m^2). The affected side: 103 (51.5%) on the right, 97 (48.5%) on the left. The average stone size was 9.0 ± 0.2 (mm), of which 155 (77.5%) < 10 mm, in 45 (22.5%) 11-16 mm. The stones were located in the calycies in 55 (27.5%), in the pelvis renalis in 16 (8.0%), in the ureter in 129 (64.5%) cases. In 180 (90%) patients, there was a dilatation of UT in the form of ureterohydronephrosis / hydronephrosis / calicectasia.

Electrohydraulic lithotripsy was performed; the mean generator power was 17.9 ± 0.3 V; the number of strikes was 681.35 ± 192.

Results. In 186 (93%) patients, after the first session within 20 days, the stone fragments came off and we got Stone free condition. Renal colic developed in 19 (9.5%), of which 6 (3.0%)

due to a steinstrasse, acute obstructive pyelonephritis in 2 (1.0%), of which 1 (0.5%) developed urosepsis. 14 (7.0%) patients required repeated lithotripsy, 2 of them for a steinstrasse. Out of 14 in 10, after the second session, the fragments came off.

Also, additional interventions were required: in 3 (1.5%) cases ureteroscopy (URS) with contact lithotripsy; percutaneous nephrostomy in 1 case, URS with stone extraction in 1 case.

Conclusions. Systematization of post-procedural complications according to Clavien-Dindo (2004) showed that a total of 40 (20.0%) complications developed: I -19, II - 1, IIIa - 14, IIIb - 5, IVa - 1, IV b -0, V -0.

Key words: urolithiasis, ESWL, complications.

INTRODUCTION

According to the World Health Organization, “the incidence of urolithiasis in developed countries has reached 5%, the risk of kidney stones during a person's life has reached 8-10%” [1]. The incidence of urolithiasis varies in different regions of the world: Europe 5-9%, Asia 1-5%, and North America up to 20%. In the Russian Federation, the incidence from 2002 to 2014 increased by 27.5% [2]. The prevalence of urolithiasis in Uzbekistan varies from 1.0% to 8.5% in different regions of the republic, amounting to 4.5% in the country as a whole [3, 4]. Among urological diseases, it ranks second in frequency of occurrence after urinary tract infections. In urological hospitals, patients with urolithiasis make up to 40% of the total contingent; 35-75% of the disease is recurrent. Surgical interventions because of urolithiasis in 22-28% lead to various complications and in 11% end with nephrectomy, in 3% - with a lethal outcome [5]. According to some sources, the percentage of severe complications in patients with urolithiasis increases in direct proportion to the frequency of surgical interventions, and with repeated surgeries for urolithiasis mortality ranges from 1.8 to 3.4% [6]. There is an established fact that of all patients with urolithiasis, ureteral stones account for more than 50% of cases, about 70% of ureteral stones have pelvic stones, i.e. distal localization [7, 8], which often requires the use of minimally invasive and non-invasive methods of treatment. Today, the main methods of treating urolithiasis are non-invasive - extracorporeal (remote) shock wave lithotripsy (ESWL), minimally invasive endoscopic stone removal (percutaneous (PC) and transurethral (TU) approaches) and traumatic open surgical interventions, which are used less frequently, only in some cases for special indications The choice of treatment method for patients with urolithiasis depends on the size, number, localization, mineral composition of stones, anatomy of the upper and lower urinary tract, the functional state of the kidneys and urodynamics of the urinary tract, the equipment of the clinic, the qualifications of specialists and the wishes of the patient. The latter always turns out to be in favor of the non-invasive ESWL method. Consequently, despite the long history of introducing the ESWL technique, studying the effectiveness and

safety of its use depending on various factors, it still remains an urgent issue of modern urology.

The aim of our study was to study the effectiveness of extracorporeal lithotripsy and assess its post-procedural complications.

MATERIAL and METHODS.

We prospectively analyzed the results of treatment of 200 patients with urolothiasis who treated in the Republican Specialized Scientific-Practical Medical Center of Urology in the period 2019-2020 for upper urinary tract stone(s) that have been exposed to ESWL. The patients' age was 39.7 ± 14.7 years. A detailed description of the patients of the study group is given in Table 1.

Table 1.

Clinical characteristics of ESWL patients

Variable	Value
Number of patients	200
Average age of patients ± SD	39,7±14,7
Mean BMI (kg/m^2) ± SD	25,5±4,8
Gender	
Male, n (%)	136 (68,0)
Female, n (%)	64 (32,0)
Affected side	
Right, n (%)	103 (51,5)
Left, n (%)	97 (48,5)
Stone size	
Average stone size in mm ± SD	9,0 ± 0,2
< 10 mm n (%)	155 (77,5)
> 11-16 n (%)	45 (22,5)
Location of stones	
Renal calyces, n (%)	55 (27,5)
Renal pelvis, n (%)	16 (8,0)
Ureter, n (%)	129 (64,5)
Number of patients with dilatation of the collective system: calicoectasia / hydronephrosis / ureterohydronephrosis, n (%)	180 (90 %)
Number of patients with a ureteral stent before the procedure, n (%)	3 (1,5 %)

The analysis showed that in the largest proportion of patients 129 (64.5%) the stone(s) were located in the ureter. In 180 (90%) patients, there was a dilatation of the kidney collective system in the form of calicoectasia or hydronephrosis, or ureterohydronephrosis.

Considering that an infectious-inflammatory complication is a severe post-procedural complication, a detailed analysis of the presence of urinary tract infection during the initial treatment of patients, depending on the age of the patients, is given in Table 2.

Table 2.

Distribution of patients by age-related decades and the frequency of detection of urinary tract infection during primary visits

Patients age (years)	Number of patients		Presence of Infection		Absence of infection	
	Number	%	Number	%	Number	%
Before 10	4	2,0	2	1,0	2	1,0
11-20	6	3,0	5	2,5	1	0,5
21-30	58	29,0	45	22,5	13	6,5
31-40	45	22,5	35	17,5	10	5,0
41-50	33	16,5	20	10	13	6,5
51-60	35	17,5	28	14	7	3,5
61-70	17	8,5	9	4,5	8	4,0
≥ 71	2	1,0	2	1,0	-	-
Total	200	100	146	73,0	54	27,0

As can be seen from the table, the largest number of patients exposed to ESWL for urolithiasis turned out to be at the age of 21-60 years, which indicates the incidence of people of active working age. This contingent of patients was also diagnosed with upper urinary tract infection more often than in other age categories. All patients underwent electrohydraulic lithotripsy against the background of intravenous ataralgesia, the mean generator power 17.9 ± 0.3 V, the average number of strikes for crushing a stone in each patient was 681.35 ± 192.

Postoperative complications were classified according to the internationally accepted Clavien-Dindo classification of postoperative complications [9], Table 3.

Table 3.

Clavien-Dindo's Modified Classification of Surgical Complications (2004)

Degree	Criteria
I	Any deviations from the norm in the postoperative period that do not require surgical, endoscopic or radiological intervention. Only conservative therapy is carried out: antiemetics, antipyretics, analgesics, diuretics, administration of electrolytes, physiotherapy, 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 the 1st degree), blood transfusion and complete parenteral nutrition
III	Complications requiring surgical, endoscopic or radiological intervention:
IIIa	intervention, without general anesthesia
IIIb	interventions with general anesthesia
IV	Life-threatening complications (including the central nervous system) requiring the patient to stay in the intensive care unit:
IVa	lack of function of one organ (including dialysis)
IVb	multiple organ dysfunction
V	Fatal outcome

Statistical processing of the material was carried out using MS Office Excel 2007, Stat Soft Statistica 8.0 using Student's and Fisher's criteria. Differences were considered statistically significant at $p < 0.05$.

RESULTS.

In 186 (93%) patients, after the first session within 20 days, the fragments of the stone completely moved away during spontaneous urination in the form of sand and small fragments up to 1-2 mm and reached the state of Stone free. The nature and frequency of various complications identified in the early post-procedural period are shown in Table 4. The most frequent complication of the post-procedural ESWL period was renal colic, which developed in 19 (9.5%), of them 6 (3.0%) due to the formation of steinstrasse, acute obstructive pyelonephritis developed in 2 (1.0%) patients who had a kidney block with a stone fragment due to its ineffective crushing, of which 1 (0.5%) developed urosepsis. In 14 (7.0%) patients with residual calculus, repeated lithotripsy was required, 2 of them for the steinstrasse.

As a result, out of 14 patients in 10 after the second session of lithotripsy, stone fragments came off and achieved the state of Stone free, Table 4.

Table 4.

Nature and frequency of postoperative complications of ESWL

Complication	Number of patients	%
Renal colic	19	9,5
Formation of a steinstrasse	6	3,0
Acute Pyelonephritis	1	0,5
Acute Pyelonephritis with urosepsis	1	0,5
Residual stones	14	7,0

Also, additional interventions were required for 3 (1.5%) patients who underwent minimally invasive surgery - ureteroscopy (URS) with contact lithotripsy, one patient, due to complete blockage of the ureter with a stone fragment and developed postrenal anuria, underwent kidney unblocking by performing minimally invasive percutaneous (PC) nephrostomy. with the subsequent (after the sanation of the infection) also minimally invasive PC antegrade stone extraction, i.e. one patient underwent two interventions.

All complications were systematized taking into account the additional interventions performed (see table 5).

Table 5.

Classification of postoperative complications according to the Clavien-Dindo classification

Complication degree	Types of complications and treatment tactics	Number of complications n (%)
I	Renal colic requiring additional conservative therapy in 19;	19 (9,5)
II	Development of acute complicated pyelonephritis, requiring additional antimicrobial therapy in 1;	1 (0,5)
III a	Additional ESWL session for residual stone in 12 patients; Additional ESWL session on the “stone path” at 2.	14 (7,0)
III b	URS for residual stones in 3; PC antegrade stone extraction for residual stone in 1; PC nephrostomy for postrenal anuria in 1.	5 (2,5)
IV a	Urosepsis requiring treatment in the intensive care unit in 1.	1 (0,5)
IV b	-	-
V	-	-

Thus, a total of 40 (20.0%) postoperative complications were observed, which we systematized based on their severity. The analysis showed that 19 additional interventions were required to eliminate postoperative complications, of which 18 were needed to get rid of the residual stone. At the same time, 14 underwent repeated use of non-invasive ESWL, in 3 - minimally invasive endoscopic intervention, in 1 - kidney unblocking was performed and in no case did they resort to open traumatic interventions. A severe infectious and inflammatory complication in the form of complicated pyelonephritis developed in 2 (1.0%), of which 1 (0.5%) developed urosepsis, which required the patient to be in the intensive care unit.

DISCUSSION.

The development of a new technology in urology, namely the ESWL method, somewhat changed the current situation in the treatment of urolithiasis [10, 11]. The development of ESWL equipment began at the turn of the 70s – 80th of last century, and in the literature and in the urological community in those years there was a discussion. In the materials published by S. Chaussy during this period, the high efficiency of the method in terms of the frequency of getting rid of stones was noted, which provided a key effect in the widespread use of ESWL and limiting the indications for invasive surgical treatment. This group of scientists from Germany worked closely with “Dornier” company engineers to develop a lithotripter. Many positive reports of the results of ESWL treatment led to the fact that by the middle

and late 1980th began to limit the indications for percutaneous (percutaneous) surgery and open interventions [7, 8]. However, after a certain time, the large-scale introduction of ESWL equipment allowed urologists to identify the disadvantages of this method. The large size of the stone, damage to the urinary tract by several fragments formed after crushing one large stone, obstruction of the ureter, "stone path" and pain, justified the need to use the method of PC surgery. After 12-15 years of widespread use of ESWL, scientific work devoted to the comparative assessment of the results of PC surgery and ESWL led to a better understanding of the possibilities of the methods and the development of an ideal indication for the use of each method in the treatment of urolithiasis. It should be noted that all existing types of surgical treatment for urolithiasis have their pros and cons. With the widespread use of ESWL in the treatment of urolithiasis, the tactics of eliminating the consequences of lithotripsy is becoming relevant, although the frequency of complications is relatively low. One of the frequent complications of ESWL in kidney stones is the formation of a "stone path" (steinstrasse) that forms in the pelvic ureter and is caused by non-controlled or ineffectively controlled renal colic. A debatable question remains among urologists of various centers, the choice of method in case of ineffectiveness of conservative therapy of the "stone path" - repeated use of ESWL or endoscopic removal of fragments by transurethral access. According to some sources, during a remote lithotripsy session, the overall complication rate reaches 15.3%, which is lower than with percutaneous and ureteroscopic interventions. The most common complications are cardiac arrhythmias (11-59%), bacteriuria (7.7-23%), hematoma (4-19%), stone path (4-7%), renal colic (2-4%) and sepsis (1-2.7%), as well as sporadic severe cardiovascular events, intestinal perforations, hematomas of the liver or spleen [12]. It should be noted that the frequency given by the authors is without systematization of complications, since the experience of using the Clavien classification has shown that with systematization, the frequency increases due to mild complications, which are not customary to indicate in many clinics. Thus, in a large study, Duvdevani M. et al. in 1.4% of 11,500 ESWL cases, fever developed up to 38 °C [13]. As risk factors for the development of postoperative fever, the authors identified: positive urine culture ($p < 0.05$), the presence of a permanent nephrostomy or ureteral stent, as sources of infection ($p < 0.001$), as well as symptomatic urinary tract infection preceding the crushing procedure ($p < 0.05$) [14]. In our study, we also confirmed the above literature data on the cause of the development of infectious and inflammatory complications. In a study conducted by Mira Moreno A. et al., urine cultures of 366 patients who underwent ESWL without prior antibiotic prophylaxis were studied. Microflora in urine was detected

in 8.5% of patients 7 days after the ESWL procedure. Of these, only 2.1% of patients developed symptoms of urinary tract infection, in other cases asymptomatic bacteriuria occurred [15]. In another large, in our opinion very interesting, twenty-year study carried out by Alexander C. et al., there were no significant differences in the rate of development of infectious and inflammatory complications after ESWL in patients who received preliminary antibiotic prophylaxis (1.1%), and in patients without it (1.3%) [16].

The ESWL success rate has an inverse relationship with the size of the stone over 10 mm [17-19], which is confirmed by the study of M. Abdelghany et al. [20], which presents the results of treatment of 100 patients with distal ureteral stones who underwent ESWL as the first line of treatment.

Complete removal of stones was ascertained in 84% of cases when only 32.1% of patients had to perform 2 ESWL sessions. At the same time, in the case of a stone larger than 10 mm, the effectiveness of the procedure did not exceed 71%. At the same time, the authors draw attention to the statistical significance of the dependence of the ESWL efficiency on the size of the calculus ($p = 0.016$). In our study, it was also found that in 80% of cases, repeated ESWL sessions were performed in patients with a stone size of more than 10 mm.

The classification of some complications after ESWL according to the Clavien-Dindo classification of post-operative complications remains controversial.

According to the logic of classification [9], formally, all cases of additional interventions in the postoperative period should be attributed to the III degree of severity, which we did. But, the question arises, should 14 cases of repeated ESWL sessions be regarded as complications and systematized? Indeed, prior to the initial ESWL session, due to certain characteristics of the stone (size, density, estimated composition), patients were warned that they might have to perform two or three ESWL sessions. At the same time, informed consent was obtained from patients for such a tactic of treatment. Evaluation of the performed invasive additional interventions to remove residual stones, unblock the kidney, eliminate infectious and inflammatory complications - as a complication and their systematization, we have no questions

CONCLUSIONS.

Thus, the most severe complication after ESWL was complicated pyelonephritis 2 (1.0%), of which 1 (0.5%) had urosepsis, which requires the development of additional preventive measures. Systematization of post-procedural complications according to Clevien-Dindo (2004) showed that after

ESWL a total of 40 (20.0%) complications developed and their systematization showed the following picture: I -19, II - 1, IIIa - 14, IIIb - 5, IVa - 1, IV b - 0, V- 0.

The classification of surgical complications by Clevien-Dindo (2004) is universal, simple and informative, but for a correct assessment of postoperative complications, it requires adaptation to each method of intervention, taking into account the specifics of a particular method.

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