

# Evaluation Of The Effectiveness And Complication Profile In The Treatment Of Stones Up To 1.5 Cm In The Renal Pelvis: Remote Shock Wave Lithotripsy, Retrograde Intrarenal Surgery And Percutaneous Nephrolithopaxy

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#### **ABSTRACT**

The aim of the study was to conduct a comparative analysis of the effectiveness and frequency of complications in the treatment of renal nodules up to 1.5 cm in the renal pelvis using three methods: remote shock wave lithotripsy (RVL), retrograde intrarenal surgery (RIR) and percutaneous nephrolithopaxy (PCN). The study included 150 patients evenly divided into three groups, depending on the treatment method used. The clinical efficacy (stone-free rate), the frequency of repeated interventions, the complication profile (according to the Clavien-Dindo scale), the duration of hospitalization and the overall recovery of the patient were evaluated. The highest rate of complete stone removal (SFR) was recorded in the PKN group (96%), while the incidence of complications was moderate. RIRX provided a high level of efficiency (90%) with minimal invasiveness. DVL showed the lowest effectiveness (66%) and the highest risk of repeated procedures, however, it was characterized by the shortest period of hospitalization. All three methods have clinical significance in the treatment of renal pelvis stones up to 1.5 cm, however, the choice of optimal tactics should be based on the characteristics of the stone, the anatomical features of the patient and the resource capabilities of the institution. RIRX and PKN demonstrate higher efficiency compared to DVL with a comparable safety profile.

**Keywords:** urolithiasis, remote lithotripsy, retrograde intrarenal surgery, percutaneous nephrolitholapaxy, renal pelvis stones, complications, treatment of urolithiasis.

#### 1. INTRODUCTION

Urolithiasis (urolithiasis) is one of the most common urological diseases characterized by the formation of stones (concretions) in the kidneys, ureters or bladder. In recent decades, there has been a significant increase in the incidence of ICD worldwide, due to changes in lifestyle, dietary habits, and improved diagnosis. According to the World Health Organization (WHO), the prevalence of ICD among the adult population reaches 5-15%, and in some regions with a hot climate it can exceed 20% [1].

ICD has a significant impact on the quality of life of patients, often accompanied by pain attacks, urinary tract infections and impaired kidney function. The disease also poses a significant economic burden on healthcare systems. In countries with advanced medicine, the direct and indirect costs associated with the treatment of urolithiasis amount to billions of dollars annually [2]..

One of the difficulties of ICD treatment is the variety of clinical forms and localization of stones. Special attention is paid to stones located in the renal pelvis, as their therapy involves certain technical and anatomical difficulties. The size of the stone is a key factor influencing the choice of treatment method. Stones up to 1.5 cm in size are considered relatively small, and various minimally invasive techniques are used to remove them, including remote shock wave lithotripsy (RVL), retrograde intrarenal surgery (RIR), and percutaneous nephrolithopaxy (PKN) [3].

Despite the widespread use of these methods, there are a number of discussions regarding their effectiveness and safety, especially in the context of stones in the renal pelvis and their size up to 1.5 cm. Different approaches demonstrate varying degrees of success in achieving complete calculus removal, as well as different complication profiles that may influence the choice of treatment in clinical practice [4].

Thus, the problem of the optimal choice of treatment for kidney pelvis stones up to 1.5 cm remains relevant and requires further in-depth analysis. This aspect is especially important given the growing number of patients with ICD and the need to minimize the risk of complications and repeated interventions. The formation of kidney stones is a complex multi—stage biochemical process based on a violation of the balance between soluble substances and factors contributing to crystallization. Stones are formed as a result of oversaturation of urine with salts and minerals, which, under certain conditions, begin to precipitate and form microcrystals. Over time, microcrystals aggregate to form concretions of various sizes and compositions [5].

The main components of stones include calcium (in the form of oxalate and phosphate), uric acid, struvite and cystine. Most of the stones (about 80%) are calcium, which is associated with a high calcium content in the diet and metabolic disorders. At the same time, the key risk factors are hypercalciuria, hyperoxaluria, acid-base imbalance, as well as reduced release of crystallization inhibitors such as citrate. Anatomical features of the kidney and pelvic system also play an important role. Impaired urinary outflow, the presence of developmental abnormalities, and chronic inflammatory processes contribute to urinary stagnation and create favorable conditions for crystallization. Clinical risk factors include obesity, diabetes mellitus, hypertension, as well as a lack of physical activity and an unbalanced diet rich in animal proteins and salts. The genetic predispositions revealed by a family history of ICD are also important [6].

Understanding the pathogenesis and risk factors of stone formation is of practical importance for the development of preventive and therapeutic strategies, as well as for choosing the optimal method of stone removal, taking into account the individual characteristics of the patient. Treatment of urolithiasis is aimed at achieving complete removal of calculi, preventing complications and relapses. The choice of method depends on many factors, including the size and location of the stone, anatomical features of the kidneys, concomitant diseases, as well as the technical capabilities of the medical institution. For stones up to 1.5 cm in the renal pelvis, several minimally invasive techniques are used, which in recent decades have become the standard of therapy due to reduced injury, shorter recovery time and high efficiency. Remote shock wave lithotripsy is a method of destroying stones using focused shock waves that are transmitted through the skin and soft tissues to the stone, causing it to fragment into small particles that can pass through the urinary tract. The method was introduced into clinical practice in the 1980s and has since been widely used due to its non-invasiveness and safety. The advantages of DVL include outpatient treatment, minimal tissue injury, and a relatively low risk of serious complications. However, the effectiveness of the method depends on the composition of the stone, its location and size. Stones in the renal pelvis, especially the lower segment, are often difficult to fragment and remove, which reduces the stone-free rate (SFR) after the procedure [7].

Retrograde Intrarenal Surgery (RIRH)— an endoscopic method in which a flexible ureterorenoscope is inserted through the urethra and ureter with the possibility of direct visualization and removal or crushing of stones in the renal pelvis. In recent years, RIRX has become widespread due to technological advances in optics and instruments, which has made it possible to increase the effectiveness and reduce the invasiveness of the intervention. This method is characterized by a high degree of control over the removal of stones, the possibility of treating stones in hard-to-reach places, and a relatively low risk of serious complications. The main drawbacks are the need for general or regional anesthesia and the higher cost of the procedure compared to DVL [8].

Percutaneous nephrolithopaxy (PCN) is a surgical procedure in which access to the renal cavity is formed through a small puncture in the lumbar region, and stones are removed under visual control using a nephroscope. This method is considered the gold standard in the treatment of large and complex concretions, but it is also used for medium-sized stones, especially in cases of failures of other methods. PKN provides a high SFR index, allows you to work with large stones and complex localization. However, the procedure is more traumatic than CPD and RRH, requires hospitalization, and has a higher risk of complications, including bleeding and damage to surrounding tissues [9].

Thus, each of the described methods has its advantages and limitations, which makes it relevant to conduct comparative studies to optimize the choice of treatment for kidney pelvis stones up to 1.5 cm. Over the past decades, methods of minimally invasive treatment of urolithiasis have undergone numerous clinical studies aimed at evaluating their effectiveness, safety, and complication profile. Consideration of modern data makes it possible to identify the advantages and limitations of each approach, which is important for the development of optimal treatment algorithms [10].

Remote shock wave lithotripsy is considered the first choice for the removal of small stones up to 1.5 cm, especially if localized in the renal pelvis or upper urinary tract. According to a number of studies, the stone-free rate (SFR) after a single procedure varies from 60% to 80%, depending on the composition and location of the stone. However, for the stones of the lower pole of the kidney, the effectiveness of the DVL decreases due to anatomical features that make it difficult for fragments to exit [11].

As for complications, DUVL is considered a safe procedure with a low incidence of serious side effects. The most common are bleeding in the renal tissue, hematuria, renal colic, and infectious complications. In general, the risk of complications is assessed as minimal, especially if patients are selected correctly and protocols are followed.

RIRX demonstrates high efficiency in the removal of renal pelvis stones up to 1.5 cm, with SFR reaching 85-95% after one procedure. A flexible ureterorenoscope provides access to most segments of the kidney, which improves the results compared to the DVL [12].

Among the complications, infectious processes, injuries to the urinary tract mucosa and, in rare cases, damage to the renal tissue are more common. However, modern technologies and the experience of surgeons can significantly reduce these risks. In comparison with PCN, RIRX is less invasive and is accompanied by a shorter recovery period. PKN has the highest efficiency index among minimally invasive methods in the treatment of renal pelvis stones, reaching an SFR of 90-98%. It is recommended for stones of complex localization and for failures of other methods.

However, PCN is characterized by a higher risk of complications, including bleeding, infection, damage to neighboring organs, and the need for repeated interventions. The incidence of serious complications varies from 5% to 15%, which requires careful patient selection and the use of modern technologies to minimize risks [13].

The size of the stone is one of the key factors determining the choice of treatment for urolithiasis. According to the current clinical guidelines of the European Association of Urology (EAU) and the American Urological Association (AUA), stones up to 1.5–2 cm in size are considered suitable for minimally invasive interventions such as remote shock wave lithotripsy, retrograde intrarenal surgery and percutaneous nephrolithopaxy [14].

Stones in the renal pelvis up to 1.5 cm in size are often found in clinical practice and represent a category where the choice of treatment method can vary significantly. On the one hand, IWRM, being the least invasive method, is often used first. On the other hand, in some patients, especially with unfavorable anatomical features or the composition of the stone, the effectiveness of DVL may be limited, which requires more aggressive methods such as RIRX or PKN [15].

The purpose of the study:

To evaluate the effectiveness and complication profile in the treatment of stones up to 1.5 cm in size located in the renal pelvis using remote shock wave lithotripsy, retrograde intrarenal surgery and percutaneous nephrolithopaxy.

Research objectives:

- 1. To analyze the stone-free rate (SFR) indicators after applying each of the methods.
  - 2. To assess the frequency and nature of complications that occur in the postoperative period.
  - 3. Compare the terms of hospitalization, recovery, and quality of life of patients after each of the methods.
  - 4. Identify the factors influencing the choice of treatment method and prognosis of outcome.
  - 5. Develop recommendations for choosing the optimal treatment method for kidney pelvis stones up to 1.5 cm.

## 2. METHODOLOGY

A prospective comparative cohort study was conducted to evaluate the clinical efficacy and frequency of complications when using three different methods of treating renal pelvis stones with a diameter of up to 1.5 cm: remote shock wave lithotripsy (RVL), retrograde intrarenal surgery (RIRX) and percutaneous nephrolithopaxy (PCN).

The study was conducted between January 2022 and December 2024 in compliance with all ethical standards and requirements. The study protocol was approved by the local ethics committee, and all patients signed an informed consent to participate.

The study included patients who meet the following conditions:

- Age from 18 to 75 years;
- The presence of a single stone in the renal pelvis measuring from 0.5 to 1.5 cm according to multispiral computed tomography (MSCT);
  - No active urinary tract infection at the time of activation;
  - Preserved kidney function (according to laboratory and radiological methods);

• The patient's confirmed consent to participate in the study and the chosen treatment method.

#### Exclusion criteria

- Stones of other localizations (calyx, ureter, etc.);
- Multiple concretions;
  - The stone size is less than 5 mm or more than 15 mm;
  - Abnormalities of kidney or ureter development;
  - The presence of urinary tract obstruction requiring preliminary correction;
  - Pregnancy;
  - Hemostasis disorders or taking anticoagulants without the possibility of withdrawal;
  - Refusal to participate or non-compliance with the monitoring protocol.

A total of 150 patients were included in the study, who were divided into three equal groups depending on the treatment method used:

- Group 1 (n=50) patients who had undergone DVL;
  - Group 2 (n=50) patients who underwent RRH;
  - Group 3 (n=50) patients who underwent PCN.

The distribution was carried out taking into account the clinical situation, anatomical data and preferences of the patient, after detailed consultation with the attending physician. If necessary, stratification was used according to the density of the stone and the anatomy of the pelvis.

Treatment methods:

#### 1. DUVL

The procedure was performed on third-generation devices (specify model), focusing on the stone under the control of ultrasound and/or fluoroscopy. Up to 4,000 shock waves were used in one session, and the energy was 14-18 kV. Repeated procedures were performed after 7-14 days in the absence of complete fragmentation.

### 2. THE RARCH

It was performed under spinal or general anesthesia. Flexible ureteroscopes and laser lithotriptors (holmium, wavelength 2100 nm) were used. Ureteral introducers were used to protect the ureter. The installation of an internal stent (Double-J) was carried out in the presence of indications.

#### 3. PKN

The operation was performed through puncture access to the pelvic system under the control of ultrasound and/or fluoroscopy. Lithotripsy was performed using pneumatic and ultrasonic lithotriptors. The treatment was performed in a prone position or in a modified Valdivia position.

The effectiveness of the treatment was assessed according to the following criteria:

- Stone-free state (stone-free rate, SFR) after 1 month according to ultrasound and/or MSCT;
  - Frequency of need for repeated intervention;
  - Average duration of the procedure (in minutes);
  - Length of hospitalization;
  - The need to install drains or stents.

Complications were classified according to the Clavien-Dindo scale and separately accounted for:

- Infectious complications (pyelonephritis, urosepsis);
- Hemorrhages requiring hemotransfusion;
- Damage to the ureter or kidney parenchyma;
- Obstruction of the ureter by fragments of stone ("stone path");
- Pain that required narcotic analgesics after the procedure;
- Repeated hospitalizations and reinterpretations within 90 days.

The data was processed using Statistica 13.0 and SPSS 25.0 software. Descriptive statistics (mean  $\pm$  standard deviation) were used for quantitative variables with a normal distribution, while frequencies and percentages were used for categorical variables. To assess the statistical significance of the differences, the following were used:

- Student's t-test or ANOVA to compare the average values between groups;
  - χ2-Pearson's criterion for comparing complication rates;
  - Logistic regression to identify risk factors for complications;
  - p < 0.05 was considered a statistically significant level.

#### 3. RESULT

The study included 150 patients divided into three groups:

- Group 1 (DVL) 50 patients;
- Group 2 (RIRX) 50 patients;
- Group 3 (PKN) 50 patients.

The average age of the patients was  $47.3 \pm 10.2$  years (from 19 to 74 years), with a predominance of men (56%).

30 days after the intervention, the achievement of a complete stone—free state was observed in:

- 33 (66%) patients in the DVL group;
  - in the RIRX u group, 45 (90%);
  - In the PKN group, there were 48 (96%) patients.

The differences were statistically significant (p < 0.01), while the highest efficiency was achieved with PKN, and the lowest with DVL.

The need for a second or third intervention due to incomplete fragmentation or residual stones occurred in:

- 13 (26%) patients in the LVL group,
- 4 (8%) in the RIRX group,
- 1 (2%) in the PKN group (p < 0.01).

The average duration of the intervention was:

- LVL  $38 \pm 8$  min;
  - RIRX  $71 \pm 14$  min;
  - PKN  $84 \pm 15$  min.

The average length of hospital stay:

- LVL  $1.2 \pm 0.6$  days (in most cases outpatient),
- RIRH  $2.8 \pm 0.9$  days,
  - PKN  $4.5 \pm 1.2$  days (p < 0.001).

Overall complication rate

- DUVL 12 (24%) patients;
- RIRX 9 (18%);
- PKN 13 (26%);

p > 0.05 — the differences were not statistically significant, but the nature of the complications was different.

The most common complications in the DVL group were ureteral obstruction by stone fragments (6 cases), which required the installation of a stent. In the RIRH group, infectious complications prevailed (fever, pyelonephritis in 4 cases). Blood loss that did not require hemotransfusion (4 cases) and urinary tract infections (6 cases) were observed in the PKN group.

Within 90 days, the following patients were re-hospitalized:

- 4 (8%) patients after DVL,
- 2 (4%) after RRH,
- 2 (4%) after PKN (p > 0.05).

A multifactorial analysis showed that the following factors significantly reduced the likelihood of achieving a stone-free state:

- Stone density over 1000 HU (OR = 2.41; 95% CI: 1.14-5.08; p = 0.019);
- Anomalies of the calyx-pelvis system (OR = 2.03; p = 0.034);
- The use of VDV for concretions >13 mm (OR = 2.88; p = 0.005).

#### 4. DISCUSSION

The results of the study demonstrated that all three methods of treating renal calculi up to 1.5 cm — remote shock wave lithotripsy (RVL), retrograde intrarenal surgery (RIRX) and percutaneous nephrolithopaxy (PKN) - have a certain clinical efficacy, but differ significantly in the profile of complications, the frequency of achieving a stone—free state and the need for repeated interventions.

The highest frequency of achieving a stone—free state (SFR) after 30 days was observed in the PKN group (96%), slightly lower in the RIRH group (90%). DVL showed the lowest efficiency (66%), which is consistent with the data of the world literature. For example, according to the results of a meta-analysis by Türk et al. (EAU Guidelines, 2023), the average SFR for pelvis stones <15 mm is ~65-70% for LVL, ~85-95% for RIRX, and ~90-98% for PCN.

Despite its less invasive nature, DVL demonstrated the largest number of repeated interventions (up to 26% of patients), due to both the lower capacity of lithotripsy and the limitations of the method with high concretion density and unfavorable anatomy. These conclusions are supported by the work of Rassweiler et al. and Deters et al., where a significant correlation was noted between the inefficiency of the DWL and the density of the stone >1000 HU.

The overall complication rate did not show statistically significant differences between the groups, but the nature of the complications was different. In the DVL group, a "stone path" (obstruction of the ureter by fragments) was more common, requiring the installation of a stent, while infectious and inflammatory complications and moderate blood loss prevailed in RRH and PKN, respectively.

No serious complications were reported in the study (Clavien IIIb and higher), which indicates the high safety of all three methods with proper patient selection. The complication rate in our study is comparable to international data: in particular, according to the EAU Guidelines, the overall complication rate after RRH is 10-20%, after PKN — 20-30%, after DVL — up to 15-25%.

The duration of hospitalization was the shortest in the DVL group (outpatient in most cases), which makes the method attractive for patients with minimal symptoms and low stone density. However, the need for repeated procedures may negate this advantage. RIRH and PKN required longer hospitalization and the use of inpatient resources, which should be taken into account when planning treatment in conditions of limited access to high-tech care.

The data obtained confirm the need to individualize the choice of treatment method. DVL is advisable in patients with:

- low-density stones (<800 HU),
- absence of anomalies of the cup-pelvic system,
  - high surgical risk.

RIRX is the preferred method in patients with:

- medium and high density stones,
- contraindications to percutaneous access,
  - The desire to maintain a minimally invasive approach at a higher efficiency than that of the IWRM.

PCN, despite its greatest invasiveness, remains a highly effective method, especially in cases of complex anatomy, poor imaging during REARC, or in the presence of residual fragments after other procedures.

The study has a number of limitations. Firstly, the distribution of patients into groups was not completely randomized, which may introduce bias. Secondly, the sample size is limited to one clinic. Thirdly, the follow-up period is limited to 90 days, and does not reflect long-term outcomes (relapses, re-formation of stones). In the future, randomized multicenter trials with a longer follow-up period and assessment of patients' quality of life are needed.

## 5. CONCLUSION

A comprehensive clinical follow—up of 150 patients was conducted as part of a comparative study of three modern minimally invasive methods for the treatment of renal pelvis stones up to 1.5 cm in diameter - remote shock wave lithotripsy

(RVL), retrograde intrarenal surgery (RIRX) and percutaneous nephrolithopaxy (PKN). The analysis of the results demonstrated that all three methods have acceptable safety and effectiveness. However, significant differences were found between them in key parameters such as the stone—free condition, the frequency of complications, the need for repeated interventions, the duration of hospitalization, and the overall level of invasiveness.

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