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Single-use flexible digital ureteroscopy and Holmium Laser lithotripsy in the endoscopic treatment of renal lithiasis

PHD THESIS SUMMARY

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Content of the thesis

Introduction

I. The general part

1. Information about renal lithiasis

1.1 Notions of anatomy

1.2 Notions of epidemiology

1.3 Types of renal lithiasis

1.4 Laser lithotripsy

2. Guide recommendations

3. Flexible ureteroscopy

3.1. Indications

3.2 Instrumentation, technique, operative time

3.3. Intra and postoperative complications

3.4. Functional characteristics

II. Personal contributions

4. Working hypothesis and general objectives

5. Research methodology

6. Study Comparison between the qualities of disposable versus reusable ureteroscopes

6.1. Introduction

6.2 Material and Method

6.3 Results

6.4 Discussions

6.5 Conclusions

7. Study Treatment of renal lithiasis with the disposable versus the reusable ureteroscope

6.1. Introduction

6.2 Material and Method

6.3 Results

6.4 Discussions

6.5 Conclusions

8. Conclusions and personal contributions

Introduction

Urolithiasis has a high prevalence worldwide with an increase in recent decades of approximately 2-3%. Over the last years, the surgical management of lithiasis kidney benefits from multiple technological advances.

The miniaturization of the instruments allowed access through the interior of the urinary system and greatly changed the treatment of renal lithiasis. Until recently, the only way to perform retrograde intrarenal surgery was the use of semi-rigid and subsequently reusable fURS, with many significant weaknesses: the possibility of transmission of infection between patients, fragility, fatigue, poor visibility, restrictions in the use of accessory instruments.

For these reasons fURS has evolved to provide increased access, flexibility, visibility and durability. Thanks to all these technological developments fURS has gained in popularity and become a desirable treatment modality in renal lithiasis. About 3 years ago, the first significant clinical evaluations of the use of single-use ureteroscopes appeared worldwide.

For every patient, there should be a flexible ureteroscope. The advantages for the patient are major: new instrument for each kidney stone patient, safer procedure, no need for sterilization (the device is already sterile from the factory), absence of contamination, possibility to use this technology immediately and at any time, no repairs required, etc Innovation and technical progress in the field of endourology is reflected in the variety of ureteroscopes available today.

Despite the frequent use of flexible ureteroscopes, a robust evaluation of data regarding the efficacy and comparative technical properties of different ureteroscopes is still lacking. Currently, "personalized minimally invasive surgery" is practiced in accordance with the particularities of each patient and the associated pathology. Flexible retrograde ureteroscopy with laser lithotripsy (Holmium or Thulium) is increasingly used in most urological referral centers worldwide.

The laser lithotripsy technique is relatively simple and involves placing the fiber in contact with the surface of the calculus before activation. The laser is absorbed by water which

gives an advantage considering that tissues are mainly composed of water, the laser energy is absorbed superficially. The laser fiber must be kept at least 1 mm from the ureteral wall.

The most recent development in fURS has been the introduction of digital disposable ureteroscopes. Good visibility is essential to prevent ureteral perforation. After the initiation of laser lithotripsy, a short pause is often required due to the "snowstorm" effect determined by the lithiasis fragments[1].

For flexible intracorporeal lithotripsy, 200, 260 and 365 μm fibers can be used. Ho:YAG laser lithotripsy depends on the pulsed energy generated and the diameter of the fiber. Thus, its effectiveness is correlated with the energy density, which increases with the reduction of the fiber diameter [2].

The effectiveness of Ho:YAG laser lithotripsy is between 91-100% without being modified by the hardness of the stone. The energy required to fragment the stones is lower than that used for other therapeutic applications of the laser. In general, a power of 0.6-1.2 J is used, with a frequency of 5-15 Hz.[3]

About 2 years ago, the first significant clinical evaluations of the use of single-use ureteroscopes appeared worldwide. For every patient, there should be a flexible ureteroscope. The first evaluations with this type of minimally invasive technique present over 200 cases operated with this method, the accumulated experience being one of reference on a European level. In particular, Pusen technology was used: digital flexible ureteroscope PU3022a (Zhuhai Pusen), with very good results. The rate of complete treatment of lithiasis (stone-free) for lithiasis under 2 cm, with any location in the kidney, is over 95%. If comparative studies with classical instruments (reusable ureteroscopes) demonstrated similar technical characteristics (maximum deflection with or without laser fiber), with a slight advantage of disposable ureteroscopes, the full-HD novelty of the image quality brought a special feature. It is safer for the patient when what the surgeon sees and treats is better visualized.

Indications:

- in case of stones where ESWL treatment has failed

- The first treatment alternative in the case of stones located at the level of the lower calyx

- It can be used in the treatment of stones located at the level of diverticula

- Can treat kidney stones much more easily in patients with morbid obesity, skeletal abnormalities, kidney malformations

- Recommended if NLP treatment is contraindicated (hemorrhagic diathesis)

- Flexible ureteroscopy can now treat kidney stones regardless of calyceal groups

Flexible ureteroscopy has no contraindications and, according to the EAU guidelines, it is aimed at kidney stones under 2 cm in any location. Disposable devices are much easier to use and more reliable, they do not require maintenance and handling by other people in advance or training in this regard.

It is a new method that imposes itself as the first therapeutic method going in tandem with Holmium Laser fragmentation.

Retrograde ureteroscopy has evolved over the past few years, and an increasing use of intrarenal surgery is being advocated, in favor of percutaneous techniques and extracorporeal shock wave lithotripsy. Flexible ureterorenoscopes have evolved from the first generation with a limited degree of deformation to highly maneuverable digital models.

Technical limitations of visibility and access, once considered a limitation, have now improved to complement the treatment of stones in all renal calyces. Until recently, reusable ureteroscopes were the only instruments available for performing ureteroscopy.[4] The durability of reusable digital ureteroscopes, although superior to fiber optic models, continues to be a concern.[5,6,7] With each use, recurrent damage can occur, leading to problems such as loss of deflection and, in turn, degradation of deflection performance for subsequent interventions.[8]

In recent years, single-use fURS has been developed as an alternative to reusable ureteroscopes to eliminate another unresolved weakness: the risk of infections. [4] Finally, an important concern for the use of reusable flexible ureteroscopes is sterilization. [8,9] A study by Ofstead et al. showed that even when reusable ureteroscopes were manually cleaned and sterilized with hydrogen peroxide gas, contamination (with bacteria, adenosine triphosphate, hemoglobin, and/or protein) could still be found in the tested endoscopes.[10]

Another possible advantage of flexible URS is the future development of the procedure without radiation exposure through other new guidance methods. [9, 11-13]. The management of renal lithiasis is based on ionizing radiation from diagnostic procedures to treatment and post-operative follow-up. Studies demonstrate that flexible ureteroscopy without fluoroscopy can be performed safely following intraoperative measurements of access sheath insertion in selected cases. This will constitute an additional advantage of this technique for the patient and the medical staff, but further studies are needed in this direction.

There are already many single-use digital fURS on the market. Disposable fURS aim to overcome the main limitations of conventional reusable fURS in terms of acquisition and maintenance costs.[14]

Single-use devices showed similar stone-free rates to reusable ureterorenoscopes. [15, 16]

The ability of a flexible ureteroscope to deflect is essential for intrarenal procedures, as it is necessary for accessing and exploring the renal pelvis, calyces, and approaching diverticula. [15] It is particularly important when attempting treatment of lower pole calculi because the lower pole has been noted to be more difficult to access.

Kam J. et al. performed a prospective comparative study that included 31 patients who underwent retrograde URS using the UscopeUE 3022 versus 64 patients who used the Olympus URF-V2. The URF-V2 group scored higher in visibility and maneuverability compared to the Uscope 3022.[17]

Single-use fURS have the distinct advantage of not requiring any sterilization process. In terms of maneuverability, quality of vision and clinical efficacy, they are similar to reusable fURS. Other advantages are the avoidance of increased rework and repair costs. But the main debatable issue with single-use fURS remains cost. In some situations, even a new reusable fURS model can be used for an average of 21 procedures before requiring repair.2 In addition, additional costs come from the higher rate of urinary tract infections, total operative time, etc. may result in substantial additional costs. The costs of single-use fURS are still considered to be relatively high.

Study Oversight

This study aimed to compare two of the latest flexible reusable ureteroscopes with a single-use ureteroscope in a variety of scenarios, including intraoperatively as well as ex vivo, using objective and subjective factors. The aim of this study was to compare disposable fURS with conventional reusable fURS in terms of their functional characteristics. To date, we have compared two of the latest flexible reusable ureteroscopes with the disposable one, both intraoperatively and ex vivo, using objective and subjective parameters. The number of sessions needed to extract the calculus, the time needed to perform the intervention, the need for patient presentation, the impact of the calculus treatment on the instrumentation was determined, referring to the reusable devices so that the use of one of them can be recommended.

The aim of the study was to obtain statistically significant data on the results of Holmium laser lithotripsy for kidney stones with the help of disposable flexible ureteroscopy.

It was desired to determine the complication rate, the number of sessions required to extract the stone, the time required to perform the intervention, the need for the patient's presentation, the impact of stone treatment on the instrumentation, referring to the reusable devices so that the use of one of them can be recommended.

Materials and Method

A prospective study was carried out between 2020 and 2023, to compare disposable and reusable flexible ureteroscopes to verify the efficiency and safety of these endoscopes for the same type of endoscopic intervention.

We compared three of the latest types of flexible ureteroscopes: two reusable digital models (Olympus URF-V and Olympus URF-V2) and a single-use model (Pusen MedicalUscope UE3022). To be as close as possible to the real working conditions, the reusable ureteroscopes were initially used and rechecked before starting the procedures to ensure their optimal functioning. The main practical outcome of these measurements is to predict in vivo performance, thus contributing to optimal case selection. Based on the available literature, the three domains we selected have not been properly compared and tested.

We included patients with single kidney and ureteral lithiasis hospitalized in the Urology Department of Sp Sf Ioan, where the intervention is represented by flexible ureteroscopy, after signing the informed consent by the enrolled patients.

The inclusion criteria :

- age older than 18 years,
- sterile urine culture or patient with 72 hours of antibiotic treatment prior to the intervention,
- single kidney stone identified by ultrasound or RRVS.

Exclusion criteria:

- age under 18 years
- coagulation disorders
- comorbidities with high anesthetic risk
- acute pyelonephritis
- urine culture$\geq 10^5$UFC/ml
- history of ureteral stenosis requiring presentation

Also, risk factors such as:

Urological pathologies (Neoplasias, Anomalies of the urinary tract, Urinary lithiasis, Benign Prostate Hyperplasia)

Comorbidities (Diabetes, Chronic Kidney Disease)

Location calculus lower, middle, lower or pelvis, ureteral

Presence of a urinary catheter (ureteral stent, urethro-vesical probe)cation calculus lower, middle, lower or pelvis, ureteral

All patients were biohumorally examined, following the following parameters: Blood count, Urea, Creatinine, Glucose, Urinary water ultrasound, UIV, RRVs, CT, Urine summary, Uroculture

If a patient had a positive urine culture, he was treated with an antibiotic according to the antibiogram and rescheduled later.

Each patient received prophylactic antibiotic therapy according to the EAU Guidelines.

Patients were randomized into three groups: one group treated with Uscope UE3022 flexible ureteroscope (Pusen, Zhuhai, China) and two groups treated with two different reusable ureteroscopes Olympus URF-V and Olympus URF-V2.

The patients were reevaluated with native CT at 1 month. The CT image without stones or with stones smaller than 3 mm and an asymptomatic patient with a negative uroculture were considered stone-free criteria.

The database includes: the initials of the patient's name and surname, the patient's sex, the urban/rural environment, the patient's weight, the size of the stone, the composition of the stone, the year of diagnosis of lithiasis, the initial presentation of the patient with the JJ probe, the UTI before the intervention, the location of the kidney stone according to Moore and O^Boyle, postoperative fever over 38 degrees, residual postoperative lithiasis, stone free (remaining stones below 3 mm), use of probe with basket, use of flexible access sheath, operative time, EKG changes, preprocedural hydronephrosis, urinary lithiasis history, antecedents heredocollaterals, postURS SUV maintenance days, pre-intervention and post-intervention hemoglobin values at 24 hours, pre-intervention blood glucose values, pre-procedural urea/creatinine values, pre-procedural/post-procedural leukocyte values, intraoperative urine culture, initial antibiotic treatment, anticoagulant treatment, technical details related to ureteroscopes.

For all 3 groups of patients, the operative technique was the same. Urethrocystoscopy was performed with the identification of the ureteral openings and subsequent placement of the guide in the ureter related to the lithic kidney, the cystoscope was removed and a lumen catheter was passed over the guide. This 8-10 Fr catheter allowed the placement of a second working guide that facilitated the insertion of the flexible ureteroscope. The flexible ureteroscope was then passed over the working guide to the pathologic point. Dilation of the ureteral orifice with the double-lumen catheter is usually sufficient to allow passage of the flexible ureteroscope. The working channel of flexible ureteroscopes is not centrally located, so the tip of the ureteroscope is positioned eccentrically to the guidewire. If the flexible ureteroscope does not pass through the

ureteral orifice, it should be rotated 90 to 180 degrees on the guidewire to better position the tip of the ureteroscope relative to the ureteral orifice. If difficulty is encountered in passing the flexible ureteroscope through the ureteral orifice, a dilator catheter (Nottingham) or dilator balloon catheter can be used to dilate the ureteral orifice.

A safety guide has routinely been used during upper tract endoscopy to maintain access throughout the procedure, allowing ureteral stent placement if ureteral injury occurs.

If passage of the flexible ureteroscope is difficult in the absence of any significant ureteral stricture or other source of obstruction, the use of a polyurethane nitinol guide may be helpful. As previously presented, these stiffer and smoother wires allow for more efficient transmission of thrust from the operator to the tip of the ureteroscope.

Basic movements of the flexible ureteroscope include deflection, rotation, advancement and retraction of the ureteroscope. The active deflection is obtained by actuating with the police a mobile part at the level of the body of the ureteroscope. For lower caliceal lithiasis, repositioning of the calculus was practiced only for the reusable ureteroscope to minimize deflection overload at this level.

The dusting was carried out with the help of the 270 µm laser fiber of the Holmium-YAG Cyber Ho 100 W device at 0.6 Joule and 45 Hz. The cosulet probe was also used to extract the lithic fragments. At the end of the procedure, a JJ 6 Ch probe was mounted to facilitate the removal of post-laser fragmentation fragments and avoid the occurrence of Stain-Strasse Syndrome. The JJ catheter was maintained for 2-4 weeks. The collected data were analyzed using the Student t test, the limit of statistical significance was considered $p < 0.05$.

Synthesis of chapters

Single-use versus reusable ureteroscopes - a functional evaluation of the parameters

Olympus URF-V has an external diameter of 8.5Fr, 9.9 Fr external diameter at insertion, an effective length of 670 mm, a standard working channel of 3.6 Fr, 180 a deflection up and 270 a deflection down.

The Olympus URF-V2 is 8.4Fr, 670 mm long and is more rigid than its predecessor, for easier access to the kidneys. It also has a standard working channel of 3.6 Fr and a bi-directional deflection of 275. Both reusable ureteroscopes have an insertion tube with improved rotation function, allowing the operating surgeon to hold the endoscope in a neutral position and independently rotate the insertion tube.

Uscope UE 3022 is a disposable digital ureteroscope with 9.2 Fr distal tip, 650 mm length, 3.6 Fr working channel for irrigation and instrument insertion and bi-directional deflection of 270^0.

Irrigation flow rate and diflection loss when accessory instruments were inserted into the working channel were compared in an ex vivo setting.

Irrigation flow and peak deflection in all three ureteroscopes were measured with an empty working channel and accessory instruments in place: a 0.035-inch guidewire, a 2F ZeroTip basket, and a 270 micron Ho:YAG laser fiber . For all these tests, the ureteroscope was fixed in the right position, to avoid possible variations in flow and deformation related to a curved working segment.

For irrigation flow measurements, saline was used 150 cm above the endoscope. Flow was measured with the working segment of the fURS in the upright position, initially with the channel empty and then with different instruments occupying the channel.

The measurements were repeated three times. The mean value was finally used. The angle of deviation was measured between the tangents to the right working segment and the deviated tip with a protractor on a photograph of the ureteroscope superimposed on graph paper. The deflection capabilities of all fURS were evaluated in different positions, starting with the

empty working channel and then with the channel occupied by various instruments: 270 μm laser fiber, a 2Fr basket, and a 0.035 inch guide. The maximum deflection was recorded in both directions in all positions. In the last two years, a total of 60 patients with lithiasis were included in the present study. Among them, 20 consecutive patients underwent retrograde URS using URF-V, 20 consecutive patients with URF-V2, and 20 consecutive patients with disposable URS. Flexible ureteroscopes were compared intraoperatively by the same urologist. At the end of each case, the surgeon evaluated on a 5-point scale (1 – bad, 2 – poor, 3 – fair, 4 – good, 5 – very good) the visibility and maneuverability of the fURS for each case.

A ureteral access sheath was used in all 60 cases to avoid any possible injury. During the procedures, the performance and limitations of each fURS were recorded and compared. Tool durability, optical system damage and deformation losses were also recorded as very important parameters.

Regarding maneuverability and quality of vision, they are similar: reusable (URF-V and URF-V2) versus disposable (USCOPE UE3022) visibility score 4.8, 4.7 versus 4.8, $p>0.4$.

The maneuverability score was similar when using Uscope UE3022 and URF-V2 (4.2) and significantly lower when URF-V was used (3.8, $p=0.03$)

Irrigation was similar to reusable ureteroscopes and 50% improved with disposable ureteroscopes.

When inserting a 270 micron Holmium laser fiber, the deflection loss was 13% for URF-V2 and 8.7% for URF-V (significantly lower, $p<0.07$) Several studies have shown that reusable ureteroscopes suffer damage, sometimes requiring repairs after 10 to 20 procedures. [17] Technological progress has made life spans much longer. [18]

Single-use fURS were developed with the intention of improving some of the unfavorable characteristics that reusable ureteroscopes may have, such as their availability, sterilization, or expensive repairs. In recent years, many disposable ureteroscopes have been developed, but not all of them have been properly studied and compared. Comparative studies of different models of flexible ureteroscopes are extremely useful in describing differences between manufacturers in terms of irrigation rates or deformation with either empty or occupied working

channels. One of the first in vitro evaluations of UscopeUE3022by was done by Marchini et. al. [16] while Salvado et al. [15] did an intraoperative evaluation, reporting stone-free rates of up to 95% in 71 patients with a mean stone size of 11.4 mm. In 2017, Johnston et al. performed a prospective cohort study to evaluate UscopeUE3022 in terms of ease of insertion, deformation, image quality, maneuverability and overall performance, study with a total of 56 procedures performed in 11 international centers. The UscopeUE3022 performed well in handling, deflection and limb fatigue.[19]

Our study showed that all 3 models have specific advantages and disadvantages. Disposable ureteroscopes have the clear advantage that they do not require sterilization. They are similar to the reusable ureteroscope in terms of maneuverability, image quality and clinical efficiency. Other disadvantages include the costs of sterilization and repairs.

In this study, only one endoscope from each reusable model was tested. We also did not measure stonefree rate or postoperative complications. This, together with the small sample size and number of procedures are the limitations of the evaluation.

According to the research paper, disposable and reusable ureteroscopes are at least comparable in terms of visibility and maneuverability.

Single-use ureteroscopy appears to be superior in terms of irrigation flow and deflection. It also has the potential to provide additional resources when it encounters certain difficulties

Treatment of renal lithiasis with the single-use ureteroscope versus the reusable one

Disposable flexible ureteroscopes were developed as an alternative to reusable ureteroscopes, which have the problem of damage after multiple uses, special equipment for sterilization and the cost of repairs. Some disposable ureteroscopes have similar features to reusable flexible ureteroscopes, and others have even more advanced features. There are already over twenty models of su-fURS on the market, each with its own unique set of attributes and level of performance.

One of the most famous and used ureteroscopes is the Uscope 3022. The purpose of this study was to analyze the effectiveness and safety of Pusen Uscope UE 3022.

Material and method

A randomized prospective study was carried out in the Urology Department of St. John's Hospital in the period 2021-2023, using the Pusen Uscope 3022 single-use flexible ureteroscope.

After signing the informed consent, we included 111 patients with single kidney stones, of which 100 met the inclusion criteria. The inclusion criteria were the following: age older than 18 years, sterile urine culture or patient with 72 hours of antibiotic treatment prior to the intervention, single renal stone identified by ultrasound or RRVS.

Exclusion criteria: age under 18 years, coagulation disorders, comorbidities with high anesthetic risk, acute pyelonephritis, urine culture$\geq 10^5$UFC/ml, history of ureteral stenosis requiring presentation, multiple lithiasis, malformations of the upper urinary tract.

Also, risk factors such as:

Urological pathologies (Neoplasias, Anomalies of the urinary tract, Urinary lithiasis, Benign Prostate Hyperplasia), comorbidities (Diabetes, Chronic Kidney Disease), location calculus lower, middle, lower or pelvis, ureteral, presence of a urinary catheter (ureteral stent, urethro-vesical probe)cation calculus lower, middle, lower or pelvis, ureteral

All patients were biohumorally examined, following the following parameters: blood

count, urea, creatinine, glucose, urinary water ultrasound, UIV, RRVs, CT, urine summary, uroculture. If a patient had a positive urine culture, he was treated with an antibiotic according to the antibiogram and rescheduled later.

Each patient received prophylactic antibiotic therapy according to the EAU Guidelines.

The patients were analyzed in three groups according to the size of the kidney stones: group I with stone size <10 mm, group II with stone size between 10-20 mm, group III with stone size > 20 mm but not larger than 40 mm.

Group I was represented by 54 patients, group II by 34 patients and group III by 12 patients for whom 57 procedures were performed (group I), 39 (group II) and 17 (group III). The average age of the patients was 65+/-2.4 years (group I), 67+/-3.9 years (group II) and 66+/-2.5 years (group III). The average stone size was 8.3 mm (group I), 12 mm (group II), 27 mm (group III)

The PUSEN Uscope 3022 model was used.

Results

The results were evaluated using the obtained success rates and the Clavien-Dindo system.

In the first group of 54 patients, after one procedure, a stone-free status of 94% resulted, which represented the complete resolution of a number of 51 patients. For the remaining 3 patients, a second flexible ureteroscopy intervention was performed, subsequently obtaining the stone-free stage for them as well. Thus, in the first batch, 57 procedures were performed.

In the second group, 34 flexible ureteroscopies were performed, obtaining a stone-free status in 88.2%, representing 34 patients completely resolved. Thus, 4 patients needed a second intervention, but only 3 of them returned to the second flexible ureteroscopy. After the second procedure, the stone-free increased to 91.2%, another 2 patients needing endoscopic reintervention for the third time with a 94.1% success rate. Thus, the second batch required the performance of 39 procedures.

In the 3rd group, 12 flexible ureteroscopies were initially performed with a stone free rate of 75%, representing 9 patients. The rest required a second endoscopic procedure, reaching Stone-free status in 83.3% of cases. 2 patients required a second flexible ureteroscopic intervention with a success rate of 91.7%. Thus, a total of 113 procedures were performed with

an overall success rate of 90% after one procedure, 95% after two procedures, 97% after three procedures.

In group I, most of the stones were located at the pelvis and upper calyx level (28, respectively 13 patients) and at the middle and lower calyx level in the case of 7, respectively 6 patients. In group II, the majority of patients also had stones located in the pelvis and upper calyx (18, respectively 7 patients) and only 5 in the middle calyx and 4 in the lower one. In group III, 8 patients had pelvic stones and 2 each in the middle and lower calyx. We had no patients with stones in the upper calyx in this group.

The collected data were analyzed using the Student t test, the limit of statistical significance was considered $p < 0.05$.

The comparator was represented by a group of 98 patients operated with URF-V2, in a retrospective study with/without fluoroscopy between September 2020 and December 2021. Thus, 98 patients with kidney stones were evaluated. We included patients with single kidney and ureteral lithiasis hospitalized in the Urology department of Sp Sf Ioan, in which the intervention is represented by flexible ureteroscopy. The patients were divided into two groups - the first group with the use of fluoroscopy included 24 men and 23 women and the second group without fluoroscopy included 31 men and 20 women.

The demographic characteristics of the patients, the characteristics of lithiasis, the use of fluoroscopy, the operative time (in minutes) and postoperative complications, the stone-free rate were compared between the two groups (Group I with fluoroscopy and Group II without fluoroscopy). All patients had analyzes (hemoleukogram, serum creatinine, coagulation, urine culture).

CT and ultrasound were used to diagnose urolithiasis preoperatively. The location, dimensions and characteristics of the stones were estimated using preoperative CT.

The informed consent was signed by all patients. Besides the fact that all patients had negative urine cultures, they received 1 g of 3rd generation cephalosporin before the operation.

As an alternative technique, ureteroscopy was performed without Rx exposure in selected patients to later compare with a control group. The technique used was similar to the one used

for radiological exposure, with the exception of pre-interventional guide measurements and at the time of ureteroscope insertion.

The length of the inserted guide wire was measured from the ureteropelvic junction to the external meatus. Later, without fluoroscopy, the ureteroscope was withdrawn and reintroduced on the guidewire into the urinary bladder and later into the ureter, ensuring that there was no resistance to the insertion of the sheath (the 10.7/12F Cook Flexor access sheath was used), otherwise the patients were moved in the group with radiological control and C-ARM was used. Fragmentation of the calculations was performed with the Holmium laser using the 270 μm fiber in dusting and fragmentation mode. The basket probe was also used to extract the stones, an inspection of the pyelo-calyceal system was performed and the JJ probe was mounted in all patients postprocedurally.

Also, if the easy access sheath could not be mounted initially, a JJ probe was pre-procedurally mounted for 2 weeks.

On the first postoperative day, all patients had an x-ray, and one month postoperatively, they underwent ultrasound or CT with a low radiation dose. The residual lithiasis and the stone-free rate were thus established. The stone-free state was defined in an asymptomatic patient, without signs of infection, without obstructive lithiasis or with fragments smaller than 3 mm.

The Clavien classification system was used for postoperative complications.

Python version 3.11.2 was used for the statistical analysis.

The results were evaluated using the obtained success rates and the Clavien-Dindo system.

In the first group of 54 patients, after one procedure, a stone-free status of 94% resulted, which represented the complete resolution of a number of 51 patients. For the remaining 3 patients, a second flexible ureteroscopy intervention was performed, subsequently obtaining the stone-free stage for them as well. Thus, in the first batch, 57 procedures were performed.

In the second group, 34 flexible ureteroscopies were performed, obtaining a stone-free status in 88.2%, representing 34 patients completely resolved. Thus, 4 patients needed a second intervention, but only 3 of them returned to the second flexible ureteroscopy. After the second procedure, the stone-free increased to 91.2%, another 2 patients needing endoscopic reintervention for the third time with a 94.1% success rate. Thus, the second batch required the performance of 39 procedures.

In the 3rd group, 12 flexible ureteroscopies were initially performed with a stone free rate of 75%, representing 9 patients. The rest required a second endoscopic procedure, reaching Stone-free status in 83.3% of cases. 2 patients required a second flexible ureteroscopic intervention with a success rate of 91.7%. Thus, a total of 113 procedures were performed with an overall success rate of 90% after one procedure, 95% after two procedures, 97% after three procedures.

The success rate in the first group was 100% after 2 procedures in terms of the dimensions of the calculus - with the smallest dimensions of the 3 groups, in group II and III with larger dimensions of the calculus, 3 procedures were necessary, obtaining a rate of success increasing from one procedure to another as follows: in group II the success rate after the first procedure was 88.2%, 91.2% after the second and 94.1% after the third procedure . In the third group, the success rate was 75% after the first procedure, 83.3% after the second procedure and 91.7% after the third procedure.

A total of 113 procedures were performed with an overall success rate of 90% after one procedure, 95% after two procedures, 97% after three procedures.

In the comparison group, 98 cases were analyzed, 24 men and 23 women in Group I (with fluoroscopy) compared to 31 men and 20 women in Group II (without fluoroscopy) with an average age of 63.2 years in Group I and 61.6 years in Group II.

In most cases, lithiasis was in the renal pelvis in Group I and at the level of the lower calyx in Group II. The less frequent locations were located in the middle calyx in group I and the upper calyx in group II.

The success rate in the study in which the URFv2 ureteroscope was used was 89% in the group with fluoroscopy and 92% in the group without fluoroscopy.

The overall success rate in the study using the Pusen ureteroscope was 90% after one procedure, while in the comparison study using the reusable Olympus URFV2 ureteroscope it was 89% in the group with fluoroscopy and 92% in the group without fluoroscopy.

The complications were mostly medium level classified Clavien I and II and were treated successfully. There were no complications during the insertion of the access sheath.

In most cases, the lithiasis was in the renal pelvis and the rest of the stones were at the caliceal level.

There was an increase in the stone-free rate in Group 1 and 2, but the statistical analysis did not show significant differences.

Most of the complications were minor under Clavien I (which did not require pharmacological or surgical treatment, endoscopic or radiological intervention, mild analgesics, antiemetics, antipyretics, diuretics were used) and Clavien II (different medication was used than the one previously used, including blood transfusion and parenteral nutrition). There were also complications IIIa and Ivb in the Group with bulky stone that required admission to Intensive Care. The subsequent evolution was favorable.

The success rate was the highest in the first group after 2 procedures, being also influenced by the size of the calculus, in this group having the smallest size below 1 cm. With the increase in size of the calculations in groups II and III, the success rate was lower and required a third procedure

Complications in the study that used the disposable Pusen ureteroscope were Clavien-Dindo I to the same extent in the 3 groups (4 in Group I, 4 in Group II and 4 in Group III) and Clavien Dindo II in almost equal proportion (2 in Group I, 3 in Group II and 3 in Group III) compared to the comparison group in which there were more Clavien I complications than Clavien II type ones. Unlike the comparison group, in the one in which the Pusen ureteroscope was used, there were also complications that required admission to ATI Clavien IIIa and Ivb. Thus, the percentage rate of complications per total was 11.11% in the first group, 23.52% in the

second group and 91.66% in the third group compared to the comparator group in which URF v2 was used with a complication rate of 10.64% in the group with fluoroscopy and 9.8% in the group without fluoroscopy.

In the groups of the comparative study, all complications were of medium level classified Clavien I and II and were treated successfully. There were no complications during the insertion of the access sheath. In two cases, the guide was not visualized sonographically at the level of the pyelocalyceal system after performing the semi-rigid ureteroscopy, so the installation of the access sheath was delayed until the reassembly of the access guide.

Conclusions and personal contributions

These findings provide reasons for an optimistic future. Thus, technological and technical advances have allowed the expansion of indications for flexible ureterorenoscopy (fURS). The development of smaller caliber ureteroscopes, with their increased deflection capacity, single-use ureteroscopes together with Holmium or Thulium lasers (TFL), make fURS an attractive treatment modality for addressing the often challenging intrarenal anatomy. ” in these special situations [20]. Although in 2021 there is still no “queen” of the minimally invasive treatment of renal lithiasis on the malformed kidney, flexible ureteroscopy is exponentially used successfully to treat these “special” endourological patients. Anatomical variations of the kidneys due to congenital abnormalities certainly lead to difficulties in locating or accessing stones. Current technology makes the notion of "stone-free" more and more possible in these patients as well, even if "multi-staged ureteroscopy" is now needed in many cases.

It is known that single-use flexible ureteroscopy is an effective method of treating renal lithiasis, it can now treat kidney stones regardless of calyceal groups. This method has been adopted on a large scale, the only limitations being related to the costs of acquisition and maintenance, sterilization / risk of infection and poor durability of reusable ureteroscopes. Disposable ureteroscopes have become a solution to the problems associated with reusable ureteroscopes.

The novelty and originality of the doctoral thesis comes from the presence of the permanent technological evolution that led to the appearance of this type of single-use device that can in the future create the premises of increased accessibility with the follow-up of a large number of patients who can benefit from minimal modern urological treatment invasive.

Flexible ureteroscopy has no contraindications and is performed according to the EAU guidelines for kidney stones under 2 cm with any location. Single-use devices are much easier to use and more reliable, they do not require maintenance and handling by other persons in advance or preparation in this regard.

The difficulties encountered during the doctorate years were the patient's low adherence to the urological treatment - the periodic return for successive sessions of fragmentation and stone extraction, the periodic follow-up of patients through various visits set at certain time intervals, the control study group represented by operated patients through flexible multipurpose URS, during the pandemic.

Through the doctoral thesis, I achieved a more detailed knowledge of the single-use flexible ureteroscopic method for the treatment of urinary lithiasis. It has been shown that the therapeutic success rate with this treatment method is almost 100%. Another great advantage is the possibility of performing flexible ureteroscopy on an outpatient basis, which lowers therapeutic costs. Using the anatomical ways, it becomes safe even for more fragile, elderly or overweight/obese patients.

The development of single-use ureteroscopes with smaller caliber, with increased deflection capacity, make fURS an attractive treatment modality for approaching the often challenging intrarenal anatomy through the prism of the patient's particularities. In our country, disposable ureteroscopes are an alternative to reusable ureteroscopes. There is still a big difference in price, although the reasoning behind the creation of disposable ureteroscopes was to counterbalance the costs necessary for the repairs and sterilization of conventional ureteroscopes.

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