

EFFICACY AND SAFETY OF FLEXIBLE DISPOSABLE URETERORENOSCOPE WISCOPE – A SINGLE INSTITUTION EXPERIENCE

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Received 26 Dec 2021, Accepted 25 Jan 2022

<https://doi.org/10.31688/ABMU.2022.57.1.04>

ABSTRACT

Introduction. According to the European Association of Urology guidelines, flexible ureterorenoscopy is one of the treatment modalities for kidney stones less than 2 cm. Disposable flexible ureterorenoscopes are superior to reusable ones in terms of scope performance deterioration, damage repair costs and special gas-sterilization equipment. Despite the undeniable progress of disposable flexible ureterorenoscopes in everyday urological practice, the literature lacks a rich database on their technological design and clinical effectiveness.

The objective of this paper is to present our experience in the management of kidney stones by a flexible disposable ureterorenoscope – WiScope™.

Material and methods. Between the 1st of January 2020 –the 1st of January 2021, 76 patients with kidney stones were treated in our centre by flexible ureterorenoscopy and laser lithotripsy. The evaluation of demographics, efficacy and safety of the procedure was performed.

Results. A successful procedure was recorded in 94.7% (72/76) of the patients. We evaluated the total

RÉSUMÉ

Efficacité et sécurité de l'urétérorénoscope flexible jetable – une expérience institutionnelle unique

Introduction. Selon les directives de l'Association Européenne d'Urologie, l'urétérorénoscopie flexible est l'une des modalités de traitement des calculs rénaux de moins de 2 cm. Les urétérorénoscopes flexibles jetables sont supérieurs aux réutilisables en termes de détérioration des performances de l'oscilloscope, de coûts de réparation des dommages et d'équipement spécial de stérilisation au gaz. Malgré les progrès indéniables des urétérorénoscopes flexibles jetables dans la pratique urologique quotidienne, la littérature mondiale manque d'une riche base de données sur leur conception technologique et leur efficacité clinique.

L'objectif de l'article est de présenter notre expérience dans la gestion des calculs rénaux avec un urétéroscope jetable flexible – WiScope™.

Matériel et méthodes. Entre le 1er janvier 2020 et le 1er janvier 2021, 76 patients souffrant de calculs rénaux ont été traités dans notre centre par urétéroscopie

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stone-free rate 8 weeks after the intervention, which was 94.4% (70/72). The complications rate was 13.1% (10/76). No serious adverse events were observed.

Conclusions. The use of flexible disposable ureterorenoscopes has proven a good efficacy and safety. WiScope™ is a comparable option among all available flexible disposable ureterorenoscopes, in terms of all basic characteristics.

Keywords: flexible ureterorenoscopy, single-use, efficacy, safety.

List of abbreviations:

FURS – flexible ureterorenoscopy

SFR – stone-free rate

US – ultrasound

CT – computed tomography

MCCS – modified Clavien classification system

INTRODUCTION

Urolithiasis accounts for about 50% of daily urological practice and a large proportion of urological emergencies¹. According to the European Association of Urology guidelines, flexible ureterorenoscopy (FURS) is one of the treatment modalities for kidney stones less than 2 cm of size². The results of this type of procedure were first published in the literature by Marshall in 1964³. Twenty-three years later, Bagley implemented in clinical practice a disposable flexible ureterorenoscope⁴.

Disposable flexible ureterorenoscopes are superior to reusable ones in terms of scope performance deterioration, damage repair costs and special gas-sterilization equipment. With the development of this type of technology, several models of major global manufacturers – Polyscope™, LithoVue™, Uscope 3022™, WiScope™ and others appeared on the market.

Despite the undeniable progress of disposable flexible ureterorenoscopes in everyday urological practice, literature lacks a rich database on their technological design and clinical effectiveness.

THE OBJECTIVE OF THIS PAPER is to present our experience in the treatment of urolithiasis by WiScope flexible disposable ureterorenoscope, its design and clinical efficacy characteristics.

MATERIAL AND METHODS

The study protocol was approved by the local ethics committee (Approval no. 7/ 10 May 2021). We retrospectively analysed 76 patients with kidney stones less than 2 cm, treated by flexible ureterorenoscopy in our centre (UMHAT “St. George“- Plovdiv) from the 1st of

flexible et lithotripsie au laser. Une évaluation de la démographie, de l'efficacité et de l'innocuité de la procédure a été réalisée.

Résultats. Un procédé réussi a été enregistré chez 94,7% (72/76) des patients. Nous avons évalué le taux total sans calculs à la 8e semaine après l'opération, qui était de 94,4% (70/72). Le taux de complications était de 13,1% (10/76). Aucun événement indésirable grave n'a été observé.

Conclusions. L'utilisation d'urétéroscopes jetables flexibles a prouvé son efficacité et sa sécurité. WiScope® est une option absolument comparable parmi tous les urétéroscopes jetables flexibles disponibles sur le marché en termes de toutes les caractéristiques de base.

Mots-clés: urétérorénoscopie flexible, à usage unique, efficacité, tolérance

January 2020 to the 1st of January 2021. The interventions were performed by only two surgeons experienced in flexible ureterorenoscopy. Patients with multiple stones, pre-existing ureteral stricture, renal failure, active inflammatory disease of the genitourinary system and pregnancy were excluded from the study.

The hospital database and “Gama CodMaster“ software product were used to obtain the following information: patient's demographics, size and localization of stones, operative time, number of hospitalization days, stone-free rate (SFR), post-operative complications and scope malfunction (bad image quality), loss of deflection and issues with the working channel. The preoperative examinations of patients included urinalysis, complete blood count, biochemistry, and imaging diagnoses – ultrasound (US) and computed tomography (CT). All patients had negative urine culture, with or without previous antibiotic treatment.

As a usual practice in our department, we placed a JJ ureteral stent two weeks prior to the procedure, so all the patients were pre-stented. The procedure always begins with a cystoscopy with 26Fr cystoscope (Olympus, Hamburg, Germany), removal of the JJ ureteral stent and placement of a hydrophilic guide (Roadrunner™, Cook Medical, Bloomington, USA) in the corresponding ureter straight to the renal pelvis. This is followed by ureteroscopy with a 6.4Fr semi-rigid ureteroscope (Olympus, Hamburg, Germany), which helps to dilate the ureter, and the placement of a second hydrophilic guide – the so-called “safety guide-wire“. Ureteral access sheath 12/14Fr (Flexor™, Cook Medical, Bloomington, USA) was used in all the patients, with the following advantages: optimal visualization, minimum intra-pelvic pressure, easier extraction of the fragments. After the outflow of urine from

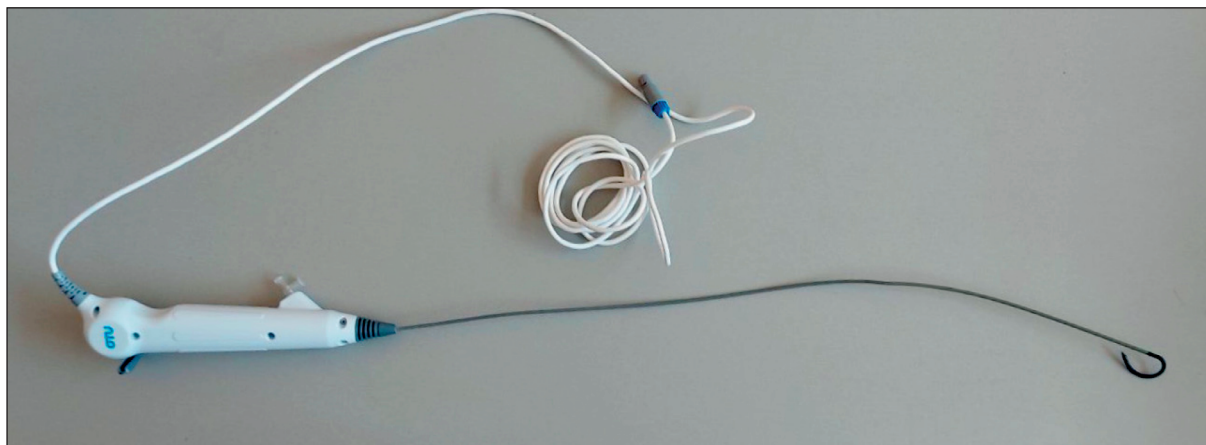


Figure 1. WiScope flexible disposable ureterorenoscope.

the ureteral sheath, the guide wire was pulled out. A disposable flexible ureterorenoscope (WiScope™, OTU Medical, San Jose, USA) and a 273µm holmium laser fiber (Cook Medical, Bloomington, USA) were subsequently used for treatment. WiScope has a similar design to other disposable ureterorenoscopes on the market (Figure 1). Most of the components are plastic (without camera connection to the screen) and it has a built-in camera. This type of construction makes it very light. The shaft of the WiScope is 8.6 Fr with a 3.6 Fr working channel, and a deflection of 275°. The usual technique for stone fragmentation was dusting, and basketing (N-gage™, Cook Medical, Bloomington, USA) was performed on the fragments larger than 2 mm. Following the lithotripsy, a JJ ureteral stent was left. In the absence of fever or bacteremia, the urethral catheter was removed on the first post-interventional day and stent removal was done after 14-21 days. Common broad-spectrum antibiotics were used for prophylaxis.

The stone size was quantified as the mean diameter of each stone on CT images. The success rate of flexible ureterorenoscopy was defined as accessing the collecting system of the kidney and stone visualization. The total SFR, defined as residual stone less than 5 mm, was evaluated by CT scan 2-3 weeks (just before stent removal) and 3 months post-surgery.

Statistical data processing was performed with SPSS 27.0v software. The statistical methods used were descriptive analysis of all variables, Fisher's exact test and T-test.

RESULTS

The group of study included 76 patients, 56 men and 20 women. The average age was 39 years (Table 1) and the average stone size was 1.34 cm. Different

Table 1. Patients' demographics.

Sex	
male	56
female	20
Age (years, range)	16-74

Table 2. Stones' characteristics.

Stone size (cm)	1.34 ± 0.44
Upper calyx	16
Middle calyx	20
Lower calyx	18
Pelvis	22

Table 3. Surgical data of the patients from the group of study.

Operative time (min)	58.3 ± 16.4
Hospitalization (days; range)	3-4
Success rate of FURS	94.7% (72/76)
SFR at 3 months	92.1% (70/76)
Lower calyx	77.7% (14/18)
Pelvis, middle and upper calyx	96.5% (56/58)

localizations of stones were observed: 16 in the upper, 20 in the middle, 18 in the lower calyx and 22 in the renal pelvis (Table 2).

The following laser settings were used: 1J, 10-20Hz (dusting technique). In 48 patients, after stones fragmentation by laser, their extraction was performed using a nitinol basket. All patients underwent only one lithotripsy procedure. The intervention outcomes are presented in Table 3.

The average intervention time was 58 minutes and the average hospitalization period three days.

Table 4. Complications classified according to MCCS.

Grade	Complication	Total (n=10)
Grade I	Fever requiring antipyretics	2
Grade II	Fever requiring antibiotics	1
	Hemorrhage	2
Grade IIIb	Steinstrasse	1
	Ureteral trauma	1
Grade IVb	Bacteremia	3

The success rate of flexible ureterorenoscopy was 94.7% (72/76). Among 72 patients, in 71 lithotripsy was performed. The total SFR was 92.1% (70/76), SFR of the lower calyx was 77.7% (14/18), and 96.5% (56/58) in the middle-upper calyceal and renal pelvis.

The incidence of complications was 13.1% (10/76) and they were stratified according to the modified Clavien classification system (MCCS). None of the patients had serious adverse outcomes (Table 4).

Two patients had severe bleeding, requiring transfusion and conservative therapy without surgery. The steinstrasse (accumulation of ureteric stone fragments causing a ureteric blockage) patient underwent ureteroscopy to remove stones in the distal ureter. Antibiotic and fluid treatments were routinely given in patients with infectious complications. Ureteral injury (partial transection) was treated with a double-J stent in place for 6 weeks, without stenosis as complication. Regarding the flexible disposable ureterorenoscopy, no damage or any other problem was observed.

DISCUSSION

The incidence of urolithiasis world-wide varies between 5-15%, and in most cases requires surgical treatment⁵. Flexible ureterorenoscopy has several advantages: minimal invasiveness, safety, efficacy, almost complete absence of pain and rapid recovery⁶. After its introduction into clinical practice in 1964, it underwent important technological improvements in terms of fiberoptic bundles for light transmission and image relay, passive and active deflections in upward and downward directions, working channel and miniaturization of the outer diameter. However, the question of ureterorenoscopes' durability has always been on the agenda: they are extremely fragile, especially in the hands of inexperienced surgeons. Data from several studies have been published in the literature, showing the average time of use of various flexible reusable ureterorenoscopes before damage and repair⁷⁻⁹.

It is well known that the economic benefits of flexible reusable ureterorenoscopes strongly depend on how many times they are used before damage appears. The introduction of this type of surgical intervention in the daily practice of the hospital requires a serious initial investment, which is unaffordable for some centres^{10,11}. Also, flexible reusable ureterorenoscopes require a high level of disinfection between procedures, a well-trained team and available sterilization equipment, all of which lead to increased costs¹². In their study, Martin et al. proved that the use of flexible reusable ureterorenoscopes is justified only in centres that perform more than 99 procedures annually¹³. With the development of technology in urology, the use of flexible disposable ureterorenoscopes was introduced. After Bagley's introduction to clinical practice in 2009, Boylu et al. used a disposable fiberoptic flexible ureterorenoscope named SemiFlex™ Scope, which was made of a reusable eyepiece and a semiflexible shaft with a 3.3-Fr working channel¹⁴. For unknown reasons, this scope did not gain popularity, and no further evaluation has been done. Next on the market was PolyScope™, which was composed of a single-use flexible catheter, reusable 10,000 pixels fiberoptic bundles, but had only a unidirectional deflection of 220°-240° of maximum deflection¹⁵. Hu et al. have reported that the maneuverability and vision of the PolyScope was not good enough to perform a satisfactory procedure¹⁶. In 2015, LithoVue™, a single-use digital flexible ureteroscope, was initially trialed in Europe¹⁷. A recent multi-centre, prospective, comparative study by Usawachintachit et al., who compared procedural outcomes between LithoVue™ and reusable ureteroscopes, found that LithoVue™ is associated with shorter learning curve and had comparable procedural outcomes and complication rates when compared with reusable flexible ureterorenoscopes¹⁸. The Uscope UE3022 is a novel single-use digital disposable flexible ureterorenoscope developed by Pusen™ (Zhuhai Pusen Medical Technology Co, Ltd., Zhuhai,

China). Salvado et al. published the clinical results obtained with Uscope UE3022, which are similar to those published using reusable equipment¹⁹.

The WiScope™ flexible disposable ureterorenoscope used in our study has all the advantages of this type of technique: high image quality and resolution, adequate maximum deflection, optimal maneuverability and high durability. The average operative time of the procedures performed in our patients was 58 minutes, which is slightly longer than in other studies using a flexible disposable ureterorenoscope – 40 minutes²⁰. In our study, ureteral access sheath was used in all patients, to increase the safety of the manipulation, unlike other studies in which the frequency of its use varies: 25% in the study of Delfidio et al., 58% in the study of Traxer et al., 71% in Miernik et al., and 100% in Ding et al. The final SFR in our study was 94.4%, comparable to data from previous similar studies. According to the literature, the incidence of complications with flexible ureterorenoscopy varies between 6 and 16%²¹. In our study, the complication rate was 13.1%, with one of the most significant complications (ureteral stricture) having a rate of 2.63%, comparable to the literature^{22,23}. Regarding the ureterorenoscope itself, we did not observe any technical problems or damage.

The main limitations of this study are the number of patients included, and the lack of comparison with reusable or disposable equipment under similar conditions. All surgical procedures were performed by only two surgeons. This design may include biases related to the skills and experience differences of more than one surgeon. However, this research could be considered as a preliminary assessment of this endoscope and as a basis for further studies.

CONCLUSIONS

The use of flexible disposable ureterorenoscopes has proven its efficacy and safety. WiScope™ is a comparable option among all available flexible disposable ureterorenoscopes on the market, in terms of all basic characteristics.

Author Contributions

“A.I. and P.A. were responsible for the surgical procedures. A.I. and P.U. analyzed and interpreted the patient data. P.A. and P.U. performed the literature review. A.I. was the major contributor for writing the manuscript. All authors read and approved the final manuscript.”

Compliance with Ethics Requirements:

“The authors declare no conflict of interest regarding this article”

“The authors declare that all the procedures and experiments of this study respect the ethical standards in the Helsinki Declaration of 1975, as revised in 2008(5), as well as the national law. Informed consent was obtained from all the patients included in the study”

“No funding for this study”

Acknowledgements:

None

Availability of data and material

The datasets generated and/or analyzed during the current study are available in the “Gama CodMaster” software product.

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