Initial Experience with the New Super Thin Single-use Pusen Flexible Ureteroscope 7.5 Fr in Renal Stones Endoscopic Treatment

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Rezumat

Experiență inițială cu noul ureteroscop flexibil Pusen 7.5 Fr, super-subțire, de unică folosință în tratamentul endoscopic al litiazei renale

Introducere: Ureteroscopia flexibilă de unică folosință (SU-fURS) par să depășească principalele limitări ale ureteroscopiilor reutilizabile convenționale în ceea ce privește costurile de achiziție, întreținere, precum și defecțiunile apărute. Scopul nostru a fost de a analiza eficiența și siguranța de cel mai subțire ureteroscop flexibil de la Pusen: Uscope Pusen, PU 3033A (Diametru = 7.5 Fr.). **Material și metodă:** Am analizat datele a 24 de pacienți cu litiază pielocaliceală din ianuarie până în martie 2021. Vârsta medie a pacienților a fost de 49 de ani (interval de 27 până la 71 ani). Au fost calculi unici, 7 pielici, 10 în calicele inferioare, 4 în calicele mijlocii și 3 în calicele superioare. Dimensiunea medie a calculului a fost de 18 mm (12-26 mm). Am folosit Uscope Pusen 7.5 Fr. (PU 3033A) și Dornier Medilas H Solvo laser. În toate cazurile, am aplicat tehnica no touch (NTT). Nu am folosit C-Arm pentru controlul progresiei ureteroscopului. Am evaluat pacienții pentru rata de stone free (SFR), timpul mediu operator și rata de complicații.

Rezultate: Timpul mediu operator a fost de 72 ± 21 de minute, cu un interval de 66-131 min. Pentru niciunul din cei 24 de pacienți nu s-au folosit fire sau teacă de acces ureteral (NTT). În ceea ce privește setările laser pentru modul dust am folosit energie scăzută: 0.5J, frecvență înaltă: 50 Hz, pentru pop-corning am folosit energie ridicată: >1 J, frecvență medie: 10-50 Hz, iar pentru fragmentare, energie ridicată: >1 J, frecvență joasă: <10 Hz. Rata de stone free (fragmente reziduale sub 3 mm) după o lună a fost de

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91,7%. La 2 pacienți a fost nevoie de o a doua sesiune de litotritie. Vizibilitatea a fost optimă și nu am descris nici o leziune a mucoasei ureterului la retragerea ureteroscopului. Manevrabilitatea intrarenală a fost foarte bună. Complicații cu scorul Clavien I și II au apărut la 6 pacienți.

Concluzii: Acest nou SU-fURS (7.5 Fr.) pare a fi foarte eficient și sigur, prin utilizarea tehnicii no touch a mucoasei ureterale. Nicio deteriorare ureterală și o intervenție chirurgicală cu spitalizare minimă, reprezintă avantaje principale ale acestui ureteroscop.

Cuvinte cheie: ureteroscop flexibil cu utilizare unică, litiază, tehnică no touch

Abstract

Introduction: Single-use flexible ureteroscopes (SU-fURS) seems to overcome the main limitations of conventional reusable ureteroscopes in terms of acquisition and maintenance costs and break-ages. Our aim was to analyze the efficiency and safety of the thinnest single use flexible scope from Pusen: Uscope Pusen, PU 3033A (Tip = 7.5 Fr.).

Material and methods: We analyzed data from 24 patients with pyelocaliceal stones from January to March 2021. The mean age of the patients was 49 years (range 27 to 71 years). There were unique stones, 7 pyelic, 10 in inferior calyx, 4 in the middle calyx and 3 in superior calyx. The average stone size (larger diameter) was 18 mm (12-26 mm). We used Uscope Pusen 7.5 Fr. (PU 3033A) and Dornier Medilas H Solvo laser. In all cases we applied no touch technique (NTT). We didn't use C-Arm for progression control of the ureteroscope. We evaluated the patients for stone-free rate (SFR), mean operation time and complication rate.

Results: The average operative time was 72 ± 21 minutes, range 66-131 min. For all 24 patients we didn't use wires or ureteral access sheath (NTT). Concerning the laser settings for dusting we used low energy: 0.5J, high frequency: 50 Hz, for pop-corning we used high energy: >1 J, medium frequency: 10-50 Hz, and for fragmenting high energy: >1 J, low frequency: <10 Hz. The stone-free status (residual fragments under 3 mm.) after one month was 91,7%. In 2 patients we need the second session with completely dusting of the residual stones. The visibility was optimal and we didn't describe any mucosal lesions of the ureter when we retired the scope. The intrarenal maneuverability was very good. Clavien I and II occurred in 6 patients.

Conclusions: This new SU-fURS (7.5 Fr.) seems to be very effective and safe offering us an easy NTT. No ureteral damage and one day surgery are the main real minimally invasive characteristics of this ureteroscope.

Key words: single use flexible ureteroscope, lithiasis, no touch technique

Introduction

Flexible ureteroscopy (fURS) became one of the most frequent procedure in urology in the last years. There were a lot of aspects that contributed to its success, like the narrow diameter, highly maneuverability and the high-quality images of the urinary tract (1). As a consequence of that, the stone free rate increased in patients with upper urinary tract

stones while the operating time, the complication rates and the number of re-interventions decreased significantly (2). The preferred method for lithotripsy is Ho:YAG laser both for ureteral and renal calculi (3). Ureteral access sheath is also popular in using flexible ureteroscopes, because of the improved vision by establishing continuous outflow, it allow multiple accesses, decrease intrarenal pressure and reduce intraoperative time (4, 5). However,

reusable flexible ureteroscopes still remain expensive devices because of the purchasing and therefore of maintenance costs (6). In this context, a new class of single use flexible ureteroscopes which to overcome the disadvantages linked by reprocessing and repair costs of multi-use devices was developed. There are many single-use digital fURS already on the market, including PU3022A (Pusen, Zhuhai, China), LithoVue (Boston Scientific, Marlborough, MA, USA), Polyscope (Lumenis, Yokneam, Israel, Polydiagnost, Hallbergmoos, Germany), Semi-Flex Scope (Maxiflex, Los Angeles, CA, USA), FlexoVue (Cook Medical, Bloomington, IN, USA) and Yc-FR-A (YouCare Tech, Wuhan, China) (7). The most studies agreed with similar performances between single use and multi-use flexible ureteroscopes, with a relative superiority of single use fURS concerning the deflexion degree (8). The next step was represented by the development of a thinner devices, capable to reach every area of the kidney both in pediatric or adult patients. A comparison between an Ultra-Thin fURS (4.5 Fr) and a standard fURS showed a similar success rate as the 7.5–9.5Fr fURS in the treatment of ureteric stones being a feasible option in patients in whom a conventional URS cannot be advanced through any segment of the ureter (9). Of course, the natural step forward consisted in the launching of thin and ultra-thin single use flexible ureteroscopes. For the first time in Romania, it arrived the thinnest single use flexible scope from Pusen (7.5 Fr.), our aim being to analyze the efficiency and safety of Uscope Pusen, PU 3033A (Tip = 7.5 Fr.).

Material and Methods

We analyzed data from 24 patients with pyelocaliceal stones from January to March 2021 in a retrospective single center study. The inclusion criteria were: patients undergoing retrograde fURS for the management of renal calculi, aged over 18 years. All patients had a preoperative urine culture with preoperative antibiotics if required. All uretero-

scopic interventions were performed under spinal anaesthesia by a single experimented surgeon. The evaluation of the stone was performed using native CT scan (NCCT). The patients were followed-up with plain abdominal radiograph and urinary ultrasonography to detect residual stone fragments and hydroureteronephrosis at 1 month post-operatively. NCCT was performed for uncertain residual fragments on plain radiograph or in the patients with non-opaque stones. The success of treatment was defined as stone free. We used Uscope Pusen 7.5 Fr. (PU 3033A) and Dornier Medilas H Solvo laser, with an energy level of 0.8–1.0 J and a frequency of 8–12 Hz. (*Fig. 1* and *2*). In all cases we applied no touch technique (NTT). We didn't used C-Arm for progression control of the ureteroscope. We evaluated the patients for stone-free rate (SFR), mean operation time, hospitalization time and complication rate.

Results

The mean age of the patients was 49 years (range 27 to 71 years). The average stone size (larger diameter) was 18 mm (12–26 mm). There were unique stones, 7 pyelic, 10 in inferior calyx, 4 in the middle calyx and 3 in superior calyx. The average operative time was 72 ± 21 minutes (66–131 min). For all 24 patients we didn't use wires or ureteral access sheath (NTT). Of 24 cases, there were 3 cases which failure with the 9 Fr scope so there were converted to 7.5 Fr Uscope Pusen, because of the ureter narrowing. Concerning the laser settings for dusting (*Fig. 3*) we used low

Figure 1. Single-use flexible ureteroscope Pusen – PU3033A. The newest, thinner, effective and safer in flexible ureteroscopy (very few centers in the world starting recent experiences with this new ureteroscope)

Figure 2. Aspect from operative room with this innovative technology (Sanador Hospital)

energy: 0.5J, high frequency: 50 Hz, for pop-corning (*Fig. 4*) we used high energy: >1 J, medium frequency: 10-50 Hz, and for fragmenting (*Fig. 5*) high energy: >1 J, low frequency: <10 Hz. The stone-free status (residual fragments under 3 mm) after one month was 91,7% (*Fig. 6*). In 2 patients we needed the second session with completely dusting of the residual stones. The hospitalization period was of average 21.3 h (17.5-24.5 h). In 24 interventions, the maneuverability was in (15/24) very good, in (6/24) good and in (3/24) satisfying. In (16/24) the visibility was marked as very good, in (6/24) as good, in (1/24) as satisfying and in (1/24) as enough. The intrarenal maneuverability was very good. The JJ stenting was necessary only in 8 cases (33.3%). Concerning the post-operative

Figure 3. Endoscopic view of the dusting procedure

Figure 4. Endoscopic view of the pop-corning procedure

Figure 5. Endoscopic view of the fragmenting procedure

evolution, the Clavien I and II complications occurred in 6 patients. There were not observed significant scope damages after the procedures.

Discussions

Multiuse flexible ureteroscope was a real discovery at that time, providing easier access to renal pelvis and minimally invasive treatment of renal stones. However, after years of exclusive reusable fURS, the incidence of breakage, maintenance costs followed by the unavailability of the devices due to the service operations, especially in the less wealth departments, made from the introduction of single-use with reusable fURS a substantial help to maintain operatory activity (10). Also, there are studies that showed a better deflection of single use devices, versus multiuse devices (8), but a certain advantage of multi-use fURSs concerning vision characteristics in

Figure 6. Endoscopic view – stone-free status. We specially mention that it was a procedure using No Touch Technique (NTT) only because of this new digital ureteroscope (the thinner in the word in this moment)

comparison with single-use fURSs (11).

The interventions with single use flexible ureteroscope Uscope Pusen 7.5 Fr using no touch technique seem to have less consequences over the ureteral mucosa, the intrarenal pressure and also over the ureteral passage, with all the possible associated complications of those. These aspects were mentioned also by Atis et al. who observed a reduced need for ureteric balloon dilatation and reported less complications, such as mucosal injury and haematuria (12). It is also claimed that forceful mechanical dilatation with large caliber URSs can lead to ischaemic damage and stenosis (13). Nevertheless, the recommendations of the EAU Guidelines showed that the ureteral access sheaths allow easy, multiple, access to the UUT and therefore significantly facilitate URS. The use of ureteral access sheaths improves vision by

establishing a continuous outflow, decreases intra-renal pressure, and potentially reduces operating time according to the studies (4). However, the Guidelines mention that use of ureteral access sheaths depends on the surgeon's preference. In our study, we performed all the interventions without using a safety guide wires. There are a lot of controversies in the literature about the question: is a safety wire necessary during routine flexible ureteroscopy?. The studies on large series of patients showed that a safety guidewire was not necessary for routine cases of flexible URS with laser lithotripsy on renal or UPJ stones. However, particular cases with complicated anatomy, difficult access, concomitant ureteral stones, simultaneous stone basketing, or bulky stone burden still necessitate use of a safety guidewire because of increased risk of adverse outcomes (14).

The operatory time was reduced for the studied device, but in the literature, there are controversies regarding this topic. Usawachintachit et al. (15) remarked that single-use scopes significantly decreased operating time, but there are other studies which confirmed the superiority of single use over multi use in terms of operatory time (16). Also, the complete stone-free status remains a major outcome for every surgeon when performing flexible ureteroscopy for stone removal, regardless of stone composition. It is presumed that a good irrigation flow in combination with an optimal view is essential to allow efficient lithotripsy and to remove completely the stones in a fast and secured manner. Otherwise, the outcomes are sub-optimal. In this context, many studies showed that Pusen had the best outcomes in the evaluation of the irrigation in comparative tests with other single use flexible ureteroscopes (17) and that aspect was also confirmed by our outcomes. We had an excellent stone free rate due to a good view and an optimal irrigation flow. Concerning the reduced number of the complications in our study, that was also confirmed by the existing data from the literature, Soylemez et al. reporting similar values (18).

Conclusions

The new SU-fURS Pusen Uscope (7.5 Fr.) seems to be effective and safe in comparison with multiuse devices. No touch technique could be applied without ureteral damage and one day surgery represent the main characteristics of this ureteroscope. There are necessary many studies for establishing the exact place for single use together with multi-use flexible ureteroscope in the urological armamentarium.

Conflicts of Interest

The authors declare no conflicts of interests.

Ethics of Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee, and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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