

# Endoscopic treatment of lower pole stones: is a disposable ureteroscope preferable?

## Results of a prospective case-control study

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**Introduction** The best option for lower pole stone management is still under debate. With the recent incorporation of disposable ureteroscopes, discussion on this topic has been renewed. The aim of the present study was to compare the results obtained with flexible disposable ureteroscopes with those obtained using reusable ureteroscopes in the treatment of inferior calyx stones.

**Material and methods** A case-control study was carried out using data registered prospectively in a database at our center. The clinical results obtained in two groups of patients were analyzed. In the first group of patients, a reusable flexible fiber-optic ureteroscope (Cobra<sup>®</sup>, Richard Wolf) was used, and in the second group, a disposable flexible ureteroscope was used (Uscope 3022<sup>®</sup>, Pusen Medical). The variables analyzed included: operative time, fluoroscopy time, need for postprocedure ureteral catheter, stone-free rate (fragments <1 millimeter) and complications. The results were evaluated using a Student's t test, a Mann-Whitney test and a Fisher's test.

**Results** There were 31 cases with disposable ureteroscopes and 30 cases with a reusable ureteroscope. Both groups were comparable in their demographic and clinical variables. The characteristics regarding length, width and angle of the infundibulum (measured by retrograde ureteropyelography) were also comparable. There were no differences in the clinical findings with respect to the stone-free rate, need for a ureteral catheter, complications or hospital stay. Significant differences were found in the average surgery time (56.1 vs. 77 minutes;  $P = 0.01$ ) and in the fluoroscopy time (66.1 vs. 83.4 seconds;  $P = 0.02$ ), both favoring the use of single use ureteroscopes.

**Conclusions** In this study, disposable flexible ureteroscopes have been validated as an option that is in the least equivalent to reusable ureteroscopes based on clinical results. The shorter surgical and fluoroscopy durations are possible advantages considering the high costs associated with time spent in the operating room and the need to reduce ionizing radiation.

**Key Words:** flexible ureteroscopy ↔ lower pole stone ↔ urolithiasis

## INTRODUCTION

Nephrolithiasis is a health problem of great worldwide importance, with approximately 10% of the population of developed countries presenting with this condition [1]. The formation of renal stones is

multifactorial in origin, with determinants being, among others, environmental, dietary and hereditary. The anatomy of the collecting system could be another potential risk factor. Some studies have focused on the characteristics of the inferior calyx that would be associated with a greater possibility

of stone formation [2, 3]. In 1992, Sampaio was the first to describe the influence of the spatial distribution of the inferior calyx on the results obtained with shock wave lithotripsy (SWL) and the spontaneous passage of fragments achieved after treatment [4]. Currently, stone free rates after SWL in stones of the lower pole range from 48% to 58%, regardless of the size of the stones, and are affected mainly by the poor drainage of this location [5, 6]. Improvements in image quality, the possibility of deflection and the minimal invasiveness of Retrograde Intra Renal Surgery (RIRS) have positioned it as an effective tool for treating stones in this location, especially in cases of hard stones (calcium oxalate monohydrate, brushite or cystine) or unfavorable anatomy (acute infundibulum-pelvic angle, long calyx or narrow infundibulum) [7]. One of the limitations of this technique is the potential damage that flexible ureteroscopes can induce by forcing their deflection to access the lower pole [8]. The recent emergence of single-use flexible equipment has once again focused interest on endoscopic surgery of lower pole stones, as their characteristics can yield good clinical results without risking delicate equipment or generating the higher costs that occur when reusable equipment is used [9]. This paper presents the results obtained from a comparative study evaluating the use of a disposable flexible ureteroscope (Uscope 3022, Zhuhai Pusen Medical Technology Co, Ltda., Zhuhai, China) versus a reusable flexible device (Cobra, Richard Wolf, Knittlingen, Germany) in the treatment of inferior calyx stones. There are some technical differences between both endoscopes; while the shaft of the Uscope 3022 is 9.5 French with a single 3.6 French working channel, the Cobra® endoscope has two channels of 3.6 and 2,4 French and a total diameter of 9.9 French. The deflection mechanism is the same in both endoscopes, achieving 270° in both directions. The total length of the equipment is 63 centimeters for the Uscope 3022 and 69 centimeters for the Cobra®, and the total weight is 147 g and 351.5 g respectively.

## MATERIAL AND METHODS

A prospective case-control study was conducted using the clinical data from the procedures performed by an endourologist, in the Santa María Clinic, with the prior approval of the Local Scientific Ethics Committee. The information was obtained from the renal stones treatment database of our department. Prior to the procedure, all patients signed an informed consent form. The controls correspond to patients who underwent the operation with a reusable flexible fiber-optic ureteroscope (Cobra® Endo-

scope, Richard Wolf, Knittlingen, Germany) between March and October 2016, while the patients in the case studies underwent surgery between November 2016 and November 2017 with a disposable digital flexible device (Uscope 3022®, Zhuhai Pusen Medical Technology Co, Ltda., Zhuhai, China). For laser lithotripsy, a 30-Watts holmium laser (Odyssey 30®, Cook Medical, Bloomington, IN, USA) with 270-micron fibers was used in all cases. All of the procedures were performed uniformly, using intracorporeal lithotripsy laser parameters in dusting or fragmentation mode depending on the characteristics of the stone. For this study, only patients with a single stone located in the inferior calyx were considered. The pre-operative study included the following in all patients: computerized axial tomography (CT Scan) of the abdomen and pelvis without contrast; creatinine; and, as a prerequisite, the absence of bacteria in urine (negative urine culture). All procedures were performed under general anesthesia by the same surgeon. The 12/14-French ureteral access sheath (Proxis™, Bard) was used as long as insertion was possible. Fragment extraction was accomplished with a 1.7-French niti-nol grasper (NGage™, Cook Medical, Bloomington, IN, USA). The stone-free rate was evaluated one month after surgery by performing a CT scan of the abdomen and pelvis without contrast, and patients with fragments smaller than 1 mm were considered stone-free. The measurements of the anatomical characteristics of the lower pole were obtained using a radioscopic retrograde ureteropyelography (infundibular length, infundibular width and infundibulo-pelvic angle) performed at the time of the surgery, according to the method described by Elbahnasy et al. [10]. The other clinical parameters measured were: demographic characteristics, total surgery time (minutes), total fluoroscopy time (seconds), presence of a double-J ureteral catheter in the pre- and post-operative period and complications (Clavien-Dindo). A Wilcoxon-Mann-Whitney test was used for quantitative variables, and a Fisher's test was used for categorical variables (STATA 2.0 program). The level of statistical significance was set at 0.05.

## RESULTS

Both groups were comparable. The demographic and preoperative variables are described in Table 1. There were no Stone size was slightly higher in the disposable ureteroscope group ( $10.8 \pm 5.0$  millimeters in the disposable group and  $9.0 \pm 3.3$  millimeters in the reusable group); however, this result was not statistically significant ( $P = 0.2$ ). The anatomical characteristics of the inferior calyx (length, width and angle of the infundibulum) were simi-

**Table 1.** Patient demographic and perioperative parameters

Parameter	Uscope 3022 (n = 31)	Reusable ureteroscope (n = 30)	p
Age at surgery (years), Mean $\pm$ SD	50.4 $\pm$ 13.8	49.9 $\pm$ 16.5	0.9
Gender, n (%)			
Female	9 (29%)	9 (30%)	1
Male	22 (71%)	21 (70%)	1
Total stone burden (millimeters), mean $\pm$ SD	10.8 $\pm$ 5.0	9.0 $\pm$ 3.3	0.2
Infundibular length (millimeters), mean $\pm$ SD	23.7 $\pm$ 4.0	22.8 $\pm$ 3.2	0.3
Infundibular width (millimeters), mean $\pm$ SD	7.8 $\pm$ 1.7	8.4 $\pm$ 2.4	0.2
Pelvic infundibulum angle (degrees) mean $\pm$ SD	60.8 $\pm$ 8.9	63.2 $\pm$ 8.6	0.4
Hounsfield units	906 $\pm$ 69.8	866.9 $\pm$ 271	0.5
Prestenting, n (%)	16 (51.6%)	13 (43.3%)	0.6
Intracorporeal lithotripsy, n (%)			
Basketing	2 (6.5%)	2 (6.7%)	1
Dusting	29 (93.5%)	28 (93.3%)	1
Ureteral access sheath utilization, n (%)	28 (90.3%)	25 (83.3%)	0.4

SD – standard deviation

**Table 2.** Intraoperative and postoperative outcomes

Parameter	Uscope 3022	Reusable ureteroscope	p
Operative time (minutes), Mean $\pm$ SD	56.1 $\pm$ 34.8	77 $\pm$ 37.4	0.01
Fluoroscopy time (seconds) Mean $\pm$ SD	66.1 $\pm$ 60.9	83.4 $\pm$ 44.9	0.02
Stone free rate (%), mean	95%	88.2%	0.1
Postoperative ureteral catheter requirement, n (%)	19 (61.3%)	18 (60%)	1

SD – standard deviation

lar in both groups. A total of 51.6% of the patients in the disposable ureteroscope group had a previously installed double-J ureteral catheter, which is slightly higher than the percentage in the reusable group (43.3%,  $P = 0.6$ ). The reason for a previous double j insertion was: presence of infection in the upper urinary tract at the time of stone diagnosis (56%), acute renal failure secondary to ureteral obstruction (36%) and the inability to achieve adequate dilation of the ureter to introduce the flexible ureteroscope (narrow ureter) (8%).

The intracorporeal laser lithotripsy technique used most frequently in both groups was dusting (>83%). In the disposable ureteroscope group, use of the access sheath was more frequent; however, the difference was not significant between the disposable and reusable groups (90.3% vs. 83.3%,  $P = 0.4$ ).

Table 2. Summarizes the intraoperative and postoperative results of this series.

On average, the total surgery time was 21 minutes shorter for the procedures performed with single-use ureteroscopes (56.1 minutes for single-use ureteroscopes and 77 minutes for reusable ureteroscopes,  $P = 0.013$ ). A similar result was observed with respect to the total fluoroscopy time (66.1 seconds for single-use ureteroscopes and 83.4 seconds for reusable ureteroscopes,  $P = 0.02$ ). The stone-free rate was higher in the disposable group, but the difference was not statistically significant (95% for single-use ureteroscopes and 88.2% for reusable ureteroscopes,  $P = 0.1$ ). There was also no significant difference in the use of a postoperative ureteral catheter (61.3% for single-use devices vs. 60% for reusable devices,  $P = 1$ ). The indication for a postoperative double j stent was mainly related to the clinical suspicion of ureteral edema development after the procedure, including: prolonged operative time (more than 60 minutes), significant stone fragments after intracorporeal lithotripsy and surgeon preference. In terms of complications, only one case of postoperative renal colic was recorded in the single-use ureteroscope group, which corresponded to a patient in whom a double-J catheter was not installed after surgery, requiring rehospitalization for 24 hours to optimize analgesic management.

## DISCUSSION

Several studies regarding the influence of the collecting system on the stone-free rate have been published since the original study by Sampaio et al. [4]. Some of these studies related certain characteristics of the infundibulopelvic angle and the width of the infundibulum, as measured by standard excretory urography, with a significant decrease in the inferior calyx stone removal rate after successful SWL [10, 11]. Moreover, with the goal of improving the outcome of this scenario, the possibility of combining diuresis, mechanical percussion and inversion therapy has been proposed [12, 13]. For the abovementioned reasons, endoscopic therapies have emerged as an alternative for treating lower pole stones, as their results do not depend directly on the force of gravity. A recently published systematic review showed a higher stone-free rate for stones smaller than 20 millimeters using percutaneous nephrolithotomy (PCNL) or RIRS as compared to SWL, especially for stones between 10 and 20 millimeters in size [14]. Another meta-analysis comparing the three aforementioned techniques, though only focused on stones between 10 and 20 millimeters in size, showed a superior result for SWL when analyzing the length

of hospital stay and operative time; however, this treatment alternative yields lower stone-free rates. Furthermore, the complications associated with the procedure were not different from those associated with PCNL and RIRS [15]. Finally, this review failed to reveal the best alternative with respect to other outcomes, including complications, surgical times and the need for complementary procedures.

One of the reasons traditionally used to promote the use of SWL over RIRS is how minimally invasive the first alternative treatment is. This argument has not been validated in medical literature; in fact, a study that compared the objective and subjective results of lower pole stone treatment showed that the satisfaction rate of patients undergoing RIRS is much higher than that achieved with SWL (62 vs. 34%,  $P = 0.03$ ), and the RIRS group was able to return to work earlier [16].

Despite the good results obtained with RIRS, the anatomy of the inferior calyx can alter the results of this procedure, as demonstrated by the study carried out by Jessen et al, which showed that the presence of a very long infundibulum or a very acute infundibulum-pelvic angle ( $<30^\circ$ ) could adversely affect the stone-free rate. It also showed that the size of the stone and brushite composition were related to lower fragment-free rates [17].

One of the main disadvantages of flexible ureteroscopy lies in the high economic investment associated with equipment incorporation and maintenance, with costs of up to almost US \$ 100,000 per year [18]. The source of the damage to these devices has been previously studied and exceeding the equipment's deflection limit has been clearly identified as a risk factor. This has been also been found to occur most often in the treatment of inferior calyx stones [8]. In recent years, a new series of single-use ureteroscopes has emerged, most notably the LithoVue™ (Boston Scientific, Marlborough, MA) and Uscope 3022™ (Pusen, Zhuhai, China). The first new ureteroscope to be validated clinically was LithoVue™ in 2015 [19], and subsequent studies have confirmed its usefulness and competitiveness with respect to reusable equipment [20, 21]. The same results were obtained with the Uscope 3022®, which was validated first in vitro [22] and later in a clinical setting [23, 24].

Two important arguments in favor of using single-use instruments have been described; specifically, each procedure uses new equipment (without defects), and costs are saved due to sterilization not being required. However, concerns regarding the costs associated with this type of technology have been raised. In a study published in 2017, Martin et al. analyzed the economic implications of using disposable equipment and concluded that in centers where

less than 99 flexible ureteroscopies are performed yearly, using single-use equipment would be justified [25]. This analysis is based on the number of cases addressed before damage or failure of the reusable equipment occurs; however, it is unclear whether this is a local finding or is globally applicable.

Regarding the clinical results of our study, it is important to consider that the controls correspond to patients who underwent the procedure using fiber-optic equipment prior to the incorporation of disposable technology (March–October 2016), which could constitute a bias in our study. However, the same surgeon performed the procedure in all of the patients, which could eliminate the learning curve factor. The main limitations of this study are the low number of patient included as well as the fact that we could have stronger result, if the cases were randomized at the time of the surgery. The stone-free rate was lower in the reusable device group but not significantly lower, and there was no difference between the groups in regards to the inferior calyx anatomy (length, width and angle of the infundibulum).

It can be hypothesized that the shorter operative time and fluoroscopy time is due to the fact that the use of a disposable device permits the urologist to take the endoscope to the limits of its deflection and treat the stone at its location, without needing to transfer it to the upper calyx, as traditionally practiced to avoid forcing reusable equipment. Another influential factor is that the Uscope 3022® device is much lighter than a reusable device [21], which could reduce surgeon fatigue, resulting in a shorter operative time and, consequently, a lower need for fluoroscopy. A previous publication, which compared the use of the LithoVue™ versus reusable equipment, also showed a shorter operative time by an average of 10 minutes. However, this work included the treatment of stones at different locations within the collecting system as well as the use of this instrument as a diagnostic tool and not only a therapeutic tool [20]. These hypotheses require confirmation in future investigations, ideally prospective, that consider the aforementioned factors. Finally, in this series of patients, there were no infection-related complications. This result favors the use of disposable equipment, as there is no contamination risk for this type of device, which does not require a preceding sterilization step for its use. A study published in 2017 showed the detection of 100% contamination in flexible ureteroscopes, with bacterial growth in up to 13% of cases [26].

## CONCLUSIONS

The use of disposable flexible ureteroscopes has been progressively validated in recent years and

is considered an alternative that is at the least equivalent to reusable equipment. When evaluating the clinical results, specifically in the treatment of inferior calyx stones, the decreased operative time and the lower need for fluoroscopy could favor their use in the future, considering the high costs

associated with time spent in the operating room and the need to reduce ionizing radiation for patients and medical personnel.

#### CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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