Article

Arch. Esp. Urol. 2023; 76(1): 65–69
https://doi.org/10.56434/j.arch.esp.urol.20237601.6

Single-Use Versus Reusable Cystoscope for Ureteral Stent Removal: A Comparative Study of Perceived Pain and Procedure Times

Jorge Panach-Navarrete[1,2,3,*], Marcos Antonio Lloret-Durà[1,2,3], Silvia Sánchez-Gimeno[1,2,3], Esther Murcia-Díez[1,2,3], José María Martínez-Jabaloyas[1,2,3]

[1]Department of Urology, University Clinic Hospital of Valencia, 46010 Valencia, Spain
[2]INCLIVA, Instituto de Investigación Sanitaria, 46010 Valencia, Spain
[3]Facultat de Medicina i Odontologia, Universitat de València, 46010 Valencia, Spain
*Correspondence: jorge.panach@uv.es (Jorge Panach-Navarrete)
Published: 28 February 2023

Introduction: The aim of this study was to compare the Isiris™ cystoscope with a common reusable flexible cystoscope in terms of patient perceived pain and endoscopy time in the ureteral stent removal setting.

Materials and Methods: A non-randomized prospective study comparing the Isiris™ single-use cystoscope with a reusable flexible cystoscope. A visual analogue scale (VAS) was used for pain assessment and endoscopy time was recorded in seconds. Univariate and multivariate analyses were performed to assess the correlation between endoscope type and clinical variables with VAS score and endoscopy time.

Results: A total of 85 patients were included in the study: 53 in the disposable cystoscope group and 32 in the reusable cystoscope group. Ureteral stent extraction was successful in all cases. The mean VAS score was similar between groups (single-use group was 2.09 +/– 2.53 vs 2.53 +/– 2.14 in the reusable cystoscope group) ($p = 0.13$). Same was observed endoscopy time (74.92 +/– 74.45 s. in the single-use group vs 98.87 +/– 153.33 s. in the reusable group) ($p = 0.07$). Age (coefficient $\beta = –0.36$, $p < 0.04$) and body mass index (BMI) (coefficient $\beta = –0.22$, $p < 0.02$) were inversely correlated with perceived pain during ureteral stent removal, measured by VAS score.

Conclusions: Ureteral catheter removal with a flexible cystoscope is a well-tolerated procedure in patients. Older age and high BMI are associated with better intervention tolerance. Use of a single-use flexible cystoscope is comparable to that of a common flexible cystoscope in terms of pain and endoscopy time.

Keywords: cystoscopy; ureteral stent; endourology; pain

Introduction

During recent years, the Isiris™ single-use flexible cystoscope (Coloplast®) has been used as an extra tool for ureteral stent removal. In the first multicenter clinical evaluation of this endoscope, this instrument was rated by urologists as very good in terms of image quality in 72.3%, deflection in 78.3%, maneuverability in 72.3%, and grasper functionality in 73.5% of procedures [1]. Regarding image quality and water flow, Isiris™ has proven to be comparable to any other digital cystoscope, even though it shows a narrower field of view [2].

Availability of this single-use instrument in the Clinique, obviating the need for an endoscopy room for ureteral stent extraction, shorten indwelling times and objectively improves patient experience and reduces complications [3]. In addition, using Isiris™ enables stent removal during the outpatient Clinique, which save more than £100 per procedure, based on a British micro-costing study [4].

Although previous studies of technical and practical characteristics of the disposable flexible cystoscope support its use, the aim in the present study was to verify other clinical aspects. The principal study endpoint was the assessment of differences in patient's perceived pain and endoscopy time between Isiris™ cystoscope with another common reusable flexible cystoscope in terms of during ureteral stent removal. The secondary endpoint was to establish clinical variables different to instrument type that could be related to perceived pain or procedure lenght.

Materials and Methods

Study Design

This is a non-randomized prospective study conducted in a single center between January 2019 and December 2020. We consecutively collected the cases of all ureteral stent patients undergoing stent removal as an outpatient procedure. Patients were divided in two groups, the single-use

flexible cystoscope or the common reusable flexible cystoscope used for ureteral stent removal. Randomization could not be performed because cystoscope type selection varied according to urologist preferences and endoscope availability.

Inclusion criteria were ≥18 years, indwelling ureteral stent (regardless of underlying pathology), appointment to undergo stent removal, and signed informed consent for the study.

Procedure Protocol

All patients attending the clinic for ureteral stent removal were invited by a nurse to participate in the study if they met the inclusion criteria. Patients were recruited into the study sample if informed consent was understood and signed.

In the outpatient endoscopy room, the patient was placed at lithotomy position in preparation for the procedure. The genital area was disinfected by a nurse. In male patients 12.5 g sterile lubricant with lidocaine was injected through the urethra and retained in place for 5 minutes by use of a penile clamp.

After preparation, the urologist removed the ureteral stent. Endoscopy was timed from the moment the bladder neck was reached by endoscope until the ureteral stent protruded through the urethral meatus. When using the reusable cystoscope, ureteral stent extraction was carried out using a foreign-body forceps introduced through the working channel of the endoscope. For single-use cystoscope, the stent was removed using the integrated grasper.

Once the procedure was finished and the urologist departed, the nurse recorded patient-reported pain, endoscopy duration, and the remaining clinical variables for the study.

Types of Cystoscope

The single-use cystoscope was the Isiris™ by Coloplast® (Fig. 1), a flexible 16-Fr and 39 cm long cystoscope connected to a specifically designed monitor provided by the manufacturing company (8.5 inches for a resolution of 800 × 600 pixels). This endoscope has an irrigation channel, and a grasper with three wires to grip the stent, which can be observed at 9-o'clock position in the image. The minimum length of the grasper open to grip the stent is 4.5 mm and the maximum is 18 mm, the maximum angle of the instrument is 80° upwards and 90° downwards. Each instrument was discarded after one use.

The common reusable cystoscope was an Olympus® CYF-V2/VA2™ (Fig. 1), a flexible 16.2-Fr and a working channel of 6.6-Fr. The length of the instrument is 65 cm and the maximum angle is 210° upwards and 120° downwards. This cystoscope was connected to a camera system used in the endoscopy room for viewing on a monitor. For ureteral stent removal with this instrument, a reusable foreign-body clamp was inserted through the working channel.

All the stents removed were 6 Ch-26 cm.

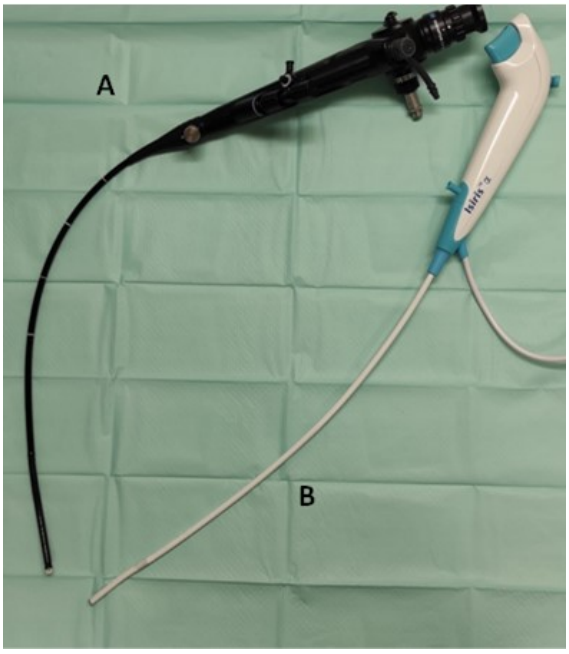

Fig. 1. The two types of cystoscopes used in the study. (A) Reusable cystoscope, Olympus® CYF-V2/VA2™. (B) Single-use cystoscope, Isiris™ by Coloplast®.

Registered Variables

Nurses recorded the study variables and endoscope type used once the procedure was completed, and the urologist left the room. Pain was measured with a Visual Analogue Scale (VAS). The patients were instructed to mark their pain perception during the procedure along a horizontal line from 0 (no pain) to 10 (worst pain). Endoscopy time was measured in seconds from the time the endoscope reached the bladder neck (in both males and females) to when the stent showed through the urethral meatus.

The collected clinical variables were age (in years), sex, and all patient comorbidities. After recording the latter, the Charlson comorbidity index was calculated for each patient. Other recorded variables were status of the urologist who carried out the endoscopy (attending or resident), height and weight of each patient for subsequent body mass index (BMI) calculation.

Statistical Analysis

To achieve the primary and secondary study endpoints, two types of univariate and multivariate analyzes were performed, one using the VAS score as the dependent variable, and the other using procedure time in seconds. Both, the VAS score and the time in seconds were considered continuous variables. For the univariate analysis, Pearson's correlation test and the Mann-Whitney's U test were used. Variables tentatively approaching significance ($p <$

Table 1. Baseline patients' characteristics, including comorbidities potentially affecting pain perception.

Variable	Value
Age in years (average +/– SD)	60.64 +/– 16.53
Sex (n (%))	
Male	42 (49.4%)
Female	43 (50.6%)
Diabetes mellitus (n (%))	21 (24.7%)
Oncology patient (n (%))	27 (31.8%)
Dementia (n (%))	22 (2.4%)

SD, standard deviation.

0.3) in the univariate analysis were subsequently included in the multivariate analysis (linear regression). Differences with a $p < 0.05$ were accepted as statistically significant. SPSS v. 20 was used to perform the statical analysis (IBM Corp., Armonk, NY, USA, Released 2011).

Results

A total of 85 patients were included in the study, 53 in the single-use cystoscope group and 32 in the reusable cystoscope group. In all cases, extraction of the ureteral stent was successful. Among these procedures, 29 (34.1%) were performed by resident physicians and 56 (65.9%) by attending physicians. Table 1 shows baseline patients' characteristics. Among all the patients, 34 (40%) had a BMI of 25 or less, 26 (30.6%) between 25 and 30, and 25 (29.4%) of 30 or greater.

Univariate analyses results are reported in Table 2. There were no missing values in any variable. Cystoscope type used, age, BMI, and the Charlson comorbidity index tended to be significant factors affecting VAS scores ($p <$ 0.3). Cystoscope type, sex and operator experience tended to factors affecting endoscope time ($p < 0.3$).

Multivariate analyses results are reported in Table 3. Higher age and higher BMI are related with lower pain during ureteral stent removal. None of the variables were related to endoscopy time. Finally, cystoscope type was not related to any of the analyses with the dependent variable.

Discussion

Ureteral stent removal is a common procedure in urological routine practice. Although aspects related to this intervention, such as risk of infection or need for antibiotic prophylaxis have already been evaluated, to the best of our knowledge this is the first study assessing pain or discomfort experienced by patients [5,6]. In addition, results presented here provide novel data on routine clinical practice using the Isiris^{TM} disposable cystoscope. To our knowledge this endoscope has not been compared to a reusable flexible one in terms of patient-perceived pain and endoscopy time. Foreign-body forceps passage through the working channel of an inventoried flexible cystoscope may cause damage. Thus, evaluating factors such as patient comfort and procedure time with a single-use cystoscope intended for ureteral stent removal can contribute to justify its use against reusable devices.

Our results revealed no differences in VAS score between the two cystoscope types during catheter removal. VAS mean score was slightly higher in the reusable cystoscope group, however the difference was not statistically significant. Although this study is the first evaluating this aspect, other studies with a similar design have verified pain differences after evaluating other diagnostic cystoscopy factors. The most frequent studied aspect is whether there are differences in pain depending on the time lag between intraurethral lubrication and procedure [7–11]. Studies including different types of flexible cystoscopes concluded that diagnostic cystoscopy is a well-tolerated procedure and that there are no differences in pain despite of waiting times variation after the anesthetic lubricant application. Our results are consistent with these findings, the use of different flexible endoscopes showed similar patients' tolerability.

Here, no relationship was found between cystoscope type and endoscopy duration. A study by Pietropaolo *et al.* [4] compared the time factor between Isiris^{TM} and a reusable cystoscope. Although these authors reported a mean procedure time of 14.4 minutes for the reusable endoscope and 2.1 minutes for the disposable cystoscope, however it should be noted that preparation time was included. Given the differences in preparation between endoscopes (reusable requires extraction of the sterilization system, camera connection, preparation and passage of foreign-body forceps, etc.), we consider that our evaluation of time is more representative of typical practice. In the single-use cystoscope group the mean endoscopy time was 74.92 s., compared to 98.87 s. in the inventoried cystoscope group. Despite of the lack of significant differences in times between endoscopes, this data should be interpreted with caution, since a mean difference of almost half a minute, could be vital in clinical practice to reduce patient discomfort. A larger sample could confirm whether these differences in mean times are significant in a multivariate analysis.

The only two variables associated with VAS scale were age and BMI, showing both a negative relation. This has been reported previously. Aging has been shown to reduce pain sensitivity, especially at low intensity [12], which is likely the case in the procedure of this study, although the pathophysiological mechanisms are not totally understood. Other similar studies have also observed less pain with increasing age, however without reaching statistical significance [7]. The inverse relation found between BMI and VAS score was contrary to our expectations due to the systemic pro-inflammatory status of obese patients that would increase pain during an invasive procedure. Nevertheless, this hypotheses has been questioned, and there are studies that found no relationship between the two [13]. During this study we tried to obtain a clinical profile of patients with

Table 2. Univariate analysis: Factors affecting VAS score and endoscopy time.

Variable	VAS score	*p*	Endoscopy time	*p*
Cystoscope type (average +/– SD)				
Single-use	2.09 +/– 2.53	0.13$^{\Delta}$	74.92 +/– 74.45	0.07$^{\Delta}$
Reusable	2.53 +/– 2.14		98.87 +/– 153.33	
Age (correlation coefficient)	–0.41	<0.001$^{\partial}$	–0.05	0.64$^{\partial}$
Sex (average +/– SD)				
Male	2.40 +/– 2.64	0.73$^{\Delta}$	97.98 +/– 142.09	0.12$^{\Delta}$
Female	2.12 +/– 2.14		70.21 +/– 65.65	
Operator status (average +/– SD)				
Resident	2.41 +/– 2.36	0.64$^{\Delta}$	88.68 +/– 65.01	0.04$^{\Delta}$
Attending	2.18 +/– 2.42		81.30 +/– 127.16	
BMI (correlation coefficient)	–0.21	0.05$^{\partial}$	–0.05	0.62$^{\partial}$
Charlson cormorbidity index (correlation coefficient)	–0.35	0.001$^{\partial}$	–0.08	0.46$^{\partial}$

$^{\Delta}$Mann-Whitney U test; $^{\partial}$Pearson correlation. SD, standard deviation; VAS, visual analog scale; BMI, body mass index.

Table 3. Multivariate analysis: Factors affecting VAS score and endoscopy time.

Dependent variable: VAS score			
Variable	Coefficient β	CI 95%	*p*
Reusable cystoscope	0.13	–0.32–1.63	0.18$^{\Delta}$
Age	–0.36	–0.10– –0.01	0.04$^{\Delta}$
BMI	–0.22	–0.19– –0.01	0.02$^{\Delta}$
Charlson	–0.07	–0.41–0.26	0.67$^{\Delta}$
Dependent variable: Endoscopy time			
Variable	Coefficient β	CI 95%	*p*
Reusable cystoscope	0.11	–25.01–74.78	0.32$^{\Delta}$
Sex	–0.13	–78.73–18.11	0.21$^{\Delta}$
Status	–0.04	–60.94–41.98	0.71$^{\Delta}$

$^{\Delta}$Linear regression. BMI, body mass index; VAS, visual analog scale.

poorer tolerance to ureteral catheter removal, but a pathophysiological explanation for why increased BMI was inversely related to pain is still not forthcoming.

No association was found between other studied variables and either VAS score or endoscopy time, not even operator status emerged as a risk factor for greater pain or longer endoscopy duration. This last factor has been shown to be relevant in other urological surgical procedures, such as transurethral resection and nephrostomy puncture, where surgeon inexperience has been described as a factor increasing the risk of complications [14,15]. One hypothesis is that the relative simplicity of the ureteral catheter removal procedure makes physician experience less determinant in terms of pain and time.

The main potential advantage that we found in the use of a single-use cystoscope is a theoretically lower risk of infection, and a longer half-life of use of the inventoriable cystoscope, as it does not require manipulation with the forceps of foreign bodies through its delivery channel.

The present study has several limitations, it is a single center study with a limited sample. Multicenter research would provide more robust results. Secondly, despite being a prospective study, randomization was not possible. It should be added that the two main study groups had different patient numbers with the single-use cystoscope group being more numerous. Finally, the learning curve was not considered in single-use cystoscope usage, which could be a confounding effect on the results.

Conclusions

Ureteral catheter removal with a flexible cystoscope is a well-tolerated procedure in patients, older patients with high BMI were found to be associated with higher pain threshold during the intervention. The single-use flexible cystoscope is comparable to the common flexible cystoscope in terms of pain and endoscopy time, and as an easy-to-use outpatient device, the former could prove a cost-effective alternative. Further extended studies in multiple centers with larger patient samples could verify the results shown here.

Abbreviations

VAS, visual analogue scale; BMI, body mass index.

Availability of Data and Materials

All data included in this study are available upon request by contact with the corresponding author. Available at: jorge.panach@uv.es.

Author Contributions

JPN—study design, text writing and principal investigator; MLD—data collection and review of ethical aspects; SSG—data collection and editorial changes; EMD—data collection and editorial changes; JMJ—study coordinator and study reviewer.

Ethics Approval and Consent to Participate

This study was approved by the Research Ethics Committee of our center (INCLIVA Biomedical Research Institute), with reference number 2018.243.

Acknowledgment

Not applicable.

Funding

This research received no external funding.

Conflict of Interest

The authors declare no conflict of interest.

References

[1] Doizi S, Kamphuis G, Giusti G, Palmero JL, Patterson JM, Proietti S, *et al*. First clinical evaluation of a new single-use flexible cystoscope dedicated to double-J stent removal (Isiris™): a European prospective multicenter study. World Journal of Urology. 2017; 35: 1269–1275.

[2] Talso M, Emiliani E, Baghdadi M, Orosa A, Servian P, Barreiro A, *et al*. The new grasper-integrated single use flexible cystoscope for double J stent removal: evaluation of image quality, flow and flexibility. World Journal of Urology. 2017; 35: 1277–1283.

[3] Baston EL, Wellum S, Bredow Z, Storey G, Palmer A, van Dellen D, *et al.* Office-based ureteric stent removal is achievable, improves clinical flexibility and quality of care, whilst also keeping surgeons close to their patients. Central European Journal of Urology. 2018; 71: 196–201.

[4] Pietropaolo A, Hughes T, Tear L, Somani BK. Comparison of ureteric stent removal procedures using reusable and single-use flexible cystoscopes following ureteroscopy and lasertripsy: a micro cost analysis. Central European Journal of Urology. 2020; 73: 342–348.

[5] Gregg JR, Kang CL, Talbot TR, Moore D, Herrell SD, Dmochowski R, *et al*. Symptomatic Urinary Tract Infections in Renal Transplant Recipients after Cystoscopy for Ureteral Stent Removal. Urology Practice. 2017; 4: 405–411.

[6] Gould CV, Umscheid CA, Agarwal RK, Kuntz G, Pegues DA. Guideline for Prevention of Catheter-Associated Urinary Tract Infections 2009. Infection Control and Hospital Epidemiology. 2010; 31: 319–326.

[7] Panach-Navarrete J, Martínez-Jabaloyas JM. Is a retention time after the instillation of anesthetic lubricant necessary when performing male flexible cystoscopy? Journal of Endourology/Endourological Society. 2015; 29: 223–225.

[8] Cano-García MDC, Casares-Pérez R, Arrabal-Martín M, Merino-Salas S, Arrabal-Polo MA. Perception of pain in flexible cystoscopy using intraurethral lidocaine. Archivos Españoles de Urología. 2016; 69: 207–211.

[9] Rodríguez-Rubio F, Sanz G, Garrido S, Sánchez C, Estudillo F. Patient Tolerance during Outpatient Flexible CystoscopyA Prospective, Randomized, Double-blind Study Comparing Plain Lubrication and Lidocaine Gel. Scandinavian Journal of Urology and Nephrology. 2004; 38: 477–480.

[10] Choong S, Whitfield HN, Meganathan V, Nathan MS, Razack A, Gleeson M. A prospective, randomized, double-blind study comparing lignocaine gel and plain lubricating gel in relieving pain during flexible cystoscopy. British Journal of Urology. 1997; 80: 69–71.

[11] Losco G, Antoniou S, Mark S. Male flexible cystoscopy: does waiting after insertion of topical anaesthetic lubricant improve patient comfort? BJU International. 2011; 108: 42–44.

[12] Lautenbacher S, Peters JH, Heesen M, Scheel J, Kunz M. Age changes in pain perception: a systematic-review and meta-analysis of age effects on pain and tolerance thresholds. Neuroscience and Biobehavioral Reviews. 2017; 75: 104–113.

[13] González-Callejas C, Aparicio VA, De Teresa C, Nestares T. Association of Body Mass Index and Serum Markers of Tissue Damage with Postoperative Pain. The Role of Lactate Dehydrogenase for Postoperative Pain Prediction. Pain Medicine. 2020; 21: 1636–1643.

[14] Panach-Navarrete J, Tonazzi-Zorrilla R, Martínez-Jabaloyas JM. Dislodgement in Long-Term Patients with Nephrostomy Tube: Risk Factors and Comparative Analysis Between Two Catheter Designs. Journal of Endourology/Endourological Society. 2020; 34: 227–232.

[15] El Hayek OR, Coelho RF, Dall'oglio MF, Murta CB, Filho LAR, Nunes RLV, *et al.* Evaluation of the Incidence of Bladder Perforation after Transurethral Bladder Tumor Resection in a Residency Setting. Journal of Endourology. 2009; 23: 1183–1186.