First clinical evaluation of a new single-use flexible cystoscope dedicated to double-J stent removal (Isiris™): a European prospective multicenter study

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*both authors contributed equally

Word count: manuscript: 2380, abstract: 246

Runninghead: Evaluation of a single use flexible cystoscope for double-J stent removal.

Keywords: cystoscopy, double-J stent, ureteral stent, stents, device removal

Steeve Doizi (MD, MSc)
Department of Urology, Tenon Hospital, Assistance-Publique Hôpitaux de Paris, Paris France.
Pierre et Marie Curie University, Paris, France.
Groupe de Recherche Clinique sur la Lithiase Urinaire, Tenon Hospital, Assistance Publique – Hôpitaux de Paris, Paris, France
Email: steeve.doizi@aphp.fr

Guido Kamphuis (MD)
Department of Urology, Academic Medical Center, Amsterdam, the Netherlands.
Email: g.m.kamphuis@amc.uva.nl

Guido Giusti (MD)
Department of Urology, IRCCS San Raffaele Scientific Institute, Ville Turro Division, Milan, Italy.
Email: info@guidogiusti.it

Jose Luis Palmero (MD)
Department of Urology, Hospital Universitario La Ribera, Alzira, Valencia, Spain
Email: jlpalmero@hospital-ribera.com

Jake Patterson (MD)
Royal Hallamshire Hospital, Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield, United Kingdom
Email : jake.patterson@nhs.net

Silvia Proietti (MD)
Department of Urology, IRCCS San Raffaele Scientific Institute, Ville Turro Division, Milan, Italy.
Email: proiettisil@gmail.com

Michael Straub (MD)
Department of Urology, Technische Universität München, Munich, Germany.
Email: michael.straub@tum.de

Jean de la Rosette (MD, PhD)
Department of Urology, Academic Medical Center, Amsterdam, the Netherlands.
Email: j.j.delarosette@amc.uva.nl

Olivier Traxer (MD)
Department of Urology, Tenon Hospital, Assistance-Publique Hôpitaux de Paris, Paris France.
Pierre et Marie Curie University, Paris, France.
Groupe de Recherche Clinique sur la Lithiase Urinaire, Tenon Hospital, Assistance Publique – Hôpitaux de Paris, Paris, France
Email : olivier.traxer@aphp.fr

CORRESPONDING AUTHOR:
Prof. Olivier Traxer
Department of Urology, Tenon Hospital, Assistance-Publique Hôpitaux de Paris, Paris France.
4 rue de la Chine, 75020, Paris, France
Phone: (+33) 1 56 01 61 53
Fax : (+33) 1 56 01 63 77
Email: steeve.doizi@aphp.fr

ABSTRACT

Purpose: We evaluated a new single use digital flexible cystoscope with an integrated grasper designed for double-J stent removal, Isiris™ addressing success rate, image quality, deflection, maneuverability and grasper functionality.

Methods: In September 2015 a prospective cohort study was conducted in six tertiary European reference centers. All consecutive patients included underwent double-J stent removal and were 18 years or older. Success rate was defined by complete stent removal. Image quality, deflection, maneuverability and grasper functionality were rated with a Likert scale.

Results:

A total of 83 procedures were performed. 82% of procedures were performed in the endoscopy room while the others were in the operating room since a consecutive endourological intervention was planned. The median duration of stent implantation was 28 days [14; 60]. In five patients, stent removal was not possible. Four patients had an incrusted double-J stent and in one patient the stent migrated into the ureter. After unsuccessful attempts of stent removal with conventional flexible cystoscope and grasper, the five patients had to be scheduled for an ureterorenoscopy procedure to remove the stent. In the other 78 patients all double-J stents were removed successfully. Image quality, deflection, maneuverability and grasper functionality were rated as “very good” in 72.3%, 78.3%, 72.3% and 73.5% respectively.

Conclusion: This multicenter clinical evaluation of Isiris™ displayed good image quality, active deflection, maneuverability and grasper functionality. Further evaluation of stent

removal outcomes, cost analysis and microbiology will help to delineate the possible place of Isiris™ in the current practice.

INTRODUCTION

Since their introduction in 1978, double-J stents have become a fundamental tool in the urological armamentarium and their placement is one of the most common procedures performed in modern urology [1]. Although these stents are inserted for various indications, the most common is probably after an ureterorenoscopic procedure to prevent the incidence of postoperative ureteric obstruction and renal colic secondary to ureteral edema. Ureteric stenting has also been advocated to facilitate the passage of stone fragments secondary to the passive ureteric dilation [2-6]. Although this common practice is still debated, it has been reported in large series that approximately 80% of urologists place a ureteric stent after uncomplicated ureteroscopy for stone disease [7-15]. Once the double-J stent has been placed, this has to be removed after a while. Currently, there are two options common in practice to remove these stents: to use the extraction string suture with which the current stents may be packaged, or a cystoscopic removal using a flexible or rigid cystoscope with a grasper. For the latter procedure, this requires a dedicated place with video equipment as well as cystoscopes and graspers. These instruments are fragile and have to be disinfected after each procedure, which may limit the number of procedures due to their availability [16-19].

For these reasons, a single use flexible cystoscope with integrated grasper dedicated to double-J stent removal has been developed.

The objective of the current study was to evaluate the first clinical performance of the Isiris™ flexible cystoscope for double-J stent removal.

MATERIAL AND METHODS

Study design and participants

A prospective cohort study was conducted in six tertiary reference centers in Europe (France, Germany, Italy, Spain, the Netherlands, and United-Kingdom) in September 2015. All consecutive patients included were 18 years or older and had to undergo a double-J stent removal. The following preoperative data were prospectively collected: gender, indication for double-J stent placement, stent characteristics (length, diameter, type and manufacturer), duration of stent implantation and type of anesthesia performed for stent removal. All patients gave informed consent to undergo a cystoscopic removal of stent with Isiris™, and the principles of the Declaration of Helsinki were followed.

Isiris™

Isiris™ (Porgès-Coloplast) is a single use digital flexible cystoscope, CE approved, with an integrated grasper designed for double-J stent removal (Figures 1, 2 and 3). Isiris™ is designed for ureteric stent removal only and not to perform regular diagnostic cystoscopy. This flexible cystoscope has a 16-Fr outer diameter from the tip to the main part, no working channel for insertion of instruments, minimum of 80˚ deflection in upward and 90° in downward directions and a length of 39 centimeters (Figures 1 and 4). The handle includes an irrigation connector, a deflection lever for upward and downward directions and a grasper activation button (Figure 1). The digital camera is made of a complementary metal oxide semiconductor (CMOS) sensor located at the tip of the endoscope and provides 0° direct view with 85° field of vision. The scope is connected via a cable to a reusable dedicated LCD portable monitor (Figure 3). The dimensions of display on monitor are 8.5

inches for a resolution of 800x600 pixels. A USB port is integrated in the monitor allowing connecting a USB drive to record the case if needed. The Isiris™ cystoscope cannot be sterilized.

Procedures

According to local protocol, preoperative urine analysis and culture were performed and appropriate prophylactic antibiotics were given. Procedures were performed as office-based cystoscopy in the outpatient clinic if no other intervention was planned. Patients were placed in dorsolithotomy position. The procedure was performed without anesthesia, local anesthesia (intraurethral lidocaine gel instillation) or general anesthesia if patient had to undergo an ureterorenoscopic procedure. All procedures were conducted by experienced endourologists. Each procedure was performed as a regular flexible cystoscopy, starting with disinfection of the genitalia with antisepsis according to local protocol followed by Isiris™ cystoscope insertion. Then, the stent was removed using the integrated grasper by activating the button located on the handle.

Evaluation criteria

The main outcome was the evaluation of success for stent removal.

The secondary outcomes were the performance characteristics of the instrument as experienced by the surgeon according to the following criteria evaluated during the procedure:

- Image quality displayed on the monitor with native resolution: rated according to a Likert scale of “bad” to “very good”.

- Active deflection: upward and downward deflections were rated according to a Likert scale of “bad” to “very good” by the surgeon during the cystocopy.

- Maneuverability: surgeons rated the maneuverability on a Likert scale of “bad” to “very good”.

- Grasper activation: participants rated the ability to use the grasper by activating the button using a Likert scale of “very difficult” to “very easy”.

- Grasper functionality: participants rated the ability of grasper to catch the stent using a Likert scale of “bad” to “very good”.

- Estimation of procedure duration with Isiris™ compared to the usual double-J stent removal with flexible cystoscope: participants rated the duration between shorter, similar or longer than the usual one.

- Overall satisfaction: participants rated their overall satisfaction using a Likert scale of “bad” to “very good”.

The following data were also collected: need of assistant and his role.

Per operative complications and technical failures were collected. No data were captured on postoperative complications.

Statistical analysis

Qualitative variables were described as numbers and percentage. Quantitative variables were described as median [interquartile range] values.

RESULTS

Patient characteristics

A total of 83 procedures were performed with Isiris™. The study included 45 men (54%) and 38 women (46%). 82% of procedures were performed in the endoscopy room while the others were in the operating room as further urological intervention was planned. Double-J stent diameters were 7-Fr, 6-Fr and 4.8-Fr in 60%, 36% and 4% respectively. Length of stent was 24 cm, 26 cm, 28 cm in 31.3%, 14.5% and 30.1% respectively. The median duration of stent implantation was 28 days [14; 60]. Indications for stent placement were drainage after a ureterorenoscopy procedure for stone disease in 73.5% of cases, ureterorenoscopy procedure for upper urinary tract tumor in 7.3%, ureteral stenosis, renal transplant and other indications in 6% for each (Table 1).

Primary outcome

In five patients, stent removal was not possible. Four patients had an incrusted double-J stent and in one patient the stent migrated into the ureter. In the four cases with encrusted double-J stent, stent removal with conventional flexible cystoscope and grasper was attempted and did not succeed. Finally, the five patients had to be scheduled for an ureterorenoscopy procedure to remove the stent.

In the other 78 patients, all double-J stents were removed successfully (Table 2).

No complication occurred during the procedures and no technical failure has been experienced.

Secondary outcomes

Image quality was rated as “very good” in 72.3%, “good” in 22.9% and “fair” in 4.8% of cases.

Deflection was rated as “very good” in 78.3%, “good” in 20.5% and “fair” in 1.2% of cases.

Maneuverability was rated as “very good” in 72.3%, “good” in 25.3% and “fair” in 2.4% of cases.

Grasper activation button was rated as “very easy” to use in 69.9%, “easy” in 27.7% and “fair” in 2.4%.

Grasper functionality was rated as “very good” in 73.5%, “good” in 22.9%, “fair” in 2.4% and “poor” in 1.2% of cases.

Duration of procedure compared to conventional cystoscopic double-J removal was considered “shorter” in 37.4%, “similar” in 57.8% and “longer” in 4.8% of cases.

Overall satisfaction was “very good” in 68.7%, “good” in 22.9%, “acceptable” in 7.2% and “poor” in 1.2% of cases (Table 2).

An assistant was present during the procedure in 51.8% of cases. His role consisted of connecting the irrigation and scope to the monitor in 36.4%, preparing the endoscopic room in 24.2% or because the hospital regulations required an assistant in 39.4%.

DISCUSSION

This study evaluated the first single use digital flexible cystoscope integrating a grasper dedicated to double-J stent removal. We showed this device obtained a 94% success rate for ureteric stent withdrawal and very good results in almost 70% of cases according to the Likert scale rating for evaluation of image quality, deflection, maneuverability and grasper. The five double-J stents that could not be successfully removed by the Isiris™ were also unsuccessfully engaged by conventional cystoscopy.

As this is the first disposable device dedicated to double-J stent removal and no comparison with similar instruments can be done, the release of Isiris™ addresses some questions. First of all, the question arises if this instrument is functional for its purpose and safe to use. In this first evaluation we confirmed that double-J stents can be removed safely with very good results regarding of image quality, deflection, maneuverability and instrumentation of the integrated grasper. The next question is related to costs. Since this endoscope is single use and does not require a dedicated place with equipment to remove the stents, cleaning and storage, the only direct costs are the one of the Isiris™ cystoscope. Besides this, the set up with the Isiris™ might change the need for an assistant in the room. However, this has to be balanced with the cost of a double-J stent removal using a flexible cystoscope and grasping forceps. Many studies focused on the cost of ureteroscopy but no evaluation on the direct and indirect costs of cystoscopic double-J stent removal is available. The only study partly addressing this question is the one of Netto and colleagues where they assessed the cost-effectiveness of routine ureteral stenting after ureteroscopic stone removal. They found that the hospital charge per patient for stent use after uncomplicated ureteroscopy for stone removal was $2,445.31 with and $3,727.82 without the string left in place. However, they

specified that stent removal was performed in the operating room, which may add an extra charge compared to the office cystoscopic removal setting [11]. Another issue is the flexible cystoscopes durability, implying repair costs. Although the durability of flexible ureteroscopes has often been reported, only few studies assessed this issue on flexible cystoscopes. In 2013, McGill et al prospectively evaluated the durability and repair costs of six flexible cystoscopes over a study period of 14 months on an outpatient setting. They excluded of their analysis the costs associated with cystoscope purchase. They found a total of five failures occurring in four cystoscopes, with a mean of 412.8 procedures per cystoscope. Damages occurred after 70, 194, and 236 uses for three cystoscopes and one cystoscope had 2 failures after 168 and 255 uses. This meant a cost of cystoscope maintenance of $5.41 per procedure during the study period. They also underlined that cystoscopes damages occurred earlier in cystoscopes with a higher percentage of uses secondary to stent removals, biopsies, and fulgurations [16]. In 2011, Söylemez et al reported a purchase cost of $18.342 for a flexible cystoscope and $2.057 for a 3-Fr flexible grasper. The maintenance interval for each instrument was 10 times with a repair cost of $1.487 and $491 for the flexible cystoscope and forceps respectively [17]. In a retrospective study, Canales et al showed that flexible cystoscopes required repair every 2 to 3 years over a four year study period. However, they did not report the number of uses before repair and the mechanism of damage [18]. And finally, Fuselier and Mason found that 7 cystoscopes were damaged over a two year study period including approximately 2,000 procedures. Similarly, no details on number of procedures performed before repair and cause of failure were reported and it was unclear whether the endoscopes were used or new before the

onset of the study [19]. None of the studies included costs related to cleaning instruments as well as costs related to handling them.

The other issue addressed is the risk of urinary tract infection after flexible cystoscopy. Flexible cystoscopes mostly undergo high level disinfection (HLD) rather than sterilization between patients [20]. Thus, the question of pathogenic cross contamination between patients is addressed given that there is now an alternative with this single use cystoscope. In the field of endourology, Chang et al first reported in 2013 15 patients developing ertapenem-resistant Enterobacter cloacae urinary tract infections due to a contaminated ureteroscope [21]. However, we have to emphasize that the risk of urinary tract infection after flexible cystoscopy is low. In two large prospective studies, Herr et al reported that 1.9% of patients undergoing a diagnostic flexible cystoscopy developed a febrile urinary tract infection within 30 days after the procedure [22, 23]. In another large study, the authors found a 9% incidence of bacteriuria after cystoscopy and only 1.2% developed a symptomatic urinary tract infection [24]. Other studies reported an incidence of bacteriuria up to 7.8% and symptomatic urinary tract infection up to 3% [25-39].

And finally, what is the environmental impact of the single use devices? Further studies should be conducted comparing this issue between single use endoscopes with reusable scopes requiring disinfection with highly toxic detergents.

The present study has several limitations. First, we did not compare the clinical performance of Isiris™ to a control group including current practice to remove ureteric stents i.e. flexible cystoscope with grasping forceps. This may impact the strength of our results. However the current study should be considered as a preliminary evaluation of this new device. All the

concerns discussed earlier highlight the need of further studies to define the place of Isiris™ in the current practice. A comparison with conventional flexible cystoscopic stent removal is needed where the clinical performance, direct and indirect costs with cost-effectiveness analysis are assessed. However, such studies comparing the costs of care display great variation across countries due to differences in practices methods of calculating costs and billing. Furthermore, studies comparing microbiological evaluation and the risk of urinary tract infection between this new device and traditional stent removal with flexible cystoscope are needed.

This new concept of double-J stent removal and single use endoscopes such as flexible ureteroscopes may open a new era in the field of endourology [30]. However, further evaluations are required to delineate the position of these instruments in the current practice.

CONCLUSIONS

This preliminary study evaluated the Isiris™, the first single use digital flexible cystoscope integrating a grasper dedicated to double-J stent removal. The evaluation of instrument characteristics of image quality, active deflection, maneuverability and grasper functionality by the surgeons on Likert scales was good. There were no complications or technical failures. In five cases the double-J stent required additional ureteroscopic surgical removal due to stent encrustation or stent migration into the ureter.

The position of single use endoscopes in day to day practice will depend on functional outcome in larger series, local practice and local cost analysis and concerns about possible infections.

RESEARCH INVOLVING HUMAN PARTICIPANTS AND/OR ANIMALS

Ethical 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.”

Informed consent: “Informed consent was obtained from all individual participants included in the study.”

AUTHORS' CONTRIBUTION

Doizi: Protocol/project development, Data collection or management, Data analysis, Manuscript writing/editing

Kamphuis: Protocol/project development, Data collection or management, Data analysis, Manuscript writing/editing

Giusti: Protocol/project development, Data collection or management, Manuscript writing/editing

Palmero: Protocol/project development, Data collection or management, Manuscript writing/editing

Patterson: Protocol/project development, Data collection or management, Manuscript writing/editing

Proietti: Protocol/project development, Data collection or management, Manuscript writing/editing

Straub: Protocol/project development, Data collection or management, Manuscript writing/editing

de la Rosette: Protocol/project development, Data collection or management, Manuscript writing/editing

Traxer: Protocol/project development, Data collection or management, Manuscript writing/editing

CONFLICT OF INTEREST

Steeve Doizi: None.

Guido Kamphuis: None.

Guido Giusti: Boston Scientific, Coloplast, Cook Medical, Olympus, Karl Storz, Rocamed.

Jose Luis Palmero: Boston Scientific, Coloplast, Cook Medical

Jake Patterson: Boston Scientific, Coloplast

Silvia Proietti: None.

Michael Straub: Richard Wolf Endoskope, Sanochemia Pharmazeutika AG

Jean de la Rosette: Boston Scientific, Coloplast, Olympus, Karl Storz.

Olivier Traxer: Boston Scientific, Coloplast, Lumenis, Olympus, Rocamed.

SUPPORT/FINANCIAL DISCLOSURES

The Isiris™ scopes were made available by Porgès-Coloplast.

ACKNOWLEDGMENTS

The authors would like to thank Porgès-Coloplast for providing Isiris™ endoscopes in each centre in order to evaluate its performance.

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426

427 **LEGENDS**

428 Table 1. Demographic data.

429 Table 2. Primary and secondary outcomes.

430 Figure 1. Isiris™ flexible cystoscope. Plain arrow: grasper activation button. Square
431 dotted arrow: irrigation connector. Round dotted arrow: deflection lever.

432 Figure 2. Activation of grasper. Maximum length of protruded grasper is 18 mm.
433 Minimum grasper opening distance is 4.5 mm.

434 Figure 3. Isiris™ connected via its cable to the reusable dedicated LCD portable monitor.
435 A: Activation of the grasper. B: Grasper catching a double-J stent.

436 Figure 4. Downward (left) and upward (right) deflections.

Characteristics		
Number of procedures	83	
Gender, n (%)		
Male/Female	45/38	(54/46)
Double-J stent characteristics, n (%)		
Diameter (Fr)		
4.8	3	(4)
6	30	(36)
7	50	(60)
Length (cm)		
16	1	(1.2)
18	2	(2.4)
22	3	(3.6)
24	26	(31.3)
26	12	(14.5)
28	25	(30.1)
Other	14	(16.9)
Duration of stent implantation, median days	28	[14 ; 60]
Anesthesia, n (%)		
None	12	(14.5)
Local	59	(71)
General	12	(14.5)
Double-J stent removal indication, n (%)		
Stone	61	(73.5)
Upper Urinary Tract Tumor	6	(7.3)
Ureteral stenosis	5	(6)
Renal transplantation	5	(6)
Ureteral reimplantation	1	(1.2)
Unspecified	5	(6)
Data are presented as median with interquartile range		

Table 1. Demographic data.

Category	
Success, n (%)	**78/83 (94)**
Deflection	
Very good	65/83 (78.3)
Good	17/83 (20.5)
Fair	1/83 (1.2)
Poor	0/83
Bad	0/83
Image quality, n (%)	
Very good	60/83 (72.3)
Good	19/83 (22.9)
Fair	4/83 (4.8)
Poor	0
Bad	0
Maneuverability, n (%)	
Very good	60/83 (72.3)
Good	21/83 (25.3)
Fair	2/83 (2.4)
Poor	0
Bad	0
Grasper activation button, n (%)	
Very easy	58/83 (69.9)
Easy	23/83 (27.7)
Fair	2/83 (2.4)
Difficult	0
Very difficult	0
Grasper funtionality, n (%)	
Very good	61/83 (73.5)
Good	19/83 (22.9)
Fair	2/83 (2.4)
Poor	1/83 (1.2)
Bad	0
Procedure duration compared to usual stent removal, n (%)*	
Shorter	31/83 (37.4)
Similar	48/83 (57.8)
Longer	4/83 (4.8)
Overall performance satisfaction, n (%)	
Very good	57/83 (68.7)
Good	19/83 (22.9)
Acceptable	6/83 (7.2)
Poor	1/83 (1.2)
Bad	0

Table 2. Primary and secondary outcomes.