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

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

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

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68 ABSTRACT

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

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

77 Results:

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

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

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

92

93 INTRODUCTION

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

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

112 The objective of the current study was to evaluate the first clinical performance of the Isiris™
113 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 antiseptis 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 cystoscopy.
- 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 encrusted 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

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

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

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

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

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

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

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

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

213

214 **DISCUSSION**

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

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

237 specified that stent removal was performed in the operating room, which may add an extra
238 charge compared to the office cystoscopic removal setting [11]. Another issue is the flexible
239 cystoscopes durability, implying repair costs. Although the durability of flexible
240 ureteroscopes has often been reported, only few studies assessed this issue on flexible
241 cystoscopes. In 2013, McGill et al prospectively evaluated the durability and repair costs of
242 six flexible cystoscopes over a study period of 14 months on an outpatient setting. They
243 excluded of their analysis the costs associated with cystoscope purchase. They found a total
244 of five failures occurring in four cystoscopes, with a mean of 412.8 procedures per
245 cystoscope. Damages occurred after 70, 194, and 236 uses for three cystoscopes and one
246 cystoscope had 2 failures after 168 and 255 uses. This meant a cost of cystoscope
247 maintenance of \$5.41 per procedure during the study period. They also underlined that
248 cystoscopes damages occurred earlier in cystoscopes with a higher percentage of uses
249 secondary to stent removals, biopsies, and fulgurations [16]. In 2011, Söylemez et al
250 reported a purchase cost of \$18.342 for a flexible cystoscope and \$2.057 for a 3-Fr flexible
251 grasper. The maintenance interval for each instrument was 10 times with a repair cost of
252 \$1.487 and \$491 for the flexible cystoscope and forceps respectively [17]. In a retrospective
253 study, Canales et al showed that flexible cystoscopes required repair every 2 to 3 years over
254 a four year study period. However, they did not report the number of uses before repair and
255 the mechanism of damage [18]. And finally, Fuselier and Mason found that 7 cystoscopes
256 were damaged over a two year study period including approximately 2,000 procedures.
257 Similarly, no details on number of procedures performed before repair and cause of failure
258 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

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

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

293

294 **CONCLUSIONS**

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

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

304 **RESEARCH INVOLVING HUMAN PARTICIPANTS AND/OR ANIMALS**

305

306 Ethical approval: "All procedures performed in studies involving human participants were in
307 accordance with the ethical standards of the institutional and/or national research
308 committee and with the 1964 Helsinki declaration and its later amendments or comparable
309 ethical standards."

310

311 Informed consent: "Informed consent was obtained from all individual participants included
312 in the study."

313 **AUTHORS' CONTRIBUTION**

314 **Doizi:** Protocol/project development, Data collection or management, Data analysis,

315 Manuscript writing/editing

316 **Kamphuis:** Protocol/project development, Data collection or management, Data analysis,

317 Manuscript writing/editing

318 **Giusti:** Protocol/project development, Data collection or management, Manuscript

319 writing/editing

320 **Palmero:** Protocol/project development, Data collection or management, Manuscript

321 writing/editing

322 **Patterson:** Protocol/project development, Data collection or management, Manuscript

323 writing/editing

324 **Proietti:** Protocol/project development, Data collection or management, Manuscript

325 writing/editing

326 **Straub:** Protocol/project development, Data collection or management, Manuscript

327 writing/editing

328 **de la Rosette:** Protocol/project development, Data collection or management, Manuscript

329 writing/editing

330 **Traxer:** Protocol/project development, Data collection or management, Manuscript

331 writing/editing

332

333 **CONFLICT OF INTEREST**

334 **Steeve Doizi:** None.

335 **Guido Kamphuis:** None.

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

337 **Jose Luis Palmero:** Boston Scientific, Coloplast, Cook Medical

338 **Jake Patterson:** Boston Scientific, Coloplast

339 **Silvia Proietti:** None.

340 **Michael Straub:** Richard Wolf Endoskope, Sanochemia Pharmazeutika AG

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

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

343

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

346

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LEGENDS

Table 1. Demographic data.

Table 2. Primary and secondary outcomes.

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

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

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

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 functionality, 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.