Original Research Article

UJ Urologia Journal

Urologia Journal
2020, Vol. 87(1) 29–34

DOI: 10.1177/0391560319859797
journals.sagepub.com/home/urj
SAGE

Cost-effectiveness analysis of a single-use digital flexible cystoscope for double J removal

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Abstract

Introduction and objective: The novel single-use digital flexible cystoscope Isiris™ has been developed to perform in-office JJ stent removal, without the need of special equipment nor limitations linked to the disinfection of a reusable device. The aim of our study was to perform a cost-effectiveness analysis of Isiris™ in our institution.

Patients and methods: A total of 127 consecutive patients undergoing in-office stent removal with Isiris™ were prospectively included in study. After each procedure, the urologist filled a questionnaire specifically developed to evaluate the efficiency of the device and the invasiveness of the procedure. We performed a cost analysis of the main variables involved in JJ removal using Isiris™ versus the traditional Storz™ reusable flexible cystoscope used for all our previous patients.

Results: The procedure was successful in all cases except for one, where the device did not work due to the failure of the grasper and had to be replaced. Overall, the performance of Isiris™ was judged by the physician "very good" and "good" in 90.6% of the cases. Both median pain and invasiveness felt by the patient were 0 (range = 0–8). The mean cost of procedure was estimated at €361 for in-office stent removal with Isiris™, and €1.126.8 for stent removal in operatory room with a reusable flexible cystoscope. Considering the 127 procedures performed in office, 64 h of operatory room time was saved.

Conclusion: In institutions where JJ removal is performed in the operatory room, Isiris™ leads to a significant advantage in terms of money saved per procedure, operatory room time gained and patient satisfaction.

Keywords

Flexible cystoscope, Isiris, cost-effectiveness, single use

Date received: 29 September 2018; accepted: 2 June 2019.

Introduction

The placement of ureteral JJ stents is one of the most performed procedures in urology. These stents are inserted for various indications, most commonly after ureterorenoscopic procedures to prevent the incidence of postoperative renal colic due to ureteral edema.[1] Once in place, they must be removed after a while. Removal of JJ stents can be done using the dedicated extraction string suture integrated into the stent, if available and for short dwell-time, or by cystoscopy. Cystoscopic removal is usually performed using a flexible cystoscope with a grasper and requires an endoscopic room with video equipment and endoscopic instruments that need to be disinfected after each procedure, which might limit the number of procedures. In the absence of the endoscopic room, all cystoscopic procedures must be performed in the operatory room (OR), with obvious consequences in terms of OR occupancy and overbooking. To overcome these issues, the novel single-use digital flexible cystoscope Isiris™ has been developed to perform in-office JJ stent removal, without the need of special equipment nor

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limitations linked to the disinfection of the device. The effectiveness and technical quality of Isiris™ have already been assessed.[1,2] The aim of our study was to perform a cost-effectiveness analysis of Isiris™ in our institution.

Patients and methods

A total of 127 consecutive patients undergoing in-office stent removal with Isiris™ in our institution from March to December 2017 were prospectively included in study. A questionnaire specifically developed to evaluate the efficiency of the device and invasiveness of the procedure was filled after each procedure: the urologist filled the section concerning the efficiency of the device, whereas the patient filled the section concerning the invasiveness and tolerability of the procedure. The following items were assessed: gender, stent characteristics, indication for JJ stent placement, type of anesthesia used for stent removal, quality of performance of Isiris™, length of the procedure, pain and invasiveness score according to the 10 points Numeric Pain Rating Scale (NRS). All patients gave informed consent to stent removal with Isiris™, and the principles of the Declaration of Helsinski were followed.

We performed a cost analysis of the main variables involved in JJ removal using Isiris™ versus the traditional 16-Ch Storz™ reusable flexible cystoscope used for all our previous patients. Our calculations were based on the following items: cost of a Storz™ flexible cystoscope plus grasper; cost of OR occupancy; cost of medical personnel, considering also the aid of a nurse; cost of high-level cystoscope disinfection; cost of Isiris™ cystoscope and Isiris™ monitor purchase; cost of repairs in case of damages to reusable cystoscopes (we considered one serious damage each year, mainly to the sheath or to the operative channel).

Stent removal with Isiris™

Isiris™ (Porgès-Coloplast) is a single-use digital flexible cystoscope with an integrated grasper designed for JJ stent removal (Figure 1). It has a 16-Ch outer diameter, no working channel for the insertion of instruments, complementary metal oxide semiconductor 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 8.5-in. LCD portable monitor (Figure 2).[1,2] Stent removals were performed as in-office procedures, with patients in dorso-lithotomy position. Each procedure was performed as a regular flexible cystoscopy without anesthesia, removing the stent with the integrated grasper by activating the button on the handle of Isiris™.

Statistical analyses

Qualitative variables were described as number and percentages. Quantitative variables were described as median and ranges.

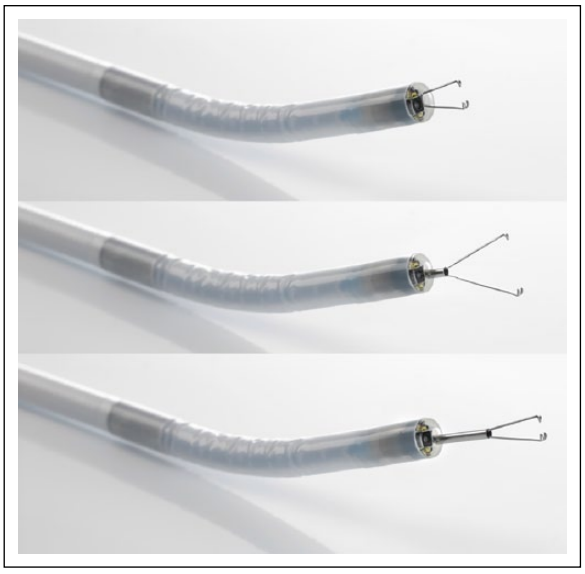

Figure 1. Isiris™ integrated grasper.

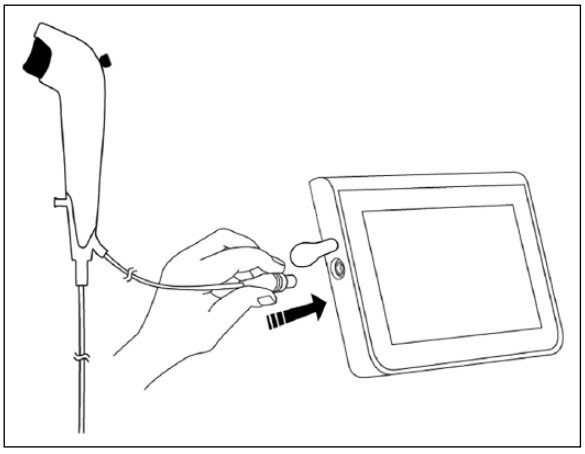

Figure 2. The scope of Isiris™ is connected via a cable to a reusable dedicated 8.5-in. LCD portable monitor.

Results

Patients' characteristics are shown in Table 1. Mean stent indwelling time was 37.5 days (SD = 22.5). The most common indication for stent placement was drainage after ureterorenoscopy procedure for stone disease (85.8% of the cases). The outcomes of stent removal with Isiris™ are reported in Table 2. The procedure was successful in all cases except for one, where the device did not work due to the failure of the grasper and had to be replaced with Porgès-Coloplast without additional costs. Image quality, deflection, and maneuverability were judged as "very good" or "good" in most cases. The same goes for grasper activation button and functionality, which were reported as "very easy" and "easy" more than 90% of the cases. An assistant was required for the procedure in 70.9% of the cases, mainly for the connection of the irrigation or due to

Table 1. Patients' characteristics.

Number of patients enrolled	127
Gender, n (%)	
– Males	70 (55.1)
– Females	57 (44.9)
JJ length, n (%)	
– 24 cm	54 (42.5)
– 26 cm	66 (52.0)
– 28 cm	1 (0.8)
– Missing	6 (4.7)
JJ diameter, n (%)	
– 6 Ch	118 (92.9)
– 7 Ch	3 (2.4)
– Missing	6 (4.7)
JJ removal indication, n (%)	
– Stones	109 (85.8)
– Ureteral stenosis	5 (3.9)
– Pyeloplasty	6 (4.7)
– Ureteral reimplantation	4 (3.1)
– Other	2 (1.6)
– Unspecified	1 (0.8)
JJ indwelling time, days, mean (SD)	37.5 (22.5)

institutional policy requiring the presence of a nurse for stent removal. Overall, the performance of Isiris™ was judged by the physician "very good" and "good" in 90.6% of the cases. Both median pain and invasiveness felt by the patient were 0 (range = 0–8).

As for cost-effectiveness analysis, we compared the costs of JJ removal performed in the OR with a Storz™ reusable flexible cystoscope (170 procedures performed in 2016) with those of the same procedure performed in office in 2017 with Isiris™. According to an in-house survey dating 2016, the hourly cost of OR occupancy was estimated at €2.051, including the personnel (three nurses) and the consumables. Median operative time was 3 min (range = 1–8) in the OR versus 2 min (range = 1–5) in office. Considering the entire length of the procedure, including patient entrance to next patient entrance, patient positioning, and room cleaning, median duration was 30 min (range = 20–38) in the OR versus 14 min (range = 12–20) in office. Calculations were made considering that three reusable flexible cystoscopes are available in our institution and one repair was needed during the timespan considered; a lifetime of 5 years was taken into account for every flexible cystoscope.

Considering all the variables summarized in Table 3, the mean cost for procedure was estimated at €361 for in-office stent removal with Isiris™, and €1.126.8 for OR stent removal with our Storz™ reusable flexible cystoscope. Considering the 127 procedures performed in office rather than in the OR, 64 h of OR time was saved.

Table 2. Outcomes of JJ stent removal with Isiris™.

Number of procedures	127
Success of JJ stent removal, n (%)	126 (99.2)
Failures of Isiris™, n (%)	
– Damaged grasper	1 (0.8)
Image quality, n (%)	
– Very good	91 (71.6)
– Good	22 (17.4)
– Fair	7 (5.5)
– Poor	6 (4.7)
– Bad	1 (0.8)
Deflection, n (%)	
– Very good	93 (73.3)
– Good	20 (15.7)
– Fair	13 (10.2)
– Poor	1 (0.8)
– Bad	0 (0)
Maneuverability, n (%)	
– Very good	93 (73.3)
– Good	21 (16.5)
– Fair	10 (7.8)
– Poor	3 (2.4)
– Bad	0 (0)
Grasper activation button, n (%)	
– Very easy	88 (69.2)
– Easy	29 (22.8)
– Fair	10 (7.8)
– Difficult	0 (0)
– Very difficult	0 (0)
Grasper functionality, n (%)	
– Very easy	93 (73.2)
– Easy	23 (18.1)
– Fair	8 (6.3)
– Difficult	2 (1.6)
– Very difficult	1 (0.8)
Need for assistance during the procedure, n (%)	
– Yes	90 (70.9)
– No	37 (29.1)
Procedure duration compared to usual stent removal, n (%)	
– Shorter	45 (35.4)
– Similar	74 (58.3)
– Longer	8 (6.3)
Overall Isiris™ performance satisfaction, n (%)	
– Very good	100 (78.8)
– Good	15 (11.8)
– Acceptable	10 (7.8)
– Poor	1 (0.8)
– Bad	1 (0.8)
Pain felt by the patient (NRS score), median (range)	0 (0–8)
Invasiveness felt by the patient (NRS score), median (range)	0 (0–8)

NRS: Numeric Pain Rating Scale.

Table 3. Cost analysis of single-use Isiris™ versus reusable Storz™ flexible cystoscope (VAT included).

Single-use Isiris™ flexible cystoscope			Reusable Storz™ flexible cystoscope		
	Cost	Cost/procedure[a]		Cost	Cost/procedure[b]
Isiris™ cystoscope purchase	€317	€317	Storz™ flexible cystoscope purchase	€11.000	€38.8
Isiris™ LCD monitor purchase	€3.367	€26.5	Storz™ grasper purchase	€300	€5.3
Isiris™ repairs	None: single-use instrument		Storz™ flexible cystoscope repairs	€2.400	€14.1
Urologist work (14 h considered)	€51.2/h	€11.9	Urologist work (30 h considered)	€51.2/h	€25.6
Nurse work (14 h considered)	€24.1/h	€5.6	Nurse work (15 h considered)	Included in costs of OR occupancy	
Isiris™ sterilization	None: single-use instrument		Storz™ flexible cystoscope decontamination and Sterrad® sterilization plus detergents	€17.5	€17.5
Office occupancy	–	–	OR occupancy including personnel and consumables (30 h considered)	€2.051/h[c]	€1.025.5
Total	–	€361	Total	–	€1.126.8

OR: operatory room.
[a]A total of 127 procedures performed from March 2017 to October 2017.
[b]A total of 170 procedures performed in our institution in 2016, considering the availability of three cystoscopes and three graspers, and an average lifetime of 5 years for every flexible cystoscope and 1 year for the grasper.
[c]In-house survey 2016.

Discussion

Isiris™ is the first disposable device dedicated to JJ removal, designed to give an easy access to flexible cystoscopy and to streamline the process of stent removal.[3] In line with other studies in the literature,[1,2] our study confirmed the effectiveness and functionality of this device, which achieved a 99.2% success rate for ureteric stent withdrawal and good results in terms of image quality, deflection, maneuverability, grasper, procedure duration, and performance satisfaction. Isiris™ allowed to perform the procedure without the aid of any assistant, even if per our institutional policy, a nurse was present in most cases to prepare the room and to connect the irrigation. Except for one case where the grasper was damaged and the device had to be replaced (the costs were assumed by the company producing the device), all the other 126 procedures were successful, without any inconveniences. Pain and invasiveness felt by the patients were very low according to the NRS score, demonstrating a good tolerability of the procedure that was conducted without any anesthesia in all cases. Much less anxiety was experienced by patients who underwent JJ removal in the office rather than entering once more into the OR.

In our experience, we found Isiris™ to be a versatile tool: we used it several times in the emergency ward to perform different procedures such as diagnostic cystoscopies, withdrawal of small bladder stones, or even removal of small fragments of prostatic adenoma following laser enucleation of the prostate. In all cases, the procedures were quick, successful, and well tolerated by the patients. The integrated grasper was efficient even if not specifically designed to remove materials other than JJ stents. In our study, the average JJ indwelling time was quite long, due to institutional habits of keeping in place the stent for about 1 month after ureteroscopy. The availability of Isiris™ should allow to decrease the mean stent indwelling time, which often depends more on the availability of the endoscopic room than on clinical reasons.

The main issue concerning Isiris™, however, is not related to its functionality but to its costs: as highlighted by Doizi et al.,[1] since this endoscope is single-use and does not require a dedicated place for stent removal, cleaning, and storage, the only direct costs are the one of Isiris™ itself. In our institution, these costs were estimated at €361 per procedure (VAT included), including the purchase of the cystoscope, the cost of the monitor, and the work of the urologist and the nurse. We compared these costs with those of a standard JJ removal with a reusable Storz™ flexible cystoscope, which in our institution amounted to €1.126.8 per procedure, mainly due to the elevated hourly cost of OR occupancy. It is very difficult to perform a reproducible cost analysis, as in different institutions and countries, we find different hospital policies, OR costs, instruments maintenance contracts, and so on. All these things limit the generalizability of our results.

In our hospital, like in many others, all endoscopic procedures are performed in the OR, due to the unavailability of a dedicated endoscopic room with the necessary equipment, or in alternative a telepack with enough reusable flexible cystoscopes to perform JJ removal in an in-office setting. In these cases, the advantage of a portable, single-use device such as Isiris™ becomes obvious in terms of versatility, avoidance of OR overbooking, and OR time saved. Across 9 months, we estimated that 64 h of OR time was saved in our institution!

In our hospital, there is no dedicated endoscopy room (EnR), so we were not able to compare the costs of JJ removal in this setting. We can imagine that the amount of money saved transferring the procedure from the EnR to the office is inferior in this case, as the hourly cost of the EnR is inferior as compared to the OR. According to a recent French study, the average total cost of a JJ removal in the EnR can be estimated at around €400, leading to consider the adoption of single-use devices such as Isiris™ as a rentable option for the hospital.[4] Another study has previously addressed the same issue, concluding that Isiris™ is a cost-effective option for the in-office removal of JJ stents, allowing to triple the removal activity and better manage stent indwell duration, saving precious hours of EnR time.[5] Other solutions have been recently proposed in the literature to simplify JJ removal procedure, such as a newly developed magnetic JJ stent that can be removed by a special catheter-like retrieval instrument with a magnetic tip,[6] or even the stent retrieval using rigid ureteroscopy under topical anesthesia, which has been described as cheaper than flexible cystoscopy in a Chinese study.[7] To date, we have no direct experience on these other solutions.

Our study is the first Italian study to properly evaluate the cost-effectiveness of Isiris™ in the setting of a public hospital. In our analysis, we have taken into account the durability of reusable flexible cystoscopes, considered as 5 years on average, and the costs associated with their maintenance and repairs, considering that in the timespan of study, one of our cystoscopes had to be repaired. As a limitation of study, we must acknowledge that the lifetime of a reusable flexible cystoscope can be only estimated and that the duration of warranty varies according to the institution and country. In 2013, McGill et al. found a total of five failures occurring in four cystoscopes over a study period of 14 months, underlining that cystoscopes damages occurred earlier in higher percentages of operative procedures such as stent removals, biopsies, and fulgurations.[8]

A final issue to be considered is the risk of urinary tract infections (UTIs) after flexible cystoscopy. The sterility of these devices is a major concern, as flexible cystoscopes are generally disinfected at high level but not sterile.[9] In our institution, flexible cystoscopes undergo initial decontamination with Septozym® detergent, followed by a cycle of Sterrad® sterilization using a combination of hydrogen peroxide vapor and low-temperature gas plasma. Proper cleaning of the instrument and working channel are essential, to obtain a good disinfection without causing damages. Serious cross-urinary infections by *Pseudomonas Aeruginosa* and *Enterobacter cloacae* have been reported after endourological procedures.[10,11] In the literature, symptomatic UTIs and bacteriuria after flexible cystoscopy were reported in up to 1.9% and 9% of the cases, respectively.[12,13] The use of a disposable and sterile device could definitely avoid these risks. To our knowledge, to date, no prospective randomized trial has been conducted comparing post-procedure UTIs using single-use or reusable flexible cystoscopes. Unfortunately, in this retrospective study, we were not able to retrieve data about the incidence of UTIs among our patients treated with single-use and reusable instruments.

A major limitation of this study resides in its retrospective design, which did not allow a randomized comparison between single-use and reusable devices, to be done in a prospective fashion. No direct comparison was performed in terms of efficiency of the devices, invasiveness, and tolerability of the procedure, and the dedicated questionnaire was administered only to patients treated with Isiris™. Despite these limitations, this study provides an interesting insight into the costs and criticalities of JJ removal procedures.

Conclusions

Isiris™ represents an efficient and versatile instrument to perform JJ stent removal or other cystoscopic procedures in different hospital settings. The cost-effectiveness of such instruments becomes particularly evident in institutions where JJ removal is performed in the OR, leading to a significant advantage in terms of money saved per procedure and OR time gained.

Author contributions

M.O. contributed to project development, data collection and analysis, and article writing; J.A. contributed to project development and data collection; S.L. contributed to data collection; and G.F. contributed to article editing.

Declaration of conflicting interests

M.O. has worked as consultant for Urology Diagnostic (Koelis) and has received speaker honoraria from Coloplast. J.A. has worked as consultant for Coloplast. M.F., S.L. and G.F. have no conflicts of interest to disclose.

Ethical Approval

This was an observational study involving human participants, conducted after institutional board approval according to the Helsinki Declaration standards.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

Informed consent

All patients gave informed consent to participate to the study.

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