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UROLITHIASIS

Comparison of ureteric stent removal procedures using reusable and single-use flexible cystoscopes following ureteroscopy and lasertripsy: a micro cost analysis

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Introduction Diagnostic pressure on endoscopy suite can lead to delay in flexible cystoscopic stent removal. We compare the cost and organizational impact of reusable flexible cystoscope versus single-use, flexible cystoscope with a built-in stent grasper (Isiris®).

Material and methods Data for the reusable cystoscopic stent removal performed in endoscopy room, group A (period 1) were compared to Isiris disposable stent removal performed in outpatient clinic, group B (period 2). We chose the same calendar months in successive years for these two different groups (9 months each). A micro cost analysis was performed evaluating the impact on costs, complications and organizational benefit.

Results A total of 72 patients (37, group A; 35, group B) were included with no significant differences in age and gender ratio. The mean procedure time was 14.4 and 2.2 minutes, and the mean stent dwell time was 26.8 and 15.4 days in groups A and B respectively ($p < 0.001$). In group A, 5 patients (14%) developed stent encrustation, of which 3 needed a ureteroscopic removal subsequently. No complication occurred in group B. More staff on average were needed for procedures done in group A, than group B ($p < 0.001$).

The number of patients who had cancer diagnostic wait of >2 weeks for flexible cystoscopy and the mean number of days they waited, reduced from 16 to 3, and 21 days to 3 days respectively between period 1 to period 2. The cost per procedure between group A and group B was £267.2 and £252.62 ($p < 0.05$) if the cost of managing complications was not considered, and £365.40 and £252.62 ($p < 0.001$) if the cost of managing complications was also considered.

Conclusions Isiris significantly reduced stent dwell time, procedural time and staff needed to carry out the stent removals. It also allowed the procedures to be done in the outpatient setting thereby reducing the organizational pressure on endoscopy related diagnostic procedures.

Key Words: stent ‹› isiris ‹› disposable ‹› cystoscopy ‹› urolithiasis ‹› ureteroscopy

INTRODUCTION

The double-J ureteric stent is a prosthetic device, widely used in urological practice since the 1970s to ensure an adequate urine drainage and overcome ureteric obstruction [1]. The most common indication for their use is following ureterorenoscopy (URS) and stone surgery to promote drainage of retained dust, clot and stone fragments or to prevent ureteric obstruction when there is a prediction of post-operative ureteric mucosal oedema [2, 3, 4]. However, the routine use of ureteric stents following URS for stone surgery is disputed and many suggest that ureteric stents are not indicated

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in uncomplicated procedures [4]. Nonetheless, in a large multi-centre international study, it was found that ureteric stent placement following URS for ureteric and renal stones resulted in significantly fewer post-operative complications [5]. Wide variation exists on the type of stent used, duration of stent-dwell time and mode of stent removal, with over three-quarters of urologists reporting their use in practice [6–10].

There are no strict guidelines for indwelling stent dwell time post-operatively, although most urologists would agree that this should be limited to a few days only and removed at the earliest. While this practice varies, a recent meta-analysis has shown significant variability in the length of stent indwelling time prior to removal, ranging from 3 days to 6 weeks [6]. The waiting time for stent removal post-operatively depends on the underlying reason for stent insertion, any intra or post-operative complications, patient unavailability or choice and hospital waiting list linked to its capacity to remove it in a given time frame.

Stents have long been known to cause discomfort, pain and lower urinary tract symptoms (LUTS), affecting majority of patients. It can also become a source of infection and cause urinary tract infections (UTIs) or encrustations, and a greater incidence of which has been seen if ureteric stents are in situ for >15 days [7]. Stent encrustation of up to 47% has been reported, the incidence of which increases from 27% at 6 weeks, to 57% by 12 weeks, and 76% if left beyond 12 weeks [8]. With an indwelling time of 3 months, these stents became heavily encrusted needing additional procedures for removal.

Once ureteral stents are placed, it is commonplace for it to be removed via a flexible cystoscopy in operating theatre (OT) or an endoscopy room-based outpatient setting. This requires access to re-usable flexible cystoscope, endoscopy room and staff. The availability of these resources affects the organisational capacity, that can delay the stent removal with the prolongment of the hospital endoscopy waiting time. The same resources are also needed for diagnostic procedures for suspected and follow-up in patients with bladder cancer, thereby competing with the stent removal procedure slots.

Coloplast developed a new single-use digital flexible cystoscope 'Isiris®', with an integrated grasper to perform double J stent removal [11–16] as an alternative to traditional stent removal via flexible reusable cystoscope. Isiris could be connected to a dedicated digital display monitor that is battery operated and portable in order to be used outside the dedicated endoscopy suite and save resources and time for other endoscopic procedures.

The aim of this study was to compare the indwelling stent time, cost, stent-related complications and organizational impact for standard cystoscopic stent removal in endoscopy room versus out-patient clinic based Isiris stent removal for patients who underwent prior ureteroscopy and stone treatment.

MATERIAL AND METHODS

We maintain a prospective database of all adults who undergo ureteroscopy and stone surgery (URSL). It is registered with our hospital 'Clinical Effectiveness (CE) and Audit office'. All patients had stone surgery performed or supervised by a single surgeon (BS) and they were performed in the same hospital. After URS, patients who had a ureteric stent inserted were placed on a stent removal waiting list, which is managed by the urology hospital management team. This team is responsible to allocate flexible cystoscopy slots which are used for stent removals, all new haematuria investigations, suspected and/or follow-up surveillance of bladder cancer patients.

Data for the reusable cystoscopic stent removal performed in endoscopy room, group (A), were retrospectively collected from the prospective database from May 2018 to January 2019 (period 1). Isiris disposable stent removal was introduced in outpatient clinic from May 2019 and data for this, group (B), were prospectively collected from May 2019 to January 2020 (period 2). In this study, we compared the outcomes of ureteric stent removal (USR) between groups A and group B in patients who had stent insertion following URSL. Removal of stent following other procedures were excluded from this. We chose the same calendar months in successive years for these two different groups (9 months each) to avoid any calendar bias.

While the procedures for group A took place in the endoscopy room, it was done in outpatient clinic room for group B. After explaining the details of the cystoscopy and stent removal, the responsible clinician or nurse obtained patients' consent for the procedure. Both procedures took place after local anaesthetic lidocaine gel instillation in the urethra and were done under gravity irrigation.

In group A, the reusable cystoscope (16 Fr Pentax digital cystoscope) relied on the introduction of an external grasper, inserted by an assistant through the cystoscope's working channel. It was done in the endoscopy room, required an endoscopic stack with video equipment and disposable grasper. In group B, the disposable cystoscope Isiris (16 F) had an integrated grasper which is activated and handled by the same person without the need for an assistant or extra equipment for stent removal. It had

a battery-operated portable monitor plugged directly to the scope and did not need an endoscopic stack. After the procedure, while the scope was disposed, the monitor was used again.

Procedural time was measured with a chronometer and also included preparation time. While the preparation time for group A included collection and preparation of the flexible cystoscope from the endoscopic tray, opening the grasper and connecting the endoscopic stack; for group B, the procedure included removing the Isiris from the package and its connection to the monitor. As for staff needed, group A needed 3–4 staff who helped with cystoscopy assembly, set-up and helping with the grasper, while group B only needed 2 staff to complete the procedure. The stent dwell time was calculated from the time of stent insertion to its removal. The number of staff needed for the groups were calculated and were based on individual procedures. All encrusted stents were noted and documented. Micro costs were done for both groups. Outcomes were compared between the two groups for demographics, stent encrustations, stent dwell time, staff involved, procedural time (including preparation time), complications, cost and departmental access/impact to diagnostic and surveillance cystoscopy in the successive years.

Data collection was done by the endoscopy and specialist nurse team. Statistical analysis was displayed with P values and 95% confidence intervals, using Chi squared and Fisher's exact test. A P value <0.05 was considered statistically significant.

RESULTS

A total of 72 patients (37 in group A, 35 in group B) were included in the study (Table 1). There were no significant differences in the age and gender ratio

Table 1. *Patient and procedural differences between the two groups*

Variable	Group A (Reusable scope)	Group B (Isiris scope)	p
Patient (n)	37	35	NS
Gender ratio	M – 32%: F – 68%	M – 31%: F – 69%	NS
Mean age (SD) (years)	61.7 (10.9)	58 (12.5)	NS
Mean (SD) Procedure time (min) (including preparation time, chronometer measurement)	14.4 (7.69)	2.19 (2.19)	p <0.001
Mean (SD) stent indwelling time (days)	26.8 (12.16)	15.4 (11.47)	p <0.001
Staff immobilized (mean ±SD)	3.74 (0.47)	2	p <0.001
Encrustation ratio % (n)	14% (5)	none	p <0.05

SD – standard deviation; NS – not significant; M – male; F – female

Table 2. *Outcome and cost difference between the two groups*

Variable		Group A (Reusable scope)	Group B (Isiris scope)	p-value
Room used		Flexible cystoscopy suite (92%) Operating theatre (8%)	Outpatient clinic room (100%)	
Outcome % (n)		8% (3) failed removal 92% (34) successful	100% (35) successful	
Cancer diagnostic wait (>2 weeks) for flexible cystoscopy slots during the study period		Year 2018: 16 patients	Year 2019: 3 patients	
Mean (number of days) wait after the breach period (2 weeks) for cancer diagnosis		Year 2018: 21 days	Year 2019: 3 days	
Cost evaluation per procedure (£)	Cystoscope amortization	21.4	250	
	Single use grasper	28	–	
	Room immobilization	109.3	2.12	
	Monitor	0.42	–	
	Reprocessing consumables	67.6	–	
	Reprocessing wages	21.9	–	
	Reprocessing washing machine amortization	3.33	–	
	Waste process	–	0.5	
	Maintenance repair	15.3	–	
	Sub-Total (£)	£267.2	£252.62	p <0.05
	Complications (3 URS to remove encrusted stent)	£98.2	–	
	Total (£)	£365.4	£252.62	P <0.001

Table 3. *Micro costing analysis for reusable cystoscope and Isiris*

Reusable cystoscope		Calculation
Total number of cystoscopies during 2019	2617	
Cost of the cystoscope purchase (£)	£17500	
Number of cystoscopes	16	
Number of cystoscope breakage during 2019	7	
Washing machine purchase cost (£)	£61500	
Number of washing machines	5	
Maintenance and repair contract cost (£) for all cystoscopes (16 cystoscopes)	£39920 (£2495/scope)	
Numbers of reprocessing during 2019 for all scopes	9238	
Cystoscope amortization (amortization period of 5 years):	£21.4	(17500x16)/(2617x5)
Cost of a single cystoscopy using a re-usable scope	£21.4	
Monitor		
Monitor purchase cost (£)	£5526	
Number of monitors	2	
Monitor amortization cost per procedure (amortization period of 10 years)	£0.42	(5526x2)/(10x2617)
Room immobilization cost		
Endoscopy room	£226.4/30 minutes	
Average procedure duration in endoscopy (Group A)	14.54 minutes	
Group A room occupancy procedure cost	£109.3	(14.54 x 226.92)/30
Outpatient clinic room	£30.3/30 minutes	
Average procedure duration in endoscopy (Group B)	2.19 minutes	
Group B room occupancy procedure cost	£2.12	(2.19 x 34.8)/30
Reprocessing consumables		
Equipment used	Cost per unit/ number of units needed	Cost/item
Hair Cover	0.05/ 2	0.100
Pop-up face shield	0.43/ 2	0.860
Drop-down face shield	2.5/ 2	5.000
Surgical mask	0.05/ 2	0.100
Exam gloves (pair)	0.26/ 7	1.820
Extended-cuff gloves (pair)	0.76/ 2	1.520
Impermeable apron	2.83/ 2	5.660
Shoe covers (pair)	0.09/ 2	0.180
Reusable cloth	0.08/ 3	0.240
Single-use sponge	1.4/ 1	1.400
Single-use port/valve brush	6.25/ 1	6.250
Single-use channel brush	3/ 1	3.000
Disinfectant wipes for sinks and counters	0.17/ 4	0.680
Disinfectant (Aplan A&B)	4.75/ 5	23.750
Sterile water 5 L (tap water)	7/ 1	7.000
Protein test (1/week)	10.08/ 1	10.080
Total cost of reprocessing consumables	£67.64	
Cumulative staff time for scope reprocessing procedure	39.89 minutes	
Other cost		
Re-processing wages (average wage: £32.9/hr)	£21.9	(32.9x39.89)/60
Washing machine amortization (amortization period of 10 years)	£3.33	(61500x5)/(9238x10)
Maintenance and repair cost per procedure	£15.3	39920/2617
Treatment of complications (URS cost £1212/procedure)	£98.2	(1212x3)/37
Waste process cost for single use Isiris per scope	£0.5	

between the two groups. The mean procedure time was 14.4 and 2.2 minutes for groups A and B respectively ($p < 0.001$). The stent indwelling time was 26.8 and 15.4 days in groups A and B respectively ($p < 0.001$). In group A, 5 patients (14%) developed stents encrustation, of which 2 could still be removed under a local anaesthesia (LA) but 3 others needed a ureteroscopic removal subsequently under a general anaesthesia (GA) utilising additional anaesthetic and theatre scrub team staff (Table 2). More staff on average were needed for procedures done in group A, than group B ($p < 0.001$). While 5 patients had stent encrustations in group A, no patient had this issue in group B ($p < 0.05$).

Once Isiris was used for stent removal in the outpatient clinic, it released capacity in the endoscopy room to perform urgent diagnostic flexible cystoscopy for potential or proven bladder cancers for purposes of diagnosis and surveillance. While the number of patients who had cancer diagnostic wait of >2 weeks for flexible cystoscopy decreased from 16 to 3 between period 1 and period 2, the mean number of days they waited reduced from 21 days to 3 days.

Looking at the cost per procedure between group A and group B, it was £267.2 and £252.62 ($p < 0.05$) if the costs of managing complications were not considered, and £365.40 and £252.62 ($p < 0.001$) if the costs of managing complications were also considered. The micro cost analysis of both groups is covered in Table 3 [11, 17, 18].

DISCUSSION

Findings of our study

Our study shows that the Isiris solution is an effective method of ureteric stent removal thereby reducing delays and cost associated with traditional reusable flexible cystoscopy. Despite the initial cost outlay of the Isiris scope, the cost saving related to staffing, procedural room, camera system, disposable grasper and disinfection process collectively add to a higher cost of reusable cystoscopy procedure. This difference in cost is even more substantive if the cost of managing complication related to stent encrustation is taken into account.

Compared to group A, the stent dwell time in group B was significantly shorter. Due to a shift of this stent removal procedure from endoscopy to outpatient clinic, more endoscopy slots were created. This led to only 3 rather than 16 patients waiting for >2 weeks (breach period) for their cystoscopy and the breach waiting time was reduced from 21 days to 3 days in period 2.

Meaning of the study and comparison with other previous studies

A short stent dwell time is desirable to reduce the risk of stent-related adverse events, especially increased risk of infection and stent encrustation [7, 8]. The higher encrustation rate in group A is related to the longer urology waiting list and consequently longer stent indwelling time. It is therefore prudent that this is kept as short as possible. Previously, other studies have also shown a reduction in stent dwell time with the use of Isiris [10, 11]. While Isiris was shown to be cost effective in our study in line with previous studies from Australia and Italy [13, 14], there are studies that display a higher cost associated with it. In this case, the author arrived at this result without including in their cost analysis, the cost benefit resulting from the use of the endoscopy room [11]. An enhanced cost saving of almost £40,000 per hundred stent removals was calculated on the basis of extra endoscopy slots that were used for diagnostic flexible cystoscopy [10].

Published clinical experience of the Isiris stent removal solution has been reviewed favourably with an overall satisfaction rated as good or very good by 90.6–91.6% of practitioners [12, 13, 14]. A single case of grasper failure has been reported in which the manufacturing company provided a replacement cystoscope [14]. The image quality of the Isiris system has been deemed to be comparable to other flexible cystoscopes and although there was a narrower field of view, this was adequate for the purpose of stent removal [15]. In our study, no case of Isiris failure was noted.

The Isiris system has shown to be highly versatile, as it can be used in the outpatient clinic environment as well as in the ward and emergency department, sparing the resources of the endoscopy room and extra personnel. In the United Kingdom, the National Health Service has a diagnostic target of 2 weeks for suspected cancers [16]. Our study has shown that by reducing the burden on flexible cystoscopy waiting lists by removing stents in outpatient clinics, fewer patients exceeded the 2-week wait target. This not only allowed a faster diagnostic route for patients, but also reduced the fines imposed on hospitals which did not meet this target. Earlier stent removal also led to fewer emergency and hospital admissions [10]. Smith et al. reported another example of the versatility of Isiris where an obstructive foreign body was successfully removed from the urethra, restoring urethral patency in emergency setting [19]. This was performed in the emergency department, preventing hospital admission.

The time taken to remove the stent was significantly shorter with Isiris than with standard flexible cystoscopy [10–14]. We had a single clinician or nurse specialist along with a health care assistant or outpatient nurse helping us with stent removals. Another consideration is the risk of endoscope-related transmission of infection, which although very low, is a concern with reusable endoscopes and has been reported in both cystoscopy and ureteroscopy [20, 21, 22]. Most cases arise from defective equipment or reprocessing failures, which would be avoided when using a disposable, single-use scope.

The timing of ureteral stent removals is especially important in patients with renal transplant. A shorter stent dwell time of 3 weeks as opposed to 6 weeks decreased the risk of UTIs in these patients [23]. In a prospective study of 103 renal transplant patients, Isiris could be used with ease and convenience on the ward, ICU and outpatient department and showed a cost saving for the hospital [24].

Strength and weakness

This is one of the first clinical studies of Isiris which used a micro cost analysis to show a true cost comparison with single use flexible cystoscope. The model of financial benefits identified in our micro cost analysis can be applied to other healthcare set ups. A cost saving was seen irrespective of whether costs of complications associated with group A were considered. Further organisational benefit was obtained from savings through reduction of urgent 2 week wait diagnostic procedures, stent dwell time and complications. The later helped with reduced re-admissions and ureteroscopy procedures that were needed.

Despite comparing the cost of the two groups prospectively, it was not a randomised control trial (RCT). Although we included all patients who had ureteroscopy performed by the same surgeon in similar calendar months, the reason for stent insertion and delays associated with its removal were not identified. Similarly, the reason for scope damage in group A was not identified, although it is plausible that majority of them were from insertion of stent grasper in the working channel of the cystoscope. We did not formally measure stent symptoms or quality of life in our patient groups.

Areas of future research

There is perhaps a need to understand and reduce the overall stent insertion after ureteroscopy, given the stent symptoms that majority of patients suffer from [25]. Randomised trials need to be done for stenting versus no stenting, and for different stent removal techniques such as stent on string, magnetic stent removals and Isiris [9, 10]. Attention must be paid not only to cost, but also to their lower urinary tract symptom, pain and quality of life associated with the stents. Future studies should also consider the environmental impact of using disposable scopes. It is plausible that Isiris scopes can be developed further to overcome the field of view, which could allow diagnostic procedures to be carried out using the second generation of these scopes [15].

CONCLUSIONS

Our results show that Isiris significantly reduced stent dwell time, procedural time and staff needed to carry out the stent removals. It allowed the procedures to be done in the outpatient setting thereby reducing the organizational pressure on endoscopy related diagnostic procedures, and the cost associated to the procedure. Further randomised multicentric prospective studies with patient reported outcome measures are needed to show the benefits in all types of healthcare settings.

CONFLICTS OF INTEREST

The ISIRIS scopes were purchased by the hospital, but the cost of running the study was supported by Coloplast.

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