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Reusable *vs.* single-use cystoscope for removal of double-J stent: a prospective randomized comparison and cost analysis

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Abstract. – OBJECTIVE: Two main types of cystoscopes, reusable cystoscope (RC) and disposable cystoscope, (DC) are used for the removal of ureteric stents. This study aimed to prospectively compare the effectiveness of disposable and reusable cystoscopes for the removal of ureteric stents.

PATIENTS AND METHODS: Patients who recently underwent double-J stent insertion were recruited and randomly assigned to the disposable and reusable cystoscope groups. Data were collected prospectively, which included pain scores (10-point visual analog scale), operation time, complications, and a 5-point Likert scale satisfaction assessment for surgeons, nurses, and patients. A cost analysis was also performed. The association between categorical data was assessed using the Chi-square/Fisher's exact test. The *t*-test was used to assess the mean difference in surgery time.

RESULTS: Overall, 128 patients (mean age, 46.8 years) were included in the study; 64 procedures were completed using each cystoscope type. Stent removal satisfaction among surgeons and patients was equivalent in both groups, while nurses favored the disposable cystoscope. A significant reduction of 23% in the procedural time and 27% in the total operative time was observed in the disposable cystoscope group. Pain score was the same for both groups. Two patients in the reusable cystoscope group had UTI. No complications were reported in the disposable cystoscope group.

CONCLUSIONS: Both disposable and reusable cystoscopes are comparable in terms of pain score and surgeons' and patients' satisfaction. Disposable cystoscope is more cost effective than reusable cystoscope.

Key Words:
Cystoscope, Ureteroscopy, Stents, Urolithiasis.

Introduction

Double-J stent insertion is one of the most common urologic procedures[1]. It has different prophylactic and therapeutic indications, renal stones being the most common[2]. With the advancement in urological procedures, new cystoscope designs have emerged. There are two primary types of the cystoscope, reusable cystoscope (RC) and single-use disposable cystoscope (DC).

A multicenter study by Doizi et al[3] evaluated the single-use flexible cystoscope in double-J stent removal and reported promising results in terms of image quality, active deflection, maneuverability, and grasper functionality. Conversely, RC showed strong durability related to optimum handling and storage[4]. In addition, the maintenance cost of RC, due to possible mechanical failure, is high, whereas the only associated cost of DC is the cystoscope itself. Furthermore, DC has an integrated grasper, unlike RC, where assistance is needed for grasper insertion. Traxer et al[5] indicated that 36% of surgeons reported shorter time, and 59% reported the same time in urethral stent removal while using DC compared to RC.

To the best of our knowledge, there has been no study comparing RC and DC in double-J Stent removal; hence, the objective of this study is to per-

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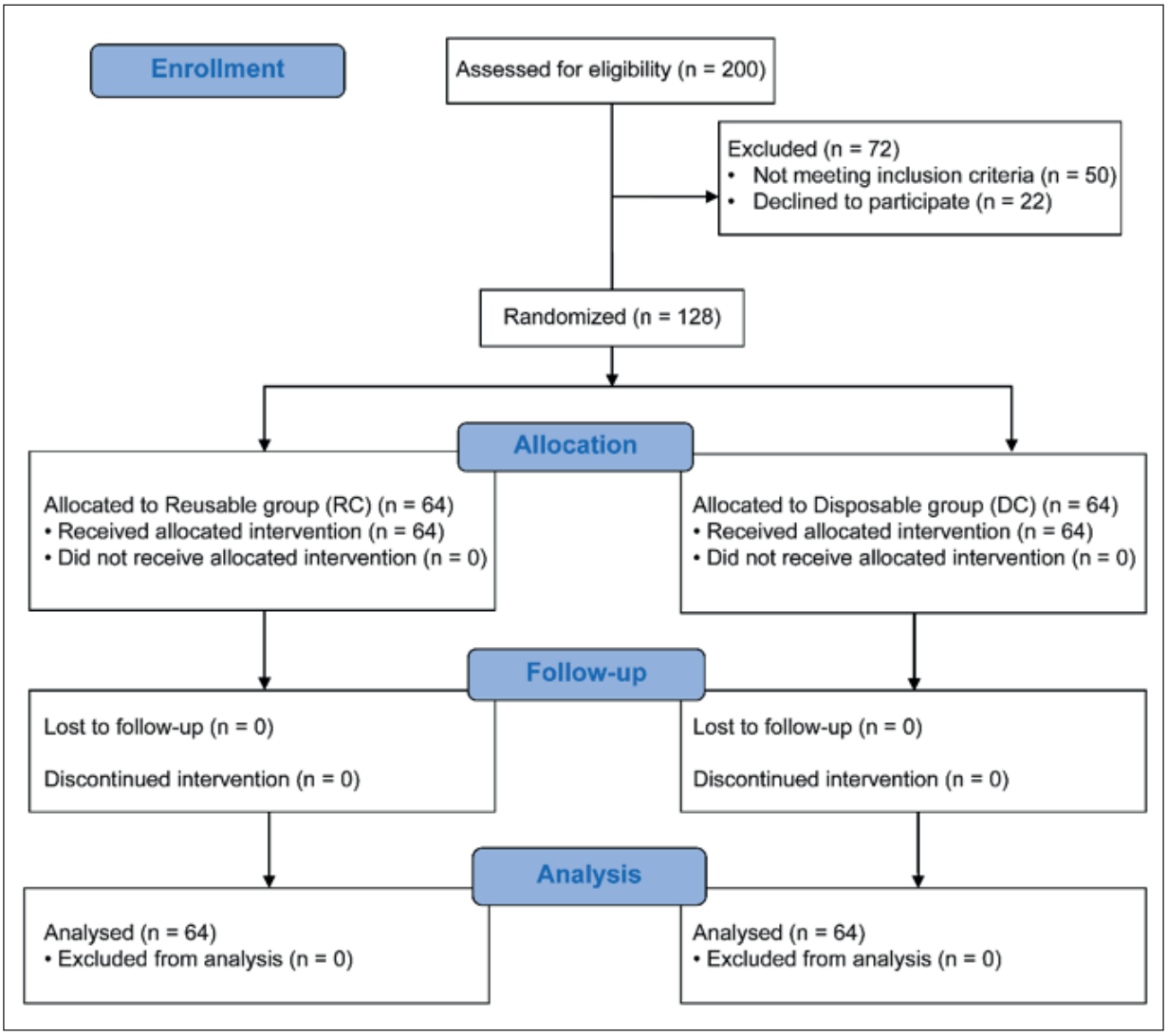

Figure 1. A study flow diagram outlining patients' enrollment process, exclusion and inclusion criteria, and patients' follow-up.

form this comparison in a prospective randomized manner. We hypothesize that DC is superior to RC in terms of pain score reduction, operative time, associated cost, fewer complications, and has a higher satisfaction rate among surgeons, nurses, and patients.

Patients and Methods

Patients

The protocol of this prospective randomized control single-center trial was approved by the Institutional Review Board of King Abdullah International Medical Research Center (KAIMRC), under study number (RC18/397/R). Patients (aged 18-60 years) who underwent recent double-J stent insertion after undergoing Retrograde Intrarenal Surgery (RIRS) in the Department of Urology at King Abdulaziz Medical city (a tertiary care center in Riyad, Saudi Arabia) were considered for this study. Patients with bilateral ureteric stents, enlarged prostate, neurogenic bladder, and infectious stones were excluded. Moreover, patients with an indwelling ureteric stent for >6 weeks were not included to avoid encrusted stents. From July 2019 to March 2020, 128 patients (mean age, 46.8 years; 73% male) were recruited. All recruited patients were randomly assigned into two groups, DC (Coloplast Isiris™ Cystoscope) group and RC (Olympus CYF-VH) group. Subject numbers were assigned sequentially by trial entry (Figure 1), and subjects were then randomly

assigned to each group (using a computer-generated lottery to enroll the subject into either DC or RC group) by simple randomization. A new RC not previously used was employed for the purpose of this study. All patients scheduled for the procedure had a negative urine culture test result within 7-10 days of the procedure.

Cystoscopy Procedure

All recruited patients were asked to arrive at the Day Surgery Unit on the day of the procedure. After obtaining written informed consent, patients were taken to the Day Care Endourology room, where all minor surgeries were performed. After prepping and draping the patients, males were placed in supine position and females in frog-leg position. An envelope containing the group assignment was then opened, and the assigned cystoscope was used accordingly. Two senior urologists performed all procedures. A 2% lidocaine gel was infused intra-urethrally (with penile clamp application in males) by the primary surgeon. After 5 minutes, the flexible cystoscope was then inserted through the urethral meatus into the bladder. The integrated stent grasper of the DC was then used to grasp the stent and extract it through the urethral meatus. With the RC, an external grasper was used for stent extraction. After the procedure, the patients returned to the Day Surgery Unit and then discharged home on the same day.

Measurable Outcomes

Data were collected using a data collection sheet that included baseline characteristics such as age, gender, and body mass index. Intraoperative parameters included procedure time (time of cystoscope insertion to stent removal) and total operative time (time between patient entrance into the operating room (OR) and exit). Patients were asked about their pain score immediately postoperatively using a 10-point visual analog scale (VAS). Surgeons' opinions on vision, maneuverability, overall satisfaction, as well as the satisfaction of nurses and patients, were also collected. All patients were followed up for 30 d after the procedure. Complications reviewed from patients' files included renal colic, febrile urinary tract infection (UTI), hematuria, and procedure-related ER visits. Satisfaction was assessed using a 5-point Likert scale where all variables were considered as an outcome, while the grouping variable was the procedure.

Cost Analysis

The procedure of ureteric stent removal using DC carries no additional cost apart from the purchase price of the device itself. On the contrary, the sterilization and repair costs of RC were calculated and added to the purchase price. Because both procedures are performed in Day Care Endourology Room and a difference in procedure time was hypothesized, the cost of OR occupancy was included in the cost analysis.

Statistical Analysis

The main outcome variable was the pain score. At a 5% significance level and to detect a difference $\geq$1 point (10%) in pain score between the two procedures with SD of 2 and a power of 80%, the required sample size was calculated to be 64 from each group. Calculations were conducted using Piface Java applets[6].

Data were collated and analyzed using IBM SPSS Statistics for Windows, Version 20.0. (IBM, Armonk, NY, USA) software. Categorical data are presented as counts and percentages, while numerical data as means ± SD. Continuous variables were assessed for normality of distribution using the Kolmogorov-Smirnov test. Association among categorical data was assessed using the Chi-square/Fisher's exact test. A Student's *t*-test was used to assess the mean difference in surgery time between the two procedures, and a test with a two-tailed *p*-value < 0.05 was considered significant.

Results

A total of 128 patients (mean age, 46.8 ± 14.4 years) were included in the study; 64 procedures were performed using DC (Coloplast Isiris Cystoscope) and 64 using RC (Olympus CYF-VH) (Figure 1). Patient baseline demographics are shown in Table I. The most common age group undergoing stent removal was 41-50 years old, and most enrolled patients were males (n = 94, 73%). Stent removal satisfaction among surgeons and patients in both groups was not significantly different. However, the nursing team in the DC group was more satisfied with the procedure than the nursing team in the RC group (*p*-value = 0.033), as shown in Table II. The mean surgery time was 64.38 ± 41.628 s, while the total operative time was 10.61 ± 3.943 min for DC compared to RC, which had a mean surgery time of 84.27 ± 48.99 s and a total operative time of 14.59 ± 4.23 min (Table III), which was significantly different (*p*-value = 0.015 and *p*-value <0.001, respectively). No association was found between pain score and type of cystoscope. Two (3.1%) patients in

Table I. Baseline demographics.

		Reusable Cystoscope (RC)		Disposable Cystoscope (DC)		Total (n)	%
		n	%	n	%		
Age (years)	19-30	10	16%	9	14%	19	14.8%
	31-40	15	23%	12	19%	27	21.1%
	41-50	21	33%	13	20%	34	26.6%
	51-60	9	14%	18	28%	27	21.1%
	61+	9	14%	12	19%	21	16.4%
Gender	Female	14	22%	20	31%	34	26.6%
	Male	50	78%	44	69%	94	73.4%
Side	Left	34	53%	29	45%	63	49.2%
	Right	30	47%	35	55%	65	50.8%
	Normal	26	40%	16	25%	42	32.8%
Body Mass Index	Overweight	18	29%	25	39%	43	33.6%
	Obese	20	31%	23	36%	43	33.6%

the RC group had documented UTIs, while no complications were reported in the DC group. No other complications were recorded in both groups.

The cost of purchasing the reusable cystoscope used in our study (Olympus CYF-VH) was 26,667 USD, and the sterilization process cost 84.4 USD per procedure. During our study, a leak damage to the RC cost 533 USD to repair; hence, the average cost of the procedure using the RC for the 64 cases in our study was 509.4 USD per patient. In comparison, the total cost of DC was 533 USD per unit.

Discussion

Removing double-J stents using a flexible cystoscope is one of the most common urological procedures[1]. It is more prevalent in countries with high rates of nephrolithiasis, such as Saudi Arabia. In this study, we compared the removal of double-J stents using a single-use disposable cystoscope (Isiris™) by Coloplast to the removal of double-J stents using a reusable digital video cystoscope designated for this study.

The success rate of double-J stent removal in our study was 100% in both groups, showing that removal by disposable cystoscopes is as effective as reported by Doizi et al[3], who reported a removal success rate of 94%, with 5 cases of failed removal; however, different endoscopic devices were employed in that study. Similarly, 97% of patients in a study by Donato et al[7] had their stents successfully removed using DCs (Isiris™). Despite the narrow field of vision, surgeons using different scopes did not report a significant dif-

Table II. Stent removal outcomes.

		Type of cystoscope				
		Reusable		Disposable		Fisher's exact test
		N	%	N	%	*p*-value
Surgeon overall satisfaction	Satisfied	59	93.7%	62	96.9%	0.44
	Unsatisfied	4	6.3%	2	3.1%	
Manipulation	Satisfied	60	95.2%	61	95.3%	1
	Unsatisfied	3	4.8%	3	4.7%	
Vision	Satisfied	61	96.8%	60	93.8%	0.68
	Unsatisfied	2	3.2%	4	6.2%	
Nurse satisfaction	Satisfied	56	88.9%	63	98.4%	0.033
	Unsatisfied	7	11.1%	1	1.6%	
Patient satisfaction	Satisfied	56	88.9%	62	96.9%	0.096
	Unsatisfied	7	11.1%	2	3.1%	

Table III. Mean operation time based on the type of cystoscope used.

	Cystoscope	Mean	SD	*p*-value
Procedure time (s)	Reusable	84.27	48.99	0.015
	Disposable	64.38	41.628	
Total operative time (min)	Reusable	14.59	4.23	< 0.001
	Disposable	10.61	3.943	

ference between DCs, such as Isiris™, and other flexible cystoscopes. This may be because the high image quality is not needed during double-J stents removal[7,8].

One significant advantage of a disposable grasper-integrated cystoscope is that it is easy to use; thus, it requires fewer assisting staff. In our study, the role of nurses was only to prepare the room and connect the irrigation once the DC cystoscope was used. This could be why nurses were more satisfied with DC than with RC. In contrast, among urologists and patients, there was no significant difference in satisfaction. Patients' satisfaction in the DC group may improve if the procedures were conducted in the outpatient department, thus sparing the patient the inconveniencies of day-surgery admission.

The incidence of bacteriuria and febrile UTI after cystoscopy ranges from 1.9% to 9%[9,10]. Cross infection between patients using the same endoscopic equipment has been reported[11,12]. In our study, two UTI cases were reported in the RC group, while no case was observed in the DC group.

The mean operative time and the mean procedural time were evaluated. In the DC group, both procedural and operative times were reduced by 23% and 27%, respectively.

Cost analysis was performed for both devices. As indicated earlier, all procedures were conducted in an OR and not in an outpatient setting; therefore, if the cost associated with OR occupancy was included, the overall cost would increase. Doizi et al[13] reported that each hour spent in the OR used in their study costs 788 USD. Taking this into consideration, along with the time saved by using DC (approximately four min per case), the total cost per case will then be 696.2 and 668.8 USD for RC and DC, respectively. All DCs are manufactured for outpatient or emergency department use, thus saving costs associated with OR. This also makes more room for urgent cystoscopic procedures. Moreover, using DC allows for more procedures in a shorter period without the need of sterilizing the cystoscope. Conversely, to perform multiple procedures in a given day using RC, more than one cystoscope and quick sterilization between cases is needed to maintain the same patient flow.

This study has some limitations. DC was used in the OR and not in an outpatient setting, which might have affected the patient's satisfaction and the cost of the procedure. All cases were recruited from one tertiary care center, which may have resulted in selection bias. Participants were blinded to the type of cystoscope used, while surgeons and nurses were not, which might have affected the results with regards to the level of satisfaction derived from either procedure.

Conclusions

Both disposable and reusable cystoscopes are comparable in terms of pain score as well as surgeons' and patients' satisfaction. Nurses' satisfaction, rate of UTI, and operative time were better with DC than RC. Our study also reports that, in our center, DC is more cost-effective than RC. Moreover, our study reveals that by using DC, both procedural and operative times can be reduced, creating free time slots in highly equipped ORs for more urgent and complex procedures.

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Conflicts of Interest

The authors declare they have no financial interests.

Ethics Approval

The protocol of this prospective randomized control single-center trial was approved by the Institutional Review Board of King Abdullah International Medical Research Center (KAIMRC), under study number (RC18/397/R).

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Consent to Participate

All patients provided written informed consent.

Consent for Publication

Not applicable.

Availability of Data and Materials

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Code Availability

Not applicable.

Authors' Contribution

M. Alkhamees: Protocol/project development, Data analysis, and Manuscript writing/editing.
A. Alothman: Protocol/project development and Data analysis.
M. Alzughaibi: Data collection or management and Manuscript writing/editing.
A. AlAsker: Protocol/project development and Data collection or management.
Y. Ghazwani: Protocol/project development and Data collection or management.
E. Masuadi: Data analysis.
S. Hamri: Protocol/project development and Manuscript writing/editing.

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