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Outcomes of Ureteral Stent Removal by Flexible Cystoscope Versus Semirigid Ureteroscope: A Prospective Randomized Clinical Trial

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What's known on the subject? and What does the study add?

In developing countries, where the availability of expensive instruments like flexible cystoscopes may not be available everywhere, the semirigid ureteroscopes can be as comfortable as flexible cystoscopes for both patients and surgeons. The study findings can lead to increased use of semirigid urteroscope for Double J stent removal and it is very commonly available in the urology armamentarium everywhere.

Abstract

Objective: Ureteral stents are usually removed after 2-4 weeks. Classically rigid cystoscope was used for stent removal along with retrieval forceps. A flexible cystoscope is an excellent alternative to a rigid cystoscope to reduce discomfort. In this study we compared semirigid ureteroscope with a flexible cystoscope for retrieving stents.

Materials and Methods: It was a prospective randomized clinical trial including 100 patients. All patients were divided into two groups: Group A: Patients undergoing Double J stent (DJS) removal using a flexible cystoscope. Group B: Patients undergoing DJS removal using a semirigid ureteroscope. Outcome parameters compared in both groups were pain during and after the procedure, operative time, and operative difficulty.

Results: There were 70 males and 30 females in the study. Mean visual analogue scores (VAS) for pain during the procedure in groups A and group B were 5.2±1.4 and 5.82±1.8 (p=0.057) and after the procedure were 1.95 and 2.25 in group A and group B, respectively (p=0.253). Mean VAS scores for pain during the procedure in males in groups A and B were 5.2±1.6 and 5.9±1.7, respectively (p=0.080). The mean operative times in groups A and group B were 4.9 and 4.2 min, respectively (p=0.076). VAS scores for operative difficulty overall were 3.6±1.1 and 2.9±1.2 (p=0.058), while in males were 3.7±1.0 and 2.8±1.3 (p=0.002) for groups A and B, respectively.

Conclusion: Ureteral stents removal by semirigid ureteroscope is a good alternative as it is readily available, with the same degree of discomfort as flexible cystoscopes. They are inexpensive and easier to operate than flexible scopes.

Keywords: Ureteral stent, cystoscope, ureteroscope

Introduction

Ureteral stents are an integral part of urological practice. They are placed for better urinary drainage after urological procedures like ureteroscopic stone removal, percutaneous nephrolithotomy, extra-corporeal shock wave lithotripsy, and reconstructive surgeries like pyeloplasty and ureteric re-implantation. These stents are usually removed after 2-4 weeks of surgical intervention, mostly by a retrograde cystoscopic method as a short office-based procedure under topical anesthesia (1,2).

Any endoscopic intervention tends to cause pain and significant discomfort when performed under topical anesthesia, particularly in male patients because of the longer and curved urethra (3). A flexible cystoscope is an excellent alternative to a rigid cystoscope to eliminate the above limitations and is widely adopted by many urologists worldwide for stent removal (4).

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Several studies have reported better patient acceptance during flexible cystoscopy because of reduced pain and discomfort (5,6). However, these studies have mostly compared diagnostic cystoscopy only, without any adjuvant procedure. Besides, there are only very few studies assessing the incidence of pain during cystoscopic stent removal (1,4). Though the duration of stent removal is shorter than flexible diagnostic cystoscopy, there is a need to introduce an adjuvant instrument to grasp the ureteral stent. This factor can confound the perception of pain. Moreover, a flexible cystoscope has a higher purchase cost than that of a rigid scope (7).

Many times, the removal of the stent is impossible by cystoscope due to urethral stricture or other reasons. In such cases, alternate instruments could be either a flexible cystoscope or a narrow caliber semirigid ureteroscope. A semirigid ureteroscope is widely available with the urologist for ureterorenoscopy. It has a narrow diameter (7.5-9 Fr) and a working channel that can be used to introduce a stent retrieval instrument. It is also inexpensive compared to a flexible cystoscope and has a longer life. This study was designed to compare the surgical outcomes of ureteral stent removal with semirigid ureteroscope and flexible cystoscope, focusing primarily on male patients.

Materials and Methods

Data Sources and Patient Selection

The study was conducted at the Department of Urology, Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER) from March 2018 to August 2019. The research was conducted in accordance with the Helsinki Declaration. The ethical clearance was taken from the Institutional Ethics Committee, JIPMER, Puducherry with approval number JIP/IEC/SC/2/302/2013. A total of 100 patients were included in the study after written informed consent. All adult patients above 18 years with unilateral Double J stent (DJS) *in situ* for 2-4 weeks, due for stent removal were included. Patients with migrated stents, severe co-morbidities, encrusted stents, post-renal transplant, residual or bilateral stones and patients with active urinary tract infection with positive urinary culture were excluded from the study. All patients who met the inclusion and exclusion criteria were included in the study after obtaining informed consent. Patients were blinded to the type of instrument used in stent removal and randomized into the following two groups by allocation concealment and closed envelope.

1. Group A: Patients undergoing DJS removal using a flexible cystoscope.

2. Group B: Patients undergoing DJS removal using a semirigid ureteroscope.

Surgical Procedure

Stent removal was performed under local anesthesia after instillation of 10 mL Lignocaine jelly 2% for 5 min in all patients using either a flexible cystoscope (group A) or Semirigid Ureteroscope (group B). The diameter of the flexible cystoscope used was 15 Fr, and the semirigid ureteroscope was 9/7.5 Fr. Immediately after the procedure, all patients were asked to mark the degree of pain using the visual analog pain score (VAS). No pain was graded as 0 points, and the most intractable pain ever felt as 10 points. Surrogate markers for pain (peak SBP and pulse rate were also documented before, during and after the procedure. Blood pressure and HR were recorded by attaching the monitor and pulse oximeter to the patient before starting the procedure in the operative room. So the continuous monitoring was done. Any change in the parameters during the procedure compared to those before starting it was noted and compared. Operative time was calculated from the time of insertion of the stent removal device to the removal of the device and stent. The degree of difficulty, as felt by the operator, was measured using VAS. Score 1 as no difficulty and score five as most problematic. The parameters recorded included pain scores, operative time, and operative difficulty.

Sample Size Calculation

The sample size was estimated with an expected difference in the mean of pain score as 1.0 with a standard deviation of 1.5 between the procedures. The sample size was estimated at a 5% level of significance and 90% power. Hence, a sample size of 50 was allotted in each group with 20% attrition rate anticipated. G powder was used for calculating the sample size (8).

Statistical Analysis

The distribution of data on the VAS score of pain, operative difficulty, and operative time was expressed as mean with standard deviation or median with range, whichever was appropriate. The comparison between the groups was done using independent Student's t-test or Mann-Whitney U test. The distribution of data related to the complication was expressed as frequencies and percentages. Subgroup analysis for male patients was done separately. All statistical analysis was carried out at a 5% level of significance, considering p-value <0.05 as significant. Statistical analysis was performed using IBM SPSS Statistics for Windows, version 19. Armonk, NY: IBM Corp.

Results

The stents were successfully removed in all 100 patients. Overall, there were 70 male and 30 female patients in the study. The gender ratio in groups A and B was 36:14 and 34:16, respectively, and the mean age was 40.1 and 40 years, respectively (range 18

to 70). There was no statistical difference in sex ratio, mean age, and stented time between the groups (Table 1).

The data of the outcome parameters of all 100 patients were available for the final analysis. There was no complication reported in our study population. Mean VAS for pain during the procedure in groups A, and B were 5.2±1.4 and 5.82±1.8 (p=0.057). The mean VAS scores for pain after the operation were 1.95 and 2.25 in groups A and B, respectively (p=0.253) (Table 2).

Other surrogate markers for patient discomfort and pain were also measured like change in systolic blood pressure (SBP) and heart rate (HR). Mean changes in SBP in groups A and B were 7.3 and 8.3 (p=0.120), and that of HR was 6.6 and 7.6, respectively (p=0.260).

The mean operative times in groups A and group B were 4.9 and 4.2 min, respectively (p=0.076). VAS for operative difficulty, as reported by surgeons, was 3.6±1.1 and 2.9±1.2 in group A and group B, respectively (p=0.058).

Since we had an equal number of male patients in both groups, we performed a subgroup analysis of male patients separately. Out of 70 male patients in the study, groups A and B had 36 and 34 patients, respectively (Table 3). Mean VAS scores for pain during the procedure in males in groups A and B were 5.2±1.6 and 5.9±1.7, respectively (p=0.080). The mean VAS scores for pain after the procedure for males in groups A and B were 1.9±1.4 and 2.3±1.5, respectively (p=0.252), and mean operative time was 5.3±2.2 and 4.4±1.8 min, respectively (p=0.066). The VAS for operative difficulty, as reported by surgeons, were 3.7±1.0 and 2.8±1.3 for groups A and B, respectively, and the difference was significant (p=0.002).

Table 1. Demographic data and cause of stent placement

Variable		Group A (flexible cystoscopy) n=50	Group B (semirigid ureteroscopy) n=50	p-value
Gender ratio (Male: Female)		36:14	34:16	0.450
Mean age in years (SD)		40.1 (12.1)	40 (10.5)	0.252
Mean duration of DJs *in situ* in days (SD)		25.2 (7.8)	27.6 (6.5)	0.120
Cause of stent placement	URSL	34 (68%)	32 (64%)	
	Post pyeloplasty	5 (10%)	4 (8%)	
	PCNL	7 (14%)	4 (8%)	
	ESWL	4 (8%)	10 (20%)	

SD: Standard deviation, URSL: Ureteroscopic lithotripsy, PCNL: Percutaneous lithotripsy, ESWL: Extracorporeal shock wave lithotripsy, DJS: Double J stent

Table 2. Outcome parameters

Variable	Group A (flexible cystoscopy) n=50	Group B (semirigid ureteroscopy) n=50	p-value
Mean pain on VAS during the procedure (SD)	5.2 (1.4)	5.82 (1.8)	0.057
Mean pain on VAS after the procedure	1.95 (1.2)	2.25 (1.4)	0.253
Mean operative time in minutes (SD)	4.9 (2.0)	4.2 (1.9)	0.076
Mean score on VAS for operative difficulty (SD)	3.6 (1.1)	2.9 (1.2)	0.058

SD: Standard deviation, VAS: Visual analogue scale

Table 3. Outcome analysis in males

Variable	Group A (flexible cystoscopy) n=36	Group B (semirigid ureteroscopy) n=34	p-value
Mean pain VAS during the procedure (SD)	5.2 (1.6)	5.9 (1.7)	0.080
Mean pain VAS after the procedure	1.9 (1.4)	2.3 (1.5)	0.252
Mean operative time in minutes (SD)	5.3 (2.2)	4.4 (1.8)	0.066
Mean VAS for operative difficulty (SD)	3.7 (1.0)	2.8 (1.3)	0.002

SD: Standard deviation, VAS: Visual analogue scale

Discussion

In our study, the pain on VAS and other markers for discomfort during and after the procedure were similar for patients who had stent removal by flexible cystoscope and semirigid ureteroscope in both males and females. Operative time and difficulty in removing the stent was also identical in both males and females. On comparing the surgeon's difficulty in male patients, it was found that removing a ureteral stent through a flexible cystoscope was significantly difficult than removing it through a semirigid ureteroscope (p=0.002). The difficulty with flexible cystoscopy was mainly due to difficult maneuverability compared to the semirigid ureteroscope, which is easy to handle and orient inside the bladder.

Several studies have documented that flexible diagnostic cystoscopy is better than rigid cystoscopy (RC) for better patient tolerance and pain perception. Denholm et al. (5) demonstrated in their study of 200 patients that flexible cystoscopy under local anesthesia was well tolerated and had lower morbidity compared with RC under general anesthesia. Flannigan et al. (6) reported similar outcomes in their cohort of 53 patients. Several authors also reported that flexible cystoscopy is well tolerated in females as well. Gee et al. (7) randomized 36 women to flexible and RG with comparable pain scores in both groups. In a similar randomized trial, Quiroz et al. (9) showed that urinary frequency and duration of urinary burning post-procedure occurred more frequently in the FC group, although these symptoms were transient. Besides, office FC and RC are generally well tolerated in women with overall low morbidity, different from this study, in all above studies, only diagnostic cystoscopy was compared without any adjuvant procedure.

Researchers have also evaluated FC for the adjuvant procedure like ureteral catheters insertion, removal of ureteral stents and foreign bodies, and treatment of small bladder tumors with the Nd: YAG and fragmentation of bladder calculi with a pulsed-dye laser (10). Kaabneh et al. (11) showed in their study of 600 patients that operative pain score, lower abdominal pain score, dysuria, urgency, and hematuria were less in male patients subjected to DJS removal using flexible cystoscopy. However, a statistically significant outcome was not seen in female patients.

A flexible cystoscope has high initial and maintenance costs. A systematic review conducted by Canales et al. (12) found that Olympus cystoscopes require repair every 2 to 3 years. The distal deflection tip, specifically the outer bending rubber, is the most common site of flexible cystoscope damage. Despite significant improvements in the deflection apparatus, the number of repairs has not changed significantly with time.

Söylemez et al. (2) randomized 67 patients of stent removal to a flexible cystoscope and ureteroscope. There were no statistical differences in the two groups regarding mean operative pain score, irritative voiding symptom scores, and hematuria. They reported higher prices for buying and maintenance of flexible scope. Besides, ureteroscope offered an added advantage in the removal of mildly up-migrated ureteral stents under local anesthesia.

Jeong et al. (13) compared ureteral stent removal by rigid cystoscope and flexible cystoscope in 104 male patients. They reported that the VAS pain score was lower, and the satisfaction scale score was more in the flexible cystoscope group compared with the rigid cystoscope, and the difference was statistically significant.

Similar to our study, Lai et al. (14) prospectively compared the removal of ureteral stents by rigid ureteroscope and flexible cystoscope in a cohort of 300 patients. They reported no statistical difference between both the techniques of stent removal in terms of operative time, pain scores, hematuria after stent removal, and irritable symptoms. They reported a significantly higher cost per use for stent removal by flexible cystoscopy (US dollars 107.9 versus 28.2). However, this study did not compare the surgeon's perspective on difficulty level in stent removal by both the above techniques.

Flexible cystoscopes have a higher cost, and their durability is lower than the semirigid ureteroscopes. Moreover, the flexible cystoscopes and their accessory instruments are liable to easy wear and tear. These factors increase the per use cost of flexible cystoscopy (14). Thus, stent removal by semirigid ureteroscopes is a good alternative as it is equal in discomfort, more comfortable to operate, and inexpensive than the flexible cystoscopes. Moreover, the ureteroscopes are readily available in every health setup.

Study Limitations

There were some limitations to our study. First, the sample size was relatively small. Second, it was a single-center study. A multi-center study with a larger sample size can give better results.

Conclusion

Ureteral stents removal by semirigid ureteroscope is a good alternative as it is readily available, with the same degree of patient discomfort as flexible cystoscopes. Moreover, they are inexpensive and easier to operate than flexible scopes.

Ethics

Ethics Committee Approval: The ethical clearance was taken from the Institutional Ethics Committee, JIPMER, Puducherry with approval number JIP/IEC/SC/2/302/2013.

Informed Consent: A total of 100 patients were included in the study after written informed consent.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: K.M., N.A., R.M., Concept: R.M., Design: K.M., N.A., R.M., Data Collection or Processing: K.M., N.A., Analysis or Interpretation: K.M., N.A., R.M., Literature Search: K.M., N.A., R.M., Writing: K.M., N.A., R.M.

Conflict of Interest: No conflict of interest was declared by the authors.

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