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An Economical and Effective Alternative to Flexible Cystoscope for Ureteric Stent Removal Using Semirigid Ureteroscope-A Randomised Trial

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Abstract | **Original Research Article**

Ureteric stent removal is integral part of urological practice done mostly in outpatient basis. Stent removal with Flexible cystoscope (FC) is associated with higher costs. So, we designed this study to know the usefulness of Semirigid Ureteroscope as an alternative to Flexible cystoscope for Ureteric stent removal. We designed this study as prospective Randomised Single Blinded Trial. A total of 100 patients due for Ureteric stent removal under local anaesthesia (LA) were enrolled in study after informed consent. All patients were randomly assigned into two groups by block randomisation - Group 1 were stent removal done with Flexible cystoscope and in group 2 stent removal was done using Semirigid Ureteroscope. The main outcomes assessed included mean pain score on Visual Analogue Scale, operative time and operative difficulty as reported by surgeon. Patients were similar in demographic profile in both groups. Ureteric stents were successfully removed in all 100 patients. There was no significant difference in mean VAS score for pain in both groups (Group 1- 5.2 and Group 2 - 5.82 (p= 0.057). There was also no statistically significant difference in mean operative time and mean score of operative difficulty in both groups. On subgroup analysis of male patients (n=70) also, there were no statistically significant difference in above parameters in both groups. During entire study only one ureteroscope and one flexible cystoscope were used, but flexible cystoscope had to be repaired once due to failed leak test. Semirigid ureteroscope is a good alternative for removal of Ureteric stents under LA. It is equally effective, safe and has similar patient acceptability as compared to Flexible cystoscope. But it has less initial and maintenance costs. The trial was registered with Clinical trials registry of India (CTRI) with registration no CTRI/2014/03/004511.

Keywords: Ureteric stents, stent removal, ureteroscope, flexible cystoscope.

INTRODUCTION

Ureteral stents mostly double j stents are an integral part of urological practice. They are placed to felicitate better urinary drainage of upper urinary tract after endoscopic and open urological procedures. These stents are usually surgically removed after 2-6 weeks of the procedure mostly by retrograde cystoscopic method as a short office procedure under Local anesthesia [1, 2].

Classically, rigid cystoscopes were used for stent removal along with retrieval forceps. But these procedures can result in great discomfort and pain, especially to male patients because of longer and curved urethra [3]. A flexible cystoscope is a good alternative to rigid cystoscope to reduce pain and discomfort and is more commonly used by many urologist worldwide for stent removal [4]. But Flexible cystoscope is costly, subject to early wear and tear and has cumbersome handling.

So, we tried to explore another alternative technique to retrieve ureteric stents, which is cost effective as well as causes least pain and discomfort to the patient. Semirigid ureteroscope is widely available with urologist for uretero-renoscopy. It is also less costly as compared to flexible cystoscope and long durability as well. There are only two studies by Soylemez *et al.* and D Lai *et al.* which compared stent removal with ureteroscope and Flexible cystoscope [2, 3, 5].

So we designed this randomised single blinded study to compare outcomes of ureteric stent removal with ureteroscope and flexible cystoscope with a larger

sample size and focusing mainly on male patients in Indian scenario.

MATERIAL AND METHODS

The study was conducted in the Department of Urology, Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER) from March 2013 to August 2014. The Clearance of institute ethics committee was obtained before starting the study. A total of 100 adult patients, 18yrs and above with unilateral Ureteric stent (US) in situ for 2-6 weeks, which were due for stent removal under LA were included in the study. Following patients were excluded - migrated stents, severe co morbidities, encrusted stents, and post renal transplant, residual or bilateral stones. Informed consent was taken from all patients of study.

Patients were randomized the following two groups by block randomization and closed envelope method. Group 1(all patients undergoing US removal using flexible cystoscope-FC) and Group 2(all patients undergoing US removal using Semirigid Ureteroscope-SRU)

Stent removal was performed under local anesthesia after instillation of 10ml Lignocaine jelly 2% for 5 min in all patients using either Flexible cystoscope (group A) or Semirigid Ureteroscope (group B). Patients were not told about the method which was used for stent removal. Just after the procedure all patients were asked to mark the degree of pain using visual analog pain score (VAS). No pain graded as 0 points and most intractable pain ever felt as 10 points. Surrogate markers for pain like peak systolic blood pressure and pulse rate during the procedure were also recorded. Operative time was calculated from the time of insertion of the instrument to the time of removal of instruments and stent. Degree of difficulty as felt by the operator was measured by VAS. Score 1 as no difficulty and score 5 as most difficult. Preoperative and postoperative complications like haematuria, urethral injury, urinary tract infections and urethral stricture were noted.

Overall Parameters studied were Pain scores, Operative time, Operative difficulty and complications. Sample sizes in each group were 50. Sample size was estimated with an expected difference in mean of pain score as 1.0 with a standard deviation of 1.5 between the procedures. The sample size was estimated at 5% level of significance and 90% power.

The distribution of data for VAS score of pain , operative difficulty and operative time are expressed as mean with SD or median with range, whichever is appropriate and the comparison between the groups are done by using independent student's T test or Mann Whitney U-test. The distribution of data related to complications was expressed as frequencies and percentages and the comparison between the groups carried out by using Chi square test or Fischer exact test. Subgroup analyses for male patients were performed separately. All statistical analysis were carried out at 5% level of significance and pvalue<0.05 were considered as significant.

RESULTS

The stents were successfully removed in all 100 patients. The demographic data, stented time and reason for stent placement were comparable in both groups as shown in table1.

Table-1

	Group 1 (FC) n=50	Group2 (SRU) n=50
Sex ratio(M:F)	36 : 14	34 : 16
Mean Age ± SD (yrs)	40.1 ± 12.1	40.0 ± 10.5
Mean Duration of Dj stent in situ (days)	25.2± 7.8	27.6 ± 6.5
Cause of stent placement		
URSL	34 (68%)	32 (64%)
Post pyeloplasty	5	4
PCNL	7	4
ESWL	4	10

Outcome parameters are shown in table2 and fig1. There was no complication in any case. Range of pain score were 2-7 in group 1 and 3-8 in group 2.

Other surrogate markers for patient's discomfort and pain were also measured like change in systolic blood pressure and heart rate. Mean change in systolic blood pressure in group 1 and 2 were 7.3 and 8.3 respectively. While, the mean change in heart rate in group1 and 2 were 6.6 and 7.6 respectively. Both differences were not statistically significant. Mean operative time in group 1- 4.9 min was marginally high as compared to group 2 - 4.2 min , but not statistically significant (p=0.075).

Table-2: (Outcome parameters)

	Group 1(FC) n=50	Group2(SRU) n =50	p value*
Pain score VAS (mean± SD) during procedure	5.2 ± 1.4	5.82 ± 1.8	0.0574
Mean Pain score after procedure	1.95 ± 1.2	2.25 ± 1.4	0.2528
Operative time (min) (mean ± SD)	4.9 ± 2.0	4.2 ± 1.9	0.0759
Operative difficulty VAS (mean ± SD)	3.6 ± 1.1	2.9 ± 1.2	0.0581

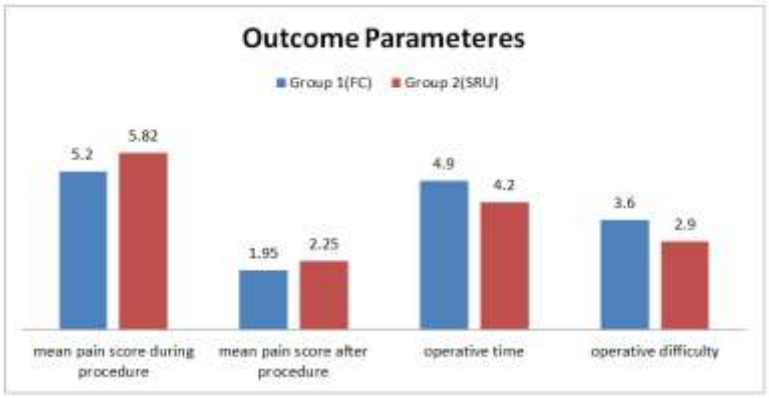

Fig-1

Since, we had almost equal number of male patients in both groups; we did a subgroup analysis of male patients separately. Total of 70 patients were male in the study, out of which group 1 had 36 patients and group2 had 34 patients. Outcome parameters for subgroup analysis of male patients is shown in Table3

Table-3: (Subgroup analysis - male)

	Group1(FC) n=36	Group2 (SRU) n=34	p value
Pain score VAS (mean± SD) during procedure	5.2 ± 1.6	5.9 ± 1.7	0.0804
Mean Pain score after procedure	1.9 ± 1.4	2.3 ± 1.5	0.2525
Operative time (mean ± SD) min	5.3± 2.2	4.4 ± 1.8	0.0662
Operative difficulty VAS (mean ± SD)	3.7 ± 1.0	2.8 ± 1.3	0.0018

DISCUSSION

Ureteric stent removal is mostly performed as an outpatient procedure with the help of rigid cystoscope. But stent removal with rigid cystoscope under local anaesthesia or intravenous analgesic causes significant pain and discomfort to patients. In a cross-sectional study of 60 patients by Kim *et al*. both pain and patient satisfaction scores in analgesic group were significantly higher as compared to sedation [1]. Some researchers have advocated the use of flexible cystoscope for stent removal [6-8]. Flexible cystoscopy solely for diagnostic purpose has proved to be superior to rigid cystoscopy in many studies [9,10]. Kaabneh *et al*. compared ureteric stent removal between flexible and rigid cystoscope and showed that flexible cystoscopy is more convenient and comfortable for ureteric stent removal under local anaesthesia as compared to rigid cystoscopy [11].

But flexible cystoscopes have high initial as well as maintenance costs, and in a developing country like India cost is a major limiting factor. Canales et al did a systemic review of repairs of flexible cystoscopes, they found that Olympus cystoscopes require repair every 2 to 3 years [12]. The distal deflection tip and the outer rubber is the very common site of damage to flexible cystoscope. Mcgill did analysis of 6 different flexile cystoscopes. Five failures occurred in 4 cystoscopes, with a mean of 495.4 procedures per failure. Hole in bending rubber was most common problem [13]. In spite of significant improvements in design, they still require multiple repairs.

Various alternative method of stent removal have been described to overcome the discomfort of patients like, Fluoroscopy guided stent removal, stent with a magnetic tip, steel bead, suture lasso and string [14-20]. But these techniques require specially made ureteral stents, which may not be available everywhere and also may be costly.

Ureteroscopes are commonly available with all urologists. Use of Semirigid Ureteroscope has been described for stent removal in children [20]. Ureteroscopes have a narrow diameter as well as adequate side channel for introducing stent removal instrument.

We could find two studies by Soylemez *et al*. [2] and Lai D *et al*. [5] which compared ureteric stent removal with ureteroscope and flexible cystoscope in a prospective randomised trial. Mean VAS scores of pain in above two studies and our study are shown in table4.

Table-4

	Mean VAS score for pain Flexible cystoscope	Mean VAS score for pain Uretersoscope	p value
Soylemez *et al*. (n=67)	1.8	2	Not mentioned
Lai D *et al*. (only for male patients) (n=151)	3.1±1.8	4.3±0.9	0.324
Neeraj *et al*. (n= 100)	5.2 ± 1.4	5.82 ± 1.8	0.0574

Mean operative time in study by Soylmez *et al*. were 3.1 and 2.8 minute in cystoscopic and ureteroscopic group respectively.While in our study, mean operative time in group 1(FC) and group 2(SRU) were 4.9 min and 4.2 min respectively. In both studies, the difference was not statistically significant. In the subgroup analysis of male patients separately, mean VAS score for pain during the procedure in group 1(FC) and group 2(SRU) was 5.2 and 5.9 in our study which was also not significantly significant.

We also measured other parameters like mean change in systolic blood pressure, heart rate, postoperative pain score, operative difficulty and found that there was no significant difference between both groups. In a comparative study by Kaabneh *et al*. stent retrieval under local anaesthesia was successful in 95% by flexible cystoscopy and 84% using rigid cystoscopy. Rest of the patients required sedation or other techniques for stent removal [11]. While in our study, stent removal was successful in all 100 patients under local anaesthesia without any complications. In our experience, ureteroscopic removal of uretric stent under local anaesthesia was safe, well tolerated and efficient method.

Another advantage of ureteroscope is that it can be used for removal of upmigrated stents and even ureteroscopy under local anesthesia [21-23]. In a prospective trial by Livdas *et al*. 37 patients with mildly upmigrated stents,were tried for stent removal under local anaesthesia out of which removal was successful in 34 patients [24]. There were no complications, and no procedure had to be abandoned due to intolerable pain. However, none of our patients had upmigrated stents, but still efficacy and safety of removal of upmigrated stents with ureteroscope can be reviewed in further trials. Park *et al*. compared ureteroscopic lithotripsy with cystoscopy under local anaesthesia in 200 patients [25].

In future, randomized trials can be done for evaluating ureteroscopy under local anaesthesia for up migrated stent removal and ureteric stone removal.

CONCLUSION

In our study, we found that ureteroscopic stent removal was a feasible option since it is widely available with urologists. It is effective, since stent removal was possible in all cases. Handling of ureteroscope is also easier. There was no complication in any case showing that it is safe. It was well tolerable with pain scores comparable to flexible cystoscopic removal in adult patients, even in males. Ureteroscopic stent removal is also cost effective as compared to flexible cystoscopes, as later has very high initial and maintenance costs.

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