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Original Article

A randomized trial investigating clinical outcomes and stent-related symptoms after placement of a complete intra-ureteric stent on a string versus conventional stent placement

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Study Registration: Clinical trials registry–India.

Objective

To compare stent-related symptoms (SRS) associated with conventional ureteric JJ stent (CUS) placement and SRS associated with placement of a modified complete intra-ureteric stent (CIUS) with extraction suture, designed to minimize SRS, using the validated Ureteral Stent Symptom Questionnaire (USSQ).

Materials and Methods

We randomized 124 patients who had undergone uncomplicated ureteroscopic lithotripsy into a CIUS and a CUS placement group. USSQ scores were evaluated on postoperative days 1 and 7 (just before stent removal) and 4 weeks after stent removal (control values). Pain scores on a visual analogue scale (VAS) after stent removal were also recorded. Subdomain analysis of all SRS and stent-related complications were also compared.

Results

No significant intergroup differences were found in the domain scores for urinary symptoms ($P = 0.74$), pain ($P = 0.32$), general health ($P = 0.27$), work ($P = 0.24$), or additional problems ($P = 0.29$). However, a statistically significant difference was noted in VAS scores ($P = 0.015$). Analysis of subdomains of USSQ item scores showed the CIUS group had significantly better scores for urge incontinence (1.21 vs 1.00; $P \leq 0.001$), discomfort on voiding (2.07 vs 1.50; $P \leq 0.001$), difficulties with respect to light physical activity (1.131 vs 1.00; $P \leq 0.001$), fatigue (1.84 vs 1.57; $P = 0.002$), feeling comfortable (3.68 vs 3.16; $P = 0.003$), need for extra help (1.96 vs 1.00; $P \leq 0.001$), and change in duration of work (4.27 vs 1.86; $P \leq 0.001$). However, the patients in the CIUS group were sexually inactive for the time during which the stent was indwelling (mean: 7.34 days). There was no difference in complication rates between the two groups.

Conclusion

The use of a CIUS with strings after Ureteroscopy decreases SRS.

Keywords

intra-ureteric stent on string, conventional stent, stent-related symptoms, quality of life

Introduction

It has been more than three decades since Surgitek (Racine, WI, USA) first commercially manufactured the JJ stent, as designed by Roy Finney [1]. JJ ureteric stenting has been one of the most common urological procedures performed as an adjunct since its first inception in 1978 [1], and the ureteric stent is one of the most important devices in the armamentarium of a modern urologist. However, conventional ureteric JJ stent (CUS) placement is associated with a reduction in patient quality of life resulting from discomfort [2]. Fewer drawbacks such as stent-related symptoms (SRS) and increased cost of procedure, followed by need for cystoscopy-guided stent removal are associated with CUS placement as compared to tailed stents [3]. Various meta-analyses, pooling the results of randomized controlled trials, have been conducted to help clinicians make appropriate decisions with regard to ureteric stent placement

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[4–7]. Studies have shown that loop-type stents are associated with fewer SRS than JJ stents because they involve less intravesical material, and this may reduce bladder irritation [2, 8, 9]. Despite recent advancements in stent design, materials, and placement and removal techniques, the perfect ureteric stent has yet to be designed [10]. We hypothesized that complete intra-ureteric stent (CIUS) placement, whereby the distal end of the ureteric stent is placed proximal to the ureteric orifice, would more effectively relieve SRS than CUS placement, whereby the distal end of the ureteric stent is placed within the bladder. Our aim was to assess the safety and efficacy of placement of a CIUS, in terms of SRS and impact on quality of life, using the validated Ureteral Stent Symptom Questionnaire (USSQ), and to compare this with CUS placement.

Materials and Methods

Study Design and Ethics Statement

This was a prospective, single-centre, single-blind, randomized study, conducted between October 2019 and November 2020. Institutional ethics committee (IEC: 585/2019) approval was obtained before the start of the study. The sample size was calculated using PASS software, with power of 80%, a significance level of 0.05, and a confidence level of 95%. A total of 124 patients were prospectively randomized into two groups (Group 1: CUS; Group 2: CIUS) at a 1:1 ratio, using a computer-generated simple randomization method. The randomization sequence was concealed using the 'sequentially numbered, opaque sealed envelopes' method. Randomization was performed intra-operatively (after lithotripsy but before stent placement), and was revealed to the operating surgeon.

Study Participants

All patients aged >18 years with symptomatic unilateral ureteric stones <15 mm in diameter who underwent uncomplicated Ureteroscopy (URS) were eligible for the study. Patients for whom one of the following criteria applied were excluded from the study: (i) a vesico-ureteric junction (VUJ) calculus; (ii) preoperative ureteric stenting; (iii) being in the paediatric age group (age <18 years)/pregnancy or breast feeding; (iv) bilateral URS surgery; (v) solitary kidney; (vi) need for longer duration of in-dwelling stent (more than 14 days); and (vii) difficulty in obtaining consent or in other areas such as rating the degree of pain.

Intervention

Under spinal or general anaesthesia, after placement of a Teflon-coated guidewire with a hydrophilic tip (0.081 cm) into the ureter with the calculus, URS was performed with a 6/7.5-F semirigid ureteroscope (Richard Wolf, Knittlingen, Germany). According to the above-mentioned exclusion criteria, patients with a VUJ calculus, oedema or inflammation, as well those requiring balloon dilatation before negotiating the ureteroscope, were excluded from the study. After appropriate visualization, the stone was fragmented using a pneumatic lithotripter. If residual fragments were present at conclusion of the URS, those patients were also excluded from the study. For CIUS placement, a single-loop stent with extraction thread (5 F/26 cm, 6 F/26 cm, 6 F/24 cm, 5 F/24 cm [polyurethane stent; Blueneem, Medical Devices Private Ltd, Bengaluru, India]) was chosen according to actual ureter length, which was defined as the length between the VUJ and PUJ as measured by ureteric catheter (Fig. 1). The steps involved in the CIUS placement procedure are described in Fig. 2. Direct stent insertion without cystoscopy guidance was avoided as a radio-opaque button is not available on the suture and the suture itself is radiolucent with the position confirmed on fluoroscopy. Finally the stent string was cut at approximately 4–5 cm from the tip of the urethra.

Postoperative Follow-up

The validated USSQ was completed by patients in both groups on postoperative day 1, just before stent removal (range: 7−14 days postoperatively) and at 4 weeks after stent removal. The questionnaire was available in three languages: English, Hindi and Kannada. The standard protocol for cystoscopy-guided stent removal was followed for all patients in the CUS group, while stent removal was carried out using extraction string in the patients in the CIUS group. We recorded visual analogue scale (VAS) pain scores (1–10) just after stent removal for all patients in both groups. Imaging in the form of X-ray (for radio-opaque stones) and ultrasonography/non-contrast CT (for radiolucent stones) was performed to check for any significant residual fragments (>4

Fig. 1 Single-loop ureteric stent with extraction string for complete intra-ureteric stent placement.

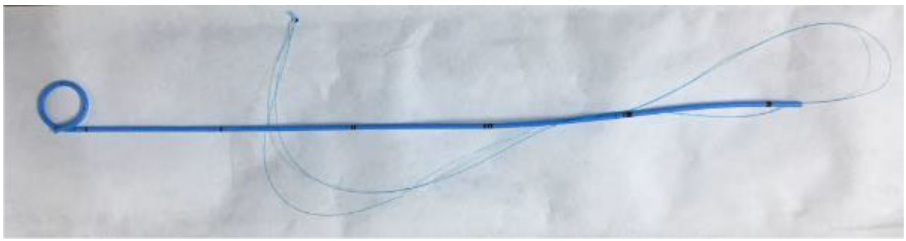
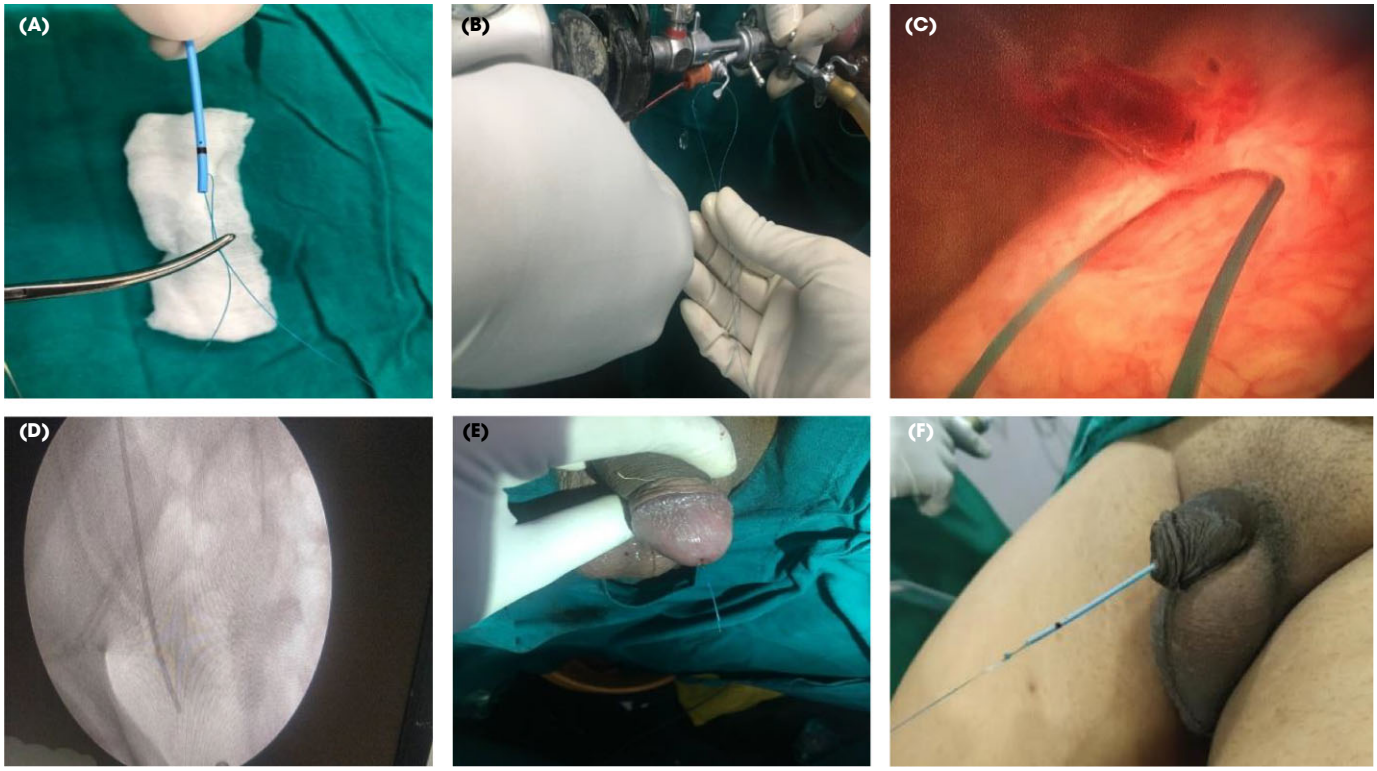


Fig. 2 Steps included in the complete intra-ureteric stent placement procedure. (**A**) A knot is tied 1–2 cm away from the distal end of the single-loop stent. (**B**) Cystoscopy-guided stent insertion, whereby an assistant holds the suture to prevent internalization into urethra. (**C**) The distal end of the stent is pushed into the ureter until the knot is seen. (**D**) Confirmation of the position of the stent on fluoroscopy. (**E**) The suture is kept 2–3 cm outside the urethral meatus for easy pull-out during stent removal. (**F**) Stent removal is carried out using the extraction suture.



mm) and the need for repeat or ancillary procedure. Patients requiring longer stent in-dwelling time or repeat procedures were excluded from the final analysis.

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics 25. Chi-squared tests were used to identify significant differences in effect between. To obtain mean scores, SD and CI values, we used descriptive statistics. P values < 0.05 were taken to indicate statistical significance. P values of 0.000 were considered to be less than 0.05, and the null hypothesis was thus rejected.

Results

Study Population

Consort study principles were followed, as shown in Fig. 3 [11]. A total of 124 patients were randomly assigned to the two study groups. Three patients from the CUS group were excluded from the final analysis. One did not complete 4-week follow-up after stent removal and two patients had insufficient clinical data. Twenty-four patients were excluded from the CIUS group: two patients did not complete follow-up, six patients withdrew consent and 16 patients had insufficient clinical data. A total of 97 patients remained for analysis, including 38 in the CIUS group and 59 in the CUS group.

All patient variables, stone parameters, operative variables as well as stent removal duration were similar in the two groups, with no statistically significant difference noted ($P > 0.05$). A significant difference was noted in terms of stent-related complications in favour of the CIUS group, as no patient had to revisit the emergency department or required readmission, and only two patients experienced stent migration and accidental pull-out (Tables 1 and 2).

Febrile UTI (>38°C with no other signs of systemic inflammatory response syndrome) was observed in two patients in the CUS group, while visible haematuria was present in one patient, requiring readmission. All patients were managed conservatively and did not require early stent removal (before 7 days).

Ureteral Stent Symptom Questionnaire Domain Scores and VAS Pain Score

Index USSQ and VAS pain scores on postoperative day 1 were lower in the CIUS group across all domains as

Fig. 3 Consort study diagram[11]. **Insufficient clinical data (failed to complete the Ureteral Stent Symptom Questionnaire).

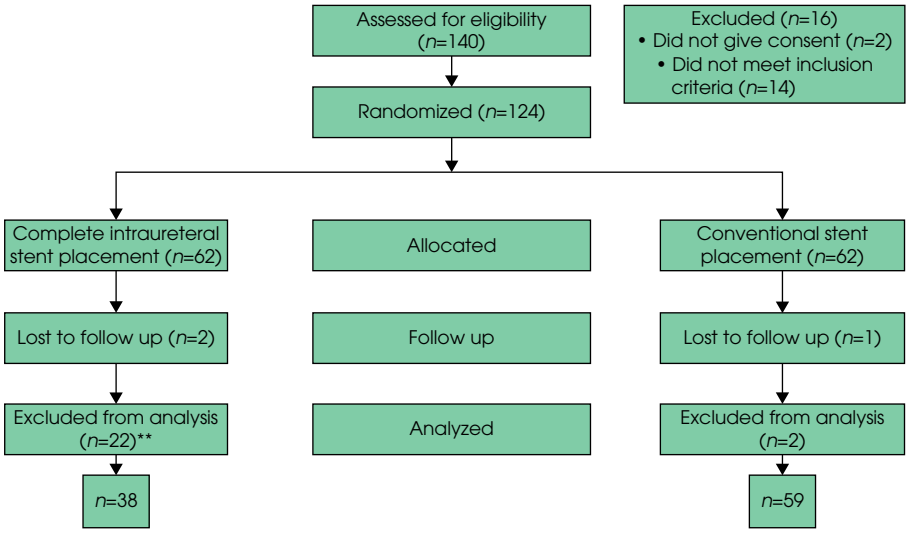


Table 1 Patient demographics, preoperative and operative variables.

Variable	CUS (Group 1; *n* = 59)	CIUS (Group 2; *n* = 38)	*P*
Mean ± SD age, years	44.31 ± 14.46	43.21 ± 12.39	0.88
Gender ratio, male:female	2.93:1	2.4:1	0.86
Mean ± SD body mass index, kg/m^2	27.31 ± 3.66	26.76 ± 4.6	0.46
Mean ± SD stone size, mm	8.27 ± 1.67	8.42 ± 1.62	0.97
Laterality, right:left	35:24	24:14	0.84
Location, proximal:mid:distal	16:17:26	9:12:16	0.86
Mean ± SD operating time, min	28.58 ± 9.55	29.77 ± 7.77	0.44
Stent removal*, mean ± SD days postoperatively	9.12 ± 2.9	7.34 ± 1.74	0.38

*CIUS, complete intra-ureteric stent; CUS, conventional ureteric JJ stent. *Range: 7–14 days.*

compared to the CUS group, but this difference was not statistically significant ($P > 0.05$; Fig. 4A). *P* values across all domains were greater than 0.05, suggesting no statistically significant difference at the time of stent removal across the two groups (Table 3). Sub-analysis showed a significant difference ($P < 0.05$) between the two groups, with lower scores in the CIUS group in terms of urge incontinence (1.21 vs 1.00; $P \leq 0.001$) and pain/discomfort during voiding (2.07 vs 1.50; $P \leq 0.001$). The results also showed that patients in the CIUS group had significantly better scores in terms of performing light physical activities (1.131 vs 1.00; $P \leq 0.001$), becoming less worn out (1.84 vs 1.57; $P = 0.002$), feeling more calm (3.68 vs 3.16; $P = 0.003$) and needing less help from relatives or friends (1.00 vs 1.00; $P \leq 0.001$), and did not require any changes in work duration (4.27 vs 1.86; $P \leq 0.001$). A significant difference in favour of the CUS group was observed for the sexual life domain as the patients in the CIUS group did not have an active sexual life after stent insertion (Table S1).

The VAS showed a mean ± SD score of 4.47 ± 0.873 for the CUS group and 2.76 ± 0.955 for the CIUS group ($P = 0.015$), suggesting that stent removal with an extraction string was associated with significantly less pain and discomfort. Scores at 4 weeks after stent removal were considered to be control or baseline values (Fig. 4C).

Discussion

Ureteric stent placement is an essential component of many urological surgeries, particularly in endourological practice. Although it has been stated in some studies that ureteric stent use is redundant after uncomplicated ureteroscopic lithotripsy, in the present study, we routinely placed a ureteric stent as an insurance against possible complications such as development of hydronephrosis and renal colic [12]. The relationship between stent characteristics including size, material, softness, position, and loop completeness and SRS has been investigated with the aim of minimizing SRS, but to date the evidence has been conflicting [10, 13, 14]. The use of appropriately sized stents in patients could potentially decrease distal migration of stents and, in turn, reduce SRS [15]. It seems that short bladder loops are more favourable than long loops that extend throughout the bladder [8, 16].

Table 2 Stent removal and stent-related complications.

Variable	CUS (Group 1; *n* = 59)	CIUS (Group 2; *n* = 38)	*P*
Stent removal*, mean ± SD days postoperatively	9.12 ± 2.9	7.34 ± 1.74	0.38
Stent migration/drop down into bladder	0	1	0.000
Accidental stent pull-out	0	1	
Febrile UTI	2	0	
Visible haematuria	1	0	
Post-procedural events			
Emergency department visits	3	0	
Readmissions	3	0	
Patient preference for early stent removal (before 7 days)	Nil	Nil	
Forgotten ureteric stent (>3 months)	Nil	Nil	

**Range: 7–14 days.*

Fig. 4 Ureteral Stent Symptom Questionnaire (USSQ) domain scores on postoperative day 1, before stent removal and 4 weeks after stent removal. CIUS, complete intra-ureteric stent; CUS, conventional ureteric JJ stent; QoL, quality of life.

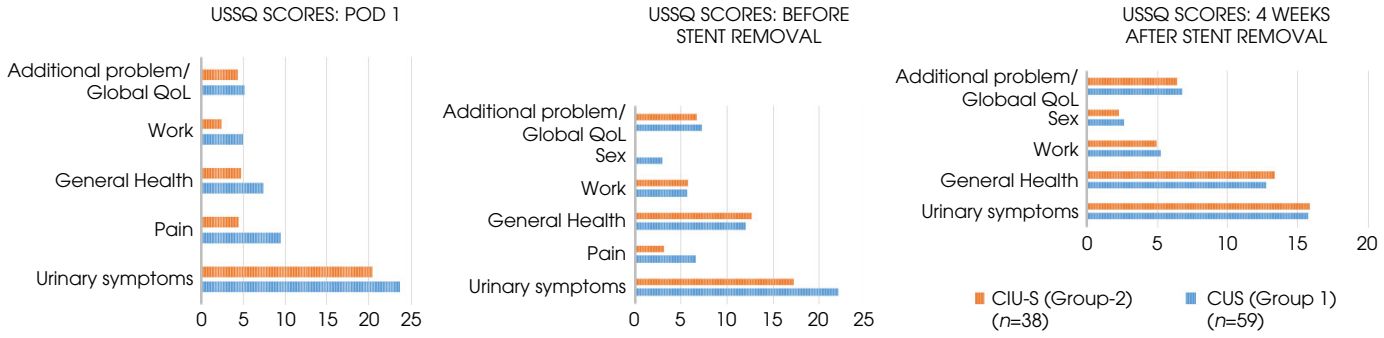


Table 3 Ureteral Stent Symptom Questionnaire domain scores before stent removal and visual analogue scale scores after stent removal.

Before Stent Removal	CUS (Group 1; *n* = 59)		CIUS (Group 2; *n* = 38)		*P*
	Mean score	S.D.	Mean score	S.D.	
Urinary symptoms	22.12	3.04	17.23	1.54	0.748
Pain	6.64	6.89	3.13	4.07	0.328
General health	11.98	1.75	12.63	1.19	0.278
Work	5.63	3.10	5.76	3.11	0.246
Sex	2.95	1.47	2.73	0.68	0.647
Additional problems/Global quality of life	7.25	1.09	6.65	1.19	0.292
VAS score (at time of stent removal)	4.47	0.87	2.76	0.95	0.015

CIUS, complete intra-ureteric stent; CUS, conventional ureteric JJ stent; VAS, visual analogue scale. Scoring system for the questionnaire consists of a simple sum of the scores for individual questions in each section. High scores indicate worse outcomes.

Giannarini et al. [16] showed in a multivariate analysis that location of the distal stent loop had the strongest association with most of the USSQ domains (7 and 28 days postoperatively). We therefore deemed it necessary to minimize the amount of material in the bladder to decrease SRS. Previous studies confirmed that the presence of foreign material in the bladder would lead to more symptoms [8, 17, 18]. Vogt et al. [18] used a pigtail suture stent (0.3 F) instead of the lower part of the JJ stent. The authors showed a clear benefit of the pigtail suture stent in terms of urinary and pain symptom scores, along with dilatation of the ureter without inflammation around the suture [18]. The same group studied the clinical efficiency of the use of novel MiniFil ureteric stents (ROCAMED, Monaco, MC) whereby a suture of 0.3 F is attached to a renal pigtail and the entire ureter is occupied only by the suture of the stent. The results were satisfactory and the MiniFil stent was considered a safe alternative for the treatment of kidney stones during minimally invasive procedures [19]. It has been suggested that gross haematuria could be closely related to stent friction in the collecting system as a result of physical activity. However, low urine volume and retrograde pressure caused by stent-related excessive and steady spasm in the ureter have also been associated with the development of haematuria

[20], although in the present study no macroscopic haematuria development was observed in the CIUS group and it was observed only in one patient in the CUS group. We believe that CIUS is effective against local irritation, persistent ureteric spasm, and reflux, all of which are associated with use of the JJ stent, in the CUS group. Yoshida et al. [21] conducted a similar study but did not use the validated USSQ to compare various domains. Nevertheless, their results also showed that CIUS placement was associated with less stent-related discomfort.

Park et al. [22] compared the impact of Percuflex and Polaris stent placement on SRS using the validated USSQ. They reported that the soft tip of the Polaris stent had some clinical advantages over the Percuflex stent with which the Polaris was being compared stents, but that the impact was not statistically significant with regard to any domain of the USSQ [22]. Bostanci et al. [23] compared the single suture pigtail stent and conventional double pigtail urethral stent and found that the SSPS was associated with better symptom scores with regard to all domains of the USSQ, except for sexual and general health index scores [23]. Barnes et al. and Kim et al. [24, 25] reported that use of stents with extraction strings was not associated with increased bothersome symptoms, with no significant difference across USSQ domains in comparison to use of conventional stents without strings. The USSQ has not been validated in Japan, therefore Yoshida et al. [21] used other validated scoring systems, including the VAS pain score, and the 36-item short-form health survey (SF-36), International Prostate Symptom Score (I-PSS) and overactive bladder symptom score (OABSS) scores to compare conventional stent placement and placement of a CIUS with extraction thread. These scores cover almost all domains included in the USSQ except for haematuria rate and sexual matters. Yoshida et al. [21] reported that the CIUS group had better overall I-PSS and pain scores, with improved day time frequency on sub-analysis, as per OABBS.

The present study produced similar results to those of other authors, suggesting a decrease in symptom scores across all domains but the decrease was not statistically significant. In terms of impact of the stents on sexual health, studies have shown conflicting results. Bostanci et al. [23] suggested that single pigtail suture stents have less adverse impact on sexual health in comparison to double pigtail stents, however, this difference was not statistically significant ($P = 0.07$). Kim et al. [25] reported an overall decrease in sexual activity among patients after stent insertion, but the decrease was greater in patients with extraction strings due to stent-related problems. This difference was statistically significant ($P = 0.03$). In the present study, sexual health was affected in the patients in the CIUS group as these patients were not sexually active while the stent was *in situ* and the difference was statistically significant ($P = 0.02$). Studies have concluded that the rate of complications in stents with strings was not higher than those associated with conventional JJ stents [21, 23, 24, 26, 27]. The present study produced similar results, with only two patients having complications, including one accidental pull-out and one drop down into the bladder, and no patient required emergency department visits or readmissions.

Most studies reported that use of extraction strings for stent removal is associated with much less discomfort than the routine cystoscopy-guided stent removal of conventional JJ stents [21, 24, 25, 27]. In the present study, we also found a statistically significant reduction in pain on stent removal in the CIUS group as compared to the CUS group ($P = 0.015$).

The present study has some limitations, including the possibility of observation bias which cannot be fully excluded as it was a single-blind study. Only a well-selected cohort of patients undergoing uncomplicated URS was included in the study, and patients with VUJ calculi were excluded. The study had a relatively small sample size, with non-completion of the questionnaire by some patients, probably owing to the substantial number of questions for each domain. In addition, the ureter length was defined as the length between the VUJ and PUJ measured by using ureteric catheter, which is operator-dependent with an inherent risk of bias.

In conclusion, the use of CIUS placement with strings after uncomplicated ureteroscopy for ureteric stones is an inexpensive and feasible option. It is associated with better patient convenience and compliance compared with use of a CUS. CIUS placement might help reduce ureteric stent-related discomfort compared with CUS placement. Pain during stent removal is also lower when extraction strings are used.

Conflict of Interest

None declared.

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Abbreviations: CIUS, complete intra-ureteric stent; CUS, conventional ureteric JJ stent; SRS, stent-related symptoms; USSQ, Ureteral Stent Symptom Questionnaire; VAS, visual analogue scale; VUJ, vesico-ureteric junction.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Table S1. Sub-analysis of Ureteral Stent Symptom Questionnaire results between the CUS and CIUS group