Rigid ureteroscopy, a neglected choice for stent removal: a randomized controlled trial to compare rigid ureteroscopy, flexible cystoscopy, and rigid cystoscopy

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To the Editor: As one of the most powerful tools for urologists, ureteral stents are often used in diseases such as calculi, obstruction, ureteral injury, and kidney transplantation and are removed after 3 days to 4 weeks with a visualization instrument. Initially, rigid cystoscopy (RC) was most often used for stent removal, but due to its inflexibility and large diameter, RC often results in pain and potential damage to patients like hematuria, pain, and lower urinary tract symptoms, especially to men.

In 1973, Tsuchida and Sugawara[1] reported flexible cystoscopy (FC), which could be used to observe the bladder neck. Several studies have revealed that the effectiveness of FC during surgery is similar to that of RC.[2] However, the cost of FC is much higher than that of RC, and in many developing countries, FC is not available in all hospitals, preventing many patients from experiencing the higher comfort of FC.

In recent years, some studies have used rigid ureteroscopy (RU) for ureteral stent removal.[3] RU has a structure and clinical popularity similar to RC but with a much thinner diameter, thus making it a potential candidate for cystourethroscopy with less pain.

Which instrument is the most tolerant, and which has the least effect on patients' lives? To find answers to these questions, we performed a randomized controlled trial (RCT) and compared the clinical data of RU, FC, and RC patients during stent removal.

This study is an RCT and was registered in the Chinese Clinical Trial Registry on March 6, 2020, under trial registration number ChiCTR2000030520. We received study approval from our institutional Ethics Committee (No. 2019-1114) and obtained informed consent from all adult research participants. From March 2020 to June 2020, a total of 150 adult patients who underwent ureteral stent removal at the West China Hospital of Sichuan University were included in this study. Patients with kidney failure, congenital urinary tract abnormalities, urinary tract infection, high fever, sepsis, and the use of analgesics were excluded. After obtaining patients' signed informed consent, we utilized a random number table to determine the method of stent removal and divided the patients into Group A (RU, Olympus: WA29042A, French: 9.8 Fr, $n = 43$), Group B (FC, Olympus: CYF-VHA, French: 16.5 Fr, $n = 45$), and Group C (RC, Olympus: A22002A, French: 12 Fr; sheath, Olympus: A20914A, French: 22.5 Fr, $n = 62$). The patients and data collectors were blinded to the group assignments. One experienced urologist removed all patients' ureteral stents with same process.

After patients arrived at the hospital, data collection staff collected their baseline information, including age, height, weight, phone number, and reason for stent placement, and then used visual analog scale (VAS) scores to assess the baseline pain situation, which is a 10-cm ruler and the observer indicates his/her pain level by making a mark. During the stent removal process, data collectors assessed patients' discomfort through the VAS at four timepoints: (1) after local anesthesia; (2) after entry of the instrument; (3) after removal of the stent; and (4) 30 min after the operation.

One day, three days, and seven days after surgery, the data collectors enquired about fever, hematuria, International Prostate Symptom Scores (IPSS), and the patient's self-perceived degree of urinary tract symptoms' influence on quality of life (Not at all/A little bit/Moderate/Quite a bit/Extreme) by telephone.

With SPSS (ver. 25.0, IBM Co., Armonk, NY, USA) software for statistical analysis, we compared continuous

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data using the Kruskal-Wallis test, unordered categorical variables using the chi-squared test, and ordinal categorical variables using the Wilcoxon signed-rank test. The statistical significance was set at $P < 0.05$.

Finally, a total of 150 patients were included in this study, and all patients participated in follow-up telephone interviews. The stents of all patients were successfully removed without serious complications, such as severe hematuria, urinary tract infection, and subsequent hospitalization.

In different groups, no significant differences were discovered in age, male to female ratio, body mass index, disease composition, or VAS score [Supplementary Table 1, http://links.lww.com/CM9/B155].

After integrating the patient's data about pain, we found that compared with RC, patients with RU and FC had lower pain levels. During surgery, patients with FC had the lowest pain levels, while after surgery, patients with RU had the lowest pain levels.

Patient pain at different time points during the operation is shown in Table 1. In the process of placing the instrument in the bladder, the pain level of RU and FC patients was significantly lower than that of RC patients (RU: 1.79, FC: 1.53, RC: 3.05; RU *vs*. RC: $P < 0.001$, RU *vs*. FC: $P = 0.532$, FC *vs*. RC: $P < 0.001$). This effect continued till the end of the operation (RU: 1.00, FC: 0.91, RC: 1.50; RU *vs*. RC: $P = 0.053$, RU *vs*. FC: $P = 0.557$, FC *vs*. RC: $P = 0.011$).

The main postoperative pain situation of patients is also shown in Table 1, while complete data are shown in Supplementary Table 2, http://links.lww.com/CM9/B156. One day after surgery, patients experienced some pain relief, with the RU group being the lowest (RU: 0.72, FC: 0.96, RC: 1.15; RU *vs*. RC: $P = 0.147$, RU *vs*. FC: $P = 0.365$, FC *vs*. RC: $P = 0.611$). After 3 days, the pain in each group was significantly improved, and the pain during urination was obviously lower in RU patients than in RC patients (RU: 0.07, FC: 0.09, RC: 0.23; RU *vs*. RC: $P = 0.034$, RU *vs*. FC: $P = 0.693$, FC *vs*. RC: $P = 0.070$). Seven days after surgery, the pain in each group had basically returned to the baseline level.

The evaluation of the complications began with whether the first postoperative urine presented hematuria [Supplementary Table 3, http://links.lww.com/CM9/B157]. The proportion of hematuria in the RC group was higher than that in the RU and FC groups (RU: 19/43, FC: 26/45, RC: 15/62; RU *vs*. RC: $P = 0.031$, RU *vs*. FC: $P = 0.202$, FC *vs*. RC: $P < 0.001$). One day after surgery, the proportion of hematuria in each group decreased, with RU patients having the largest decrease (RU: 38/5, FC: 33/12, RC: 45/17; RU *vs*. RC: $P = 0.051$, RU *vs*. FC: $P = 0.074$, FC *vs*. RC: $P = 0.931$). For most patients, urinary symptoms did not affect their quality of life (129/150). Urinary symptoms caused by RU had a minimal impact on quality of life, which was greatly different from that of RC but not from that of FC (RU: 40/3/0/0/0, FC: 37/6/2/0/0, RC: 52/7/0/0/0; RU *vs*. RC: $P = 0.046$, RU *vs*. FC: $P = 0.070$, FC *vs*. RC: $P = 0.670$).

After 3 days, hematuria in the RU group completely recovered, reaching statistical significance compared with the RC group (RU: 43/0, FC: 42/3, RC: 55/7; RU *vs*. RC: $P = 0.023$, RU *vs*. FC: $P = 0.085$, FC *vs*. RC: $P = 0.417$). After 7 days, the patients in each group basically returned to normal.

Table 1: VAS scores of three instruments use among adult patients who underwent ureteral stent removal.

Items	Group A ($n = 43$)	Group B ($n = 45$)	Group C ($n = 62$)	*P*-value (A *vs*. C)	*P*-value (A *vs*. B)	*P*-value (B *vs*. C)
Topical anesthesia	0.91 (1, 0–6)	0.88 (0, 0–4.50)	0.90 (1, 0–5)	0.952	0.807	0.746
Entering of the instrument	1.79 (1, 0–6)	1.53 (1, 0–5)	3.05 (3, 0–7)	<0.001	0.532	<0.001
Removal of the stent	2.42 (2, 0–9)	1.98 (2, 0–7)	2.61 (2, 0–8)	0.720	0.308	0.117
When the operation ends	1.00 (1, 0–4)	0.91 (1, 0–5)	1.50 (1, 0–5)	0.053	0.557	0.011
Urethra	1.35 (1, 0–4)	1.27 (1, 0–5)	1.42 (1, 0–8)	0.826	0.753	0.538
Bladder	0 (0, 0–0)	0.18 (0, 0–4)	0.13 (0, 0–4)	0.091	0.047	0.638
Kidney front	0.02 (0, 0–1)	0 (0, 0–0)	0 (0, 0–0)	0.230	0.306	1.000
Kidney back	0.07 (0, 0–3)	0.04 (0, 0–1)	0.02 (0, 0–1)	0.783	0.605	0.383
First urination	1.21 (1, 0–3)	1.33 (1, 0–5)	1.35 (1, 0–8)	0.943	0.972	0.924
After 30 min	1.21 (1, 0–4)	0.96 (1, 0–5)	1.19 (1, 0–6)	0.829	0.238	0.278
Day 1						
VAS scores	0.72 (0, 0–5)	0.96 (0, 0–5)	1.15 (1, 0–6)	0.147	0.365	0.611
Pain during urination	0.84 (1, 0–5)	0.64 (0, 0–4)	1.03 (0.50, 0–6)	0.635	0.215	0.100
Day 3						
VAS scores	0.28 (0, 0–3)	0.42 (0, 0–3)	0.69 (0, 0–10)	0.143	0.359	0.594
Pain during urination	0.07 (0, 0–2)	0.09 (0, 0–2)	0.23 (0, 0–3)	0.034	0.693	0.070
Day 7						
VAS scores	0.14 (0, 0–2)	0.38 (0, 0–3)	0.19 (0, 0–3)	0.908	0.096	0.085
Pain during urination	0 (0, 0–0)	0.07 (0, 0–1)	0.02 (0, 0–1)	0.405	0.087	0.176

The values were shown as mean (median, range). VAS: Visual analog scale; Group A (RU group): Rigid ureteroscopy; Group B (FC group): Flexible cystoscopy; Group C (RC group): Rigid cystoscopy.

Finally, statistical analysis was performed on the hematuria days of each group. It was found that the hematuria days of the RU group were significantly shorter than those of the RC group (RU: 0.16, FC: 0.71, RC: 1.11; RU *vs*. RC: $P = 0.001$, RU *vs*. FC: $P = 0.435$, FC *vs*. RC: $P = 0.081$).

In general, we discovered that the RU and FC patients had less pain and quicker recovery during the perioperative period than the RC patients.

In the postoperative process, RU displayed the greatest advantages, followed by FC, either in pain, hematuria, or the index of "the impacts of urinary system symptoms on life." This may be correlated with RU, which has the thinnest diameter among the three instruments and helps reduce the abrasion of the urethral mucosa, thereby reducing the damage and making postoperative recovery faster.

Apart from the impacts of the operation on patients' bodies, health economics is one of the most concerning topics in various clinical examinations. We cannot provide cost data for each group because this study reduces the price difference among the different instruments. Generally, FC is the most expensive, followed by RU, and RC is the cheapest.[4] Another important reason we discuss RU is its accessibility. Many primary hospitals in developing countries do not have FC but have RU,[3,5] so it is of practical significance to observe whether RU can reduce the pain of patients, thus helping more patients experience a more comfortable operation.

Despite the above advantages of RU, clinically, the procedure of urethral penetration by RU is more complicated than that of RC, especially for younger doctors. RU has a smaller field of vision and worse definition than RC; for bladder conditions with a poor field of vision (such as mucosal bleeding), the operation is more difficult than RC. Besides, RU requires thinner forceps, which have a small clamping force and are easily damaged. These factors affect the widespread clinical use of RU.

The main limitations of this study are that it is a single-center study, and its sample size is small; a multicentre, prospective randomized controlled study with a larger sample size will be more illustrative. We used patient self-assessment combined with fever, hematuria, and IPSS to simply assess the impact on quality of life. In future studies, more authoritative questionnaires should be used for a more comprehensive assessment.

To conclude, patients who underwent RU and FC experienced less pain and fewer complications than those who underwent RC. RU showed the fastest postoperative recovery among the three instruments.

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Conflicts of interest

None.

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