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Optimizing the outcome of non-pre-stented flexible ureteroscopic lithotripsy regarding the quality of life, when to remove the stent?

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Abstract

Objectives To investigate the safety of short-term stenting following flexible ureteroscopic lithotripsy (fURL) for patients without preoperative stents. Retaining double-J stent for 1–2 weeks after fURL is a common practice. At present, data on short-term stenting after non-pre-stented fURL is still lacking.

Methods 182 patients who met inclusion criteria were retrospectively divided into the 2-days group (2-day removal, 76 cases) and the 1-week group (1-week removal, 106 cases). The study endpoint was stent-associated adverse symptoms assessed by follow-up and completed validated questionnaires on postoperative days (POD) 7 and 12. A postoperative imaging review was performed 1 month after the surgery.

Results No statistical differences were found in the patients' demographic and stone-related characteristics. The 2-days group showed fewer urinary tract symptoms and lower scores on the ureteral stent symptom questionnaire on POD 7: less backache during urination ($p=0.004$), less hematuria ($p=0.031$), less frequent urination ($p=0.004$), lower urinary symptoms index ($p<0.001$), lower general health index ($p<0.001$), and lower performance index ($p<0.001$). There were no significant differences in fever ($p=0.372$), visual analogue scale score ($p=0.760$), and painkiller requirements ($p=0.160$) on POD 7. The average general health score and work performance score remained significantly higher in the 1-week group patients at 5 days after removal compared to the 2-days group patients at 5 days after removal. ($p<0.001$, $p=0.005$). Five patients in the 2-days group and 15 patients in the 1-week group returned to the emergency department for additional treatments. No patient required rehospitalization. Stone-free rates were 85.5% in the 2-days group and 80.2% in the 1-week group ($p=0.499$), respectively, and none of the patients got aggravating hydronephrosis.

Conclusions Compared to the common 1-week stent removal option, short-term stenting after non-pre-stented fURL is safe, which can enhance the patient's quality of life.

Keywords Flexible ureteroscopic lithotripsy, double-J stent, Urinary stones, Stentless

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Introduction

Flexible ureteroscopic lithotripsy (fURL) is widely used in the treatment of upper urinary stones [1] due to its benefits of less injury, minimized blood loss, and expedited convalescence. The Double-J stents (DJ stents) are commonly used in fURL, which can facilitate the expulsion of stone fragments, prevent ureteral stricture and prevent pain caused by ureteral edema. Conventionally, about 90% of patients in China, the United States, Europe, and Japan undergo routine DJ stent placement after fURL [2, 3]. Notably, up to 50% of these patients have experienced stent-associated symptoms, such as urinary irritation, hematuria, and pain [4]. Therefore, it is important to study whether the postoperative stent carrying time can be shortened for improving the patient's quality of life. There has been discussion about whether patients with pre-stenting can shorten the stent placement time [5]. There is still a lack of research on the impact of the early removal of DJ stents in non-pre-stented patients underwent fURL. According to the EAU guidelines 2022, most urologists favor 1–2 weeks of postoperative stenting, while the ideal stent duration is not known [6]. This study aimed to investigate the safety of stent removal on postoperative day 2 after non-pre-stented fURL and whether it can reduce stent-associated symptoms compared to the 1-week removal option.

Materials and methods

Patients

In the present study, 527 adult patients (>18 years) who underwent fURL at the Urology Department of the Second Hospital of Tianjin Medical University from June 2022 to December 2023 were included.

A urologist with at least 100 independent fURL surgery experience performed the procedure. Patients with pre-stenting, severe hydronephrosis (the renal parenchyma gets thinner due to the pressure of the renal pelvis), stones larger than 20 mm, and anatomical abnormalities were excluded. Additionally, patients with high-grade ureteral injuries (intraoperative ureteral damage to submucosal or muscular lesions) according to the Traxer ureteral injury scale, severe postoperative hematuria, obvious large residual stone, hematoma, or perirenal effusion observed on postoperative day 1 (POD 1) computed tomography (CT) scan, and those with incomplete follow-up within 30 days after surgery were also excluded [7, 8]. The remaining patients were enrolled in the study. If a positive urine culture was found upon admission, antibiotics were administered continuously until the positive culture turned negative before surgery. All patients who met the inclusion criteria were fully informed about the risks of stent removal based on previous studies and signed an informed consent form. They then chose to have the stent removed either on POD 2 or on POD 7 (the

2-days group or the 1-week group), and were discharged on POD 3. Patients in the 1-week group returned to the outpatient clinic on POD 7 for stent removal.

The ethics committee of The Second Hospital of Tianjin Medical University approved this study (KY2023K145). The demographic details, comorbidities, and stone-related factors of included patients were collected retrospectively.

Technique

All fURL surgeries were performed using the single-use flexible ureteroscope (Innovex, Shanghai). Proximal ureteral stones were pushed back into the renal pelvis and pulverized. Ureteral access sheath (UAS) of 11/13Fr was used in all cases. The stones were fragmented using the holmium laser (Raykeen, Shanghai, 1.2~1.6 J x 20 Hz) and then retrieved by stone retrieval baskets until no large granular stones remained (with each fragment having a diameter less than 2 mm). The laser lithotripsy strategy was determined according to the condition of the stones. At the end of the surgery, the flexible ureteroscope was withdrawn under direct visualization to assess the condition of the ureter for any potential damage, then a DJ (Boston Scientific, America) stent with extraction string was placed. Non-contrast CT scan was performed on postoperative day 1 to assess the patient's residual stones and other conditions to evaluate whether they were suitable for stent removal. Patients had their DJ stents removed by pulling the retrieval string by physicians.

The follow-up period was 1 month. During the period, our follow-up included adverse symptoms and the ureteral stent symptom questionnaire (USSQ). Adverse symptoms include visual analogue scale (VAS) score; painkillers use; fever, hematuria, lower urinary tract symptoms, and emergency treatment. The USSQ questionnaire primarily encompasses various aspects such as urinary symptoms, pain, general health, and work performance. Its validity and reliability have been extensively verified in numerous countries [9]. We conducted the first evaluation for the 2-days group on post-extubation day (PED) 5, assessing adverse symptoms and ureteral stent symptom questionnaires from POD 2 to POD 7 (i.e., from PED 0 to PED 5). Similarly, the 1-week group was assessed twice: on POD 5 and POD 12, assessing for the POD 2 to POD 7 and from POD 7 to POD 12 (i.e., from PED 0 to PED 5). Hydronephrosis and stone-free rate (SFR) were assessed by non-contrast CT scan on POD 30 (Used to assess the hydronephrosis and residual stone, both CT scans were low-dose, both indispensable and safe for the patients). The stone-free status is defined as no fragments or a single fragment with a diameter less than 4 mm on the CT scan. The complete stone-free rate

(CSR) refers to the proportion of patients with no residual stones.

Statistical method

SPSS 25.0 and Prism 9 were used to analyze the data. The categorical data were presented as cases (%) and analyzed using the χ^2 test. The numerical data were presented as mean (M) \pm standard deviation (SD) or Median (M) (P25, P75) and either the t-test or rank-sum test was chosen based on the normality of the data. A $p < 0.05$ was considered significant.

Results

According to inclusion and exclusion criteria, 182 patients were eventually included. Of these, 76 patients were treated by stent placement for 2 days. Another 106 patients had their DJ stents removed 1 week after fURL. Exclusions were as follows: 10.4% (40 patients) due to pre-stenting; 4.8% (78 patients) due to Traxer-grade ≥ 2 ureteral injuries; 17.8% (94 patients) due to incomplete follow-up; 15 patients due to preoperative severe hydronephrosis; 22 patients due to preoperative stone size; 8 patients due to perirenal hematoma or perirenal effusion. The remaining patients were excluded due to postoperative hematuria or significant residual stones.

As shown in Table 1, the mean age of the patients was 54.42 ± 12.90 years in the 1-week group and 55.70 ± 11.94 years in the 2-days group, respectively ($p = 0.499$). The

mean stone size was 1.54 ± 0.38 cm in the 1-week group and 1.57 ± 0.42 cm in the 2-days group ($p = 0.641$). There were no significant differences in gender distribution between the two groups ($p = 0.085$). Additionally, no significant differences were observed in terms of the hydronephrosis degree ($p = 0.411$), stone laterality ($p = 0.515$), or stone position ($p = 0.475$). Approximately 23% of patients in both groups had diabetes ($p = 0.236$). Five patients in the 2-days group and nine in the 1-week group had positive urine cultures ($p = 0.336$).

1-month imaging examination

Follow-up CT scan confirmed that the SFR was 80.2% in the 1-week group and 85.5% in the 2-days group ($p = 0.431$, difference 5.3, 95%CI -0.06 to 0.16). Additionally, 55.7% of patients in the 1-week group and 64.5% of patients in the 2-days group achieved complete stone clearance ($p = 0.284$, difference 8.8, 95%CI -0.06-0.23). None of the patients experienced aggravating hydronephrosis.

Complications

As shown in Table 2, from POD 2 to POD 5 (with only the 1-week group remaining stented), there was no significant difference in VAS scores between two groups ($p = 0.760$). The use of painkillers in both groups was approximately about 17% ($p = 0.160$). Notably, the pain level (VAS score or use of painkillers) in the 1-week

Table 1 Patients' demographic and stone-related characteristics

variables	1-week group	2-days group	Difference and 95% confidence interval	p-value
Age, years, (M \pm SD)	54.42 \pm 12.90	55.70 \pm 11.94	-1.28 [-2.44-4.98]	0.499
BMI, Kg/m ² , (M \pm SD)	26.41 \pm 3.42	25.85 \pm 3.96	0.56 [-1.64-0.53]	0.312
Stone size, cm, (M \pm SD))	1.54 \pm 0.38	1.57 \pm 0.42	-0.03 [-0.09-0.15]	0.641
Sex, n (%)				
Female	77(72.6)	46(60.5)	12.1	0.085
Male	29(27.4)	30(39.5)	[-0.02-0.26]	
Side, n (%)				
Left	52(49.1)	41(53.9)	-4.8	0.475
Right	54(50.9)	35(46.1)	[-0.20-0.10]	
Position, n (%)				
Kidney	30(28.3)	28(36.8)	-8.5	0.138
Proximal ureter	43(40.6)	34(44.7)	[-0.22-0.50]	
Both	33(31.1)	14(18.4)		
Hydronephrosis, n (%)				
No obstruction	16(15.1)	15(19.7)	-4.6	0.411
Non-serve	90(84.9)	61(80.3)	[-0.16-0.07]	
Urine culture positive, n (%)				
Positive	14(13.2)	14(18.4)	-5.2	0.336
Negative	92(86.8)	62(81.6)	[-0.16-0.06]	
Diabetes, n (%)				
Yes	29(27.4)	15(19.7)	7.7	0.236
No	77(72.6)	61(80.3)	[-0.05-0.20]	

Table 2 Analysis of symptoms in both groups from POD 7 to POD 12

	1-week group	2-days group	Difference and 95% confidence interval	p-value
VAS score	3(0, 3)	3(0, 3)	0	0.760
M(P25, P75)			[-0.01-0.00]	
Fever, n (%)				
Yes	11 (10.4)	5(6.6)	3.8	0.372
No	95 (89.6)	71(93.4)	[-0.04-0.12]	
Use of painkillers, n (%)				
Use	14(13.2)	16(21.1)	-7.9	0.160
Not use	92(86.8)	60(78.9)	[-0.19-0.03]	
Hematuria, n (%)				
Yes	80(75.5)	46(60.5)	15	0.031*
No	26(24.5)	30(39.5)	[0.01-0.29]	
Frequent urination, n (%)				
Yes	52(49.1)	21(27.6)	21.5	0.004*
No	54(50.9)	55(72.4)	[0.08-0.35]	
Urinary urgency, n (%)				
Yes	83(78.3)	44(57.9)	20.4	0.003*
No	23(21.7)	32(42.1)	[0.07-0.34]	
Pain during urination, n (%)				
Yes	52(49.1)	21(27.6)	21.5	0.004*
No	54(50.9)	55(72.4)	[0.08-0.35]	
Emergency treatment, n (%)				
Yes	8(7.5)	5(6.6)	0.9	0.802
No	98(92.5)	71(93.4)	[-0.07-0.08]	
pain	1	1		
Luts	5	3		
fever	2	0		
dysuria	0	1		
Urinary symptoms index (M±SD)	27.55±4.93	24.89±5.39	2.66 [1.11-4.20]	0.001*
Body pain index (M±SD)	13.24±5.52	12.04±5.72	1.2 [-0.47-2.87]	0.157
General health index (M±SD)	15.48±5.65	12.07±4.54	3.41 [1.86-4.95]	<0.001*
Work performance index (M±SD)	7.65±2.43	5.92±2.53	1.73 [0.96-2.47]	<0.001*

*Statistically significant

group patients during PED 0-PED 5 was similar to that in the 2-days group patients ($p=0.859$, $p=0.387$), as shown in Table 3.

From POD 2 to POD 7, 11 (10.4%) patients in the 1-week group and 5 (6.6%) patients in the 2-days group developed a fever ($p=0.372$). From PED 0 to PED 5, 9.4% of patients in the 1-week group and 6.6% of patients in the 2-days group got a temperature ($p=0.936$). Fever in both groups from PED 0 to PED 5 usually occurred on the first day after stent removal and typically lasted for 1–2 days, improving with rehydration or antibiotic treatment. One patient in the 2-day group had a fever that persisted for 6 days. In the 1-week group from POD 2 to POD 7, fever lasted an average of 2.7 days during the stenting period and was and was treated with fluid rehydration, antibiotics, and anti-reflux therapy. Two patients in the 1-week group showed improvement after stent removal, and no patients required early removal of double-J tubes.

During the period of stent placement, the 1-week group exhibited stronger lower urinary tract symptoms (LUTS): more backache during urination ($p=0.004$), more hematuria ($p=0.031$), and more frequent urination ($p=0.004$). Although all these symptoms improved following stent removal, the 1-week group continued to experience slightly more intense symptoms compared to the 2-days group on PED 0–5. However, this difference was not statistically significant ($p>0.05$).

As shown in the Tables 2 and 3, 5 patients (within 5 days after stent removal) in the 2-days group and 12 patients (8 within 5 days before removal and 4 within 5 days after removal) in the 1-week group returned to the emergency department. There were no readmissions or surgical interventions for any of these patients.

Table 3 Analysis of symptoms in both groups from PED 0 to PED-5

	1-week group	2-days group	Difference and 95% confidence interval	p-value
VAS score (M±SD)	3(1, 3)	3(0, 3)	0 [0.00–0.00]	0.859
Fever, n (%)				
Yes	10 (9.4)	5(6.6)	2.8	0.490
No	96 (90.6)	71(93.4)	[-0.05-0.11]	
Use of painkillers, n (%)				
Use	17(16.0)	16(21.1)	-5.1	0.387
Not use	89(84.0)	60(78.9)	[-0.17-0.06]	
Hematuria, n (%)				
Yes	73(68.9)	46(60.5)	8.4	0.243
No	33(31.1)	30(39.5)	[-0.06-0.22]	
Frequent urination, n (%)				
Yes	36(34.0)	21(27.6)	6.4	0.364
No	70(66.0)	55(72.4)	[-0.07-0.20]	
Urinary urgency, n (%)				
Yes	86(81.1)	43(56.6)	24.5	0.001*
No	20(18.9)	33(43.4)	[0.11–0.38]	
Pain during urination, n (%)				
Yes	41(38.7)	21(27.6)	11.1	0.121
No	65(61.3)	55(72.4)	[-0.03-0.25]	
Emergency treatment, n (%)				
Yes	4(3.8)	5(6.6)	-2.8	0.494
No	102(96.2)	71(93.4)	[-0.09-0.04]	
pain	1	1		
Luts	2	3		
fever	0	0		
dysuria	1	1		
Urinary symptoms index (M±SD)	25.49±5.23	24.89±5.39	0.60 [-0.98-2.18]	0.455
Body pain index (M±SD)	12.96±5.07	12.04±5.72	0.92 [-0.66-2.54]	0.253
General health index (M±SD)	14.53±5.39	12.07±4.54	2.46 [0.95–3.94]	0.001*
Work performance index (M±SD)	7.03±2.60	5.92±2.53	1.11 [0.35–1.87]	0.005*

*Statistically significant

USSQ score

Patients in the 1-week group exhibited significantly more severe urinary symptoms 5 days before removal compared to those in the 2-days group on POD 2–7 ($p=0.001$), as the 1-week group still had stented while the 2-days group did not. However, this significant difference disappeared once both groups had their stents removed for 5 days ($p=0.455$) (Fig. 1).

The mean general health score was 15.48 ± 5.65 in the 1-week group and 12.07 ± 4.54 in the 2-days group from POD 2 to POD 7 ($p<0.001$). Significant differences were observed in terms of light physical activities ($p<0.001$), heavy physical activities ($p<0.001$), and vitality ($p=0.007$) (Fig. 2). Following stent removal, patients in the 1-week group showed improvements in all the aforementioned discomforts from PED 0 to PED 5. However, it is noteworthy that the average general health score remained significantly higher in the 1-week group compared to the

2-days group when both groups had their stents removed for 5 days ($p<0.001$). A similar trend was observed in work performance index ($p<0.05$), regardless of whether the control group had stents, as shown in Tables 2 and 3.

Discussion

In 1983, Bagley et al. from the University of Chicago in the United States developed the first flexible ureteroscopy by integrating the working and perfusion channels. Since then, fURL has gradually become a crucial surgical technique for the treatment of upper urinary stones [10]. Ureteral stent is widely recognized for its ability to facilitate the passage of residual stones and promote the healing of ureteral mucosal injuries. Moreover, it serves as a preventive measure against infection, pain, and ureteral stenosis. However, prior study revealed that 80% of patients experience stent-associated pain when indwelling DJ stents, and 78% of patients experienced urinary

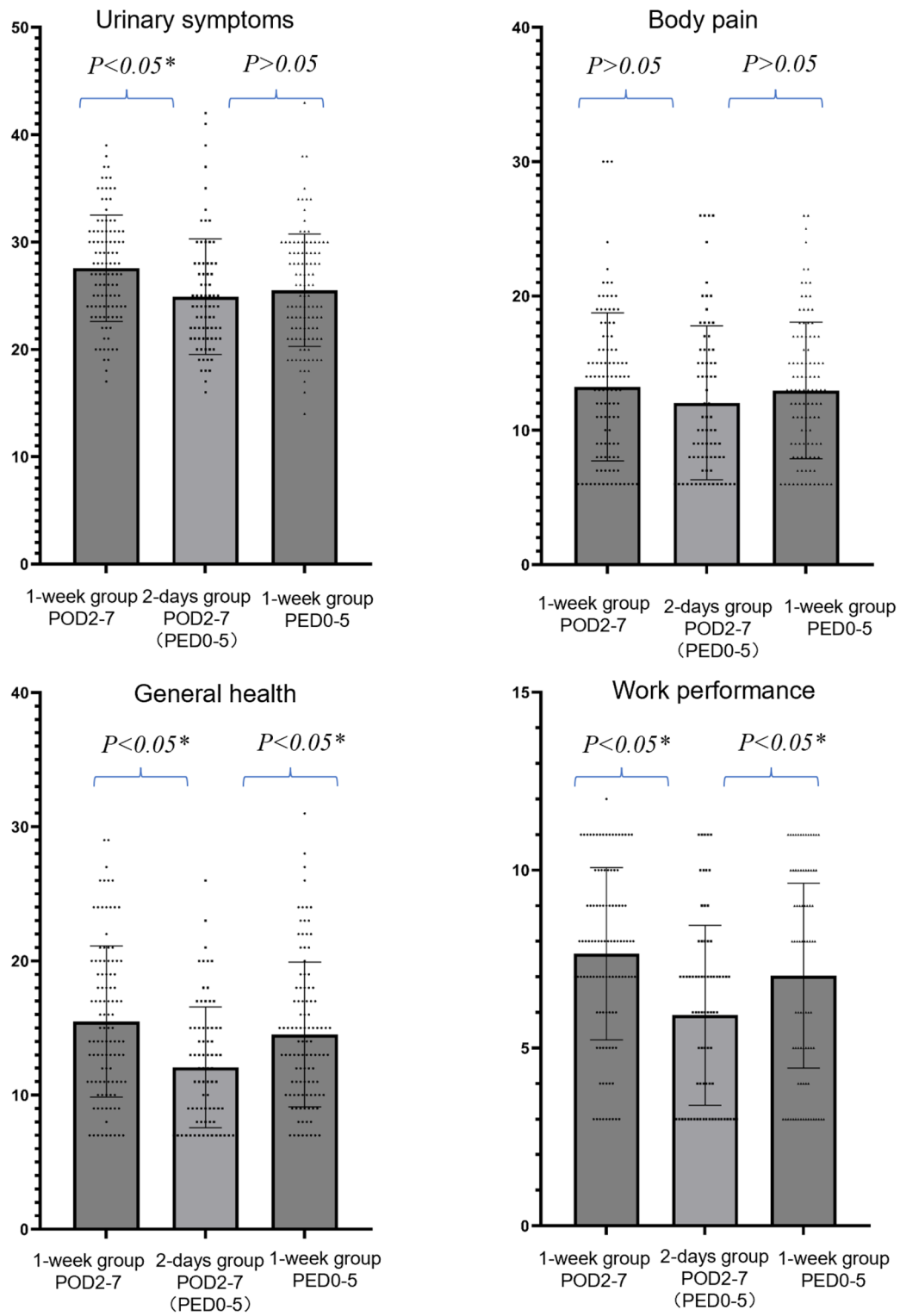


Fig. 1 Difference between the 1-week group and 2-days group in the USSQ index

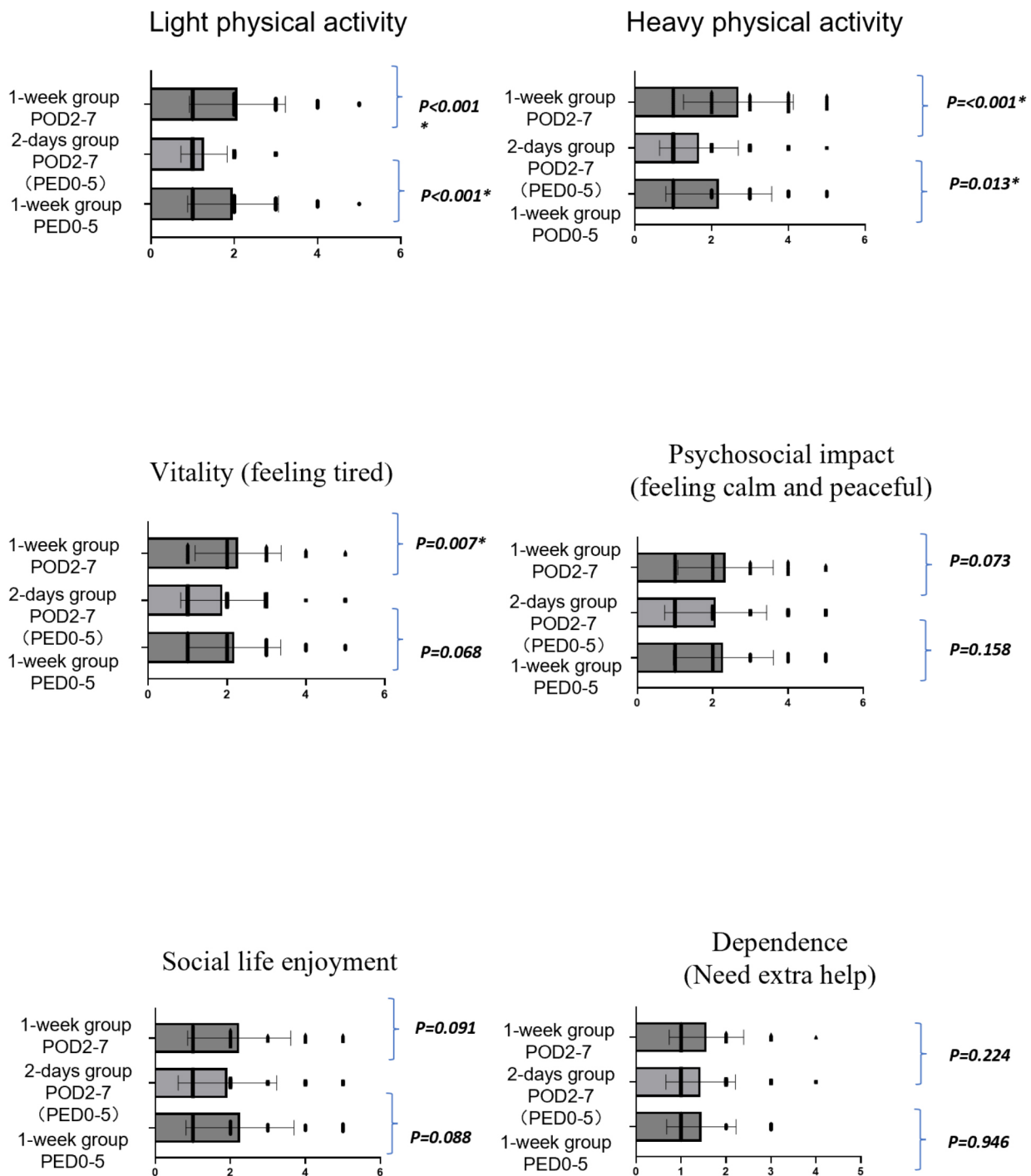


Fig. 2 Difference between the 1-week group and 2-days group in general health index

dysfunction [11]. The stent also causes stent-related LUTS, which can significantly impact patients' quality of life. Additionally, prolonged stent duration increases the risk of colonization by multi-drug-resistant flora [12] and forgetting the stent [13]. Therefore, it is of great significance to investigate whether the duration of

postoperative stent placement can be shortened to alleviate stent-related discomfort and improve patient's quality of life. Several studies have demonstrated that in cases of uncomplicated ureteroscopy for distal ureteral stones, long-term stent implantation may not be necessary [14, 15]. However, surgeons prefer the placement of ureteral

stents for 1–2 weeks when treating upper urinary tract stones [16]. At present, there is still a lack of studies on the safety of short-term stenting after fURL, especially non-pre-stented fURL.

LUTS were likely associated to the presence of the stent [17]. According to our results, LUTS in the 2-days group showed significantly improvement, particularly regarding hematuria, frequent urination, and pain during urination. In contrast, discomfort persisted for up to 1 week in the 1-week group following stent removal. There was no significant difference in fever between the two groups on POD 7, a finding similar to the meta-analysis on stentless procedures following rigid ureteroscopic lithotripsy by Song et al [4]. Although the 2-days group had a lower VAS score than the 1-week group, the difference was not statistically significant. This observation aligns with previous studies conducted by Hussein and Kenan et al [18, 19].

Shorter stent placement seemed to enhance quality of life. Patients who underwent early stent removal experienced not only milder LUTS but also a faster recovery in terms of returning to normal physical activities and mental health (Fig. 2). Even after the stents of patients in the 1-week group were removed for 5 days, 56.6% of these patients had not fully recovered in terms of light physical activities. Additionally, half of the patients in this group continued to encounter difficulties in resuming normal interpersonal interactions. In contrast, 67.1% of patients in the 2-day group achieved satisfactory recovery by POD 7. A similar trend in USSQ scores has been observed in the study by Christopher et al. [20, 21].

The mean SFR in our study was 82.9%, which closely aligns with Jacob Cohen's reported SFR of 87% [22]. On average, 60.1% of patients in our study achieved complete stone clearance. Our CSR was slightly higher than the 49.6% reported by Hyung Joon Kim et al. in the real-world setting [23]. Regardless of the diameter size used to assess SFR, there was no significant difference between the two groups. This suggests that the stent duration may not affect the passage of stone fragments.

Currently, most guidelines do not recommend routine pre-stenting. Previous research has indicated that pre-stenting, as compared to non-pre-stenting, results in a significant sevenfold reduction in the risk of severe injury [8]. Some clinical trials related to postoperative stentless procedures included pre-stented patients [3, 5]. Preoperative stents have been shown to prevent ureteral injury and improve the success rate of postoperative stentless procedures. However, it is important to consider that they may increase the patient's cost and discomfort [17].

Although omitting the use of UAS can reduce ureteral damage, the UAS can be quite beneficial in cases involving large and multiple renal stones [24]. It may be easier to achieve complete stone clearance using a UAS. Traxer

and Thomas assessed the incidence and severity of ureteral injury following the placement of 12/14Fr sheaths. According to their findings, 46.5% of cases resulted in ureteral wall injury, and severe damage to the smooth muscle layer was observed in 13% of these cases [8]. They suggested that the higher the grade of ureteral injury, the later the removal time of DJ stents. But one recent meta-article reviewing 3766 studies suggested that there was no direct evidence linking UAS to ureteral injury [25]. Makoto's study demonstrated that the incidence of ureteral injury above Traxer-grade 2 was only 19.3% when using 11/13Fr sheaths without pre-stenting, and this finding indicated a lower incidence compared to Traxer's report [26]. In our study, the 11/13Fr UAS were used in all procedures and the incidence of ureteral injury above the Traxer-grade 2 was only about 14%. Non-pre-stented patients using 11/13Fr UAS had a low probability of severe ureteral injury, and most patients could safely have the stents removed early.

Although the guidelines do not recommend the placement of DJ stents after "simple URS", the standard for stentless procedures remains strict and ambiguous [14]. In fact, urological surgeons around the world perform stentless procedures with varying standards. Arsalan Pervaiz's study concluded that patients who did not have a severe ureteral injury were suitable for stentless procedures [27]. The study conducted by Christopher et al. only excluded patients with stones over 1.5 cm or true ureteral perforation. However, the unplanned emergency treatment and readmission rates reported in their study were relatively high, reaching up to 21.6% and 8.1%, respectively [20]. Saddam had a similar report of a high emergency rate [17]. The high emergency treatment rate seems to indicate that stentless procedures treatment is not appropriate for most patients. Djaladat came up with that a short period of stent drainage seemed to eliminate the possibility of early ureteral edema, secondary hydro-nephrosis, and pain [28]. Our results also suggested that short-term stenting can decrease unplanned emergency visits [29]. In certain situations, early stent removal is not recommended: (a) possible postoperative hematoma or perirenal effusion, (b) severe postoperative hematuria, pain or dynamic obstruction due to high-grade ureteral injury, (c) patient's own concern, (d) presence of large residual stone fragments.

Previously, Bach et al. conducted extensive research. In FAST (Fast track stent study) 1, they used ureter catheters instead of stents for 6 h after URS, and the results showed that short-term stenting with straight catheters led to a better quality of life, similar to our findings [21]. In FAST 2, Bach et al. tried a tubeless procedure for pre-stented patients [30]. Although lower urinary tract symptoms, pain, and health status were improved, the reintervention rate was 10% higher than FAST 1. In FAST 3, they briefly

used mono-J stents for 6 h instead of double J stents, but the study was terminated early due to a high reintervention rate of 32.2% [3]. However, in the FAST series, their treatment didn't seem to focus adequately on patients' postoperative conditions. The timing of stent removal should be determined by both intraoperative and postoperative conditions.

As far as we know, this study is the first to specifically investigate the early removal of stents after non-pre-stented fURL. However, as this study is retrospective in nature, further large-scale prospective studies are needed to confirm our conclusion. In addition, we did not analyze the incidence of long-term complications because of the short follow-up period.

Conclusion

Two-day stent placement after non-pre-stented fURL is a safe procedure. This approach can effectively improve the quality of life compared to 1-week stent placement. Both intraoperative and postoperative conditions should be taken into consideration when determining the timing of stent removal.

Abbreviations

fURL	flexible ureteroscopic lithotripsy
CT	computed tomography
UAS	Ureteral access sheath
DJ stents	Double-J stents
POD	postoperative day
USSQ	ureteral stent symptom questionnaire
LUTS	lower urinary tract symptoms
VAS	visual analogue scale
SFR	Stone-free rate
CSR	complete stone-free rate

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None.

Author contributions

ZF, HX, and CL designed the research. FZ conducted the formal analysis. JH verified the data results. ZF wrote the original draft. JH, HG, and CL edited and modified the article. All authors reviewed and approved the manuscript.

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Data availability

The datasets used and analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethical approval and consent to participate

The ethics committee of The Second Hospital of Tianjin Medical University approved this study (KY2023K145). All methods were carried out in accordance with relevant guidelines and regulation. Informed consent was obtained by all subjects when they were enrolled.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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