

COMPARISON OF 4.8 FR AND 6 FR URETERAL STENTS ON STENT RELATED SYMPTOMS FOLLOWING URETERORENOSCOPY

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Abstract

OBJECTIVE

To compare stent related symptoms of 4.8 French and 6 French DJ stents on validated Urdu version USSQ in our population

STUDY DESIGN

This investigation was carried out using a randomized, double-blind clinical trial.

PLACE AND DURATION OF THE STUDY

The Urology Department of Liaquat University of Medical and Health Sciences, Jamshoro, between March and July 2025

METHODOLOGY

A randomized, double-blind clinical trial was carried out in the Department of Urology, Liaquat University of Medical and Health Sciences, Jamshoro, between 2nd Jan 2025 to 2nd June 2025. Through consecutive non-probability sampling, 146 patients aged 15–80 years with unilateral ureteric stones planned for uncomplicated retrograde intrarenal surgery were included. By sealed envelope lottery, they were evenly assigned to two groups of 73, receiving either a 4.8 Fr or 6 Fr stent. Symptom assessment was performed using the validated Urdu-USSQ, and categorical comparisons were analyzed with the Chi-square test in SPSS version 26.0 at a 5% significance level.

RESULTS

A total of 146 patients were randomized equally into two groups (73 each). The mean age was

44.90 ± 10.75 years in the 4.8 Fr group and 43.92 ± 12.11 years in the 6 Fr group, with males comprising 73.3% of the cohort. Patients with 6 Fr stents reported significantly higher urinary, pain, general health, work, sexual, and total USSQ scores compared to the 4.8 Fr group (all $p < 0.05$)

CONCLUSION
The trial showed that patients receiving 6 Fr stents experienced significantly greater urinary complaints, pain, poorer general health, and limitations in work and sexual activity compared to those with 4.8 Fr stents. These results indicate that using smaller-caliber stents in uncomplicated ureterorenoscopy can reduce postoperative morbidity and enhance patient quality of life, supporting their consideration as the preferred option in routine practice.

INTRODUCTION

The global burden of urolithiasis has been rising steadily, influenced by changing dietary habits, sedentary lifestyles, and metabolic risk factors [1,2]. Ureteric calculi account for a considerable proportion of these cases and are frequently associated with obstruction, severe pain, and potential loss of renal function if left untreated. With advances in endourological techniques, ureterorenoscopy (URS) has become the preferred intervention for most ureteric stones, offering excellent clearance rates with relatively low morbidity compared with traditional surgical approaches [3,4].

The use of double J (DJ) stents following URS is a common practice aimed at maintaining ureteral patency, reducing postoperative complications, and promoting smooth recovery [5]. However, contemporary evidence increasingly questions the need for routine stenting after uncomplicated procedures, as stents themselves can significantly compromise patient comfort [6,7]. Adverse effects frequently reported include urinary frequency, urgency, hematuria, flank or suprapubic pain, and reduced quality of life, with studies estimating that the majority of patients experience some degree of stent-related morbidity [8-10].

To evaluate this morbidity, the Ureteral Stent Symptom Questionnaire (USSQ) has been widely adopted as a validated tool that measures multiple domains, including urinary function, pain, work capacity, and overall quality of life [11,12]. In recent years, researchers have explored modifications in stent design, material, and size in an effort to reduce symptom severity. Among these variables, stent caliber has emerged as an important factor influencing tolerance. Smaller-caliber stents are hypothesized to lessen bladder irritation and improve patient-reported outcomes without compromising clinical safety [13,14].

Several randomized controlled trials have addressed this question with mixed outcomes. Some have shown that reducing stent size is associated with better symptom scores and improved quality of life [15,16], whereas others have not observed significant differences between smaller and larger stents [17,18]. These inconsistencies highlight the need for further

investigation, particularly in diverse clinical settings.

In Pakistan, stenting after URS continues to be widely practiced due to concerns regarding postoperative obstruction and medicolegal implications, despite evidence that questions its necessity in uncomplicated cases. Importantly, there is a lack of local data comparing stent diameters and their impact on patient well-being. The current study seeks to address this gap by comparing the symptom burden of 4.8 Fr and 6 Fr ureteral stents following uncomplicated URS, using the validated Urdu version of the USSQ. The results are expected to provide locally relevant evidence that may guide clinical decision-making toward improving patient comfort while ensuring procedural safety.

METHODOLOGY

This randomized, double-blind controlled trial was carried out in the Department of Urology, Liaquat University of Medical and Health Sciences, Jamshoro, Hyderabad, between 2nd Jan 2025 to 2nd June 2025. The study population consisted of male and female patients aged 15 to 80 years presenting with unilateral ureteric stones and scheduled for uncomplicated retrograde intrarenal surgery. Ureterorenoscopy was considered a minimally invasive endoscopic approach for the evaluation and treatment of ureteral and renal pathology, while ureteric and renal stones were defined as mineralized concretions within the urinary tract responsible for obstruction or pain. Post-stenting symptoms were described as urinary, functional, or pain-related complaints and were assessed using the validated Urdu translation of the Ureteral Stent Symptom Questionnaire (USSQ). The final sample size was calculated as 146 patients, with 73 in each study arm, using the WHO sample size calculator and assuming a 95% confidence level, 80% power, a mean USSQ score of 91.9 ± 27.9 in one group, and 103 ± 19.1 in the comparison group. Randomization was achieved through the lottery method, whereby sealed opaque envelopes containing pre-assigned group allocations (4.8 Fr stent or 6 Fr stent) were prepared in advance and

opened at the time of surgery; this ensured concealment and blinding of both the patient and surgeon to the stent size until placement. Patients were excluded if they had acute renal failure, complicated ureteroscopy, prior urinary diversion, ureteric strictures, residual calculi, previous stenting, pregnancy, bleeding disorders, psychiatric illness, or history of trauma. Ethical approval was granted by the institutional review committee, and written informed consent was obtained from every participant before recruitment. All patients underwent standardized ureterorenoscopy with pneumatic lithotripsy under fluoroscopic guidance, followed by insertion of the allocated stent. Stents were removed three weeks later, and each patient was reviewed one week after surgery and again one week following stent removal. During follow-up visits, participants completed the Urdu-USSQ, and demographic as well as clinical data were documented. Statistical analysis was conducted using SPSS version 26.0; categorical variables were compared between groups using the Chi-square test, and a p-value ≤ 0.05 was considered statistically significant.

RESULTS

A total of 146 patients were enrolled, with an equal distribution of 73 participants in each stent group. The mean age was 44.90 ± 10.75 years in the 4.8 Fr group compared to 43.92 ± 12.11 years in the 6 Fr group. Body mass index values were also comparable, averaging 25.76 ± 3.43 kg/m²

and 26.01 ± 3.33 kg/m² in the 4.8 Fr and 6 Fr groups, respectively. Regarding gender distribution, 50 males (46.7%) received the 4.8 Fr stent and 57 males (53.3%) the 6 Fr stent, whereas 23 females (59.0%) were allocated to the 4.8 Fr group and 16 (41.0%) to the 6 Fr group. In terms of marital status, 15 single patients (42.8%) were in the 4.8 Fr group and 20 (57.2%) in the 6 Fr group, while among married patients, 61 (55.0%) belonged to the 4.8 Fr group compared to 50 (45.0%) in the 6 Fr group **Table I**.

Table II compares stent-related symptoms between patients receiving 4.8 Fr and 6 Fr stents (n=146). Across all domains, significantly higher symptom scores were observed in the 6 Fr group. Urinary complaints were more pronounced with larger stents (29.33 ± 6.02 vs. 25.50 ± 6.27 , $p=0.0001$), accompanied by increased body pain (24.46 ± 5.45 vs. 19.80 ± 4.22 , $p=0.0001$) and poorer general health ratings (17.02 ± 3.90 vs. 14.21 ± 3.95 , $p=0.0001$). Work performance was more negatively affected in the 6 Fr group (11.65 ± 3.18 vs. 10.04 ± 3.10 , $p=0.002$), and sexual function scores were also worse (9.95 ± 1.84 vs. 8.43 ± 1.77 , $p=0.0001$). Overall, the mean USSQ score was significantly higher in patients with 6 Fr stents compared to those with 4.8 Fr stents (103.50 ± 18.55 vs. 92.25 ± 29.25 , $p=0.006$), reflecting a greater burden of stent-related morbidity with larger caliber devices.

Table I: Demographic Characteristics of Study Patients (n=146)

Demographic Characteristics		Groups	
		4.8 Fr Stent (n=73)	6 Fr Stent (n=73)
Age in years, Mean $\pm$ SD		44.90 $\pm$ 10.75	43.92 $\pm$ 12.11
BMI in kg/m ² , Mean $\pm$ SD		25.76 $\pm$ 3.43	26.01 $\pm$ 3.33
Gender, n (%)	Male	50 (46.7)	57 (53.3)
	Female	23 (59.0)	16 (41.0)
Marital Status, n (%)	Single	15 (42.8)	20 (57.2)
	Married	61 (55.0)	50 (45.0)

Table II: Comparison of Stent Related Symptoms Between Groups (n=146)				
Stent Related Symptoms	Groups			P-Value
	4.8 Fr Stent (n=73)	6 Fr Stent (n=73)	95% C. I	
Urinary Symptoms, Mean $\pm$ SD	25.50 $\pm$ 6.27	29.33 $\pm$ 6.02	-5.847 ~~~~~ 1.821	0.0001*
Body Pain, Mean $\pm$ SD	19.80 $\pm$ 4.22	24.46 $\pm$ 5.45	-6.255 ~~~~~ 3.062	0.0001*
General Health, Mean $\pm$ SD	14.21 $\pm$ 3.95	17.02 $\pm$ 3.90	-4.093 ~~~~~ 1.522	0.0001*
Work Performance, Mean $\pm$ SD	10.04 $\pm$ 3.10	11.65 $\pm$ 3.18	-2.634 ~~~~~ 0.579	0.002*
Sexual Matters, Mean $\pm$ SD	8.43 $\pm$ 1.77	9.95 $\pm$ 1.84	-2.113 ~~~~~ 0.930	0.0001*
USSQ Score, Mean $\pm$ SD	92.25 $\pm$ 29.25	103.50 $\pm$ 18.55	-19.265 ~~~~~ 3.235	0.006*

DISCUSSION

This randomized controlled trial assessed the impact of stent caliber on patient-reported outcomes after uncomplicated ureterorenoscopy using the validated Urdu version of the Ureteral Stent Symptom Questionnaire (USSQ). The findings demonstrated that patients with 6 Fr stents had significantly higher symptom scores across all domains compared with those with

4.8 Fr stents, with urinary symptoms (29.33 $\pm$ 6.02 vs. 25.50 $\pm$ 6.27, $p=0.0001$), body pain (24.46 $\pm$ 5.45 vs. 19.80 $\pm$ 4.22, $p=0.0001$), and general health (17.02 $\pm$ 3.90 vs. 14.21 $\pm$ 3.95, $p=0.0001$) being notably worse. Work performance (11.65 $\pm$ 3.18 vs. 10.04 $\pm$ 3.10, $p=0.002$) and sexual function (9.95 $\pm$ 1.84 vs. 8.43 $\pm$ 1.77, $p=0.0001$) were similarly impaired, while the overall USSQ score was significantly higher in the 6 Fr group (103.50 $\pm$ 18.55 vs. 92.25 $\pm$ 29.25, $p=0.006$). These results clearly indicate that larger-caliber stents are associated with greater morbidity.

Our statistical results are consistent with prior studies reporting comparable differences in stent-related symptom scores. Damiano et al. found that mean USSQ urinary domain scores were significantly lower with 4.7 Fr stents compared to 6 Fr, supporting our observation of reduced urinary symptoms in the smaller-caliber group [13]. Liang et al. reported mean urinary symptom scores of 24.2 $\pm$ 5.8 for 4.7 Fr stents and 28.5 $\pm$ 6.1 for 6 Fr stents ($p<0.01$), which closely mirror our urinary symptom results (25.50 $\pm$

6.27 vs. 29.33 $\pm$ 6.02, $p=0.0001$) [15]. Similarly, Netsch et al. demonstrated higher pain and work performance scores with larger stents, with statistically significant differences across domains, paralleling our findings in body pain ($p=0.0001$) and work performance ($p=0.002$) [16]. Xu et al. also confirmed that mean USSQ scores were higher in patients with 6 Fr stents, particularly in urinary and pain domains, consistent with our overall score difference ($p=0.006$) [17]. More recently, Kim et al. reported significantly worse outcomes in urinary and sexual domains with 6 Fr stents compared to smaller ones, supporting our observation of sexual function impairment in the larger-caliber group ($p=0.0001$) [18]. These comparisons strengthen the external validity of our statistical outcomes, demonstrating consistency across populations and study designs.

The pathophysiological basis for these results lies in the increased mechanical irritation caused by larger stents, which exert greater pressure on the bladder trigone and ureteral mucosa, leading to urgency, frequency, and pain [7,9]. Larger stents also contribute to bladder overactivity and worsen sexual discomfort, explaining the poorer scores in multiple domains observed in our study. Importantly, the overall USSQ scores highlight the broad effect of stent size, not only on urinary symptoms but also on general health, work efficiency, and psychosocial well-being.

The strengths of this study include its randomized, double-blind design, appropriate allocation concealment, and use of a validated, culturally adapted tool to measure patient-reported outcomes. The adequate sample size and comparable baseline characteristics further enhance internal validity. However, some limitations must be acknowledged. This was a single-center trial with short-term follow-up, and longer-term complications such as infection, encrustation, or obstruction were not assessed. Only two stent sizes were compared, while variations in material, length, or newer biodegradable designs were not addressed [14]. Despite these limitations, the study adds valuable evidence from a South Asian context where routine stenting remains common practice.

Clinically, the results strongly support the preferential use of smaller-caliber stents such as 4.8 Fr in uncomplicated ureterorenoscopy, as they significantly reduce symptom burden without compromising safety. Adoption of this approach can improve patient comfort, decrease unplanned healthcare visits, and enhance quality of life. Future multicentre trials with larger cohorts and longer follow-up are warranted to validate these findings and explore additional strategies such as newer materials or patient-tailored stent selection.

CONCLUSION

The trial showed that patients receiving 6 Fr stents experienced significantly greater urinary complaints, pain, poorer general health, and limitations in work and sexual activity compared to those with 4.8 Fr stents. These results indicate that using smaller-caliber stents in uncomplicated ureterorenoscopy can reduce postoperative morbidity and enhance patient quality of life, supporting their consideration as the preferred option in routine practice.

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