ORIGINAL ARTICLE

Comparative Efficacy of Tamsulosin and Solifenacin in Managing Double J Stent-Related Symptoms: A Randomized Clinical Study Using the USSQ Tool

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Abstract

Background: Double-J stents relieve obstruction but often cause urinary symptoms and pain that impair quality of life.

Objective: To compare solifenacin *vs.* tamsulosin for relief of stent-related symptoms using the Ureteral Stent Symptom Questionnaire (USSQ).

Methods: This open-label randomized controlled trial was conducted at Liaquat National Hospital from June 2024 to December 2024. Adults (20-50 years) with unilateral DJ stents were assigned to tamsulosin 0.4 mg daily or solifenacin 5 mg daily for 14 days. Symptoms were assessed on day 14 with the USSQ.

Results: A total of 60 patients were enrolled, with 30 patients in each treatment group. Solifenacin produced lower total USSQ scores than tamsulosin (60.5 ± 8.3 *vs.* 74.2 ± 7.8, p<0.001). Solifenacin also demonstrated significantly better scores across individual domains of the USSQ: urinary index (22.6±3.9 *vs.* 29.1±3.5, p<0.001), pain index (13.1±3.2 *vs.* 16.9±3.4, p=0.002), general health index (13.6±2.7 *vs.* 15.8±2.9, p =0.005), and work performance index (7.5 ± 2.0 *vs.* 9.4 ±2.2, p=0.001). Sexual function did not differ (2.3±2.0 *vs.* 2.7±2.5, p=0.450). Adverse events were mild (dry mouth with solifenacin; dizziness with tamsulosin); no discontinuations occurred.

Conclusion: Solifenacin was more effective than tamsulosin for short-term relief of DJ stent-related symptoms and may be considered the preferred monotherapy. Multicentre studies with longer follow-up are warranted.

Trial Registration: ClinicalTrials.gov NCT07114848.

Keywords: *Ureteral stent, DJ stent-related symptoms, tamsulosin, solifenacin, alpha-blocker, anticholinergic, USSQ, randomized comparative study, urinary symptoms, quality of life.*

INTRODUCTION

The medical team led by Zimskind *et al.* developed the double-J (DJ) stent in 1967 to maintain ureteral patency, facilitate urinary drainage, and prevent hydronephrosis and renal dysfunction following urinary tract surgery or ureteral trauma [1]. Ureteral stent-related symptoms (USRS) tend to worsen with prolonged stent indwelling time and may be influenced by factors such as stent length, positioning, diameter, and material [2, 3]. Statistics indicate that 80% of patients with stents develop these complications that substantially deteriorate their quality of life (QoL) [3, 4]. The multiple causes of USRS include mechanical bladder trigone irritation, together with bladder overactivity, vesicoureteral reflux, and pelvic nerve stimulation [5-7]. USRS symptoms tend to become more severe when stents remain in place longer and their length, positioning, diameter, and material selection increase [3, 8]. The morbidity of affected patients intensifies because patients develop both physical symptoms as well as psychological distress, together with sexual dysfunction and decreased capacity to perform at work [9, 10]. Alpha-adrenergic blockers, in combination with anticholinergic drugs, are the primary pharmacological treatments for USRS. At a dose of 0.4 mg daily, tamsulosin functions as an alpha-1 blocker to relax the smooth muscle in the bladder neck and ureter, thereby reducing detrusor outlet resistance, as well as symptoms of urgency, frequency, and flank pain [4, 5, 11]. The specific M3 muscarinic receptor-blocking properties of Solifenacin enable it to control involuntary bladder contractions and improve storage capacity, resulting in a reduction in irritating voiding symptoms [5, 7, 12]. The short-term administration of these drugs exhibits a favourable side effect profile, accompanied by good patient tolerance. The Ureteral Stent Symptom Questionnaire (USSQ) by Joshi *et al.* serves as the primary assessment method for evaluating the morbidity of stents, as it has established its validity for this purpose [9]. The USSQ evaluates urinary symptoms as well as body pain symptoms alongside assessments of general health and work performance, sexual health, and overall QoL. Multiple research studies have employed USSQ to evaluate monotherapies, as well as combination therapies, for managing USRS [3, 13]. Through a randomized trial, El-Nahas *et al.* confirmed that tamsulosin and solifenacin delivered better USSQ score outcomes than placebo, but solifenacin proved more effective in managing distinct symptom groups [10]. Anticholinergics demonstrated better performance

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than alpha-blockers in reducing irritative urinary symptoms and delivering enhanced patient satisfaction, according to a RCT done by Dellis *et al.* [14].

Additional evidence from various comparative research projects confirms these results. Research by Kotb *et al.* [6, 15] demonstrated that solifenacin achieved better bladder control than other options among patients with bladder stents, as reported by Lim *et al.* [16]. Established that combined treatment improved symptoms, yet solifenacin worked well alone [16]. The higher selectivity of solifenacin for M3 receptors provides patients with both better tolerability and enhanced efficacy, as indicated by findings in [5, 17]. The use of DJ stents for urolithiasis and post-ureteroscopy cases in public and private sector hospitals across Pakistan lacks peer-reviewed studies for direct assessment of these treatments [18]. A randomized clinical trial approach was employed because researchers wanted to scrutinise how tamsulosin and solifenacin work independently to help Pakistani patients manage their DJ stent symptoms using the USSQ evaluation mechanism. The research results will guide local medical prescribing practices and expand global knowledge about improving stent management from a patient-centred approach.

This study was undertaken because data directly comparing the effectiveness of alpha-blockers and anticholinergics for double-J stent-related symptoms in the Pakistani population are scarce, despite their frequent clinical use. Evaluating these medications using the validated Ureteral Stent Symptom Questionnaire (USSQ) will provide locally relevant evidence to guide prescribing practices and improve patient-centred care. Therefore, this study aimed to compare the efficacy of tamsulosin and solifenacin in reducing symptoms associated with double J stent using the Ureteral Stent Symptom Questionnaire (USSQ).

METHODOLOGY

This open-label randomized clinical trial was performed at the Department of Urology, Liaquat National Hospital, Karachi, from June 2024 to December 2024, after securing consent from the Ethical Review Committee of Liaquat National Hospital (Ref: 0996-2024-LNH-ERC). This study is registered at ClinicalTrials.gov with the identifier NCT07114848. The study was conducted in accordance with the principles outlined in the Declaration of Helsinki, and written informed consent was obtained from all patients before their inclusion.

All patients between 20 and 50 years of age who had undergone unilateral DJ stent placement for ureteric calculi and post-ureteroscopic lithotripsy were enrolled. Key exclusion criteria included bilateral stenting, a history of lower urinary tract symptoms, urological malignancy, recurrent urinary tract infection, previous bladder surgery, allergy to alpha-blockers or anticholinergics, cardiovascular instability, uncontrolled hypertension, chronic renal or hepatic failure, and stent-related complications (*e.g.*, stent migration, encrustation, or infection). Additionally, patients with pre-existing lower urinary tract conditions, those with ongoing use of medications affecting bladder contractility (*e.g.*, anticholinergics, alpha-blockers), individuals with significant cardiovascular comorbidities, and patients with other systemic conditions that could confound symptom reporting were excluded.

Patients were randomly assigned to two groups (tamsulosin *vs*. solifenacin) using a simple lottery method. Sealed opaque envelopes ensured allocation concealment. The study was open-label; however, outcome assessment using the USSQ was conducted by residents who were not involved in patient allocation or care, minimizing bias.

Sixty patients were recruited by consecutive nonprobability sampling. A sample size of 30 patients for each group was estimated using the WHO sample size calculator, based on a mean difference of 8 points in USSQ scores between the two groups, as observed by El-Nahas *et al*. [10] with $\alpha = 0.05$, power = 80%, and margin of error of 5%. Thirty patients were allocated to Group A (tamsulosin) and thirty to Group B (solifenacin). Baseline characteristics, including age, gender, BMI, indication for stenting, and stent length, were comparable between the two groups ($p > 0.05$). Stent length was standardized (24-26 cm), and indwelling duration was fixed at 14 days for all patients. No patients received additional bladder-active medications during the study period. Any concomitant drug use and comorbidities were documented at baseline to ensure protocol consistency.

Data were gathered through in-person interviews, which trained urology residents administered under the supervision of attending physicians. Demographic details, including age, sex, body mass index (BMI), indication for stenting, stent length, and comorbidities, were recorded on a structured pro forma. A postoperative follow-up was conducted in the outpatient department on the 14th day, and the USSQ was completed. The Ureteral Stent Symptom Questionnaire (USSQ), developed by Joshi *et al*. [9], is a reliable multi-dimensional questionnaire that scores urinary symptoms, pain, general health, work productivity, sexual health and overall QoL. A forward-backwards translation was used to translate it into Urdu

and pilot tested for cultural adaptation. Patients were advised to contact the investigator if they experienced an adverse drug reaction.

The data were statistically analyzed using SPSS version 25. Frequencies and percentages were used to describe categorical variables. Normality of continuous variables was tested using the Shapiro-Wilk test. For normally distributed data, the mean ± SD was shown; for all other data, the median and IQR were displayed. An independent-samples t-test was used to compare continuous variables with normal distribution, while the Mann-Whitney U test was applied for non-normally distributed data. Chi-square or Fisher's exact tests were used for comparing categorical variables among the two study groups, p-values ≤0.05 were deemed statistically significant.

RESULTS

A total of 60 patients were enrolled, with 30 patients in each treatment group. Baseline demographic and clinical characteristics are presented in Table **1** and **Fig. (1)**. No statistically significant differences were observed between the two groups in terms of sociodemographic and clinical features.

Table 1: Baseline demographic and clinical characteristics of patients in the two groups.

Variables	Tamsulosin (n=30)	Solifenacin (n=30)	p-value
Age (years), mean ± SD	36.2 ± 7.1	35.7 ± 6.9	0.780
Gender (Male/Female)	18 / 12	17 / 13	0.790
BMI (kg/m²), mean ± SD	24.5 ± 2.9	24.8 ± 3.1	0.680
Stent length (cm), mean ± SD	24.0 ± 2.1	24.3 ± 1.9	0.590
Indication for stenting (Ureteric calculi / Post-URS)	20 / 10	19 / 11	0.810

The mean total USSQ score was significantly lower in the solifenacin group compared to the tamsulosin group (60.5±8.3 *vs*. 74.2±7.8, p<0.001), indicating superior symptom control. Solifenacin also demonstrated substantially better scores across individual domains of the USSQ: urinary index (22.6±3.9 *vs*. 29.1±3.5, p<0.001), pain index (13.1±3.2 *vs*. 16.9±3.4, p=0.002), general health index (13.6±2.7 *vs*. 15.8±2.9, p=0.005), and work performance index (7.5 ± 2.0 *vs*. 9.4 ±2.2, p=0.001). There was no statistically significant difference between the two groups in terms of the sexual index (2.3 ± 2.0 *vs*. 2.7 ± 2.5, p = 0.450). These findings are summarised in Table **2**.

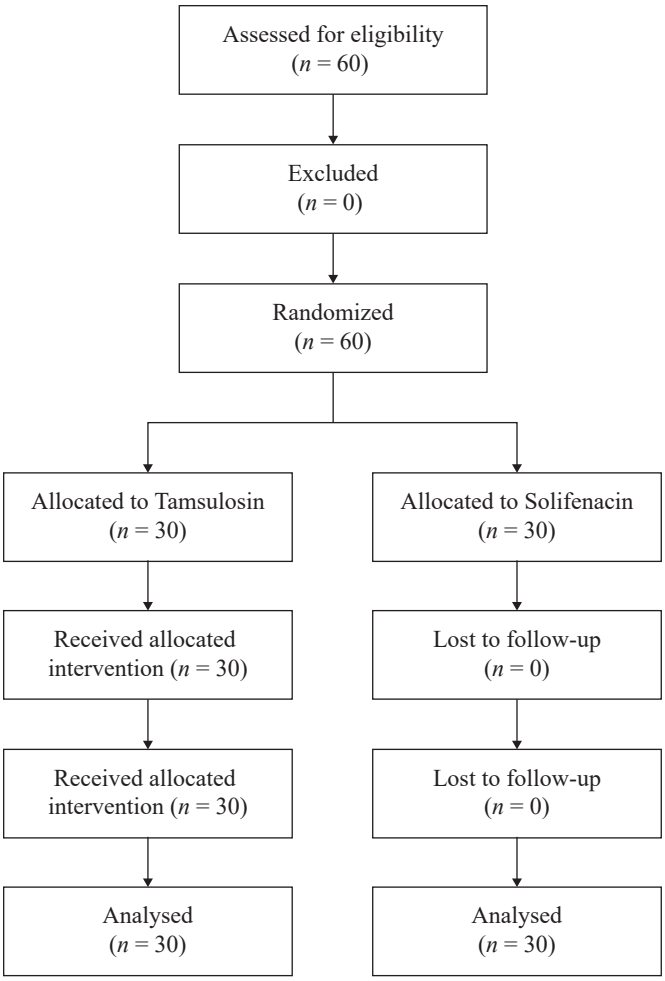

Fig. (1): CONSORT Flow Diagram for the randomized controlled trial.

Table 2: Comparison of USSQ scores between tamsulosin and solifenacin.

USSQ Domains	Tamsulosin (n=30)	Solifenacin (n=30)	p-value
Total USSQ Score, mean ± SD	74.2 ± 7.8	60.5 ± 8.3	<0.001
Urinary Index, mean ± SD	29.1 ± 3.5	22.6 ± 3.9	<0.001
Pain Index, mean ± SD	16.9 ± 3.4	13.1 ± 3.2	0.002
General Health Index, mean ± SD	15.8 ± 2.9	13.6 ± 2.7	0.005
Work Performance Index, mean ± SD	9.4 ± 2.2	7.5 ± 2.0	0.001
Sexual index, mean ± SD	2.7 ± 2.5	2.3 ± 2.0	0.450

No significant adverse effects were reported in either group. A few patients in the solifenacin group experienced mild dry mouth, while some in the tamsulosin group reported mild dizziness; however, all side effects were well-tolerated and did not lead to treatment discontinuation.

DISCUSSION

Using the validated Ureteral Stent Symptom Questionnaire (USSQ), this randomized, double-arm, single-blind clinical trial evaluated how well solifenacin and tamsulosin managed symptoms associated with double J stents. Our findings revealed notable differences between the two groups: solifenacin yielded better outcomes in the areas of work, pain, general health, and urine, and resulted in lower overall USSQ scores. The domain of sexual function showed no difference. These results lend credence to the idea that solifenacin can help patients with indwelling stents live better lives.

Our results align with previous research. A RCT done by Dellis AE *et al*. verified that antimuscarinic agents are superior to alpha-blockers in controlling irritative urinary symptoms [14]. Randomized controlled trials by El-Nahas *et al*. [10] also demonstrated that solifenacin was more effective than placebo or tamsulosin in reducing stent-related symptoms. Because it selectively blocks the M3 muscarinic receptor, solifenacin is more effective than alpha-blockade alone at reducing involuntary detrusor contractions and increasing bladder capacity [5, 12].

One of the main reasons why patients with stents experience morbidity is pain. In our investigation, solifenacin was found to have a greater analgesic effect in stented patients than tamsulosin, which is consistent with the findings of Rizvi *et al*. [6, 19]. Reduced trigonal irritation and bladder overactivity, which are impacted by antimuscarinic action, could account for the analgesic benefit [7]. Our patients' improvements in overall health and productivity at work serve as additional evidence of the broader effects of efficient symptom management on functional and physical well-being [9].

Both drugs were generally well tolerated, with only minor side effects observed (dry mouth with solifenacin and mild dizziness with tamsulosin). These findings align with previous studies that have reported a favourable short-term safety profile for both agents [4, 5].

It's interesting to note that the Sexual Index did not significantly differ between groups. The short follow-up period (14 days) and the possibility that psychological discomfort and procedural factors, rather than drug activity, are more likely to cause sexual dysfunction in stented patients could be the cause of this lack of difference. Previous studies have reported similar results [11].

The single-centre design, small sample size, and lack of long-term follow-up are some of the study's drawbacks. These elements limit the broad applicability of our results. Randomization was performed using a simple lottery method; while this ensured transparency, it may not have fully guaranteed balance between groups given the small sample size. Additionally, the use of consecutive non-probability sampling may introduce selection bias and limit external validity. The absence of a true control group and a combination therapy arm (tamsulosin + solifenacin) further restricts the ability to differentiate treatment effects from the natural course of recovery and to evaluate potential additive or synergistic benefits. Furthermore, this trial did not assess combination therapy (tamsulosin + solifenacin), which has been beneficial in other studies [20]. To confirm and build on these findings, multicenter studies with larger cohorts, longer follow-up, and evaluation of combination regimens are needed in the future.

From a clinical standpoint, our findings demonstrate that solifenacin is a viable option for reducing the burden of stent-related morbidity, which may enhance patient satisfaction, work productivity, and overall quality of life. Patients with DJ stents may use less healthcare due to stent morbidity if solifenacin is used more frequently. Future studies should assess the long-term impact of the therapy on patient outcomes and its cost-effectiveness.

The strengths of this study include its randomized design, the use of a validated and culturally adapted USSQ instrument, and a well-defined methodology with an adequate sample size calculation, which together enhance the reliability of our findings.

CONCLUSION

From a clinical standpoint, our findings demonstrate that solifenacin is a viable option for reducing the burden of stent-related morbidity, which may enhance patient satisfaction, work productivity, and overall quality of life. Patients with DJ stents may use less healthcare due to stent morbidity if solifenacin is used more frequently. Future studies should assess the long-term impact of the therapy on patient outcomes and its cost-effectiveness. These findings suggest the broader applicability of solifenacin in routine practice; however, further multicenter studies are required to confirm its generalizability across diverse patient populations.

ETHICAL APPROVAL

Ethical approval was obtained from the Institutional Review Committee of Liaqat National Hospital and Medical College, Karachi (REF letter No. App # 0996-2024-LNH-ERC). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and the principles outlined in the Helsinki Declaration.

CONSENT FOR PUBLICATION

Written and informed consent was obtained from all participants prior to their enrollment.

AVAILABILITY OF DATA

The data set may be acquired from the corresponding author upon a reasonable request.

FUNDING

None.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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Declared none.

AUTHORS' CONTRIBUTION

1. FM, WM, AA, RK, SN and GK: Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work.
2. FM, WM, AA, RK, SN and GK: Drafting the work or reviewing it critically for important intellectual content.
3. FM, WM, AA, RK, SN and GK: Final approval of the version to be published.
4. FM, WM, AA, RK, SN and GK: Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

GENERATIVE AI AND AI-ASSISTED TECHNOLOGIES IN THE WRITING PROCESS

During the preparation of this work the author(s) limitedly used ChatGPT (GPT-4, OpenAI) to get language suggestions and do minor proofreading in some parts of the manuscript. After using this tool/ service, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the published article.

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