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Efficacy and safety of terazosin versus tamsulosin monotherapy for ureteral stent–related lower urinary tract symptoms: a double-blind randomized controlled trial

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Short Title (Running Head): Terazosin vs. Tamsulosin for Stent-Related Symptoms

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Efficacy and safety of terazosin versus tamsulosin monotherapy for ureteral stent–related lower urinary tract symptoms: a double-blind randomized controlled trial

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Abstract

Background: Indwelling ureteral stents frequently cause stent-related symptoms (SRSs) that negatively impact patients' health-related quality of life. This double-blind randomized controlled trial aimed to evaluate and compare the therapeutic efficacy and safety of tamsulosin versus terazosin monotherapy in alleviating stent-induced morbidity in patients undergoing retrograde ureteral stenting.

Methods: Ninety patients with unilateral urinary tract calculi scheduled for retrograde ureteral stenting were randomized (1:1) to receive either tamsulosin (0.4 mg once daily) or terazosin (2 mg once daily) immediately after stent insertion until stent removal (4–6 weeks). The primary outcomes were evaluated at baseline and at the time of stent removal using the Ureteral Stent Symptom Questionnaire (USSQ), the International Prostate Symptom Score (IPSS), and a Quality of Life (QoL) index. Safety and adverse events were monitored throughout the trial.

Results: Baseline demographic and clinical characteristics were homogeneous between the two cohorts ($P>0.05$). At stent removal, patients receiving tamsulosin demonstrated significantly lower (better) scores in the USSQ urinary symptoms domain compared with the terazosin group (19.20 ± 2.15 vs. 21.55 ± 6.02; $P=0.017$).Similarly, the tamsulosin group exhibited significantly superior outcomes in general health (10.13 ± 1.68 vs. 11.77 ± 4.63;$P=0.029$) and additional complications domains (8.17 ± 0.61 vs. 9.08 ± 2.29; $P=0.013$).Voiding dysfunction measured by IPSS was

significantly lower in the tamsulosin group (2.11 ± 1.06 vs. 5.27 ± 2.86; P=0.038). No significant differences were observed regarding body pain, sexual function, daily work performance, or overall QoL (P>0.05). Both drugs were well tolerated, with minor self-limiting adverse events (dizziness and nasal congestion) and no severe orthostatic hypotensive episodes.

Conclusions: While both α_1-blockers were safe and well tolerated, tamsulosin monotherapy demonstrated superior efficacy over terazosin in reducing stent-induced lower urinary tract symptoms, improving general health, and minimizing stent-related complications.

Keywords: Ureteral stent; Stent-related symptoms; Tamsulosin; Terazosin; α_1-Adrenergic antagonists; Lower urinary tract symptoms; Quality of life.

Trial registration : Iranian Registry of Clinical Trials (IRCT) IRCT20220117060982N1 (Registered 17 January 2022)

Background

Ureteral obstruction represents a critical clinical challenge arising from diverse benign and malignant etiologies, including nephrolithiasis, congenital strictures, retroperitoneal fibrosis, and pelvic malignancies [1]. If left unmanaged, the resulting urinary stasis elevates hydrostatic pressure within the collecting system, precipitating progressive hydronephrosis, compromised renal parenchymal perfusion, and permanent obstructive nephropathy [2]. To counteract these sequelae, retrograde ureteral stenting has become a cornerstone of modern endourological practice. Clinical audits estimate that over 1.5 million ureteral stents are deployed annually worldwide—a number that continues to rise with the widespread adoption of minimally invasive procedures such as ureteroscopy (URS) and retrograde intrarenal surgery (RIRS) [3, 4].

Despite their indispensable role in maintaining ureteral patency and facilitating drainage, the clinical utility of double-J (DJ) stents is substantially compromised by device-associated morbidity [5]. Up to 80% of stented patients experience a complex symptom constellation known as stent-related symptoms (SRSs) [6]. This debilitating condition encompasses lower urinary tract symptoms (LUTSs)—predominantly urgency, frequency, dysuria, and macroscopic hematuria—as well as stent-induced flank and suprapubic pain [7]. As validated by the Ureteral Stent Symptom Questionnaire (USSQ), SRS imposes a substantial socioeconomic and functional burden: approximately 70% of affected individuals report pain severe enough

to reduce daily occupational performance by more than 50%, alongside noticeable declines in overall health-related quality of life [5, 8].

From a pathophysiological standpoint, SRS arises from interconnected biomechanical and neurogenic triggers. The distal intravesical curl of the stent exerts continuous mechanical friction against the sensitive urothelium of the bladder trigone, disrupting the mucosal glycosaminoglycan layer and exposing sensory suburothelial receptors to urinary solutes [9]. This local irritation provokes uninhibited smooth muscle contractions and hyperactivates mechanosensitive myelinated Aδ- and unmyelinated C-fibers, which transmit nociceptive and urgency afferent signals to the central nervous system. Concurrently, elevated intravesical pressure during micturition is transmitted retrogradely through the hollow stent lumen into the renal pelvis, resulting in dynamic vesicoureteral reflux and transient pelvic hypertension that manifest as voiding-induced flank pain [10, 11].

Because the neuro-urological mechanisms of SRS share pathways with overactive bladder and benign prostatic hyperplasia, pharmacological modulation using α_1-adrenergic receptor antagonists (α_1-blockers) has become the primary strategy for conservative management [12]. Postsynaptic α_1-receptors are densely expressed throughout the intramural ureter, bladder neck, and trigone; antagonism of these receptors relaxes ureteral and trigonal smooth muscle, attenuates intravesical resistance, and reduces reflux-induced renal back-pressure.

However, available α_1-blockers possess distinct receptor-subtype binding profiles that may directly influence their clinical balance of target-organ efficacy versus systemic tolerability [13, 14]. Tamsulosin exhibits high selective affinity for α_{1A} and α_{1D} subtypes predominantly localized in the lower urinary tract and distal ureter, with minimal affinity for vascular α_{1B} receptors. In contrast, nonselective antagonists such as terazosin block all three subtypes with equal affinity, which may predispose patients to systemic vasodilatory side effects, including orthostatic hypotension and reflex tachycardia [13, 14].

While previous research has frequently assessed combination regimens—such as combining α_1-blockers with antimuscarinics, β_3-agonists, or phosphodiesterase-5 inhibitors [4, 8, 15]—head-to-head randomized comparisons between subtype-selective and nonselective monotherapies remain limited, particularly using comprehensive, domain-specific validated metrics such as the USSQ. Consequently, high-quality comparative evidence is needed to determine whether the receptor selectivity of tamsulosin confers clinically meaningful symptomatic and safety advantages over traditional nonselective agents such as terazosin.Therefore, this double-blind, randomized controlled trial was designed to directly evaluate and compare the therapeutic efficacy and safety profiles of tamsulosin versus terazosin monotherapy in

mitigating stent-related symptoms among patients undergoing retrograde ureteral stenting for unilateral urolithiasis.

Methods

Study design and patient population

This prospective, parallel-group, double-blind, randomized controlled trial was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Ethics Committee of Arak University of Medical Sciences (Approval ID: IR.ARAKMU.REC.1400.227). The study was prospectively registered in the Iranian Registry of Clinical Trials (IRCT ID: IRCT20201006048950N3).

A total of 90 eligible adult patients presenting with unilateral ureteral obstruction secondary to urolithiasis who were scheduled for elective retrograde unilateral double-J (DJ) ureteral stent placement were enrolled at the tertiary endourology centers affiliated with Arak University of Medical Sciences during 2024. Prior to enrollment, written informed consent was obtained from all participants after the trial objectives, procedures, and potential risks were explained.

To minimize technical variability, all retrograde stent insertions were performed by a single experienced urologist using a standardized cystoscopic technique under fluoroscopic guidance. Each patient received an identical polyurethane DJ ureteral stent 6 Fr diameter, 26 cm length; Boston Scientific, Marlborough, MA, USA). Proper anatomical placement of the proximal curl within the renal pelvis and the distal curl within the bladder trigone was verified intraoperatively via fluoroscopy immediately after placement.

Inclusion and exclusion criteria

Eligible participants included male and female patients aged between 18 and 80 years scheduled for elective, unilateral retrograde DJ stenting for unilateral ureteral calculi.

Exclusion criteria were prespecified to eliminate confounding determinants of lower urinary tract symptoms (LUTSs) and safety signals:

1. Significant underlying cardiovascular, hepatic, or chronic kidney diseases.
2. Known hypersensitivity or contraindications to α_1-adrenergic receptor antagonists.
3. Active, symptomatic urinary tract infection (UTI), pyelonephritis, or acute urinary retention at baseline.

4. History of diabetes mellitus, chronic pelvic pain syndrome, neurogenic bladder, or pre-existing severe LUTS (baseline IPSS≥8).
5. History of renal transplantation, pelvic malignancy, or prior pelvic radiotherapy/chemotherapy.
6. Concurrent or long-term medication with α1\alpha_1α1-blockers, antimuscarinics, β_3-adrenoceptor agonists, selective serotonin reuptake inhibitors (SSRIs), diuretics, calcium channel blockers, or lithium within the preceding 3 months.
7. Bilateral ureteral stenting, solitary kidney, or pregnancy.

Sample size calculation

The sample size calculation was based on the primary outcome measure—the urinary symptom domain score of the Ureteral Stent Symptom Questionnaire (USSQ)—using the formula for comparing two independent continuous means. Assuming a two-sided significance level (α) of 0.05 and a statistical power (1−β) of 90%, an anticipated minimum clinically important difference (Δ) of 1.35 points, and a pooled standard deviation (σ) of 2.0 based on relevant clinical trials and institutional pilot audits, the minimum required sample size was calculated to be 38 patients per study arm. To account for an anticipated 15% attrition or dropout rate during the 4-to-6-week follow-up period, the final recruitment target was set at 45 patients per arm (total N=90N = 90N=90) [16].

Randomization, allocation concealment, and blinding

Enrolled patients were randomly assigned (1:1 ratio) to receive either terazosin or tamsulosin using a computer-generated block randomization sequence with fixed block sizes of 4. Allocation concealment was secured using sequentially numbered, opaque, sealed envelopes prepared and maintained by an independent hospital pharmacist who was not involved in patient recruitment, surgical procedures, or outcome evaluations.

To achieve strict double-blinding without altering the modified-release pharmacokinetics of tamsulosin, an over-encapsulation technique was employed. The independent pharmacist placed intact commercial tamsulosin capsules (0.4 mg) and commercial terazosin tablets (2 mg) into identical, opaque, hard-gelatin capsules matching in size, shape, color, and weight. The encapsulated medications were distributed in identical, sequentially coded containers. Patients, the operating surgeon, and the outcome-assessing clinicians were blinded to treatment allocation. Unblinding codes were securely held by an independent Data Safety Monitoring Board (DSMB) and were unmasked only after final database lock and statistical analyses.

To evaluate the success of blinding at the time of stent removal, both the patients and the evaluating clinicians completed the Bang Blinding Index (BBI) questionnaire; the resulting distribution of guesses demonstrated chance-level distribution, confirming the integrity of the double-blind design throughout the intervention.

Intervention and follow-up

Pharmacotherapy was initiated on postoperative day 0 (immediately after stent placement) and continued once daily until stent removal:

- **Terazosin group:** Terazosin 2 mg orally once daily at bedtime.
- **Tamsulosin group:** Tamsulosin 0.4 mg orally once daily after breakfast.

Stents remained in situ for a standardized clinical duration of 4 to 6 weeks. To maximize protocol adherence and minimize loss to follow-up, a patient-retention program was implemented, which included structured weekly telephone check-ins, cost-free study medication dispensation, and priority scheduling for elective stent removal. Consequently, all 90 patients completed the follow-up protocol with zero attrition (0% loss to follow-up).

Outcome measures and assessment

Clinical outcomes were prospectively assessed at two scheduled time points: baseline (preoperatively, prior to stent insertion) and immediately before stent removal (4–6 weeks post-insertion).

1. **Primary outcome:** Domain-specific stent-related morbidity assessed using the validated Persian version of the **Ureteral Stent Symptom Questionnaire (USSQ)**, evaluating urinary symptoms, body pain, general health, work performance, sexual matters, and additional problems/complications.
2. **Secondary outcomes:**
    - Lower urinary tract symptoms assessed via the **International Prostate Symptom Score (IPSS)**.
    - Patient-reported **Quality of Life (QoL)** score (assessed via the single-item IPSS-QoL index, range 0–6).
3. **Safety and tolerability:** All patients were prospectively monitored and queried for treatment-emergent adverse events throughout the trial, specifically orthostatic hypotension, postural dizziness, headache, reflex tachycardia, syncope, asthenia, and rhinitis/nasal congestion.

Statistical analysis

All statistical analyses were conducted on an intention-to-treat (ITT) basis using SPSS Statistics for Windows, version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were assessed for normal distribution using the Shapiro–Wilk test and graphical inspection of Q-Q plots. Normally distributed continuous variables were expressed as mean ±standard deviation (SD) and compared between groups using the independent-samples t test, with Levene's test applied for equality of variances. Skewed or ordinal data (e.g., QoL index) were presented as medians with interquartile ranges (IQRs) and compared using the Mann–Whitney **U** test. Categorical variables Categorical variables were reported as absolute counts and percentages (n, %) and analyzed using the Pearson chi-square (χ^2) test or Fisher's exact test where cell frequencies were <5. A two-tailed P-value <0.05 was considered statistically significant.

Results

Participant flow and baseline characteristics

A total of 90 eligible patients undergoing unilateral retrograde ureteral double-J (DJ) stenting were enrolled and randomly allocated to receive either tamsulosin (n=45) or terazosin (n=45). All 90 participants completed the designated 4-to-6-week follow-up protocol and were included in the final intention-to-treat analysis (Figure 1).

The study cohort comprised 54 men (60.0%) and 36 women (40.0%), with an overall mean age of 39.67±7.46 years. The mean age was 37.72±6.15 years in the tamsulosin group and 41.62±8.24 years in the terazosin group (P=0.081). Baseline demographic profiles, including sex, educational level, marital status, and residential area, were comparable between the two arms, confirming baseline homogeneity across study groups (**Table 1**).

Similarly, preoperative baseline evaluations showed no statistically significant differences between the tamsulosin and terazosin groups in terms of baseline USSQ urinary symptoms (12.4±1.8 vs. 12.6±1.9; P=0.620) or baseline IPSS scores (1.8±0.5 vs. 1.9±0.6; P=0.740), confirming the absence of pre-existing differences in lower urinary tract symptoms prior to pharmacotherapy (**Table 1**).

Stent-related symptoms evaluated via the USSQ

Comparative analysis of stent-related morbidity assessed at the time of stent removal (4–6 weeks post-insertion) revealed notable differences across USSQ domains (**Table 2**):

Urinary symptoms: Patients receiving tamsulosin experienced significantly fewer urinary symptoms compared with those receiving terazosin, as reflected by a significantly lower mean domain score (19.20±2.15 vs. 21.55±6.02; P=0.017).

General health: The tamsulosin arm demonstrated a significantly superior general health profile with a lower morbidity score (10.13±1.68 vs. 11.77±4.63; P=0.029).

Additional problems: Stent-associated additional complications were significantly reduced in the tamsulosin cohort compared with the terazosin cohort (8.17±0.61 vs. 9.08±2.29 ;P=0.013).

Other domains: No statistically significant intergroup differences were identified regarding body pain (16.42±3.11 vs. 16.71±4.05; P=0.710), sexual matters (P=0.223), or daily work performance (P=0.232).

Voiding symptoms and quality of life (IPSS and QoL)

Post-stenting lower urinary tract symptoms and voiding dysfunction were further quantified using the IPSS instrument prior to stent removal (**Table 3**):

- **IPSS total score:** Independent t-test analysis confirmed the clinical superiority of tamsulosin monotherapy, showing a significantly lower mean IPSS score in the tamsulosin group compared with the terazosin group (2.11±1.06 vs.; mean difference:; 95% CI:−4.08 to −2.24; P=0.038).
- **Quality of life index (IPSS-QoL):** Analysis of the subjective quality of life index via the Mann–Whitney UUU test revealed no statistically significant difference between the tamsulosin and terazosin cohorts at the end of the intervention period (P>0.05) (**Table 4**).

Safety profile and adverse events

Both pharmacological regimens were clinically well tolerated at the administered doses throughout the study period. Mild, self-limiting dizziness was reported by 3 patients (6.7%) in the terazosin group and 1 patient (2.2%) in the tamsulosin group. Transient nasal congestion was reported by 2 patients (4.4%) in the tamsulosin group and was not reported in the terazosin group. No severe

systemic adverse events, including symptomatic orthostatic hypotension requiring treatment discontinuation, syncope, or severe reflex tachycardia, were observed in either treatment group. No patient discontinued treatment because of an adverse event.

Discussion

The present double-blind, randomized clinical trial directly compared the efficacy and safety of tamsulosin and terazosin monotherapy for the management of stent-related symptoms (SRSs) following unilateral ureteral double-J (DJ) stent placement. Both treatment regimens were associated with acceptable clinical tolerability. However, tamsulosin was associated with significantly lower urinary symptom scores, better general health scores, and fewer additional stent-related problems than terazosin. Tamsulosin also produced a significantly lower IPSS score at the end of the treatment period. These findings suggest that tamsulosin may provide greater symptomatic benefit than terazosin in patients experiencing morbidity related to ureteral stents.

The pathophysiology of SRS is multifactorial and is generally attributed to both mechanical and neurophysiological mechanisms. The distal coil of the DJ stent may irritate the bladder trigone and adjacent urothelium, leading to local mucosal irritation, involuntary detrusor contractions, and activation of sensory afferent pathways [17]. Stimulation of mechanosensitive Aδ - and C-fibers may contribute to the development of urgency, frequency, dysuria, and other storage and voiding lower urinary tract symptoms (LUTSs). In addition, increased intravesical pressure during micturition may be transmitted through the stent to the upper urinary tract, contributing to dynamic vesicoureteral reflux and voiding-related flank discomfort [18, 19]. These mechanisms explain why patients may experience both irritative urinary symptoms and pain while the stent remains in situ.

The use of α_1-adrenergic receptor antagonists for the treatment of SRS is based on their ability to reduce smooth-muscle tone in the bladder neck, trigone, proximal urethra, and ureter. By antagonizing postsynaptic α_1-receptors, these agents may decrease urinary tract resistance and attenuate some of the functional consequences of stent-related irritation [17, 18]. Nevertheless, the pharmacological profiles of individual α_1-blockers differ[19]. Tamsulosin has a relatively greater affinity for the α_{1A} and α_{1D} receptor subtypes, which are expressed in the lower urinary tract and

may contribute to bladder outlet and ureteral smooth-muscle activity [20, 21]. Terazosin, in contrast, is a non-subtype-selective α_1-adrenergic antagonist. The difference in receptor profile may partly explain the significantly lower urinary symptom scores observed in the tamsulosin group in the present study. However, the present clinical findings demonstrate an association between treatment and symptom improvement and should not be interpreted as direct proof of a receptor-specific mechanism.

Our findings are generally consistent with previous evidence supporting the use of tamsulosin for stent-related morbidity. A systematic review and meta-analysis by Chen et al. reported that tamsulosin monotherapy improved stent-induced LUTSs and related functional outcomes [22]. Similarly, the meta-analysis by Madarshahian et al., which included 16 randomized controlled trials, reported beneficial effects of tamsulosin on several measures of stent-related symptoms, including IPSS, without a clear increase in adverse events [23]. The present study adds to this evidence by providing a direct comparison between tamsulosin and terazosin monotherapy. The observed differences in the USSQ urinary symptoms, general health, and additional-problem domains suggest that the choice of α_1-blocker may influence the extent of symptomatic relief achieved after stent placement. These findings are also in keeping with the view that pharmacological management should consider both urinary tract efficacy and the potential for systemic adverse effects associated with receptor activity [17].

Although tamsulosin was associated with better urinary symptom and IPSS outcomes, no statistically significant between-group difference was observed in the global QoL index (P=0.140). This finding is clinically relevant because the overall impact of a ureteral stent is not determined solely by urinary symptoms. Stent-related morbidity may also include body pain, limitations in work or daily activities, sleep disturbance, and other physical or psychosocial effects. In the present study, no statistically significant differences were observed between the groups in body pain (P=0.71) or work performance (P=0.232). Persistent symptoms in these domains may have reduced the effect of improved urinary symptoms on the global QoL assessment. Thus, the lack of a significant difference in QoL does not necessarily contradict the improvement observed in specific urinary outcomes. Rather, it may indicate that the single global QoL measure reflects the combined effect of several stent-related complaints, some of which were not significantly modified by either treatment.

The relatively short follow-up period may also have contributed to the absence of a significant difference in global QoL. Participants were assessed after approximately 4–6 weeks, immediately before stent removal, while the mechanical stimulus of the indwelling stent was still present. Although this interval is clinically relevant for evaluating symptoms during routine stent dwell time, it may not be sufficient to demonstrate differences in broader perceptions of health and well-being. Further studies with multiple assessment points could help determine whether the observed differences in urinary symptoms are associated with corresponding changes in QoL over time.

The role of combination pharmacotherapy in the management of SRS remains under discussion. Some studies have evaluated the combination of α_1-blockers with antimuscarinic agents to target both adrenergic and cholinergic pathways [16, 24]. However, a double-blind randomized trial by Sivalingam et al. found that adding tolterodine to tamsulosin did not provide additional improvement in urinary symptoms or QoL compared with tamsulosin monotherapy [25]. Moradi et al. similarly reported that additional pharmacological agents may improve selected storage symptoms without necessarily producing superior outcomes across all domains of stent-related morbidity [26]. In this context, the findings of the present study support the potential usefulness of tamsulosin monotherapy as a relatively simple treatment option for reducing urinary symptoms associated with ureteral stents. Nevertheless, treatment selection should remain individualized, and the potential benefits of monotherapy should not be generalized to all patient populations or all combinations of drugs.

Both treatment regimens were well tolerated in the present trial, and no severe systemic adverse events were reported. Mild dizziness occurred in three patients in the terazosin group and one patient in the tamsulosin group, while transient nasal congestion was reported in two patients receiving tamsulosin. These events were minor and self-limiting according to the reported study findings. The absence of severe events such as treatment-requiring symptomatic orthostatic hypotension, syncope, or severe reflex tachycardia is reassuring; however, the relatively small sample size limits the ability of the study to detect uncommon adverse events. In addition, the safety findings should be interpreted in light of the doses used and the limited duration of follow-up.

This study has several strengths. It used a randomized, double-blind design and compared two active pharmacological treatments rather than comparing treatment with no intervention. All participants received the same type and size of DJ stent, and the stent-placement procedure was standardized by using a single urologist. The use of validated symptom-assessment instruments, including the USSQ and IPSS, also allowed evaluation of multiple domains of stent-related morbidity. Furthermore, all enrolled participants completed the follow-up period, allowing analysis of the entire randomized cohort.

Several limitations should be acknowledged. First, the study was conducted at tertiary medical centers affiliated with a single university and included a relatively small number of participants; therefore, the generalizability of the findings may be limited. Second, the follow-up period was restricted to the period during which the stent remained in place, approximately 4–6 weeks, and did not evaluate symptom resolution after stent removal. Third, although the study assessed several clinically relevant outcomes, the sample size may have been insufficient to identify differences in less frequent adverse events or in individual USSQ domains. Finally, the findings demonstrate comparative clinical efficacy but do not establish the precise biological mechanism underlying the difference between the two medications.

In conclusion, both tamsulosin and terazosin were tolerated in patients with unilateral DJ stents; however, tamsulosin was associated with significantly better urinary symptom, general health, and additional-problem outcomes, as well as a lower IPSS score, than terazosin. No significant difference was observed in the global QoL index. Larger multicenter randomized trials with longer and more frequent follow-up assessments are needed to confirm these findings, evaluate their generalizability, and clarify the comparative safety and clinical relevance of different α_1-blocker regimens in patients with SRSs.

Conclusion

In conclusion, both tamsulosin and terazosin were well tolerated and were associated with the management of lower urinary tract symptoms in patients with unilateral double-J ureteral stents. Compared with terazosin, tamsulosin was associated with significantly lower urinary symptom scores, a lower IPSS score, and more favorable outcomes in the general health and additional-

problem domains of the USSQ. However, no statistically significant between-group difference was observed in the global quality-of-life index.

These findings suggest that tamsulosin may be a more favorable monotherapy option than terazosin for reducing selected urinary and stent-related symptoms during the period in which the stent remains in situ. Nevertheless, the results should be interpreted within the context of the study's sample size, follow-up duration, and clinical setting. Larger, adequately powered multicenter trials with repeated assessments are needed to confirm the comparative effectiveness and safety of these two agents.

Study limitations

This study has several limitations. First, patient outcomes were assessed only at baseline and immediately before stent removal, approximately 4–6 weeks after stent placement. Intermediate assessments, such as evaluations during the first and second postoperative weeks, were not performed. Because stent-related symptoms may change over time after insertion, the absence of early follow-up assessments limited the evaluation of the onset and temporal pattern of symptom severity.

Second, the International Prostate Symptom Score (IPSS) was used to assess lower urinary tract symptoms. Although the IPSS was originally developed and validated primarily for the assessment of urinary symptoms in men with benign prostatic hyperplasia, it is also commonly used as a measure of storage and voiding symptoms. However, its use in a cohort that included women should be considered a limitation, particularly because 40% of the study population were female. Future studies including female participants should consider incorporating instruments specifically validated for women, such as the Bristol Female Lower Urinary Tract Symptoms questionnaire, where appropriate.

Third, the study was conducted in a limited tertiary-care clinical setting and included a relatively small number of participants. These factors may limit the generalizability of the findings to other populations and healthcare settings. In addition, the follow-up period was limited to the period during which the stent remained in place, and longer-term outcomes after stent removal were not assessed. Future multicenter randomized trials with larger and more diverse populations, repeated

follow-up assessments, and longer post-removal observation are warranted to validate these findings.

Ethics approval and consent to participate

This study was approved by the Institutional Ethics Committee of Arak University of Medical Sciences (Approval ID: IR.ARAKMU.REC.1400.227). Written informed consent was obtained from all individual participants prior to enrollment in the study.

Consent for Publication: Not Applicable.

Availability of Data and Materials: The data will be made available upon request from corresponding author.

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Authors' Contribution

The contributions of the authors are as follows:

RG & MM: Conceived the study idea and participated in data collection.

HP: Assisted in the writing of the manuscript.

SF: Contributed to the development and writing of the study proposal.

AM: Performed the statistical analysis and data interpretation.

Mkh: Drafted the manuscript, provided overall supervision, and finalized the article for submission.

All authors read and approved the final manuscript.

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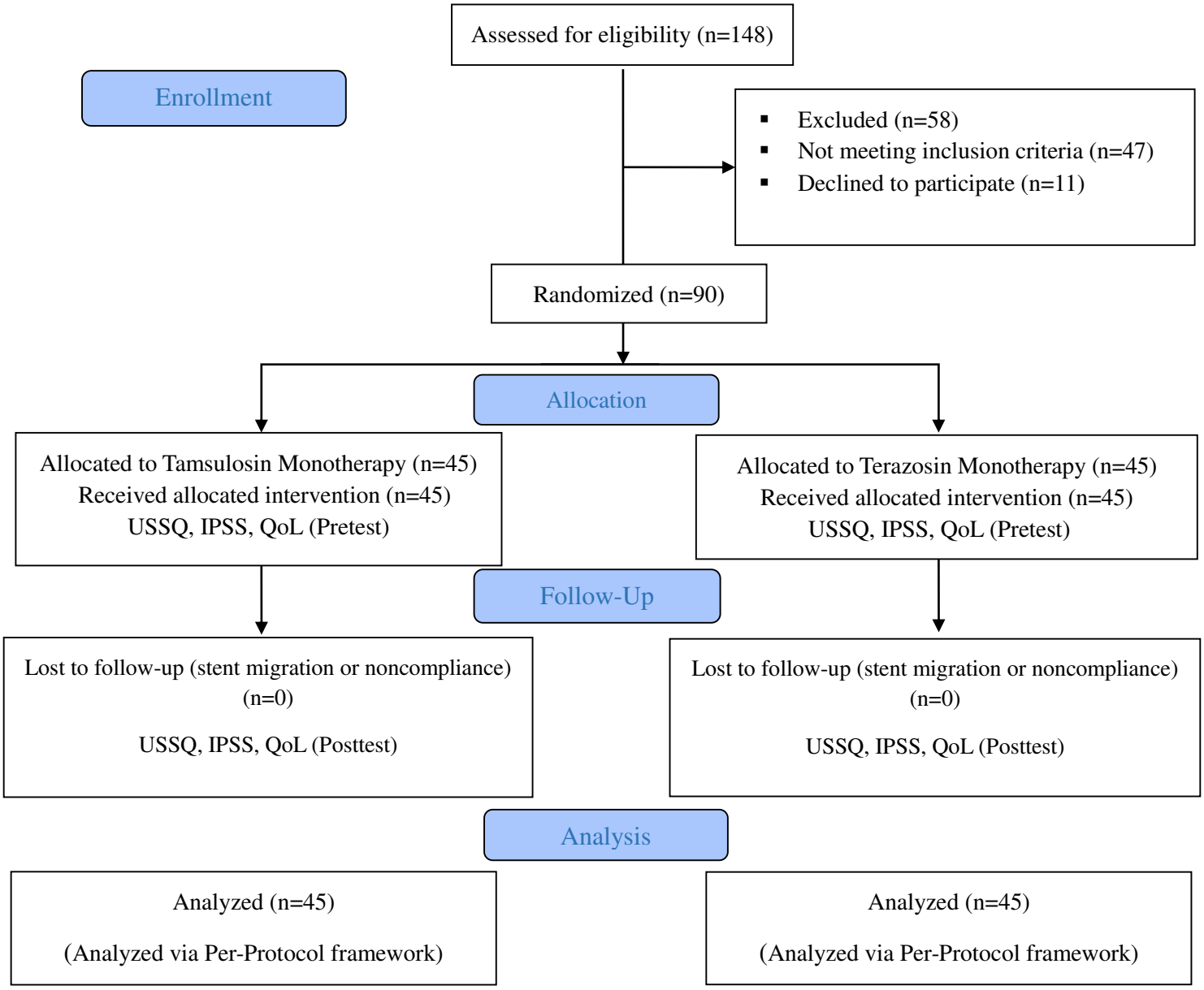


Fig. 1. The flow of participants in the study (CONSORT flow diagram)

Table 1. Relationships between the variables and the two groups receiving terazosin and tamsulosin

Variable		**Drug**		**Statistical Test Value**	**P. value**
		Tamsulosin Mean ± SD	**Terazosin Mean ± SD**		
Age (yrs)		37.72±6.15	41.62±8.24	t = -1.745 df = 88	0.085
		Tamsulosin (n=45) N (%)	**Terazosin (n=45) N (%)**		
Gender	Female	15(33.3)	21(46.7)	x^2 = 1.848 df = 1	0.174
	Male	30(66.7)	24(53.3)		
Place of residence	Village	17(37.8)	23(51.1)	x2 = 1.865 df = 1	0.172
	City	28(62.2)	22(48.9)		
Marital status	Married	35(77.8)	29(64.4)	x2 = 2.967 df = 1	0.085
	Single	10(22.2)	16(35.6)		
Education	Primary Education	9(20.0)	11(24.4)	x2 = 8.812 df = 4	0.066
	Diploma	11(24.4)	20(44.4)		
	Associate Degree	7(15.6)	6(13.3)		
	Bachelor	16(35.6)	8(17.8)		
	Master and above	2(4.4)	0(0)		

Table 2. Comparison of Mean Ureteral Stent Symptom Questionnaire (USSQ) Domain Scores between the Two Groups at Stent Removal

Variable	Drug		Independent t Value (df = 88)	P. value
	Tamsulosin Mean ± SD	Terazosin Mean ± SD		
Urinary symptoms	19.20±2.15	21.55±6.02	-2.441	0.017
Pain	16.48±6.39	15.77±11.04	0.373	0.710
General health	10.13±1.68	11.77±4.63	-2.219	0.029
work performance	11.53±2.40	10.84±2.99	1.206	0.232
Sexual issues	5.71±0.84	5.46±1.03	1.261	0.223
Other problems	8.17±0.61	9.08±2.29	-2.564	0.013

Table 3. Comparison of Mean International Prostate Symptom Scores (IPSSs) between the Two Groups at Stent Removal

Variable	Drug		Independent t Value (df = 88)	P. value
	Tamsulosin Mean ± SD	Terazosin Mean ± SD		
IPSS Score	2.11±1.06	5.27±2.86	-7.009	0.038

Table 4. Distribution of quality of life (QoL) scores between the two groups at stent removal

Variable		Drug		Mann– Whitney U Value	P. value
		Tamsulosin (n=45) N (%)	Terazosin (n=45) N (%)		
Quality of life (QoL)	Satisfied	27(60.0)	23(51.1)	U = 842.5	0.140
	Mostly satisfied	18(40.0)	14(31.1)		
	Low satisfied	0(0.0)	4(8.9)		
	Mostly unsatisfied	0(0.0)	4(8.9)		

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- cosort.pdf