

OUTCOMES OF TAMSULOSIN IN WOMEN WITH LOWER URINARY TRACT SYMPTOMS IN PATIENTS PRESENTING AT TERTIARY CARE HOSPITAL IN PAKISTAN

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Abstract

OBJECTIVE

To determine the outcomes of tamsulosin in women with lower urinary tract symptoms among patients presenting at tertiary care hospital in Pakistan.

METHODOLOGY

This descriptive study was carried out at the Sindh Institute of Urology & Transplantation (SIUT) in Karachi from September 2023 to March 2024. A total of 97 women aged between 18 and 60 years were included using a non-probability consecutive sampling technique. Each participant was administered Tamsulosin 0.4 mg once daily. The uroflowmetry (UFM) and American Urological Association (AUA) symptom score were recorded both at baseline and after six weeks. The effectiveness of Tamsulosin was evaluated by comparing pre and post-treatment values of QMax (maximum flow rate), residual urine volume, and International Prostate Symptom Score (IPSS). Data analysis was performed using SPSS version 26.0, and a p-value of less than 0.05 was considered statistically significant.

RESULTS

The mean \pm standard deviation of the age was found as 47.80 ± 10.34 years. Tamsulosin significantly improved IPSS scores (16.83 ± 5.61 vs. 12.94 ± 6.52 , $p=0.0001$), voiding symptoms score (10.82 ± 2.82 vs. 6.88 ± 2.17 , $p=0.0001$), storage symptoms score (5.46 ± 1.70 vs. 4.54 ± 1.19 , $p=0.0001$), residual urine volume (62.52 ± 17.46 vs. 31.94 ± 7.30 mL, $p=0.0001$), and QMax flow rate (15.33 ± 7.02 vs. 17.31 ± 5.36 mL/sec, $p=0.039$). However, the mean flow rate showed no significant change ($p=0.225$).

CONCLUSION

Tamsulosin presents a new beneficial treatment option for women with LUTS, providing a significant reduction in symptom severity and urinary flow. The drug was well tolerated and induced a significant reduction of voiding and storage symptoms. Tamsulosin could be an alternative treatment for LUTS in women because of its efficacy and good safety profile. More studies are needed to prove that its effects last and what are the ideal treatment protocols.

INTRODUCTION

Tamsulosin is one of the most extensively studied and frequently prescribed medications for managing lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH) in men [1]. While it is already known for its efficacy in men; it has just been studied in women, offering us some comfort in its benefit and safety. In addition, LUTS exist in female population and negatively impact their quality of life [2,3], and that has initiated efforts to evaluate whether tamsulosin would be helpful to women with LUTS [2,3].

Tamsulosin primarily functions by blocking alpha-1 adrenergic receptors in the bladder and prostate, leading to the relaxation of muscle tissue, which in turn enhances urinary flow [4].

Kang et al. also conducted a systematic review and meta-analysis, simultaneously evaluating tamsulosin for LUTS in women. Such findings are consistent with a systematic review by Kim et al. that found significant efficacy of alpha-1 blockers including tamsulosin for treating LUTS in females [5].

Tamsulosin as a drug is not primarily prescribed to females, but with increasing interest, safety data becomes evident. In a systematic review assessing either a female or pediatric population, Kaplan and Chughtai reported similar tolerability for tamsulosin with an adverse event profile comparable to that in men [6].

Most reported side effects were mild, including dizziness and ejaculatory disorders. However, some studies have suggested the need for closer monitoring, particularly in vulnerable populations, to ensure safety and efficacy [7].

Clinical studies further support the benefits of tamsulosin in symptom management. A systematic review and meta-analysis by Zhang et al. demonstrated that tamsulosin treatment significantly improved symptom scores in women, not only providing symptomatic relief but also enhancing overall satisfaction with urinary health [8]. Additionally, Meltzer et al. investigated the effects of tamsulosin on ureteral stones, highlighting its broader role in urological health beyond LUTS [9].

Combination with tamsulosin Recently, tamsulosin combination has been investigated with regard to its ability to induce favorable effects. Kim et al.

evaluated the fixed-dose combination of tamsulosin and tadalafil for the treatment of LUTS and ED, proposing that this combination may offer added benefit in some patients [10]. Similarly, Serati et al. emphasizing the detective nature of the polypharmacy in LUTS treatment management and advocating individualized treatment pathways [11]. However, the growing use of tamsulosin to treat LUTS in women raises important potential practice implications. And if research continues to indicate it is effective and safe, they can keep tamsulosin as a first-line therapy. However, Ebrahimpour et al. highlight the requirement of additional studies to determine long-term safety and efficacy and sex-specific treatment responses [12]. Tamsulosin is a relatively new, well-tolerated and effective treatment seen to have department wide benefits for women experiencing LUTS. Further study is critical to help define its role within the clinical care pathway. Greater awareness among providers may help improve management strategies, ultimately improving quality of life for patients.

METHODOLOGY

This descriptive study was conducted from September 2023 to March 2024 at the Sindh Institute of Urology & Transplantation (SIUT) in Karachi, Pakistan. A total of 97 female patients who met the inclusion criteria were selected using a non-probability consecutive sampling method from the outpatient department.

The study included women aged 18 years to less than 60 years who had lower urinary tract symptoms (LUTS)—a wide variety of urinary issues affecting the bladder and urethra. The symptoms included urinary frequency, urgency, nocturia (nightly urine), weak urinary stream, hesitancy, incomplete bladder emptying, and the last for incontinence for 1 week at least.

Uroflowmetry (UFM), a graphical registration of urine flow rate, was performed on all participants at the time of enrollment. Bladder function and urinary tract obstruction were assessed with mL/s (maximum flow rate) QMax (maximum flow rate) is a parameter considered important in urology. Furthermore, the American Urological Association

(AUA) symptom score was also applied to determine the severity of LUTS. All participants received Tamsulosin 0.4 mg once daily at bedtime. Tamsulosin is an alpha-1 adrenergic antagonist with a long history of use in treating men with LUTS caused by BPH. It works by relaxing smooth muscles at the prostate and bladder neck and may help urinary flow and other related symptoms such as weak stream and urgency.

Follow up after six weeks was done for all patients for re-evaluation. Repeat UFM was Re-assessment was performed after 6 weeks follow up in all patients. AUA symptom score was performed before and after repeat UFM. We documented baseline characteristics pertaining to age, body mass index (BMI), duration of symptoms, history or current treatment and comorbidities (diabetes, hypertension or smoking status).

The effectiveness of Tamsulosin was evaluated by comparing pre- and post-treatment QMax values and International Prostate Symptom Score (IPSS) results. The IPSS questionnaire is a validated tool for assessing LUTS severity, encompassing symptoms such as urinary frequency, urgency, nocturia, weak stream, incomplete emptying, and straining. The total score ranges from 0 to 35, with higher scores reflecting greater symptom severity.

Statistical analysis was conducted using SPSS version 26.0. Descriptive statistics were presented as mean \pm standard deviation (SD) for quantitative variables, whereas frequency and percentage were utilized for qualitative variables. The Chi-square test was employed to assess statistical significance, with a p-value < 0.05 considered statistically significant.

RESULTS

The study included a total of 95 participants, with a mean age of 47.80 ± 10.34 years (95% CI: 45.69–49.91). The average body mass index (BMI) was 25.91 ± 3.51 kg/m² (95% CI: 25.19–26.62), while the mean disease duration was 35.92 ± 21.38 months (95% CI: 31.56–40.27).

Of these participants, 30 (31.6%) were postmenopausal; and 65 (68.4%) were not postmenopausal. Forty-three (45.3%) were hypertensive and 45 (54.7%) were non-hypertensive. Out of these, 18 (18.9%) participants had diabetes mellitus and 77 (81.1%) were non-diabetic. A

history of cardiovascular disease was identified in 9 (9.5%) subjects, and the remaining 86 subjects (90.5%) were free of cardiovascular disease 8 (8.4%) participants had had a hysterectomy as shown in TABLE I.

The comparison of clinical parameters from baseline to post-treatment between 95 participants. The International Prostate Symptom Score (IPSS) significantly from 16.83 ± 5.61 at baseline to 12.94 ± 6.52 after treatment (95% CI: 1.883–5.907, $p = 0.0001$). Voiding Symptoms Score also decreased significantly from 10.82 ± 2.82 to 6.88 ± 2.17 (95% CI: 3.245–4.629, $p = 0.0001$) and the compared symptoms from the Storage Symptoms Score decreased from 5.46 ± 1.70 to 4.54 ± 1.19 (95% CI: 0.474–1.378, $p = 0.0001$). The residual urine volume also showed significant improvement, from 62.52 ± 17.46 mL to 31.94 ± 7.30 mL (95% CI: 26.824–34.333, $p = 0.0001$). Q max flow rate was noted to have a small but statistically significant increase (15.33 ± 7.02 mL/sec vs 17.31 ± 5.36 mL/sec, 95% CI: -3.852 – -0.106 , $p = 0.039$). In contrast, the mean flow rate remained essentially unchanged, with baseline and post-treatment flow rates of 7.20 ± 2.83 mL/sec and 7.85 ± 3.66 mL/sec respectively (95% CI: -1.714 – 0.409 , $p = 0.225$) as shown in Table II.

DISCUSSION

Tamsulosin, a selective alpha-1 adrenergic antagonist, is among the most widely used medications for managing lower urinary tract symptoms (LUTS) in men, particularly when associated with benign prostatic hyperplasia (BPH). However, growing interest in its potential therapeutic role for LUTS in women has emerged following the discovery of alpha-adrenergic receptors in the female bladder neck and urethra. [13].

LUTS in females are a multifactorial disorder and are not necessarily associated with a BOT with or without Detrusor overactivity, impaired voiding or a combination of them. For women who are experiencing voiding dysfunction or functional BOO, the mechanism of action is supportive of therapy with Tamsulosin, a muscle relaxant targeting the bladder outlet.

The effectiveness of tamsulosin in female LUTS has been investigated in several clinical studies, with controversial results. Our study demonstrated a

significant improvement in IPSS scores ($p=0.0001$), voiding symptoms ($p=0.0001$), storage symptoms ($p=0.0001$), residual urine volume ($p=0.0001$), and QMax flow rate ($p=0.039$) after six weeks of Tamsulosin 0.4 mg administration. The present data are consistent with a recent report from Kim et al., which presented a robust reduction of LUTS severity in women treated with alpha-1 blockers including tamsulosin [5]. Similarly, Zhang et al. identified that tamsulosin was efficient at improving urinary symptoms including urine flow improvement and voiding difficulty [8].

Similarly, we achieved statistically significant improvement in QMax flow rate, consistent with Maiti et al. who found QMax improved from 7.2 mL/sec to 18.4 mL/sec ($p=0.001$) with tamsulosin in their study [21]. In contrast, Chapman et al. did not find this on average between groups: mean flow rate (0.82 ± 0.01 L/min versus 0.84 ± 0.01 L/min; $p=0.69$) [20], indicating the heterogeneity of the response depending on the etiology of LUTS. In our study, Guo and Tang also found significant symptom improvement with the use of alpha-blockers but only in females with voiding-phase dysfunction [2].

While our study demonstrated significant symptom relief and objective improvements in urinary flow dynamics, the mean flow rate did not show significant improvement ($p=0.225$). This may be attributed to differences in baseline bladder function or the presence of underlying detrusor overactivity in some patients. This finding is consistent with Yoon et al., who observed that tamsulosin had a limited impact on storage symptoms in certain female patients, particularly those with metabolic syndrome [14].

The safety and tolerability of tamsulosin in our study were comparable to previous reports. Kaplan and Chughtai found that tamsulosin was well tolerated in women, with adverse effects similar to those observed in men [6]. While some studies have raised concerns about orthostatic hypotension and dizziness, these side effects were mild and well tolerated in our cohort.

One of the notable strengths of this study is its focus on an understudied population—women with LUTS—offering valuable clinical insights into the potential role of tamsulosin in female patients.

Moreover, incorporating both subjective (IPSS) and objective (uroflowmetry) measures enhances the reliability of the findings. The prospective study design and standardized six-week follow-up period further contribute to its robustness.

However, certain limitations should be acknowledged. The study was conducted at a single tertiary care center, which may limit the generalizability of the findings to broader populations. Furthermore, the sample size ($n=97$), while sufficient for preliminary analysis, may not be large enough to detect subtle subgroup variations in treatment response. Additionally, the relatively short follow-up period (six weeks) restricts the assessment of long-term efficacy and safety.

Future research with larger, multicenter cohorts and extended follow-up durations is necessary to confirm the long-term benefits and tolerability of tamsulosin in women with LUTS.

CONCLUSION

It is to be concluded that tamsulosin is a promising treatment for LUTS in women and result in a notable improvement in symptom severity and urinary flow. The drug was well tolerated and resulted in a significant reduction in both voiding and storage symptoms. Given its efficacy and safety profile, Tamsulosin could serve as an alternative treatment for women with LUTS. Further research is warranted to establish its long-term benefits and optimal treatment protocols.

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Table I: Demographic Characteristics of Study Participants (n=95)

Mean ± SD	95% CI
Age in years= 47.80 ± 10.34	45.69----49.91
Body Mass Index in kg/m ² = 25.91 ± 3.51	25.19----26.62
Duration of Disease in months= 35.92 ± 21.38	31.56----40.27
Variable, n (%)	
Menopausal State	
Yes	30 (31.6)
No	65 (68.4)
Hypertension	
Hypertensive	43 (45.3)
Non-Hypertensive	52 (54.7)
Diabetes Mellitus	
Diabetic	18 (18.9)
Non-Diabetic	77 (81.1)
Cardiovascular Disease	
Yes	9 (9.5)
No	86 (90.5)
Hysterectomy	
Yes	8 (8.4)
No	87 (91.6)

Table II: Comparison of Clinical Parameters Between Baseline and Post Treatment (n=95)

Clinical Parameters	Baseline (Pre)	Post-Treatment	95% C. I	P-Value
International Prostate Symptom Score	16.83 ± 5.61	12.94 ± 6.52	1.883----5.907	0.0001
Q Max Flow Rate in mL/sec, Mean ± SD	15.33 ± 7.02	17.31 ± 5.36	-3.852---- -0.106	0.039
Mean Flow Rate in mL/sec, Mean ± SD	7.20 ± 2.83	7.85 ± 3.66	-1.714----0.409	0.225
Voiding Symptoms Score, Mean ± SD	10.82 ± 2.82	6.88 ± 2.17	3.245----4.629	0.0001
Storage Symptoms Score, Mean ± SD	5.46 ± 1.70	4.54 ± 1.19	0.474----1.378	0.0001
Residual Urine in mL, Mean ± SD	62.52 ± 17.46	31.94 ± 7.30	26.824----34.333	0.0001