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Original Article

Urology Section

Efficacy and Safety of Tamsulosin Monotherapy versus Diclofenac Sodium for Non Neurogenic Female Voiding Dysfunction: A Prospective Interventional Study

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ABSTRACT

Introduction: α1-Adrenergic Receptor (AR) antagonists such as tamsulosin improve urinary flow and Lower Urinary Tract Symptoms (LUTS) in men, but evidence in women with Female LUTSs (FLUTS) and Female Voiding Dysfunction (FVD) remains limited, particularly in the Indian population.

Aim: To compare the efficacy and safety of tamsulosin monotherapy versus diclofenac sodium in women with non neurogenic FLUTS and FVD.

Materials and Methods: This prospective interventional study was conducted in the Outpatient Surgical Clinic of the Department of General Surgery, University College of Medical Sciences (UCMS) and Guru Teg Bahadur (GTB) Hospital, New Delhi, India, from May 2023 to March 2024. It enrolled 150 women (18-80 years) with International Prostate Symptom Score (IPSS) >8 and non neurogenic FLUTS. Participants were randomised into two groups, Group I-to receive tamsulosin 0.4 mg once daily (n=75) and Group II diclofenac sodium 75 mg SOS (n=75). Outcomes included changes in Qmax, IPSS, Post-Void Residual volume (PVR), and Voided Volume (VV) over eight weeks. Quantitative variables were analysed using repeated-measures Analysis of Variance (ANOVA); categorical variables using Chi-square test. A p-value <0.05 was considered statistically significant.

Results: A total of 150 women were equally randomised to the two groups, with comparable baseline characteristics and age distribution (majority aged 21-50 years). The tamsulosin group showed significantly greater improvement in Qmax (+32.4% vs +23.4%; p<0.001), IPSS reduction (-16.08 vs -5.71; p<0.001), and PVR reduction (22.8 mL vs 47.65 mL; p<0.05). VV showed no significant difference at the first visit but increased significantly in the treatment group from the second visit onward compared with controls (p<0.001), with progressive improvement through follow-up. Adverse effects were mild and transient.

Conclusion: Tamsulosin monotherapy is safe and significantly more effective than diclofenac sodium in improving voiding parameters and symptom scores in women with non neurogenic FLUTS and FVD.

Keywords: Adrenergic receptors, Alpha blockers for voiding symptoms, Female lower urinary tract symptoms

INTRODUCTION

Tamsulosin, is an α1-AR antagonist approved for the medical management of LUTS due to benign prostatic hyperplasia in men. However, it also shows strong potential for managing FLUTS. Despite the comparable prevalence of LUTS across genders, especially with age, the efficacy of tamsulosin in women remains under investigation. Many drugs have been used to treat LUTS in women, such as anticholinergics and α1-AR antagonists [1]. Tamsulosin has been shown to significantly increase urinary flow rate and improve symptom scores [1] and have been used with a therapeutic intent for treating FVD and LUTS and it represents a promising off-label indication for relieving bothersome FLUTS in select patients, though Tamsulosin is currently not approved by Food and Drug Administration (FDA) for LUTS in women [2].

The severity of LUTS has been quantified using different symptom indices with the International Prostate Symptom Score (IPSS) was developed for male LUTS assessment and has been validated secondarily for women. A recent study [1] has shown that the age-dependent prevalence of LUTS, as captured by the IPSS, is a good equivalent indicator of the degree of bothersome symptoms in both men and women, affecting the quality of life in women of various ages, independent of coexisting incontinence, suggesting that the development of LUTS might be age and not gender-specific. If this hypothesis is valid, women with LUTS may benefit from tamsulosin treatment. The Indian population has separate demographic characteristics, including dietary, lifestyle, and environmental variations/exposures, which could influence the severity of FLUTS. Although some studies on LUTS have been conducted in western populations, there is a paucity of Indian data for same [2-4]. Hence, the present study aimed to bridge this gap in literature with evidence from an Indian cohort, with clinical manifestations of FVD and FLUTS, might differ due to genetic and sociocultural factors [3,4]. This forms the rationale for the present study.

MATERIALS AND METHODS

A prospective interventional study was conducted in the Outpatient Surgical Clinic of the Department of General Surgery, UCMS and GTB Hospital, New Delhi, India, from May 2023 to March 2024. Prior approval was obtained from the Institutional Ethics Committee (IEC No: IECHR-2023-59-69 dated 30-04-2023). Written informed consent was obtained from all participants.

Sample size calculation: The sample size was calculated using the following formula:

$$n = \frac{(Z_{1-\alpha/2} + Z_1 - \beta)^2 \times (\sigma_1^2 + \sigma_2^2)}{(\mu_1 - \mu_2)^2}$$

where:

n= sample size required per group;

$Z_{1-\alpha/2}$ = standard normal deviate for two-sided significance level (α = 0.05; Z = 1.96);

$Z_{1-\beta}$ = standard normal deviate for desired power (80%; Z = 0.84);

- σ_1,σ_2= standard deviations of the outcome variable in the two groups;
- μ_1-μ_2= expected difference in mean change between groups.

Considering a mean change in IPSS from baseline to post-treatment in Tamsulosin group from Pummangura N and Kochakarn W [5] (5.6±6.3) and (2.6±6.1) in control group, in order to estimate this difference at α = 5% and Power (P)=80%; a sample of 67 people was considered and anticipating 10% attrition due to loss of follow-up 75 patients were required in each group. Hence, a sample size of 150 patients was included in the study.

Inclusion criteria: Eligible patients comprising women (18-80 years) with FVD due to clinical non neurogenic FLUTS (IPSS >8) in absence of UTI were included.

Exclusion criteria: Patients with proven UTI, incomplete medical treatment, mental disorders or illness who could not understand or comply with the study protocol, known drug allergy/contraindications to tamsulosin/diclofenac sodium, pregnant-lactating women, stress urinary incontinence, post-radiation to pelvis, bladder cancer, vault prolapse etc., urethral stricture and hepatic or renal insufficiency were excluded from this study.

Enrolled patients were randomised into two groups using computer-generated randomisation plan obtained from www.randomization.com and all patients in the test group (I) were administered tamsulosin 0.4 mg once daily at bedtime, titrated to 0.8 mg if no response was observed (Group I) while those in the control group (II) were prescribed Tab. Diclofenac Sodium 75 mg on an as per need (SOS) basis (Group II).The choice of study design and comparator was guided by recommendations of the Institutional Ethics Committee, which advised against a placebo-only or notreatment arm, as all enrolled women were symptomatic (IPSS >8) and withholding therapy was considered ethically inappropriate. Behavioral therapy was not included due to feasibility constraints related to standardisation, supervision, and patient compliance in a busy outpatient surgical setting, which could have introduced performance bias. An α-blocker versus no-treatment design was similarly discouraged to ensure adequate symptom relief in both groups. Diclofenac sodium was therefore selected as an active comparator, as it is commonly prescribed in routine clinical practice for pelvic discomfort and dysuria associated with non infective LUTS, provides ethical symptomatic relief, and lacks α1-adrenergic activity, allowing a clearer assessment of tamsulosin's specific effects on voiding parameters and symptom scores.

After detailed initial screening, including thorough history (personal, drug, and allergy), focused urological examination and laboratory tests (haemogram, liver and kidney function tests, urine routine microscopy, urine culture, and fasting blood glucose levels), imaging with (Kidney, Ureter, and Bladder X-ray ((X-ray KUB) and Ultrasonography (USG) eligible patients were screened and enrolled. FVD was diagnosed based on clinical evaluation, including a detailed history and physical examination while uroflow, Post-Void Residual (PVR) measurement, and IPSS were also used to confirm the diagnosis. Urodynamics and a voiding cystourethrogram were not performed routinely in this study, as it was designed as a minimally invasive clinical study. The IPSS was self-administered by the patients at each visit. The patients were provided with clear instructions on how to complete the questionnaire. The voiding diary was collected at every visit, and the patients recorded daytime and nighttime micturition frequencies.

Study Procedure

The choice of study design and comparator was guided by recommendations of the Institutional Ethics Committee, which advised against a placebo-only or no-treatment arm, as all enrolled women were symptomatic (IPSS >8) and withholding therapy was considered ethically inappropriate. Behavioral therapy was not included due to feasibility constraints related to standardisation, supervision, and patient compliance in a busy outpatient surgical setting, which could have introduced performance bias. An α-blocker versus no-treatment design was similarly discouraged to ensure adequate symptom relief in both groups. Diclofenac sodium was therefore selected as an active comparator, as it is commonly prescribed in routine clinical practice for pelvic discomfort and dysuria associated with non infective LUTS, provides ethical symptomatic relief, and lacks α1-adrenergic activity, allowing a clearer assessment of tamsulosin's specific effects on voiding parameters and symptom scores.

Patients were followed-up during the 1st, 2nd, 4th, 6th, and 8th week post-therapy, while the final outcome parameters were assessed after eight weeks. An uroflowmetry (uroflow) study and voiding diary to record daytime and nighttime frequencies was performed at each visit. Clinical safety was assessed by recording Treatment Emergent Adverse Events (TEAE) and side-effects during all visits. Drug compliance was measured by counting remaining administered tablets at the endpoint visit, and patients were questioned about adherence to the treatment regimen. Patients were instructed at the inclusion visit not to take any other treatment or drug for LUTS, which was reconfirmed at the endpoint visit.

Outcome measures: The primary study outcomes were assessed by evaluating changes in key parameters (≥10% or 1 mL/s improvement in average flow rate and an increase in Qmax by 2.5 mL/s) to indicate improved urine flow. Additionally, a 10% or 2-3 point improvement in the IPSS score was considered significant, along with any changes in PVR. The flow of the present study is depicted in [Table/Fig-1].

STATISTICAL ANALYSIS

Data were analysed using Statistical Package for Social Sciences (SPSS) version 20.0. Continuous variables were analysed using repeated-measures ANOVA followed post-hoc pair wise tests and Independent t-test; categorical variables using Chi-square test. A p-value<0.05 was considered statistically significant.

RESULTS

Baseline Characteristics

A total of 150 women were randomised equally into the tamsulosin (group I) and diclofenac sodium (group II) arms. The majority of participants were aged 21-50 years, with no significant intergroup differences in age distribution. Baseline biochemical parameters, including random blood sugar, liver function tests, kidney function tests, and lipid profile, were within normal limits for all participants, confirming baseline comparability [Table/Fig-2].

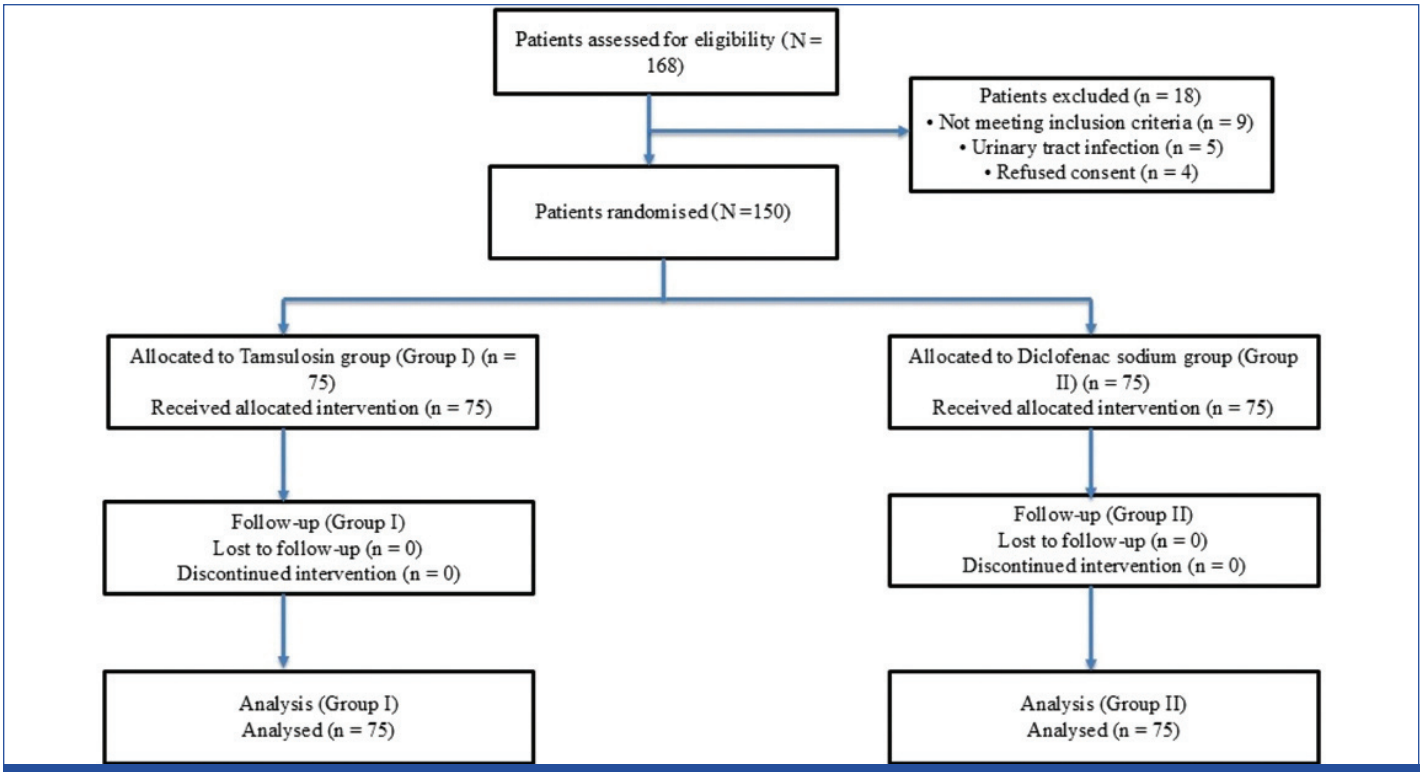
Primary Outcomes

At eight weeks, a clinically significant improvement in symptom severity, defined as a ≥ 10% or 2-3 point reduction in IPSS, was observed in 68 patients (90.7%) in the tamsulosin group compared with 41 patients (54.7%) in the diclofenac group.

Similarly, improvement in uroflowmetry parameters was significantly greater in the tamsulosin group. A ≥1 mL/sec or ≥10% increase in peak urinary flow rate (Qmax) was achieved in 62 patients (82.7%) receiving tamsulosin versus 40 patients (53.3%) in the diclofenac group by the end of the 8-week follow-up.

Secondary Outcomes

Serial uroflowmetry demonstrated a significantly greater improvement in Qmax in the tamsulosin group from the third week onward when compared with controls (p<0.001) [Table/Fig-3a]. Reduction in PVR was also more pronounced in the tamsulosin group, reaching statistical significance from the fourth week of therapy (p<0.05) [Table/Fig-3b].



[Table/Fig-1]: The Consolidated Standards of Reporting Trials (CONSORT)-Flow diagram of the study.

Baseline variables	Tamsulosin group (n=75)	Diclofenac Na group (n=75)	p-value
Age (years), (Mean±SD)	38.6±7.9	39.1±8.2	0.68
IPSS score, (Mean±SD)	22.4±4.3	22.1±4.1	0.71
Qmax (mL/sec), (Mean±SD)	10.8±2.1	10.9±2.3	0.82
Post Void Residual Volume (PVR) (mL), (Mean±SD)	70.6±18.4	62.2±17.9	0.07
Voided Volume (VV) (mL), (Mean±SD)	182±36	179±34	0.64
Increased frequency of micturition, n (%)	23 (30.7%)	22 (29.3%)	0.85
Dribbling of urine, n (%)	21 (28.0%)	22 (29.3%)	0.86
Burning micturition, n (%)	15 (20.0%)	15 (20.0%)	1.00
Painful micturition, n (%)	9 (12.0%)	8 (10.7%)	0.79
Difficulty in micturition, n (%)	7 (9.3%)	8 (10.7%)	0.78
Urine culture negative, n (%)	75 (100%)	75 (100%)	—

[Table/Fig-2]: Baseline characteristics of the study participants.
Footnote: Values are expressed as mean±standard deviation or number (percentage). Continuous variables were compared using the independent samples t-test, and categorical variables were compared using the Chi-square test. A p-value <0.05 was considered statistically significant.

IPSS scores declined progressively in both groups; however, the magnitude of reduction was significantly greater in the tamsulosin arm at all follow-up points beyond the second week (p<0.001), indicating superior symptom relief [Table/Fig-3c]. Additionally, comparative analysis of uroflow parameters revealed significantly higher improvements in both Qmax and VV in the tamsulosin group from the second week onward [Table/Fig-3d].

Association between groups change in Q-MAX (mL/sec)					
	Tamsulosin (Test -group I)		Diclofenac Na (Control group II)		p-value Difference in Q-MAX (Ml/Sec)
Time point	%Mean (SD) change	p-value	%Mean (SD) change	p-value	
1st Week	1.1% (9.3)	0.998	0.1% (9.3)	1.000	0.660
2nd Week	8.8% (10.3)	0.002	8.2% (9.5)	<0.001	0.638
3rd Week	26.7% (11.3)	<0.001	18.0% (11.4)	<0.001	<0.001*
4th Week	26.7% (11.3)	<0.001	18.0% (11.4)	<0.001	<0.001*
8th Week	32.4% (12.0)	<0.001	23.4% (12.5)	<0.001	<0.001*

Comparison of change in Post Void Residual (PVR) Vol.			
Time point	Mean change in PVR (Tamsulosin) Group I	Mean change in PVR (Diclofenac Na)- Group II	p-value
0 screening visit	70.55	62.19	0.03*
1st visit	70.55	62.19	0.03*
2nd visit	65.32	60.75	0.09
3rd visit	47.44	56.59	0.04*
4th visit	30.91	51.63	0.02*
Follow-up visit	22.8	47.65	0.02*
Comparison of change in IPSS score			
Time point	Tamsulosin (n=75) Group I	Diclofenac Na (n=75) Group II	p-value
			-
2nd visit	-1.99±1.21	-1.00±1.32	p<0.001*
3rd visit	-7.31±2.27	-3.55±1.75	p<0.001*
4th visit	-12.00±3.37	-5.29±2.60	p<0.001*
Follow-up visit	-16.08±4.36	-5.71±2.94	p<0.001*
Comparison of change in uroflow (Q max mL/sec) and VV values over time			
Change in Qmax (mL/sec) and Voided Volume (VV mls)	Tamsulosin (n = 75) Group I	Diclofenac Na (n = 75) Group II	p-value
Qmax 1st Visit	0.11±1.65	-0.06±1.69	0.523
Qmax 2nd Visit	1.50±1.80	1.40±1.62	0.724
Qmax 3rd Visit	4.72±1.80	3.13±1.84	<0.001
Qmax 4th Visit	4.72±1.80	3.13±1.84	<0.001
VV(mL) -1st Visit	-3.12±17.80	-2.00±16.81	0.692
VV(mL) -2nd Visit	17.67±18.70	-3.08±18.09	<0.001
VV(mL)-3rd Visit	37.92±20.46	-2.80±17.26	<0.001
VV(mL)-4th Visit	59.85±21.67	-2.92±17.23	<0.001
VV(mL)- Follow-Up	78.91±22.31	-3.07±17.25	<0.001

[Table/Fig-3 a-d]: Depicting association between groups in terms of change in Q-max, PVR, IPSS, and Uroflow/Voided Volume (VV) over time, respectively.
ANOVA followed Post-hoc pair wise tests

No.	Author	Design	Sample size (no.) (no)	Salient features
1	Chapman GC et al., 2021 [7]	RCT	119 (57 Tamsulosin vs 62 placebo)	Women randomised to tamsulosin (0.4 mg) vs placebo for 10d. Authors concluded that Tamsulosin had a significantly reduced rate of POUR (8.8% vs 25.8%) and improved UFL rate without increasing risk of UTI.
2	Maiti K et al., 2020 [8]	RCT	80 (40per group)	Comparative study of α1a-Adr-blockers,TamsulosinVsEstrogens for LUTS in Peri-menopausal (PM) women followed with IPSS, UFL,Qmax and PVR demonstrated significant improvement of Qmax and reduced PVR in Tamsulosin group. Authors concluded α1a-Adr Blockers could be the first-line treatment for LUTS in PM women
3	Zhang HL et al., 2017 [3]	SR- MA	6 RCTs with (764 women)	Meta-analysis of 6 RCTs compared tamsulosin vs placebo, prazosin, combination therapies for FLUTS using IPSS, QoL, Urodynamic tools. Authors concluded that "T" was more effective vs placebo in reducing LUTS and improving QoL in women.
4	Boyd K and Hilas O 2014 [2]	SRa nd RCT	15 Articles	Review of clinical trials evaluating efficacy and safety of α1a-Adr blockers for therapy of FLUTS/FVD. Authors concluded that the α1a-Adr blockers may improve FLUTS, urinary dysfunction and FBOO
5	Kaplan SA and Chughtai BI 2018 [6]	SR	160 articles with 46,072 participants	No unexpected AEs observed in women treated with tamsulosin for LUTS and overall safety profile of "T" in women appeared consistent with profile seen in men.
6	Chang SJ et al., 2008 [9]	RCT	97 women	Authors prospectively evaluated efficacy of 0.2mg "T" in women with voiding difficulty (VD) and demonstrated significant beneficial effects in women with VD
7	Taha F et al., 2020 [10]	Literature Review	17 Articles (4 RCT with placebo)	Authors evaluated clinical/urodynamic benefit of α1a-Adr blockers in women and concluded it improved non obstructive FVD with limited benefit for OAB in women
8	Pummangura N and Kochakarn W 2007 [5]	DB-RCT	140 Women	"T" was more efficacious vs placebo for LUTS in women
9	Costantini E et al., 2009 [11]	OL-LS	63 Women with BOO	Authors investigated clinical effect of "T" for treatment of functional Bladder Outlet Obstruction (BOO) in adult women. Demonstrated "T" therapy was effective for FVD due to functional BOO
10	Kim SO et al., 2014 [12]	OS	296 Women	Authors investigated effect of "T" on nocturia/sleep quality for treatment FLUTS in women with MFR (Qmax) <15 mL/sec. Demonstrated "T" significantly improved nocturia/sleep quality/FLUTS in women with low Qmax
11	Pischedda A et al., 2005 [13]	OS	18 Women	Explored therapeutic effect of "T", in women with functional bladder neck obstruction (confirmed by UDS). Demonstrated 'T' was an initial treatment option for functional FBOO (effective in >50% FVD)
12	Present study, 2026	RCT	150 Women (Tvs Control 75 each)	Evaluated safety and efficacy of off-label "T" vs diclofenac sodium in 150 women with VD due to LUTS. Demonstrated a significantly better outcome in "T"

[Table/Fig-4]: Summary of the recent studies on Tamsulosin in women with FLUTS [2,3,5,6-13].
SR: Systematic review; MA: Meta-analysis; RCT: Randomised controlled trial; DB-RCT: Double-blind randomised controlled trial; OL-LS: Open-label longitudinal study; OS: Observational study; CT: Clinical trial; LUTS: Lower urinary tract symptoms; FLUTS: Female lower urinary tract symptoms; FVD: Female voiding dysfunction; VD: Voiding dysfunction; PM: Peri-menopausal; POUR: Post-operative urinary retention; BOO: Bladder outlet obstruction; FBOO: Female bladder outlet obstruction; MFR: Maximum flow rate; Qmax: Peak urinary flow rate; PVR: Post-void residual volume; UFL: Uroflowmetry; UDS: Urodynamic studies; QoL: Quality of life; UTI: Urinary tract Infection; SE: Side effects; α1a-Adr: Alpha-1a adrenergic receptor; T: Tamsulosin hydrochloride; Pr: Prazosin

Dose Titration

Among patients randomised to tamsulosin, 17 of 75 (22.7%) required dose escalation to 0.8 mg once daily after the second week due to inadequate early improvement in urinary flow and symptom scores. These patients subsequently demonstrated further improvement without an increase in adverse events.

Safety and Tolerability

Tamsulosin was well-tolerated, with no severe adverse events reported. The most common treatment-emergent adverse events were mild dizziness in 8 patients (10.6%) and postural hypotension in 6 patients (8%), which were transient and did not necessitate treatment discontinuation.

In the diclofenac sodium group, adverse events were infrequent and mild, predominantly gastrointestinal discomfort in three patients (4%), and did not require cessation of therapy. No participants in either group discontinued treatment due to adverse events, and overall treatment compliance was high.

DISCUSSION

Although tamsulosin has not yet received FDA approval for FLUTS, it is widely prescribed off-label due to its established safety profile, comparable to its use in men, as evidenced by multiple randomised controlled trials and systematic reviews [5-14] Summary of the recent studies on Tamsulosin in women with FLUTS are shown in [Table/Fig-4] [2,3,5,6-13]. Female Overactive Bladder (FOAB) has been reported with a prevalence of up to 31.3%, exhibiting an age-related increase [15]. A clinical trial by Lee KS et al., demonstrated the efficacy of tamsulosin in FLUTS, FVD, and FBOO, irrespective of obstruction grade [16]. Similarly, Hajebrahimi S et al., demonsrated tamsulosin being superior to prazosin in their RCT for FLUTS, favouring its better safety profile [17]. A systematic review and meta-analysis by Kang TW et al., supported the effectiveness of alpha-blocker therapy in women with LUTS [18].

Reitz A et al., reported that Tamsulosin significantly reduced urethral pressure, indicating its potential role in relieving urinary retention due to a non relaxing urethra [19]. Meyer LE and Brown JN, in their review of clinical trials, concluded that while Tamsulosin showed promise in FLUTS and FVD, further research is necessary before routine prescription [20].

These findings align with the current study, suggesting tamsulosin as a promising therapeutic option for FLUTS. However, Sinha S et al., emphasised the importance of precise diagnosis using Urodynamic Studies (UDS) before initiating empirical therapy to ensure condition-specific treatment [2,3,5,6-13] [21].

Limitation(s)

The present study had some minor limitations. Its accuracy and reliability could have been enhanced through a larger, multicentre study with a longer follow-up period. Incorporating UDS-though omitted here due to their invasive nature and protocol restrictions-could have provided more robust data. Additionally, the lack of long-term follow-up limits our understanding of the extended safety and efficacy of tamsulosin in women. Future studies should include more diverse population groups to better assess the long-term effectiveness and safety of extended empirical tamsulosin therapy across different demographic groups.

CONCLUSION(S)

The current study findings support the safety and efficacy of off-label initial empirical tamsulosin therapy in select women with Functional Voiding Dysfunction (FVD) due to FLUTS. The tamsulosin group demonstrated significantly superior outcomes versus Diclofenac group, with improved higher uroflow and lower IPSS values for FLUTS.

Authors' contribution: Protocol/project development: IS; Data collection or management: NS, IS, HA; Data analysis: IS, NS, HA, HT; Manuscript writing/editing: IS, HA, HT, NS; Manuscript Protocol Inception Drafting andThesis Supervision: IS, SG, KG; Manuscript Thesis Co-supervision: SG, KG. Final review and approval of manuscript was done by all authors.

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