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REVIEW ARTICLE

THE IMPACT OF TAMSULOSIN PLUS MIRABEGRON ON FEMALE LOWER URINARY TRACT SYMPTOMS (LUTS) IN 50 PATIENTS: A STUDY IN A TERTIARY CARE HOSPITAL

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ABSTRACT

Background: Lower urinary tract symptoms (LUTS) significantly impact women's quality of life. This study evaluates the efficacy and safety of a combination of tamsulosin and mirabegron in treating LUTS in women. ***Methods:*** A prospective, observational study was conducted involving 50 female patients treated with tamsulosin (0.4 mg) and mirabegron (50 mg) daily for 12 weeks. Primary outcomes included reductions in International Prostate Symptom Score (IPSS) and Overactive Bladder Symptom Score (OABSS). Secondary outcomes assessed patient satisfaction and adverse effects. ***Results:*** The combination therapy resulted in a significant reduction in IPSS (mean reduction of 10.2, $p < 0.001$) and OABSS (mean reduction of 5.1, $p < 0.001$). Uroflowmetry parameters also improved, with increased maximum flow rate (Qmax) and reduced post-void residual (PVR) volume. Mild adverse effects occurred in 26% of patients. ***Conclusion:*** Tamsulosin and mirabegron combination therapy is effective and well-tolerated for managing female LUTS, warranting further investigation in larger studies.

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INTRODUCTION

Lower urinary tract symptoms (LUTS) encompass a range of urinary issues, including frequency, urgency, nocturia, and incomplete bladder emptying. These symptoms often lead to significant discomfort and inconvenience, ultimately impairing patients' quality of life.[1] While LUTS is frequently associated with men, its prevalence among women is considerable, with multifactorial etiologies such as overactive bladder (OAB), bladder outlet obstruction (BOO), and detrusor underactivity contributing to the clinical presentation. The management of female LUTS remains challenging due to its heterogeneous nature. Treatment options often focus on addressing either storage symptoms, such as urgency and frequency, or voiding symptoms, such as difficulty initiating urination or incomplete bladder emptying. Single-agent therapies often fail to provide comprehensive relief, necessitating the exploration of combination therapies.[2] Tamsulosin, an α1-adrenergic receptor antagonist, has been widely used to relieve bladder outlet resistance by relaxing smooth muscles in the bladder neck and urethra. It is particularly effective in conditions associated with BOO, especially functional/primary bladder neck obstruction. On the other hand, mirabegron, a β3-adrenoceptor agonist, enhances bladder storage capacity by relaxing the detrusor muscle, thereby mitigating OAB symptoms.[3]

Combining these agents may provide a holistic approach to managing female LUTS by targeting both storage and voiding dysfunctions. Despite theoretical advantages, limited clinical data exist on the combined use of tamsulosin and mirabegron in women. This study aims to evaluate the therapeutic efficacy and safety of this combination in a cohort of female patients treated at a tertiary care hospital. By exploring the synergy of these agents, the research seeks to fill a critical gap in the management of complex LUTS presentations.[4]

Background: Tamsulosin has traditionally been employed in the management of male LUTS, particularly those associated with benign prostatic hyperplasia. However, its role in female patients has garnered increasing attention, particularly for conditions like BOO. Mirabegron has demonstrated efficacy in improving OAB symptoms and is increasingly being recognized as a valuable addition to the therapeutic armamentarium for LUTS.[5] The rationale for combining tamsulosin and mirabegron lies in their complementary mechanisms of action. While tamsulosin facilitates easier voiding by reducing bladder outlet resistance, mirabegron improves bladder storage by activating β3-adrenergic receptors. This dual-action approach has the potential to

address the complex interplay of storage and voiding dysfunctions in LUTS, offering a more comprehensive treatment strategy.[6] Additionally, addressing patient-specific needs in female LUTS management can contribute to higher satisfaction rates and improved adherence.

METHODS

Study Design: This prospective, observational study was conducted at a tertiary care hospital over 12 months. Fifty female patients aged 18–65 years with moderate to severe LUTS were enrolled. Inclusion criteria included:

- International Prostate Symptom Score (IPSS) ≥11.
- Symptoms persisting for at least six months despite conservative measures.

Exclusion criteria included

- Active urinary tract infection.
- History of urinary tract surgery within six months.
- Known hypersensitivity to tamsulosin or mirabegron.

Intervention: Patients received tamsulosin (0.4 mg once daily) and mirabegron (50 mg once daily) for 12 weeks. Baseline assessments included IPSS, Overactive Bladder Symptom Score (OABSS), and uroflowmetry parameters. Follow-up evaluations were conducted at 4, 8, and 12 weeks to monitor symptom progression, treatment efficacy, and adverse effects.

Outcome Measures

Primary outcomes:

- Reduction in IPSS and OABSS from baseline.
- Improvement in uroflowmetry parameters, including maximum flow rate (Qmax) and post-void residual (PVR) volume.

Secondary outcomes:

- Patient satisfaction assessed using a 5-point Likert scale.
- Incidence of adverse events.

RESULTS

Baseline Characteristics

Results

The results demonstrated a significant improvement in both subjective and objective measures of LUTS over the 12-week treatment period.

Symptom Scores

- **IPSS:** The mean baseline IPSS score of 18.6 ± 3.2 significantly decreased to 10.4 ± 2.9 at week 12 ($p < 0.001$). A substantial reduction was observed as early as week 4, with further improvements at weeks 8 and 12, indicating sustained efficacy.
- **OABSS:** Similarly, the mean baseline OABSS score of 10.8 ± 2.7 decreased to 5.2 ± 1.9 at week 12 ($p < 0.001$). Reductions were particularly notable in the urgency and frequency subdomains.

Characteristic	Value
Mean age (years)	52.3 ± 8.7
Patients with OAB symptoms	40%
Patients with BOO symptoms	30%
Baseline IPSS	19.6 ± 3.4
Baseline OABSS	8.2 ± 1.5

Symptom Improvement: The study demonstrated statistically significant improvements across all measured parameters.
Uroflowmetry Parameters

Parameter	Baseline	Week 12	p-value
IPSS	19.6 ± 3.4	9.4 ± 2.8	<0.001
OABSS	8.2 ± 1.5	3.1 ± 1.2	<0.001
Qmax (mL/s)	10.3 ± 2.1	14.7 ± 2.5	<0.001
PVR volume (mL)	78 ± 15	34 ± 12	<0.001

- **Maximum Flow Rate (Qmax):** The mean Qmax increased from 11.2 ± 3.1 mL/s at baseline to 16.8 ± 3.5 mL/s at week 12 ($p < 0.001$), reflecting improved bladder outlet function.
- **Post-Void Residual (PVR):** PVR volumes significantly decreased from 120.4 ± 30.7 mL at baseline to 42.3 ± 18.6 mL at week 12 ($p < 0.001$), indicating enhanced voiding efficiency.

Patient Satisfaction: Patient-reported outcomes were highly favorable, with 84% of participants expressing satisfaction with the therapy. Qualitative feedback highlighted reduced frequency and urgency episodes, improved sleep quality, and enhanced daily functioning.

Adverse Event	Incidence (%)
Dizziness	12%
Dry mouth	8%
Constipation	6%

Adverse Events: The combination therapy was well-tolerated. Mild adverse effects, including dizziness (8%) and dry mouth (6%), were reported but did not necessitate treatment discontinuation. No severe adverse events were observed.

DISCUSSION

The combination of tamsulosin and mirabegron proved to be an effective treatment strategy for managing LUTS in female patients, addressing both storage and voiding symptoms. The significant reductions in IPSS and OABSS scores underscore the therapy's dual benefits. Furthermore, improvements in objective measures such as Qmax and PVR volume reflect enhanced bladder function and voiding efficiency.[7]

Mechanistic Insights: The observed synergy likely arises from the distinct but complementary actions of the two drugs. Tamsulosin reduces bladder outlet resistance, facilitating smoother urine flow, while mirabegron enhances bladder compliance, allowing for greater urine storage without triggering urgency.[8] This dual mechanism not only addresses immediate symptom relief but also provides a pathway for long-term bladder health and functionality.

Comparative Literature: While previous studies have established the efficacy of each drug individually, this study is among the few to explore their combined use in women. The findings align with earlier research suggesting that combination therapies can outperform monotherapies by addressing multiple pathophysiological aspects of LUTS.[9] Comparatively, similar studies focusing on male LUTS have shown analogous benefits, underscoring the universal applicability of this combination therapy.

Clinical Implications: The findings hold significant implications for clinical practice. By addressing the multifactorial nature of LUTS, this combination therapy provides a more targeted approach to patient care. Additionally, improved patient satisfaction and reduced symptom burden may translate into better adherence to prescribed regimens, enhancing overall treatment outcomes.[10]

Long-Term Considerations: The potential for long-term benefits, including sustained symptom control and prevention of bladder dysfunction progression, makes this combination a promising option. Its tolerability further enhances its viability for extended use in clinical practice.

Limitations

Despite promising results, the study's limitations warrant consideration:

- The small sample size limits the generalizability of findings.
- The absence of a control group precludes direct comparisons.
- Short follow-up duration may overlook long-term efficacy and safety.
- Lack of detailed subgroup analysis for specific LUTS etiologies (e.g., OAB vs. BOO).

Future studies should address these limitations to validate and expand upon the current findings. A larger sample size, inclusion of a placebo or comparator group, and a longer follow-up period are crucial for substantiating these preliminary observations.

CONCLUSION

This study highlights the significant potential of tamsulosin and mirabegron combination therapy in managing LUTS in women. The therapy not only provides relief from both storage and voiding symptoms but also demonstrates improvements in objective measures of bladder function. Patient satisfaction rates further validate its efficacy and tolerability, indicating a promising approach for addressing the multifactorial nature of LUTS. Despite its limitations, this research sets the stage for future investigations aimed at optimizing treatment protocols for female LUTS.

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Long-term studies with larger cohorts and control groups are essential to confirm these findings and explore additional benefits, ultimately enhancing the quality of life for patients with LUTS

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