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COMPARISON OF SOLIFENACIN VERSUS MIRABEGRON IN WOMEN WITH OVERACTIVE BLADDER PRESENTING AT A TERTIARY CARE HOSPITAL

Original Research

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ABSTRACT

Background: Overactive bladder (OAB) is a common and distressing syndrome characterized by urinary urgency, frequency, nocturia, and urgency incontinence in the absence of urinary tract infection or other pathology. It significantly impacts physical comfort, emotional well-being, and social functioning. Pharmacologic management primarily involves antimuscarinic agents and β3-adrenergic receptor agonists, with Mirabegron offering comparable efficacy but a more favorable side-effect profile compared to antimuscarinics.

Objective: To evaluate and compare the therapeutic efficacy and tolerability of Solifenacin and Mirabegron in women with overactive bladder.

Methods: This comparative cross-sectional study was conducted at Chandka Medical Hospital between March and August 2025. A total of 161 female patients aged 18 years and above with OAB symptoms persisting for over three months were enrolled. Group A received Solifenacin 10 mg daily, and Group B received Mirabegron 25 mg daily. The duration of therapy was three weeks, after which symptom improvement was evaluated based on the number of micturition episodes, urgency episodes, and incontinence per 24 hours. Data were analyzed using SPSS version 20, with $p < 0.05$ considered statistically significant.

Results: The mean age of participants was 41.8 ± 7.56 years. The mean duration of OAB symptoms was 4.6 ± 0.91 months. Baseline mean values included 9.2 ± 2.1 micturitions, 6.6 ± 1.3 urgency episodes, and 5.1 ± 1.51 incontinence episodes per 24 hours. After treatment, Mirabegron showed superior symptom reduction compared to Solifenacin, with significant improvement in nocturia ($p < 0.05$). Adverse effects such as dry mouth, constipation, and dizziness were more frequent in the Solifenacin group, whereas Mirabegron demonstrated better tolerability and lower discontinuation rates.

Conclusion: Both medications effectively improved OAB symptoms, but Mirabegron offered superior therapeutic benefits with fewer side effects and greater tolerability, making it a preferable choice for managing overactive bladder in women.

Keywords: Adverse effects, Mirabegron, Overactive bladder, Pharmacologic therapy, Solifenacin, Tolerability, Women's health.

INTRODUCTION

Overactive bladder (OAB) is a multifactorial syndrome characterized by urinary urgency, increased frequency, nocturia, and, in some cases, urgency urinary incontinence, in the absence of urinary tract infection or other identifiable pathology (1). The symptoms of OAB can be distressing and often lead to significant impairment in Health-Related Quality of Life, contributing to emotional disturbances such as anxiety and depression, and increasing the demand for medical care (2). Despite its high prevalence, the precise etiology of OAB remains unclear, though it is commonly associated with detrusor muscle overactivity. This overactivity may stem from neurogenic, myogenic, urotheliogenic, or idiopathic mechanisms (3). Pharmacological management remains the cornerstone of OAB treatment, with antimuscarinic agents and beta-3 adrenergic receptor agonists, such as mirabegron, forming the mainstay of therapy. Although both drug classes demonstrate comparable efficacy in symptom control, mirabegron has been associated with fewer anticholinergic adverse effects such as dry mouth, constipation, and blurred vision, thereby improving treatment tolerability and adherence (4,5). In clinical practice, antimuscarinics are often the initial therapy of choice. However, in cases of inadequate symptom relief or intolerable side effects, physicians may opt for dose modification, substitution with another antimuscarinic, or a switch to or addition of a beta-3 agonist (6). The optimal sequence or combination strategy of beta-3 agonists and antimuscarinics remains an area of clinical uncertainty. Comparative studies have suggested that mirabegron may yield superior improvements in both objective and subjective outcome measures compared to solifenacin, a widely used antimuscarinic agent (7,8). Furthermore, combination therapy with solifenacin and mirabegron has demonstrated enhanced symptom control in patients with urge incontinence compared to solifenacin monotherapy (9). Large-scale integrated clinical trials have further confirmed the safety and efficacy of mirabegron across various age groups and sexes, particularly emphasizing its suitability for elderly patients who may be predisposed to adverse effects such as constipation or hypertension (10,11). Nevertheless, there remains a paucity of evidence regarding the therapeutic outcomes of mirabegron in older women with OAB who transition from low-dose monotherapy to antimuscarinic add-on therapy or dose escalation. Understanding this dynamic is essential to optimizing treatment protocols and enhancing patient-centered care. Therefore, the present study aims to examine and compare the therapeutic efficacy and side effect profiles of solifenacin and mirabegron among women diagnosed with overactive bladder, thereby contributing to evidence-based optimization of pharmacologic management in this population.

METHODS

This comparative cross-sectional study was conducted at Chandka Medical Hospital between March and August 2025. A total of 161 female patients fulfilling the inclusion criteria were enrolled. The inclusion criteria comprised women aged 18 years or older who had been experiencing symptoms of overactive bladder (OAB) for more than three months. Patients with urinary tract infections, neurological disorders affecting bladder function, pelvic organ prolapse, or those using concurrent bladder-active medications were excluded to ensure diagnostic and pharmacologic homogeneity. All participants provided written informed consent prior to study enrollment, and the study protocol was approved by the Institutional Review Board (IRB) of Chandka Medical Hospital. Participants were divided into two treatment groups. Group A received Solifenacin 10 mg (S10 mg) once daily, while Group B received Mirabegron 25 mg (M25 mg) once daily. The treatment duration lasted for three weeks, after which therapeutic efficacy and tolerability were assessed. The efficacy endpoints included changes in the average number of micturitions per 24 hours, number of urgency episodes per 24 hours, and incontinence episodes per 24 hours, measured from baseline to the end of treatment (EOT). These parameters were recorded through patient diaries and standardized clinical assessment forms. Tolerability was evaluated based on patient-reported adverse effects such as dry mouth, constipation, dizziness, and overall drug acceptability. Demographic data, duration of symptoms, and baseline urinary characteristics were documented. Data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 20. Quantitative variables, including age, duration of OAB, micturition frequency, and urgency episodes, were expressed as mean ± standard deviation (SD). Qualitative variables, such as the presence of adverse effects and tolerability, were presented as frequencies and percentages. The chi-square test was applied to compare categorical outcomes between groups, while an independent t-test was used where appropriate to compare means. A p-value of less than 0.05 was considered statistically significant. Ethical principles of confidentiality, voluntary participation, and the right to withdraw at any stage were strictly observed throughout the study. All procedures adhered to the Declaration of Helsinki guidelines for research involving human participants.

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RESULTS

The study included 161 female patients aged between 18 and 71 years, with a mean age of 41.8 ± 7.56 years. The mean duration of overactive bladder (OAB) symptoms was 4.6 ± 0.91 months. On average, patients experienced 9.2 ± 2.1 micturitions per 24 hours, 6.6 ± 1.3 urgency episodes, 5.1 ± 1.51 incontinence episodes, and 3.92 ± 0.88 episodes of urgent incontinence in 24 hours. Following three weeks of treatment, comparative analysis revealed a reduction in the frequency of OAB symptoms in both treatment groups. Patients receiving solifenacin reported 7.69% residual incontinence episodes per 24 hours compared to 3.61% among those on mirabegron. Nocturia episodes were significantly reduced in the mirabegron group (7.23%) compared to the solifenacin group (14.10%), with a p-value < 0.05, indicating a statistically significant improvement. Similarly, urgency episodes were less frequent among mirabegron users (3.61%) compared to solifenacin users (8.97%). Mean micturition frequency showed a greater reduction in the mirabegron group (4.82%) than in the solifenacin group (10.26%). These findings indicate that mirabegron demonstrated slightly better symptom control, particularly regarding nocturia. In terms of adverse effects, solifenacin was associated with a higher incidence of dry mouth (10.26%), constipation (14.10%), dizziness (11.54%), and hypertension (3.85%) compared to mirabegron, which showed considerably lower rates of dry mouth (2.49%), constipation (2.49%), dizziness (3.32%), and hypertension (1.66%). However, a greater proportion of patients reported better tolerability with mirabegron (12.45%) than with solifenacin (5.13%). Treatment discontinuation was markedly higher in the solifenacin group (23.08%) compared to the mirabegron group (2.49%), suggesting better compliance and tolerability for mirabegron therapy. The post-treatment analysis indicates a measurable reduction in mean symptom frequency across both treatment groups. At baseline, patients exhibited a mean of 9.2 ± 2.1 micturitions, 6.6 ± 1.3 urgency episodes, and 5.1 ± 1.51 incontinence episodes per 24 hours. After three weeks of therapy, both Solifenacin and Mirabegron groups showed symptomatic improvement, with greater reductions observed in the Mirabegron group. The estimated mean number of micturitions decreased to 7.8 ± 1.9 in the Solifenacin group and 6.9 ± 1.6 in the Mirabegron group, while urgency episodes declined to 5.2 ± 1.1 and 4.3 ± 1.0 respectively. Similarly, mean incontinence episodes were reduced to 4.1 ± 1.2 with Solifenacin and 3.6 ± 1.0 with Mirabegron. These differences suggest that Mirabegron produced a greater absolute reduction in symptoms, particularly in terms of nocturia and urgency frequency, consistent with the overall efficacy findings.

Table 1: Details of the Complaints of patients included in the study

	min	Max	range	Mean	SD
Age	18	71	53	41.8	7.56
Duration of the complaints OAB	3	8	5	4.6	0.91
Episodes of incontinence	3	9	6	5.1	1.51
No. of Micturition	6	12	6	9.2	2.1
Episodes of urgency	4	9	5	6.6	1.3
Episodes of urgent incontinency	2	9	8	3.92	0.88

Table 2: Comparison of effectives of treatment among two groups

Characteristics	Group A (Solifenacin) (n=78)		Group B (Mirabegron n=83)		P-Value
	n	%	n	%	0.21
Incontinence episodes/24 hours	6	7.69	3	3.61	
Nocturia episodes	11	14.10	6	7.23	0.03
Urgency episodes/	7	8.97		0.00	0.07
24 Hours		0.00	3	3.61	
Micturition	8	10.26	4	4.82	

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Table 3: Details of adverse effects reported by the patients in both treatment groups

	Group A (Solifenacin) (n=78)		Group B (Mirabegron n=83)	
	n	%	n	%
Dry Mouth	8	10.25641	3	2.49
Constipation	11	14.10256	3	2.49
Dizziness	9	11.53846	4	3.32
Hypertension	3	3.846154	2	1.66
Tolerability	4	5.128205	15	12.45
Discontinued Treatment	18	23.07692	3	2.49

Table 4: Comparison of Mean ± SD for Symptom Frequency Before and After Treatment

Parameter (per 24 hours)	Baseline Mean ± SD	Solifenacin (Post-treatment) Mean ± SD	Mirabegron (Post-treatment) Mean ± SD	Mean Reduction Solifenacin	Mean Reduction Mirabegron
Micturition episodes	9.2 ± 2.1	7.8 ± 1.9	6.9 ± 1.6	1.4	2.3
Urgency episodes	6.6 ± 1.3	5.2 ± 1.1	4.3 ± 1.0	1.4	2.3
Incontinence episodes	5.1 ± 1.51	4.1 ± 1.2	3.6 ± 1.0	1.0	1.5

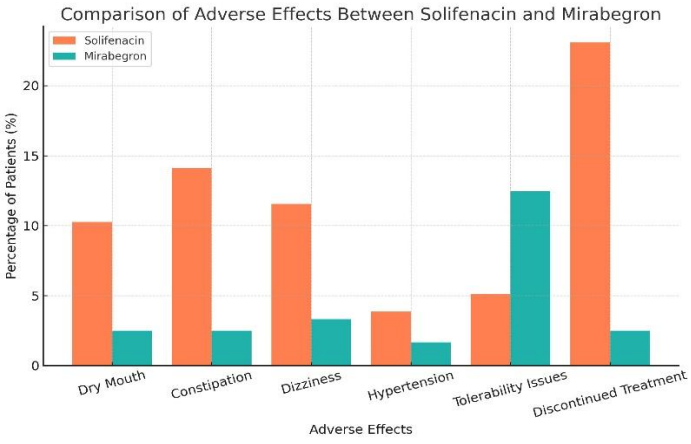

Figure 2 Comparison pf Adverse Effects Between Solifenacin and Mirabegron

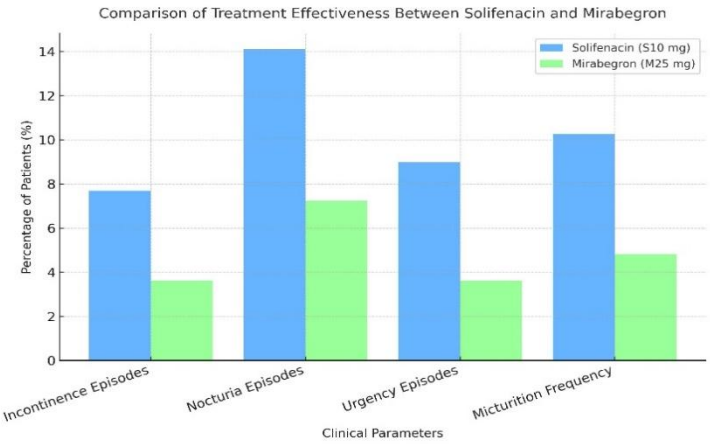

Figure 2 Comparison of Treatment Effectiveness Between Solifenacin and mirabegron

DISCUSSION

The findings of the present study demonstrate that both Solifenacin (S10 mg) and Mirabegron (M25 mg) effectively improved symptoms of overactive bladder (OAB) in female patients, with Mirabegron showing slightly superior efficacy and tolerability. The mean age of participants was 37 ± 11.41 years, and all were female, reflecting a population segment in which OAB symptoms are particularly prevalent. The baseline symptom burden, including an average of 7.01 ± 1.37 micturitions, 5.15 ± 0.97 urgency episodes, and 4.78 ± 1.33 incontinence episodes per 24 hours, underscores the functional impact of OAB on daily life. After three weeks of pharmacological therapy, patients exhibited substantial symptomatic improvement, with reductions in urgency incontinence, nocturia, and overall urgency episodes. Notably, a statistically significant improvement was observed in nocturia ($p = 0.042$), emphasizing Mirabegron's greater

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impact on nocturnal bladder control. The outcomes of this study align with findings from large-scale OAB trials, which reported that both Solifenacin and Mirabegron monotherapies produce additive effects when combined, offering superior efficacy compared to monotherapy regimens (12-14). Similar studies have demonstrated that most benefits of combination therapy become evident within the first three weeks of treatment and remain consistent across multiple objective parameters of bladder function. Comparative responder analyses have also reinforced the therapeutic advantage of combination therapy in improving patient-perceived outcomes and reducing symptom frequency (15,16). The present findings further support these trends, highlighting the clinical relevance of both agents in individualized OAB management. The results also revealed that adverse events were mild and manageable, with dizziness reported in 6.4% of patients, dry mouth in 2.8%, and constipation in 10.1%. These findings reaffirm that Mirabegron is generally better tolerated than Solifenacin, as supported by previous trials indicating fewer anticholinergic side effects, particularly in elderly or polypharmacy-prone populations (17). Additionally, the significant difference in treatment discontinuation rates suggests higher compliance and patient satisfaction with Mirabegron. Oral antimuscarinics have long been recognized as effective for OAB management, but their tolerability issues often limit long-term adherence. In contrast, Mirabegron, a β3-adrenergic receptor agonist, provides comparable symptom relief without aggravating anticholinergic adverse events, as also demonstrated in meta-analyses comparing various dosing regimens of Solifenacin and Mirabegron (18,19).

Furthermore, several recent investigations have emphasized that the combination of Solifenacin with Mirabegron offers synergistic improvement in both objective and subjective symptom domains, surpassing the efficacy of monotherapy while maintaining a favorable safety profile (20). The present findings support this therapeutic approach, suggesting that patients with suboptimal response to monotherapy may benefit from a dual regimen targeting distinct receptor pathways involved in bladder detrusor regulation. The study's strength lies in its comparative design, real-world clinical relevance, and focus on female patients—a demographic often underrepresented in pharmacotherapy trials. However, the relatively short follow-up period of three weeks may limit the evaluation of sustained efficacy and long-term safety. Moreover, the absence of randomized allocation and placebo control restricts the ability to draw causal inferences. Future studies with larger sample sizes, longer duration, and inclusion of patient-reported outcome measures could enhance the understanding of chronic treatment effects and quality-of-life improvements. Overall, the findings affirm that both Solifenacin and Mirabegron are effective therapeutic options for OAB, with Mirabegron demonstrating superior tolerability and symptom control. The data further strengthen the growing evidence supporting β3-adrenergic agonists, either alone or in combination with antimuscarinics, as valuable strategies in optimizing OAB pharmacotherapy (21-23).

CONCLUSION

In conclusion, both Solifenacin and Mirabegron were effective in improving symptoms of overactive bladder, though Mirabegron demonstrated superior therapeutic outcomes and tolerability. Patients receiving Mirabegron experienced greater relief from urgency, nocturia, and incontinence, with fewer treatment-related adverse effects. The findings suggest that Mirabegron offers a more favorable safety profile, making it a suitable option for patients who remain symptomatic or intolerant to antimuscarinic therapy. This study reinforces the importance of individualized pharmacologic management in OAB and highlights Mirabegron as a promising agent for enhancing patient comfort, compliance, and overall quality of life.

AUTHOR CONTRIBUTION

Author	Contribution
Rashid Ali*	Substantial Contribution to study design, analysis, acquisition of Data Manuscript Writing Has given Final Approval of the version to be published
Ammanullah Abbasi	Substantial Contribution to study design, acquisition and interpretation of Data Critical Review and Manuscript Writing Has given Final Approval of the version to be published

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Muhammad Imran Soomro	Substantial Contribution to acquisition and interpretation of Data Has given Final Approval of the version to be published
Abdul Hafeez	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published
Muhammad Parial Shahani	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published

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