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Research Article

Solifenacin versus Mirabegron: A Clinical Comparison in Overactive Bladder Treatment

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overactive bladder; mirabegron; solifenacin; randomized controlled trial; urinary frequency; urgency urinary incontinence

Abstract

Introduction: Overactive bladder (OAB) is a common chronic condition characterized by urinary urgency, usually accompanied by increased daytime frequency, nocturia, and, in some patients, urgency urinary incontinence. Pharmacological management primarily includes antimuscarinic agents and β3-adrenoceptor agonists; however, comparative evidence regarding their clinical effectiveness remains limited.

Objective: To compare the efficacy of solifenacin and mirabegron in the treatment of patients with overactive bladder.

Materials and Methods: This study was conducted in the Department of Urology, Ayub Teaching Hospital, Abbottabad, Pakistan, from 23 July 2023 to 23 January 2024. A total of 254 patients diagnosed with OAB were randomized in a 1:1 ratio to receive either solifenacin 5 mg/day (Group A, n=127) or mirabegron 25 mg/day (Group B, n=127) for four weeks. Baseline demographic and clinical characteristics were recorded. Treatment efficacy was assessed by changes in urinary frequency, urinary incontinence episodes, and Patient Perception of Bladder Condition (PPBC) score. Between-group comparisons were performed using independent-samples t-tests.

Results: A total of 254 participants completed the study. Baseline characteristics were generally comparable between groups. Mirabegron demonstrated a significantly greater reduction in urinary frequency compared with solifenacin (2.34 ± 1.33 vs. 2.00 ± 0.87 episodes/day; t = -2.672, p = 0.005). Although reductions in urinary incontinence episodes were observed in both groups, the between-group difference was not statistically significant (1.96 ± 1.58 vs. 1.81 ± 0.52; t = -1.017, p = 0.310). Similarly, both treatments improved PPBC scores, with no significant difference between groups (-1.51 ± 0.96 vs. -1.65 ± 0.86; t = -1.172, p = 0.242).

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Conclusion: Both solifenacin and mirabegron were effective in improving symptoms of overactive bladder. However, mirabegron was associated with a significantly greater reduction in urinary frequency, while both agents demonstrated comparable efficacy in reducing urinary incontinence episodes and improving patient-perceived bladder condition. These findings support mirabegron as an effective therapeutic option, particularly in patients with predominant urinary frequency symptoms.

Introduction

Overactive bladder [OAB] is a chronic and multifactorial clinical syndrome that is typified by urgency in the urine with or without urgency urinary incontinence [1]. In most cases, there is an augmentation of daytime frequency and nocturia. As stipulated by the International Continence Society [ICS], the symptoms should be present in the absence of urinary tract infections, metabolic malfunctions, or other pathological conditions with the potential to cause such symptoms [2]. Although OAB is mostly a symptom-based diagnosis, the syndrome is very prevalent in the entire world, with individuals from different demographic and clinical groups [3], including those with neurological conditions such as Parkinson's disease, which do not contraindicate the diagnosis.

The OAB burden has grown significantly worldwide over the last 10 years. Its global incidence in 2008 was about 10.7%, and it increased to almost 20% in 2018 as the proportion of the aged population in the world population increased [4]. This indicates a numerical increase in the affected population from 455 million to about 546 million people, a significant issue for healthy and active aging [5]. The condition has a considerable impact on the quality of life [HRQoL], which is a factor in causing emotional stress, declining work productivity, social embarrassment, sleep disturbance, and sexual dissatisfaction [6]. Further, OAB patients have increased cases of depression, anxiety, falls, metabolic syndrome, cardiovascular disease and even mortality, highlighting its health implications [7].

Among the strongest predictors of OAB is aging, due to physiological alterations in bladder function [8]. They include reduced bladder capacity, poor detrusor contractility, elevated spontaneous contractions, distorted sensory signalling, and comorbidities, such as bladder outlet obstruction caused by benign prostatic hyperplasia [BPH] in men [9]. Moreover, a few lifestyle and health causes- smoking, obesity, arthritis, heart disease, and irritable bowel syndrome- have a significant impact on increasing the risk of developing the symptoms of OAB [10]. According to the large epidemiological studies, such as the EPIC study and the population-based survey conducted in Canada, OAB is known to have an equal prevalence between the two sexes, with the prevalence rate being high in women and rising sharply after the age of 40 years, with almost half of the population being affected at the age of 75 years and onward [11,12].

OAB management is an elaborate account of a broad spectrum of management measures within the scope of behavioral interventions, alongside complex pharmacological and interventional management procedures [13]. The usual first-line treatment options include lifestyle changes, bladder training, and strengthening the pelvic floor muscles. When these elements fail to achieve the desired results, pharmacotherapy should be the primary mode of management [14]. The antimuscarinic drugs are widely used and include oxybutynin, tolterodine, and solifenacin, which inhibit involuntary detrusor contractions. Their application is, however, limited by side effects such as constipation, dry mouth, blurred vision and cognitive disturbance, which leads to low treatment compliance and discontinuation [15].

β3-adrenoceptor agonists, such as mirabegron, have become a useful treatment to overcome these limitations. Compared with conventional antimuscarinic medications, mirabegron reduces adverse effects while improving symptoms by promoting detrusor muscle relaxation during bladder filling [16]. While both solifenacin and mirabegron significantly reduce OAB symptoms, comparative studies indicate that mirabegron is better tolerated, has greater patient adherence, and has a lower incidence of treatment-related side effects [17]. These results highlight mirabegron's therapeutic potential as a preferred first-line pharmacologic choice, especially for

patients who cannot take antimuscarinic medication. Optimizing pharmacologic approaches remains crucial for improving long-term outcomes, therapeutic satisfaction, and overall quality of life for patients with OAB as its frequency increases. Since there is no obvious solution, we compared two OAB drugs, solifenacin and mirabegron, with regard to effectiveness and safety.

Materials and Methods

Study Design

This randomized controlled trial with a parallel-group design and a 1:1 allocation ratio was conducted in the Department of Urology, Ayub Teaching Hospital, Abbottabad, Pakistan, from 23 July 2023 to 23 January 2024. No changes were made to the study methods or eligibility criteria after trial commencement.

Participants and Setting

Participants were recruited from the Urology Outpatient Department (OPD) of Ayub Teaching Hospital, Abbottabad, Pakistan, using a consecutive sampling technique.

Inclusion Criteria

Patients were eligible for enrollment if they were between 20 and 70 years of age, of either sex, and had a confirmed diagnosis of overactive bladder (OAB) according to the predefined operational definition. Eligible participants were required to attend the Urology Outpatient Department during the study period and provide written informed consent prior to participation.

Exclusion Criteria

Patients were excluded from the study if they were pregnant or lactating, or had a diagnosis of neurogenic bladder. Individuals with an indwelling urinary catheter or diabetic neuropathy were also excluded. Patients with uncontrolled hypertension were not eligible for participation. In addition, patients presenting with symptomatic urinary tract infection, interstitial cystitis, bladder calculi, or any malignant pelvic organ disease were excluded from the study. Furthermore, individuals with untreated narrow-angle glaucoma or those experiencing urinary retention or gastric retention were also not included.

Sample Size

The sample size was calculated using the WHO sample size calculator with a study power of 80% and a 95% confidence level. The calculation was based on previously reported mean incontinence episodes after treatment of 1.222 ± 0.274 in the solifenacin group and 1.316 ± 0.359 in the mirabegron group. The required sample size was 254 participants, with 127 patients allocated to each treatment group.

After obtaining written informed consent, eligible participants were randomly assigned in a 1:1 ratio to either the Solifenacin group (Group A) or the Mirabegron group (Group B). The random allocation sequence was generated using a computer-generated randomization method. Participants were allocated equally to the two treatment groups (127 participants per group). Allocation concealment was maintained using sequentially numbered opaque sealed envelopes, which were opened only after participant enrollment. The randomization sequence was generated by an independent researcher who was not involved in participant recruitment or outcome assessment. Eligible participants were enrolled by the principal investigator, and treatment assignments were made according to the concealed allocation sequence.

Interventions

Participants in Group A received Solifenacin 5 mg orally once daily for four weeks, while participants in Group B received Mirabegron 25 mg orally once daily for four weeks. All participants were instructed to maintain a urinary diary throughout the study period.

Outcomes

The primary outcomes were urinary frequency, urinary incontinence episodes, and Patient Perception of Bladder Condition (PPBC) score after four weeks of treatment.Baseline demographic and clinical characteristics, including age, gender, duration of OAB symptoms, urinary frequency, incontinence episodes, and PPBC scores, were recorded before treatment initiation. Outcome measures were reassessed after four weeks using participants' urinary diaries and clinical evaluation.

Blinding

This study was conducted as an open-label trial; therefore, participants and investigators were not

blinded to treatment allocation.

Data Collection Procedure

Following approval from the Institutional Ethical Review Committee, eligible patients attending the Urology OPD were screened and enrolled after obtaining written informed consent. Baseline demographic and clinical data were recorded through history taking and physical examination. Participants were then allocated to one of the two treatment groups and followed for four weeks. Outcome measures were assessed at the end of the treatment period.

Statistical Analysis

Data were analyzed using IBM SPSS version 22.0. Quantitative variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequencies and percentages. Treatment efficacy was evaluated using the change from baseline (baseline minus post-treatment values) for each outcome. Independent-samples t-tests were used to compare the mean change scores between the two treatment groups. Although paired analyses and analysis of covariance (ANCOVA) adjusting for baseline values may provide additional statistical precision, the present study compared treatment-induced changes between groups using independent-samples t-tests because the primary objective was to evaluate differences in improvement between the two treatment arms. A p-value of less than 0.05 was considered statistically significant. To control for potential effect modifiers, stratification was performed for age, gender, and disease duration. Post-stratification independent-samples t-tests were subsequently applied to assess differences between the treatment groups within each stratum. Because a statistically significant difference in baseline age was observed between treatment groups, stratified analyses were performed according to age categories to evaluate potential confounding. No significant interaction between age and treatment effect was identified.

Results

A total of 254 patients were enrolled in the study, with 127 patients allocated to each group. Group A comprised 99 males and 28 females, while Group B comprised 113 males and 14 females (Table 1). The mean age was significantly higher in Group B (38.98 ± 13.77 years) than in Group A (34.86 ± 15.42 years), with a statistically significant difference between the groups (p = 0.025). The mean duration of overactive bladder (OAB) symptoms was 68.11 ± 19.09 weeks in Group A and 72.48 ± 17.90 weeks in Group B, with no statistically significant difference between the groups (p = 0.061). Baseline urinary frequency was 6.92 ± 2.42 episodes in Group A and 6.54 ± 2.36 episodes in Group B, with no statistically significant difference (p = 0.208; t = 1.20). Similarly, the baseline frequency of urinary incontinence was 4.05 ± 2.29 episodes in Group A and 3.61 ± 2.28 episodes in Group B, with no statistically significant difference between the groups (p = 0.125). The mean baseline PPBC score was 3.45 ± 1.02 in Group A and 3.30 ± 1.18 in Group B, and the difference was not statistically significant (p = 0.306; t = 1.025).

Table 1: Baseline Characteristics of Participants

Variable	Group A (n=127)	Group B (n=127)	p-value/t-value
Age (years)	34.86 ± 15.42	38.98 ± 13.77	0.025
Gender (M/F)	99 / 28	113 / 14	–
Duration of OAB (weeks)	68.11 ± 19.09	72.48 ± 17.90	0.061
Urinary Frequency (before)	6.92 ± 2.42	6.54 ± 2.36	0.208/t=1.2
Urinary Incontinence (before)	4.05 ± 2.29	3.61 ± 2.28	0.125
PPBC (before)	3.45 ± 1.02	3.30 ± 1.18	0.306/1.025

Both treatment groups demonstrated improvement in urinary frequency, urinary incontinence episodes, and PPBC scores after treatment (Table 2). The reduction in urinary frequency was significantly greater in Group B (2.34 ± 1.33) than in Group A (2.00 ± 0.87), with a statistically significant between-group difference (t = −2.672, p = 0.005). In contrast, the reduction in urinary incontinence episodes was slightly greater in Group B (1.96 ± 1.58) than in Group A (1.81 ± 0.52), but the difference was not statistically significant (t = −1.017, p = 0.310). Similarly, the reduction in PPBC score was comparable between Group A (−1.65 ± 0.86) and Group B (−1.51 ± 0.96),

with no statistically significant difference between the groups ($t = -1.172$, $p = 0.242$). Overall, Group B demonstrated a significantly greater improvement in urinary frequency, whereas the treatment groups showed comparable effects on urinary incontinence and PPBC scores.

Table 2: Treatment Outcomes & Stratified Analyses

Outcome	Group A	Group B	t-value	p-value/t-value
Reduction in urinary frequency	2.00 ± 0.87	2.34 ± 1.33	-2.672	0.005/-2.6
Reduction in urinary incontinence	1.81 ± 0.52	1.96 ± 1.58	-1.017	0.310/-1.0
Reduction in PPBC score	-1.65 ± 0.86	-1.51 ± 0.96	-1.172	0.242/-1.17

Discussion

OAB is a widespread clinical issue, and both solifenacin and mirabegron are drugs that are commonly utilized [18]. In our analysis of 254 patients, the groups were similar except for age, which was significantly greater in Group B. Since age is a known cause of lower urinary tract symptoms, this significant difference should be taken into account when interpreting treatment results. The groups, however, showed no significant differences in the duration of OAB symptoms, indicating that both arms had similar baseline disease burden.

The major conclusion of our work was that the decrease in urinary frequency was much greater in Group B, with the mean number of urinary episodes per day decreasing by 2.34 ± 1.33 episodes per day compared with Group A. This shows that the medication used in Group B was more effective in managing daily urinary frequency. This is consistent with previous research that found mirabegron to offer a greater improvement in quality of life for frequency-associated symptoms than antimuscarinic medications [19]. Although the between-group difference in urinary frequency was statistically significant, its clinical significance should also be considered. The additional reduction in urinary frequency observed with mirabegron was modest; however, even small improvements in urinary frequency may reduce urgency-related discomfort, improve patients' daily activities, and enhance overall quality of life. Therefore, mirabegron may be particularly beneficial for patients in whom urinary frequency is the predominant symptom or for those who prefer a treatment with a favorable tolerability profile. Treatment decisions should also consider patient preferences, comorbidities, and potential adverse effects [18].

Conversely, the reduction in urinary incontinence was not significantly different between groups compared to the reduction in urinary incontinence episodes. Both treatments minimally reduced incontinence, yet neither proved superior on this parameter. This is in line with the international literature, which has reported similar levels of effectiveness for the two agents in the management of urgency incontinence as monotherapy [20].

Likewise, the increase in PPBC was observed in both groups, but the difference between the groups was insignificant. This indicates that a similar subjective perception of improvement was observed with both treatments, though a difference was observed in urinary frequency reduction. There were no significant gender, age, or duration of OAB symptoms-stratified analyses, indicating that there were no significant differences in the pattern of response to treatment among the various demographic and clinical subgroups. This enhances the external validity of our results, demonstrating that neither gender, age, nor disease duration affected the efficacy of the medications. Although a significant baseline age difference was observed between the treatment groups, stratified analyses did not demonstrate any evidence that age modified the treatment effect. Nevertheless, residual confounding cannot be completely excluded because an adjusted multivariable analysis (e.g., ANCOVA) was not performed [19].

On the whole, our findings indicate that either treatment option is effective for OAB, yet patients who received the Group-B medication showed a greater decrease in urinary frequency. The two drugs, however, were similarly effective in treating urinary incontinence and PPBC. These results highlight that not all OAB symptoms can be treated with pharmacological therapy, and that the selection of treatment is significant. Additional multicenter studies with protracted follow-up are advised to investigate comparative effectiveness over time and whether combination

treatment may augment symptom control in patients partially responding to monotherapy.

Despite these findings, several limitations should be acknowledged. First, the study was conducted at a single tertiary care center, which may limit the generalizability of the results to broader populations. Second, the follow-up duration was relatively short [four weeks], which restricts the ability to assess long-term efficacy, safety, and treatment adherence of both agents. Additionally, the open-label design may have introduced potential performance or reporting bias, particularly in patient-reported outcomes such as PPBC scores. Although stratified analyses were performed to explore the potential influence of baseline age differences between the treatment groups, adjusted statistical analyses such as ANCOVA or multivariable regression were not performed. Therefore, the possibility of residual confounding due to the baseline age imbalance cannot be completely excluded. In addition, adverse events, treatment tolerability, and treatment discontinuation were not systematically assessed. Therefore, the comparative safety profiles of solifenacin and mirabegron could not be evaluated in the present study. Future studies should include comprehensive safety assessments alongside efficacy outcomes.

Another limitation is the lack of dose titration or subgroup analysis based on severity of overactive bladder symptoms at baseline. Overactive bladder is a heterogeneous condition, and treatment response may vary according to symptom severity, comorbidities, and patient characteristics. Future studies should incorporate longer follow-up periods, multicenter recruitment, and stratified analyses to better define patient subgroups that benefit most from either solifenacin or mirabegron therapy.

From a clinical perspective, the present findings support the use of both solifenacin and mirabegron as effective pharmacological options for overactive bladder. Although the additional reduction in urinary frequency with mirabegron was modest, it may provide meaningful symptomatic relief for patients whose predominant complaint is urinary frequency. Therefore, treatment selection should be individualized based on symptom profile, patient preferences, comorbidities, anticipated tolerability, and cost considerations to optimize clinical outcomes.

Conclusion

Both solifenacin and mirabegron were effective in improving symptoms of overactive bladder after four weeks of treatment. However, mirabegron demonstrated a significantly greater reduction in urinary frequency, while both medications showed comparable efficacy in reducing urinary incontinence episodes and improving Patient Perception of Bladder Condition (PPBC) scores. These findings suggest that mirabegron may be a preferred treatment option for patients in whom urinary frequency is the predominant symptom, whereas both agents remain appropriate therapeutic choices based on individual patient characteristics, tolerability, and clinical needs. Further multicenter randomized controlled trials with larger sample sizes and longer follow-up are warranted to confirm these findings, evaluate long-term efficacy and safety, and assess treatment adherence, patient-reported quality-of-life outcomes, and cost-effectiveness.

Author Contributions

JK: Conceptualization, study design, data collection, manuscript drafting, and literature review.
UA: Methodology development, statistical analysis, interpretation of results, and critical revision of the manuscript.
SG: Supervision of the study, project administration, validation of findings, manuscript review, and corresponding author responsibilities.
IU: Data acquisition, data management, literature search, and assistance in manuscript preparation.
AS: Statistical support, data interpretation, preparation of tables and figures, and manuscript editing.
GI: Study oversight, critical intellectual input, final review of the manuscript, and approval of the version submitted for publication.
AM: Data collection, literature review, data management, and critical revision of the manuscript.
STB: Data acquisition, interpretation of results, manuscript preparation, and critical revision of the manuscript.
WS: Literature search, data management, manuscript editing, and review of the final manuscript.
RS: Study coordination, data collection, manuscript review, and approval of the final

version.
All authors contributed substantially to the work, reviewed and approved the final manuscript, and agree to be accountable for all aspects of the study.

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