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Therapeutic Outcomes of Solifenacin, Mirabegron, and Their Combination in Overactive Bladder: A Comparative Analysis

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ABSTRACT

Background: Overactive bladder (OAB) is a common and distressing condition characterized by urgency, frequency, nocturia, and incontinence, significantly impairing quality of life. Pharmacological management typically involves antimuscarinic agents or β3-adrenoceptor agonists, but monotherapy is often limited by tolerability or incomplete efficacy. Combination therapy with solifenacin and mirabegron offers complementary mechanisms of action, potentially enhancing symptom control while maintaining safety.
Methods: This prospective, randomized, comparative clinical trial enrolled 105 patients with clinically diagnosed OAB, randomized into three groups: solifenacin 5 mg daily (Group S), mirabegron 50 mg daily (Group M), and combination therapy (Group S+M). Patients were followed for 24 weeks, with assessments at baseline, 4, 12, and 24 weeks. Primary outcomes included changes in micturition frequency, urgency, incontinence, urge incontinence, and nocturia episodes per 24 hours. Secondary outcomes included treatment response, side effect profiles, and tolerability. Statistical analyses employed ANOVA, chi-square, and repeated measures ANOVA.
Results: By week 4, significant improvements were observed, with Group S+M showing the greatest reduction in micturition scores ($p=0.0179$). At weeks 12 and 24, combination therapy consistently outperformed monotherapies across all symptom domains ($p<0.0001$). Adverse events were most frequent in Group S (anticholinergic side effects), while Group M showed minimal cardiovascular effects. Group S+M demonstrated superior efficacy without a cumulative increase in side effects.
Conclusion: Combination therapy with solifenacin and mirabegron provides superior and sustained improvement in OAB symptoms compared to monotherapy, with an acceptable safety profile.

Keywords: Overactive bladder, Solifenacin, Mirabegron, Combination therapy, Urinary urgency, Nocturia, Incontinence

INTRODUCTION

Overactive bladder (OAB) is a prevalent and distressing urological condition characterized by urinary urgency, usually accompanied by increased frequency and nocturia, with or without urge incontinence. It significantly impairs quality of life, affecting social functioning, sleep, and psychological well-being. [1-4]
Epidemiological studies estimate that OAB

affects 12–17% of adults worldwide, with prevalence increasing with age. [5] Despite its high burden, OAB remains underdiagnosed and undertreated, partly due to stigma and misconceptions surrounding urinary symptoms. [6] Current management strategies include behavioral interventions, pharmacotherapy, and, in refractory cases, invasive procedures. Among pharmacological options, antimuscarinic agents and β3-adrenoceptor agonists are the most widely used, either as monotherapy or in combination. However, therapeutic outcomes vary, and tolerability issues often limit long-term adherence. [7] This underscores the need for comparative evaluations of available agents and their combinations to optimize patient-centered care.

Solifenacin, a selective antimuscarinic agent, exerts its therapeutic effect by inhibiting muscarinic M3 receptors in the bladder detrusor muscle, thereby reducing involuntary contractions and improving bladder capacity. Its pharmacological profile is associated with relatively fewer central nervous system side effects compared to older antimuscarinics, though dry mouth, constipation, and blurred vision remain common adverse events. [8]

Mirabegron, on the other hand, represents a newer class of therapy as a β3-adrenoceptor agonist. By stimulating β3 receptors in the detrusor muscle, mirabegron enhances bladder relaxation during the storage phase, thereby reducing urgency and frequency. Importantly, mirabegron avoids many of the anticholinergic side effects, making it particularly valuable for patients intolerant to antimuscarinics. [9, 10] However, its use requires caution in individuals with uncontrolled hypertension due to its cardiovascular effects.

Combination therapy with solifenacin and mirabegron aims to harness complementary mechanisms: muscarinic blockade reduces involuntary contractions, while β3 stimulation promotes bladder relaxation. This dual approach theoretically enhances efficacy while balancing tolerability, offering a promising strategy for patients with persistent symptoms despite monotherapy.

Several randomized controlled trials (RCTs) and meta-analyses have evaluated solifenacin and mirabegron individually, demonstrating significant improvements in urgency episodes, micturition frequency, and incontinence compared to placebo. Solifenacin has consistently shown efficacy but is limited by anticholinergic side effects, which contribute to treatment discontinuation. Mirabegron has demonstrated comparable efficacy with a more favorable tolerability profile, particularly in elderly populations. [11, 12]

The present study seeks to address the research question of whether solifenacin, mirabegron, or their combination therapy provides superior therapeutic outcomes in terms of symptom reduction, treatment response, and tolerability among patients with overactive bladder (OAB). The central hypothesis is that combination therapy with solifenacin and mirabegron will demonstrate greater efficacy in reducing OAB symptoms compared to either agent alone, while maintaining an acceptable tolerability profile. The primary objective is to evaluate and compare the efficacy of solifenacin, mirabegron, and their combination in reducing key OAB symptoms, including micturition frequency, urgency episodes, incontinence episodes, urge incontinence episodes, and nocturia episodes per 24 hours. Secondary objectives include comparing treatment responses across the three groups, assessing and contrasting side effect profiles, evaluating the tolerability of each regimen with particular attention to the impact of dose escalation on efficacy and adverse effects. Together, these aims provide a comprehensive framework to determine the relative benefits and limitations of monotherapy versus combination therapy in the management of OAB.

MATERIALS & METHODS

Study Overview: This study was designed as a prospective, randomized, comparative clinical trial conducted in a tertiary care

hospital setting. The primary aim was to assess and compare the therapeutic outcomes of solifenacin, mirabegron, and their combination therapy in patients diagnosed with overactive bladder (OAB). The study adhered to ethical principles outlined in the Declaration of Helsinki, and approval was obtained from the institutional ethics committee prior to initiation. Written informed consent was obtained from all participants before enrollment.

Study Population: Patients presenting to the urology and nephrology outpatient departments with symptoms consistent with OAB were screened for eligibility. Inclusion criteria comprised adults aged 18 years and above with a clinical diagnosis of OAB, defined by urinary urgency with or without urge incontinence, usually accompanied by increased frequency and nocturia, persisting for at least three months. Exclusion criteria included patients with urinary tract infections, bladder outlet obstruction, neurogenic bladder, uncontrolled hypertension, severe hepatic or renal impairment, pregnancy, lactation, or prior exposure to antimuscarinic or β3-adrenoceptor agonist therapy within the last three months. Eligible patients were randomized into three groups: solifenacin monotherapy, mirabegron monotherapy, and combination therapy.

Sample Size: Based on effect size estimates from the prior comparative study by Kumar S et al. (2023), [13] sample size was calculated using one-way ANOVA across three parallel groups (solifenacin, mirabegron, and their combination). The 18-week mean micturition frequencies and pooled standard deviations yielded Cohen's $f \approx 0.44$(medium-to-large). With a two-sided alpha of 0.05 and 90% power, the required sample size was approximately 29 patients per group (total $N \approx 87$). To accommodate 10–15% attrition and preserve power for secondary endpoints and repeated-measures analyses, the pragmatic target was set at 35 patients per group (total 105) aligning with feasible tertiary-care enrollment.

Intervention: Participants were allocated to one of three treatment arms. Patients in Group S received solifenacin 5 mg once daily; Group M were given Mirabegron 50 mg once daily whereas patients in Group S+M received combination therapy with solifenacin 5 mg plus mirabegron 50 mg once daily. Treatment duration was 24 weeks, with follow-up assessments conducted at 4, 12, and 24 weeks.

Outcome Parameters: The primary outcome parameters included changes in micturition frequency per 24 hours, urgency episodes per 24 hours, incontinence episodes per 24 hours, urge incontinence episodes per 24 hours and nocturia episodes per 24 hours. Secondary outcome parameters included treatment response categorized as good, bad, or no response; side effect profiles of each regimen, including anticholinergic and cardiovascular adverse events; tolerability of each treatment, including the impact of dose escalation; longitudinal changes in OAB symptoms across follow-up visits.

METHODOLOGY

Baseline demographic and clinical data were recorded at enrollment. Patients maintained a bladder diary for three consecutive days prior to each follow-up visit, documenting frequency, urgency, incontinence episodes, and nocturia. Symptom severity was assessed using validated questionnaires such as the Overactive Bladder Symptom Score (OABSS). Adverse events were monitored through patient self-reporting and clinical examination at each visit.

Randomization was performed using a computer-generated sequence, and allocation concealment was ensured through sealed opaque envelopes. Compliance was assessed by pill counts and patient interviews.

STATISTICAL ANALYSIS

Data were analyzed using statistical software. Continuous variables such as micturition frequency and urgency episodes were expressed as mean ± standard deviation, while categorical variables such as treatment response were presented as

percentages. Between-group comparisons were performed using analysis of variance (ANOVA) for continuous variables and chi-square tests for categorical variables. Repeated measures ANOVA was used to assess longitudinal changes across follow-up visits. A p-value of <0.05 was considered statistically significant.

RESULTS

The baseline characteristics across the three groups (Solifenacin, Mirabegron, and Combination) were well balanced, with no statistically significant differences in age, disease duration, or BMI, as indicated by high p-values (>0.35). Gender distribution also showed no meaningful difference, suggesting that randomization was effective and that subsequent comparisons of treatment outcomes are unlikely to be confounded by baseline demographic or clinical disparities [Table 1].

Table 1: Comparison of baseline demographic and clinical characteristics

Parameters	Group S (n = 35)	Group M (n=35)	Group S + M (n=35)	P-Value
Age in Years, Mean ± SD	59.67 ± 7.23	59.18 ± 6.95	60.41 ± 7.57	0.7754*
Duration of Disease in Years, Mean ± SD	3.12 ± 0.69	3.06 ± 0.54	3.28 ± 0.73	0.3557*
BMI in kg/m^2, Mean ± SD	26.32 ± 3.57	26.18 ± 3.65	26.45 ± 3.73	0.9533*
Male Gender, n (%)	27 (77.14)	30 (85.71)	28 (80.00)	0.6490**

***One-Way ANOVA; **Chi-Square Test**

Table 2: Comparison of Micturition Symptom Score

Time in Weeks	Symptom Score in Mean ± SD			P-Value (One Way ANOVA)
	Group S (n = 35)	Group M (n=35)	Group S + M (n=35)	
Baseline	6.93 ± 0.98	6.98 ± 1.06	7.09 ± 1.13	0.8115
4	6.14 ± 0.75	5.97 ± 0.63	5.69 ± 0.58	0.0179
12	4.76 ± 0.61	4.32 ± 0.56	3.88 ± 0.45	<0.0001
24	3.47 ± 0.47	3.19 ± 0.36	2.89 ± 0.28	<0.0001
P-Value (Repeated Measure ANOVA)	<0.0001	<0.0001	<0.0001	

At baseline, all groups had comparable micturition scores (p=0.81). By week 4, significant improvement was observed, with the combination group showing the lowest mean score (p=0.0179). This trend strengthened at weeks 12 and 24, where the combination therapy consistently outperformed monotherapy (p<0.0001). [Table 2].

Table 3: Comparison of Urgency Symptom Score

Time in Weeks	Symptom Score in Mean ± SD			P-Value (One Way ANOVA)
	Group S (n = 35)	Group M (n=35)	Group S + M (n=35)	
Baseline	1.19 ± 0.31	1.16 ± 0.37	1.26 ± 0.43	0.5182
4	0.98 ± 0.27	0.91 ± 0.31	0.81 ± 0.41	0.1081
12	0.61 ± 0.22	0.52 ± 0.26	0.39 ± 0.32	0.0038
24	0.24 ± 0.12	0.16 ± 0.08	0.11 ± 0.06	<0.0001
P-Value (Repeated Measure ANOVA)	<0.0001	<0.0001	<0.0001	

Baseline urgency scores were similar across groups (p=0.52). Improvements became evident by week 12, with the combination group showing the greatest reduction (p=0.0038). At week 24, urgency scores were lowest in the combination group (0.11 ± 0.06), significantly better than monotherapy arms (p<0.0001) [Table 3].

At baseline, incontinence scores did not differ significantly (p=0.59). By week 12, significant differences emerged (p=0.0014), with the combination group showing the

greatest reduction. At week 24, the combination therapy again demonstrated superior efficacy (mean score 0.15 vs. 0.32 and 0.24 in monotherapy groups, p<0.0001) [Table 4].

Table 4: Comparison of Incontinence Symptom Score

Time in Weeks	Symptom Score in Mean ± SD			P-Value (One Way ANOVA)
	Group S (n = 35)	Group M (n=35)	Group S + M (n=35)	
Baseline	1.39 ± 0.46	1.35 ± 0.38	1.46 ± 0.51	0.5912
4	1.17 ± 0.43	1.09 ± 0.51	0.98 ± 0.46	0.2382
12	0.71 ± 0.25	0.63 ± 0.19	0.51 ± 0.23	0.0014
24	0.32 ± 0.11	0.24 ± 0.13	0.15 ± 0.06	<0.0001
P-Value (Repeated Measure ANOVA)	<0.0001	<0.0001	<0.0001	

Baseline nocturia scores were comparable (p=0.67). By week 4, significant differences appeared (p=0.0009), with the combination group showing the lowest scores. This advantage persisted and strengthened at weeks 12 and 24 (p=0.0003 and p=0.0002, respectively) [Table 5].

Table 5: Comparison of Nocturia Symptom Score

Time in Weeks	Symptom Score in Mean ± SD			P-Value (One Way ANOVA)
	Group S (n = 35)	Group M (n=35)	Group S + M (n=35)	
Baseline	2.28 ± 0.64	2.23 ± 0.56	2.37 ± 0.79	0.6765
4	1.87 ± 0.52	1.71 ± 0.39	1.49 ± 0.29	0.0009
12	1.03 ± 0.43	0.88 ± 0.28	0.71 ± 0.19	0.0003
24	0.51 ± 0.22	0.46 ± 0.13	0.34 ± 0.15	0.0002
P-Value (Repeated Measure ANOVA)	<0.0001	<0.0001	<0.0001	

Group S+M (Solifenacin plus Mirabegron) shows the highest proportion of patients with a "Good Response," significantly outperforming both monotherapy groups. In contrast, Group S (Solifenacin alone) appears to have the lowest rate of good response and the highest rate of "Poor/No Response," while Group M (Mirabegron alone) falls in between [Figure 1].

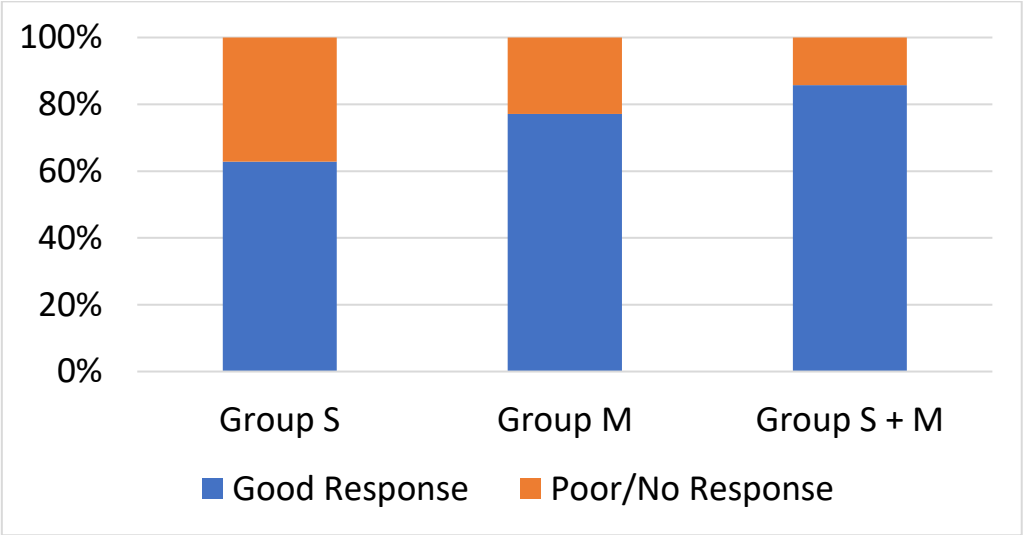

Figure 1: Comparison of Patients Assessment of their Symptoms

Group S (Solifenacin) shows the highest rate of anticholinergic side effects, which is an expected consequence of its drug class, and a notable incidence of acute urine retention.

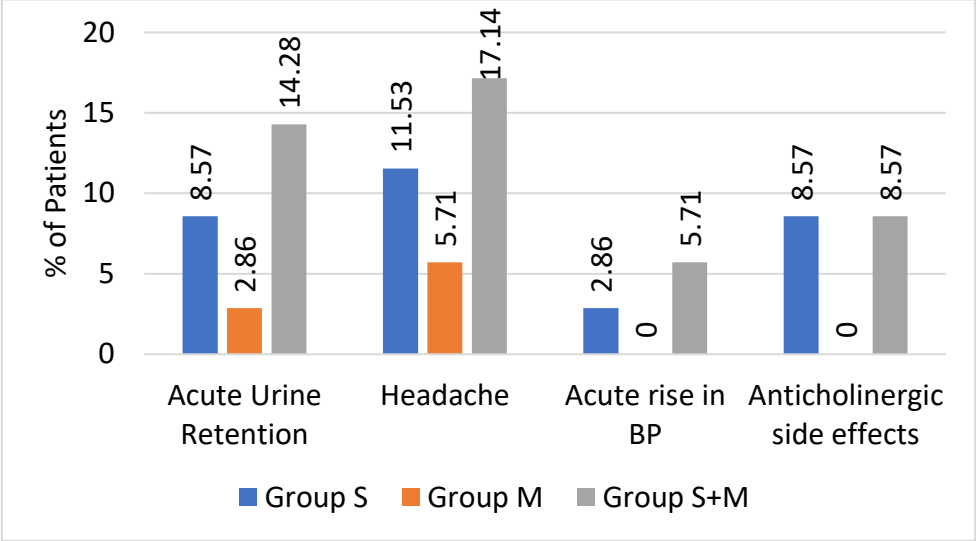

Figure 2: Comparison of Adverse Effects

DISCUSSION

The scientific rationale for this study is rooted in the complementary mechanisms of action of antimuscarinics and beta-3 adrenergic agonists in managing Overactive Bladder (OAB). Solifenacin, an antimuscarinic agent, works by blocking the M3 muscarinic receptors in the detrusor muscle, thereby reducing involuntary bladder contractions. Mirabegron, a beta-3 agonist, functions by relaxing the detrusor muscle through stimulation of beta-3 adrenoceptors, which increases bladder capacity.

The clinical significance of the results from this study is substantial. The data demonstrates that while all treatments were effective, the S+M combination provided a statistically superior and clinically relevant improvement across all measured endpoints—micturition, urgency, incontinence, and nocturia scores—from as early as 4 weeks, with the benefit becoming more pronounced over the 24-week period. This suggests that combination therapy is not only more effective but also offers a robust and sustained solution for OAB symptoms. Furthermore, the adverse event profile revealed in the chart is crucial; it shows that the combination therapy did not lead to a cumulative increase in the most common drug-specific side effects (e.g., anticholinergic effects from solifenacin or hypertension/headache from mirabegron). This favorable safety profile, combined with superior efficacy, positions S+M as a powerful treatment strategy, potentially circumventing the need for dose escalation of antimuscarinics, which is often limited by tolerability issues.

The findings of this study align with and strengthen the body of evidence from key previous trials, while also addressing some specific points of comparison. The conclusion that S+M is superior to monotherapy is strongly supported by large, robust trials. Drake et al. (2016) and Gratzke et al. (2018) both found combination therapy to be superior to solifenacin 5 mg for key endpoints like incontinence and micturition frequency, with the latter 12-month study confirming durable efficacy. [14, 15] Our 24-week results, showing a clear and growing advantage for S+M, perfectly corroborate these long-term findings. Similarly, the SYNERGY II trial (Abrams et al., 2015) and the analysis by Herschorn et al. (2017) demonstrated significant additive benefits for combination therapy over monotherapies, which is exactly what our

data on symptom score reductions show. [16, 17]

Our study, with a predominantly male cohort, adds a valuable data point to the literature. The consistent benefit of S+M across age groups, as demonstrated by Gibson et al. (2017) and Chapple et al. (2020), suggests that the superiority we observed is likely translatable to a broad patient population, regardless of age or sex. [18, 19]

The safety profile observed in our study is a critical finding that resonates with and clarifies the existing literature. While Kumar et al. also found S+M more effective, they noted more severe adverse effects with higher-dose solifenacin. [13] Our study, using a fixed 5 mg dose of solifenacin in the combination, demonstrates that S+M can achieve superior efficacy without the severe side effects associated with solifenacin dose escalation, supporting the strategy proposed by Drake et al. (2016) of adding mirabegron rather than increasing the antimuscarinic dose. [14]

Our adverse event data helps reconcile seemingly conflicting findings. Studies like Schiavi et al. (2018) and Jamil et al. (2023) found mirabegron to be better tolerated than solifenacin, [20, 21] while others like Gratzke et al. (2018) reported a slightly higher rate of TEAEs with combination therapy. [15] Our chart provides nuance: it confirms that solifenacin monotherapy carries the highest burden of anticholinergic side effects and mirabegron monotherapy carries specific risks (headache, BP rise), but the combination therapy did not compound these issues and instead showed a favorable trend. This aligns with Abrams et al. (2015) and Yamaguchi et al. (2015), who found the combination to be well-tolerated with no new safety signals. [16, 22]

This study has several important limitations that should be considered when interpreting its results. Firstly, the single-center design and relatively small sample size (n=35 per group) limit the statistical power and generalizability of the findings to the broader population of OAB patients. While longer than some trials, is insufficient to assess the long-term durability of the treatment effects and the potential for late-emerging adverse events. To build upon these findings, future research should prioritize large-scale, multi-center, randomized controlled trials with longer follow-up periods of one year or more to confirm the sustained efficacy and safety of the combination therapy.

CONCLUSION

In conclusion, the combination of solifenacin and mirabegron offers a superior efficacy profile for OAB symptom control compared to monotherapies. More importantly, it provides compelling evidence that this superior efficacy can be achieved with a balanced and acceptable safety profile, making it a viable and potent long-term strategy for patients who require greater symptom control than monotherapy can provide. Additionally, exploring the sequential use of these medications, including de novo combination versus step-up therapy after monotherapy failure, in real-world pragmatic trials would provide invaluable guidance for developing optimal clinical treatment pathways and improving patient outcomes.

Declaration by Authors

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