ISSN Print: 2394-7500
ISSN Online: 2394-5869
Impact Factor: 5.2
IJAR 2017; 3(11): 554-556
www.allresearchjournal.com
Received: 15-09-2017
Accepted: 20-10-2017

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Comparison of the effects of Solifenacin and Mirabegron for the treatment of overactive bladder

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Abstract
Background: Overactive bladder (OAB) is a common urological condition that significantly impacts patients' quality of life. Solifenacin, an antimuscarinic agent, and Mirabegron, a β3-adrenergic receptor agonist, are two commonly prescribed treatments. This study compares the efficacy and safety of Solifenacin and Mirabegron in the management of overactive bladder.
Methods: This comparative study was conducted Department of Urology at Bangabandhu Sheikh Mujib Medical University (BSMMU), Shahbag, Dhaka, Bangladesh, from January 2015 to December 2015, involving 90 randomly selected patients diagnosed with OAB. Participants were divided into two groups: Group 1 (n=45) received Solifenacin, and Group 2 (n=45) received Mirabegron. Efficacy was assessed based on changes in frequency, urgency, nocturia episodes, and quality of life (QoL) scores. Adverse effects were also recorded. Data were analyzed using SPSS version 21.0 program.
Results: After 12 weeks of treatment, both Solifenacin and Mirabegron significantly improved overactive bladder (OAB) symptoms. Mirabegron showed a greater reduction in urgency episodes (4.6±1.2 vs. 3.9±1.5 per day, $p< 0.05$) and nocturia episodes (1.7±0.8 vs. 1.2±0.9, $p< 0.05$). Solifenacin had higher rates of dry mouth (37.8%) and constipation (22.2%), while Mirabegron was better tolerated with fewer side effects.
Conclusion: This study highlights the efficacy of both Solifenacin and Mirabegron in managing overactive bladder symptoms. Mirabegron demonstrated better tolerability with fewer side effects, while Solifenacin was effective but associated with higher adverse events. Mirabegron may be preferable for patient's intolerant to anticholinergic effects, warranting further long-term evaluation.

Keywords: Overactive bladder, solifenacin, mirabegron, urgency, nocturia, quality of life

Introduction
Overactive bladder (OAB) is a common urological disorder marked by a sudden urge to urinate, frequent urination, nighttime urination (nocturia), and, in some cases, urge incontinence [1]. This condition significantly impacts quality of life by disrupting daily activities, sleep, and emotional well-being [2]. The prevalence of OAB increases with age and is observed in both men and women, though it is more commonly reported in women [3]. The pathophysiology of OAB is complex, involving detrusor overactivity resulting from neurogenic, myogenic, and urothelial factors [4]. The primary pharmacological treatment options for OAB include antimuscarinic agents and β3-adrenoceptor agonists. Solifenacin, a frequently prescribed antimuscarinic, inhibits M3 receptors in the bladder, thereby reducing detrusor overactivity [5]. It has been shown to effectively alleviate OAB symptoms; however, its use is often restricted due to adverse effects such as dry mouth and constipation [6]. On the other hand, Mirabegron, a β3-adrenoceptor agonist, facilitates bladder relaxation and enhances storage capacity while causing fewer anticholinergic side effects [7]. Research indicates that Mirabegron offers comparable efficacy to antimuscarinic agents but with improved tolerability, making it a preferred option for patients who experience side effects from antimuscarinics [8]. Multiple comparative studies have evaluated the efficacy and safety of Solifenacin and Mirabegron in individuals with OAB. A study demonstrated that both medications significantly reduced urgency episodes; however, Mirabegron was linked to fewer treatment-related adverse effects [9]. Another study highlighted Mirabegron's favorable safety profile, noting its minimal impact on cognitive function, which is particularly relevant for elderly patients [10].

Nevertheless, some research suggests that antimuscarinics like Solifenacin may provide a slightly greater reduction in urgency episodes compared to Mirabegron [11]. With the increasing emphasis on personalized treatment approaches, comparative data on these medications are crucial for helping clinicians choose the most appropriate therapy. This study aimed to evaluate the effects of Solifenacin and Mirabegron in OAB patients, focusing on symptom relief, adverse effects, and overall patient satisfaction. By assessing these factors, the study seeks to enhance pharmacological management strategies for individuals with OAB.

Methodology

This comparative, randomized study was conducted in the Department of Urology at Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh, from January 2015 to December 2015. A total of 90 patients diagnosed with overactive bladder (OAB) were randomly assigned into two groups: Group 1 (n=45) received Solifenacin, while Group 2 (n=45) received Mirabegron for 3 months. Patients were selected based on predefined inclusion and exclusion criteria. Inclusion criteria included adult patients (≥18 years) with clinically diagnosed OAB, experiencing symptoms for at least three months. Patients with urinary tract infections, bladder outlet obstruction, renal or hepatic impairment, or those on conflicting medications were excluded. Data were collected through patient interviews, clinical examinations, and validated questionnaires assessing symptom severity, quality of life, and adverse effects. Treatment outcomes were evaluated at baseline and after 12 weeks using parameters such as urgency episodes, voiding frequency, nocturia, and adverse events. Ethical approval was obtained from the institutional review board, and informed consent was secured from all participants. Statistical analysis was performed using SPSS version 21.0 program, applying descriptive statistics and comparative tests to assess the efficacy and tolerability of both drugs.

Results

This study included 90 patients diagnosed with overactive bladder (OAB) who were randomly assigned to two treatment groups: Group 1 (Solifenacin, n=45) and Group 2 (Mirabegron, n=45). The mean age of participants in Group 1 was 54.3±9.5 years, whereas in Group 2, it was 55.1±8.8 years (Table 1). The gender distribution was similar in both groups, with a slight female predominance (Table 1). The baseline characteristics, including body mass index (BMI), duration of OAB symptoms, and comorbid conditions such as hypertension and diabetes, were comparable between the two groups (Table 2). The mean OAB symptom duration was 2.8±1.4 years in Group 1 and 2.7±1.3 years in Group 2, showing no significant difference. After 12 weeks of treatment, both groups showed significant improvement in OAB symptoms. However, the mean reduction in urgency episodes was 4.6±1.2 per day in the Mirabegron group compared to 3.9±1.5 per day in the Solifenacin group, showing a statistically significant difference ($p< 0.05$) (Table 3). Similarly, the mean reduction in nocturia episodes was 1.7±0.8 in the Mirabegron group versus 1.2±0.9 in the Solifenacin group ($p< 0.05$) (Table 3). Adverse events were reported in both groups, with a higher incidence of dry mouth and constipation in the Solifenacin group (37.8% and 22.2%, respectively), while Mirabegron was associated with a lower rate of side effects, the most common being mild hypertension (15.6%) (Table 4). Patient-reported satisfaction was slightly higher in the Mirabegron group (88.9%) compared to the Solifenacin group (80.0%) (Table 5). Treatment adherence was comparable between both groups.

Table 1: Demographic characteristics of the study population

Characteristics	Solifenacin	Mirabegron	p-value
Mean age (years)	54.3±9.5	55.1±8.8	0.57
Male, n (%)	18 (40.0%)	20 (44.4%)	0.68
Female, n (%)	27 (60.0%)	25 (55.6%)	0.72

Table 2: Baseline clinical characteristics

Characteristics	Solifenacin	Mirabegron	p-value
BMI (kg/m²)	26.7±3.5	26.2±3.8	0.49
OAB symptom duration (years)	2.8±1.4	2.7±1.3	0.64
Hypertension, n (%)	14 (31.1%)	12 (26.7%)	0.65
Diabetes, n (%)	10 (22.2%)	9 (20.0%)	0.78

Table 3: Symptom improvement after 12 weeks of treatment

Symptoms	Solifenacin	Mirabegron	p-value
Reduction in urgency episodes (per day)	3.9±1.5	4.6±1.2	0.03*
Reduction in nocturia episodes	1.2±0.9	1.7±0.8	0.02*
Increase in mean voided volume (mL)	43.5±8.3	48.1±9.5	0.04*

*Significant at $p< 0.05$

Table 4: Adverse events reported in both groups

Adverse Events	Solifenacin	Mirabegron	p-value
Dry mouth	17 (37.8%)	5 (11.1%)	0.002*
Constipation	10 (22.2%)	4 (8.9%)	0.04*
Hypertension	2 (4.4%)	7 (15.6%)	0.03*
Headache	4 (8.9%)	5 (11.1%)	0.71

Discussion

Overactive bladder (OAB) significantly affects quality of life, highlighting the need for effective pharmacological treatments. This study evaluates the efficacy and safety of Solifenacin and Mirabegron, two widely used medications for OAB. Findings suggest that both drugs alleviate symptoms, but Mirabegron offers a more favorable safety profile with fewer adverse effects. Solifenacin, an anticholinergic agent, functions by inhibiting muscarinic receptors in the bladder, thereby reducing detrusor overactivity [12]. This mechanism effectively minimizes urgency, frequency, and incontinence episodes, consistent with previous studies supporting its efficacy in OAB management [13, 14]. However, concerns regarding anticholinergic side effects—such as dry mouth, constipation, and blurred vision—persist, often affecting patient adherence [15]. Our study found that a considerable number of patients in the Solifenacin group experienced these side effects, aligning with previous research [16]. In contrast, Mirabegron, a β3-adrenergic agonist, promotes detrusor muscle relaxation during the storage phase, increasing bladder capacity without inducing muscarinic-related side effects [17]. Patients receiving Mirabegron in our study reported fewer adverse effects and better tolerability, supporting prior findings that emphasize its safety advantage over anticholinergic agents [18, 19]. Additionally, studies suggest that Mirabegron offers symptom relief comparable to Solifenacin while reducing the likelihood of treatment discontinuation due to adverse effects [20]. Our

findings align with these observations, further supporting Mirabegron as a suitable alternative for OAB patients who cannot tolerate anticholinergic medications. A comparison of efficacy between the two drugs shows that both significantly reduce urgency episodes, micturition frequency, and nocturia. However, patients in the Solifenacin group experienced a slightly greater mean reduction in urgency episodes, consistent with previous studies highlighting Solifenacin's strong antimuscarinic effects [21]. Despite this benefit, Mirabegron's superior tolerability suggests it may improve long-term adherence, which is crucial for managing chronic OAB [22, 23]. Cardiovascular safety is another key consideration. Antimuscarinic agents, including Solifenacin, have been linked to an increased risk of cardiovascular events, particularly in elderly patients [24]. In contrast, while Mirabegron has been associated with mild elevations in blood pressure in some cases, its overall cardiovascular risk is lower than that of anticholinergic drugs [25, 26]. In our study, Mirabegron users exhibited a small but statistically non-significant increase in blood pressure, consistent with previous research [27].

Limitations

The limitations of this study include its relatively short duration and small sample size, which may restrict the generalizability of the findings. Long-term studies with larger cohorts are needed to validate these results and assess the sustained efficacy and safety profiles of both drugs. Additionally, patient adherence and satisfaction should be explored in real-world settings to further determine the practical benefits of each medication.

Conclusion & Recommendation

This study demonstrates that both Solifenacin and Mirabegron effectively improve overactive bladder (OAB) symptoms. However, Mirabegron provides superior reductions in urgency and nocturia episodes with a better safety profile. Solifenacin remains effective but is associated with higher rates of dry mouth and constipation. These findings suggest that Mirabegron may be a preferable option for patients' intolerant to anticholinergic side effects. Further long-term studies are necessary to evaluate sustained efficacy and safety outcomes in diverse patient populations.

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