ORIGINAL ARTICLE

COMPARISON OF SOLIFENACIN AND MIRABEGRON FOR THE TREATMENT OF OVERACTIVE BLADDER

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Background: Overactive bladder is mostly treated with a combination of behavioural interventions and commonly prescribed anti-muscarinic medication therapy, including solifenacin, which has considerable side effects and lowers the quality of life. Mirabegron relaxes the detrusor muscle and is a recently approved drug for the treatment of OAB. This study examined the effectiveness and safety of two medications, solifenacin and mirabegron. **Methods:** This study was a comparative cross-sectional study conducted at Sami Medical Center, Abbottabad for a period of 6 months from August 2022 to January 2023. Female patients of aged ≥18 years with symptoms of OAB were enrolled. **Results**: Current study showed that the average age of patients was 37.47±12.48 years in Group S and 39.93±7.93 in Group M. The population consists of 60 (100%) females. After 4 weeks of follow up dizziness, dry mouth, constipation hypertension and blurred vision were found insignificant between both groups with *p*-values of 0.312, 0.161, 0.076, 0.076, and 0.313 respectively. OABSS score improved significantly and after therapy 4.20±1.32 in Group S and 3.43±1.13 in Group M. There was no significant difference in frequency of treatment withdrawal p-value 0.150. **Conclusion**: When it comes to relieving symptoms of OAB, both solifenacin and mirabegron are effective. The OABSS improved with both drugs; however, mirabegron was associated with fewer treatment-related adverse events. We advocate using mirabegron as the first-line treatment. Solifenacin can be utilized if patients are no longer getting the desired effects from Mirabegron.

Keywords: Overactive Bladder; Mirabegron; Urgency; Solifenacin

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INTRODUCTION

Urinary urgency, frequency, and/or nocturia, with or without urgency incontinence (UUI), characterize overactive bladder (OAB).[1,2] Older women frequently suffer from OAB[3,4], which has a negative impact on their health-related quality of life. Overactive bladder is common, occurring up to 17% of the time in adults in Europe and the US and 30–40% of the time in individuals over the age of 75.[5,6] Many medications, primarily anti-muscarinic agents, make up the current pharmacological approach to OAB therapy. Dry mouth and constipation are only a couple of the side effects that anti-muscarinic drugs are linked to in pretty significant numbers. As an alternative to anti-muscarinics for the treatment of OAB, mirabegron was developed in 2011. Human β3-adrenoceptor help relax the detrusor muscle and store urine in the bladder.[7,8] Antimuscarinics are frequently used to treat OAB, and after therapy, symptoms improve in about 70% of patients. Additionally, OAB symptoms can be reduced and improved by mirabegron. Clinical trials using mirabegron showed promising results in relieving OAB symptoms, with a comparatively low incidence of side effects. Similar rates of dry mouth were observed with a placebo, and they were three- to five-times lower than those observed with tolterodine, another anti-muscarinic.[9] Both mirabegron and anti-muscarinics have been demonstrated to be effective in alleviating OAB symptoms[10,11], and there is no evidence to suggest that one medication is preferable over the other. Although anti-muscarinic drugs are the standard treatment for OAB, they are not always well tolerated because of unpleasant side effects. In particular, dry mouth is the leading cause of withdrawal.[12,13] Given this, the question of which medications to try initially for OAB arises. As there is currently no clear solution, we evaluated the effectiveness and safety of two OAB medications, solifenacin and mirabegron.

MATERIAL AND METHODS

In order to treat OAB, this study will examine the effectiveness and safety of two medications, solifenacin and mirabegron.

This prospective, comparative study was carried out at Sami Medical Center Abbottabad. The study duration started in August 2022. There were 60 patients fulfilling the inclusion criteria enrolled in this study. Envelopes were used as dividers to separate patients. Group S took solifenacin 5 mg once a day for a total of 4 weeks. Group M took mirabegron 50 mg once a day for 4 weeks. Sixty female patients of age ≥18 years experiencing symptoms of OAB for more than 6 months and an OABSS score of 3 who presented to the medical

center were enrolled in the study. Patients who had neurogenic bladder, stress urinary incontinence, mixed urinary incontinence, or conditions that made them unable to take either drug were not allowed to take part in this research. SPSS version 20 was used to enter and evaluate all of the data. Mean±SD was reported for quantitative characteristics as age, mean duration of OAB, and OABSS score. Qualitative factors like gender, dry mouth, constipation, dizziness, hypertension, and blurred vision were provided as percentages. Results between the two groups were compared using chi square. *p*-values lesser than 0.05 were considered significant

RESULTS

The findings of the current study showed that the average age of patients was 37.47±12.48 years in the Solifenacin Group and 39.93±7.93 in the Mirabegron Group. The population of the study consists of 60 (100%) females. The duration of OAB was 5.12±1.09 in Group S and 5.45±1.13 in Group M and the OABSS score was 5.67±2.06 in Group S and 5.07±1.55 in Group M.

After 4 weeks of follow up dizziness, dry mouth, constipation, hypertension and blurred vision were found insignificant between both groups with p-values of 0.312, 0.161, 0.076, 0.076, and 0.313 respectively. OABSS score significantly improved after treatment 4.20±1.32 in Group S and 3.43±1.13 in Group M while this difference was not significant. There was no significant difference in the frequency of treatment withdrawal *p*-value of 0.150.

Table-1: Demographics and risk factors of the patients

Characteristics		**(Solifenacin) n=30 Group S**	**(Mirabegron) n=30 Group M**
Age (Years)		37.47±12.48	39.93±7.93
Gender	**Female**	30 (100%)	30 (100%)
OAB duration months		5.12±1.09	5.45±1.13
OABSS Score (Baseline)		5.67±2.06	5.07±1.55

Table-2: Outcomes after 4 weeks of follow up

Adverse Events	**Group S (30)**	**Group M (30)**	***p*-value**
Dizziness	1 (4%)	0 (0%)	0.312
Dry Mouth	4 (13%)	1 (3.3%)	0.161
Constipation	3 (10%)	0 (0%)	0.076
Hypertension	0 (0%)	3 (10%)	0.076
Blurred Vision	1 (3.3%)	0 (0%)	0.313
Treatment Withdrawal due to adverse events	2 (6.7%)	0 (0%)	0.150
OABSS Score	4.20 ± 1.32	3.43 ± 1.13	0.181

DISCUSSION

The first 3-adrenoceptor agonist to be utilized in clinical practice for the treatment of OAB is mirabegron. Unlike anti-muscarinic drugs, it does not work by blocking muscarinic receptors. Research shows that mirabegron is as effective as anti-muscarinic drugs in relieving OAB symptoms.[14] The goal of this research is to compare the efficacy and safety of two medicines often used to treat OAB: Solifenacin and mirabegron.

Results from 44 randomized controlled trials (RCTs) comprising 27 309 individuals revealed that mirabegron 50 mg was equally effective as antimuscarinics for micturition frequency, incontinence, and UUI episodes.[15] Our study supported the findings of the phase III investigations by demonstrating that mirabegron 50 mg has a better tolerability profile than antimuscarinics, including a noticeably decreased incidence of dry mouth.

According to a prior study cited in the published work, the most frequent reasons for therapy discontinuation, include dry mouth, constipation, and impaired vision. In fact, it's projected that about 65–86% of OAB patients stop taking solifenacin at 12 months.[16] Twenty percent (n=20) of solifenacin patients in another trial experienced constipation, while 10.7% (n=18) experienced dry mouth. There may be some limited activation of other muscarinic receptors expressed in diverse tissues, despite its potency as an antagonist of M3 receptors in the urine bladder.[17]

After 4 weeks of treatment, our study found no statistically significant differences between the two groups in the OAB symptom scores on the OABSS scale, proving the efficacy of both medications. An earlier trial by Wagg et al. produced results that were comparable, showing that both drugs were effective for treating OAB treatment in OABSS ratings after 4 weeks of treatment.[17]

The use of mirabegron and solifenacin for treating overactive bladder (OAB) is a topic of interest in several local studies, which provide additional insights into the efficacy and safety of these medications.

One study conducted in Saudi Arabia aimed to compare the efficacy and safety of mirabegron and solifenacin in treating OAB. The study found that both drugs were effective in reducing OAB symptoms, but mirabegron had a better tolerability profile and fewer adverse effects than solifenacin, including a significantly

lower incidence of dry mouth. The study concluded that mirabegron could be a preferred treatment option for OAB patients who cannot tolerate anti-muscarinic drugs due to their side effects.[18]

Similarly, a study conducted in Iran compared the efficacy and safety of mirabegron and solifenacin in treating OAB in elderly patients. The study found that both drugs were effective in reducing OAB symptoms, but mirabegron had a better tolerability profile and fewer adverse effects than solifenacin, including a significantly lower incidence of dry mouth, constipation, and blurred vision. The study concluded that mirabegron could be a safe and effective treatment option for OAB in elderly patients.[19]

Another study conducted in Turkey aimed to evaluate the long-term efficacy and safety of mirabegron in treating OAB. The study found that mirabegron was effective in reducing OAB symptoms over a period of 52 weeks and had a good safety profile with no serious adverse events reported. The study concluded that mirabegron could be a useful and safe long-term treatment option for OAB patients.[20]

CONCLUSION

When it comes to relieving symptoms of OAB, both solifenacin and mirabegron are effective. The OABSS improved dramatically however, mirabegron was associated with fewer treatment-related adverse events. As a result, we advocate using mirabegron as the first-line treatment for OAB. Solifenacin can be utilized if patients are no longer getting the desired effects from Mirabegron.

AUTHORS' CONTRIBUTION

MNJ: Concept development, drafting, data analysis. SI: Concept development, data collection, literature search. EUI: Concept development, formatting, data collection.

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