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The comparison of outcomes of solifanacin plus behavioral therapy versus Mirabegron alone in management of overactive bladder

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ABSTRACT

BACKGROUND & OBJECTIVE: Overactive bladder is a prevalent condition that significantly impacts patients' quality of life. While pharmacological treatments are commonly used, combining medication with behavioral therapy may offer enhanced symptom management. The aim of this study is to compare the outcomes of a combination treatment—solifenacin plus behavioral therapy versus mirabegron alone in the management of Overactive Bladder.

METHODOLOGY: This is an Experimental study conducted in Out-patient department of Urology, Sheikh Zayed Hospital, Rahim Yar khan on 60 patients, diagnosed with persistent over active bladder symptoms. Group I was given Solifenacin combined with behavioral therapy, and Group II was given mirabegron alone for 12 weeks. The frequency of micturition episodes, episodes of urgency, and episodes of nocturia per 4 hours was assessed in both groups. Data was analyzed using SPSS 25.0.

RESULTS: In the study, the mean age of the sample was 52.4 ± 13.2 years. The mean micturition frequency was reduced from baseline 9.872 ± 0.215 in the Solifenacin group and 9.800 ± 0.278 in the Mirabegron group to 4.760 ± 0.129 vs 6.283 ± 0.029 ($p \leq 0.001$) after 12 weeks. The nocturia frequency per 24 hours changed from 2.065 ± 0.33 vs 2.410 ± 0.48 to 0.520 ± 0.16 vs 0.180 ± 0.07 ($p < 0.01$), and urgency episodes per 24 hours changed from 2.065 ± 0.331 vs 2.410 ± 0.482 to 0.180 ± 0.078 vs 0.520 ± 0.162($p \leq 0.001$), respectively.

CONCLUSION: The combination of Solifenacin and behavioral therapy offers a more effective and holistic approach to managing OAB symptoms compared to Mirabegron alone.

KEYWORDS: Urinary Bladder, Solifenacin Succinate, Behavior Therapy, Treatment Outcome.

INTRODUCTION

Overactive bladder (OAB) is a condition characterized by a sudden and uncontrollable urge to urinate, often accompanied by increased urinary frequency and nocturia (waking up at night to urinate), with or without episodes of urgency incontinence [1]. The global prevalence of OAB has crossed 20% with women more commonly diagnosed with this disease than men [2]. The impact of OAB extends beyond the physical symptoms, profoundly affecting multiple aspects of life. Health-related quality of life (HRQL) is notably diminished in people with OAB, as they may experience disruptions to their daily routines, social activities, and sleep patterns. The psychological toll of OAB is equally concerning, with many individuals experiencing heightened anxiety and depression [3].

Bladder emptying is a coordinated process involving afferent signaling from the bladder to the brain, central nervous system modulation, and parasympathetic activation of the detrusor muscle. In overactive bladder (OAB), this delicate balance is disrupted due to afferent nerve abnormalities and cholinergic hypersensitivity mediated by M2 and M3 muscarinic receptors, leading to symptoms such as urinary urgency, frequency, and urge incontinence [4]. Treatment options for OAB encompass a range of behavioral, pharmacological, and minimally invasive interventions. Lifestyle modifications, bladder retraining, and pelvic floor exercises form the cornerstone of first-line therapy, as recommended by clinical guidelines. These behavioral therapies are non-invasive, free from side effects, and have been shown to effectively reduce symptoms, particularly urge incontinence [5].

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Pharmacological treatments for overactive bladder (OAB) primarily target the underlying pathophysiological mechanisms contributing to symptoms such as urgency, frequency, and urge incontinence [6]. Antimuscarinic agents, including oxybutynin, tolterodine, and solifenacin, act by blocking M2 and M3 muscarinic receptors in the bladder. These receptors mediate detrusor muscle contractions, and their inhibition helps regulate bladder activity, thereby reducing involuntary contractions and improving storage capacity. While effective, the use of antimuscarinic agents is associated with a range of side effects that includes dry mouth, constipation, and blurred vision. Moreover, prolonged high-dose use, particularly in older adults, has been linked to potential cognitive risks, emphasizing cautious prescribing in this population [7].

An alternative pharmacological approach is mirabegron, a selective β3-adrenergic receptor agonist introduced globally in the early 2010s. By activating β3 receptors, mirabegron promotes bladder relaxation, reduces urgency episodes, and improves storage without affecting muscarinic pathways, with minimal side effects reported [8]. For cases refractory to oral medications, botulinum toxin injections into the detrusor muscle remain a valuable alternative, offering localized, reversible reduction in detrusor overactivity and symptom relief.

A quasi-experimental study has demonstrated statistically significant improvements in OAB symptoms in Group A, which received Mirabegron 25 mg, compared to Group B, treated with Solifenacin 5 mg. Key findings included a decrease in micturition frequency per 24 hours (4.32 ± 1.58 vs. 2.73 ± 1.37, p = 0.001), episodes of urgency per 24 hours (2.51 ± 0.98 vs. 1.73 ± 0.58, p = 0.001), urge incontinence episodes per 24 hours (1.94 ± 0.48 vs. 1.51 ± 0.55, p = 0.001), and nocturia episodes per 24 hours (1.89 ± 0.43 vs. 1.51 ± 0.66, p = 0.002) [9]. Similarly, in the SOLAR (SOLifenacin Alone and with simplified bladder Re-Training) trial, a multi-center, prospective, randomized, parallel-group, open-label study, it was observed that by week 8, solifenacin 5 mg alone reduced the mean number of micturitions per 24 hours by 2.09 from a baseline of 11.50. When combined with simplified bladder training, the reduction was greater, with a mean decrease of 2.78 ± 2.6 from a baseline of 11.49 [10].

Despite the growing body of research on the management of overactive bladder (OAB), several gaps remain in the literature. There is limited research on the long-term outcomes, including sustained symptom relief, patient adherence, and the long-term safety profile of these treatments. While the comparison between solifenacin with behavioral therapy and mirabegron monotherapy is valuable, there is a lack of head-to-head clinical trials that assess the comparative effectiveness of these treatment regimens. However, given the distinct mechanisms of action of these drugs and the added benefits of behavioral therapy, there is a growing interest in exploring whether the combination approach (solifenacin plus behavioral therapy) yields superior outcomes in terms of symptom relief, patient satisfaction, and long-term management compared to the monotherapy of mirabegron alone. The aim of this study is to compare the clinical outcomes and effectiveness of a combination treatment—solifenacin, an antimuscarinic agent, plus behavioral therapy—versus mirabegron, a beta-3 adrenergic agonist, when used alone in the management of Overactive Bladder Syndrome (OAB).

METHODOLOGY

This is an Experimental Study conducted in the Department of Urology, Sheikh Zayed Hospital, Rahim Yar Khan, from Nov 24 to April 25, after taking approval from the institutional review board (Ref No. 801/IRB/SZMC/SZH dated 18-10-2023). The Sample size was calculated by using EPI Calculator with 95% level of confidence and 80% power of study and taking expected mean changes in micturition per 24 hours to be 2.78±2.6 [10] and 4.32+1.58 [9] in patients taking solifenacin combined with behavior therapy and mirabegran alone respectively.

Inclusion criteria: A population of 60 males and females aged 18-60 years with persistent over active bladder symptoms from past 3 months presented in outpatient department along with complete medical records, were included in this study.

Exclusion criteria: On the other hand, pregnant/lactating Females, patients with neurogenic bladder, stress/urgency incontinence, indwelling catheter, diabetic neuropathy, Uncontrolled hypertension. And evidence of a symptomatic UTI, interstitial cystitis, bladder stones, malignant disease of the pelvic organs were excluded from the study. Similarly, patients with uncontrolled narrow-angle glaucoma, urinary or gastric retention, severe renal impairment, or Stage Renal disease, and suffering from bladder outlet obstruction or urogynecological fistulas were also excluded from this study.

After taking written informed consent, patients were randomized by lottery method into following two groups: -
Group-I: Taking Solifenacin 5mgOD combined with behavioral therapy (n=30)
Group-Il: Taking mirabegron50mgOD alone (n=30)

Patients in both groups were followed in OPD every 6 weeks for a total of 2 follow-ups. They were asked to complete their bladder diary containing micturition per 24hours, episodes of urgency per 24 hours, and episodes of nocturia per 4 hours for 3 days before follow-up. The demographic information, examination findings, investigation reports, and treatment outcomes of all study subjects were recorded in the data collection sheet. For behavioral therapy, Pelvic floor muscle training was conducted. Patients were guided on how to effectively contract and relax their pelvic floor muscles while avoiding engagement of their abdominal muscles. Initially, participants practiced muscle contractions for 2 to 10 seconds, followed by equal intervals of relaxation. The duration was progressively increased to a maximum of 10 seconds over time. Participants were also instructed in urge suppression techniques and limiting fluid intake (avoiding consumption within three hours of bedtime and during the night) .

Data was entered and analyzed using SPSS software (version 25.0). An independent t-test was applied. P-value < 0.05 was considered statistically significant.

RESULTS

Among the participants, 4 individuals (6.67%) were under 25 years old. The age group of 25 to 50 years comprised 13 participants (21.67%), while the majority, 43 participants (71.67%), were over 50 years of age with an overall mean age of 52.4 ± 13.2 years (Table-I). The gender distribution shows 21 males (35%) and 39 females (65%) (Figure-I). The study evaluated the change in micturition frequency over 24 hours among participants receiving either Solifenacin combined with behavioral therapy (n = 30) or Mirabegron (n = 30). At baseline, the mean micturition frequency was 9.872 ± 0.215 in the Solifenacin group and 9.800 ± 0.278 in the Mirabegron group. By the first visit (6th week), these values decreased further to reach 4.760 ± 0.129 in the Solifenacin group and 6.283 ± 0.029 in the Mirabegron group at 2nd visit (p≤0.001) (Table 2). Table 3 illustrates the changes in nocturia frequency per 24 hours among participants treated with Solifenacin combined with behavioral therapy (n = 30) and Mirabegron (n = 30). At baseline, the mean nocturia frequency was 2.065 ± 0.33 in the Solifenacin group and 2.410 ± 0.48 in the Mirabegron group, which declined to 0.520 ± 0.16 in the Solifenacin group and 0.180 ± 0.07 in the Mirabegron group after 12 weeks (p≤0.001). The changes in urgency episodes per 24 hours among participants treated with Solifenacin combined with behavioral therapy (n=30) and Mirabegron (n=30) changed from 2.065 ± 0.331 in the Solifenacin group and 2.410 ± 0.482 in the Mirabegron groupto 0.180 ± 0.078 in the Solifenacin group and 0.520 ± 0.162(p≤0.001), in the Mirabegron group over the course of treatment (Table 4). Compared with mirabegron, the combination therapy of solifenacin and Behavioral therapy has shown a significant reduction in micturitions per 24 hours, episodes of urgency per 24 hours, and episodes of nocturia per 4 hours over the course of treatment. The patients treated with combination therapy have reported fewer side effects than those treated with mirabegron alone.

Table-I: Age and gender distribution of patients suffering from overactive bladder.

Variable	Category	Outcome n(%)	Mean ± SD
Age	< 25 years	4 (6.67)	52.4 + 13.2
	25- 50 years	13 (21.67)	
	> 50 years	43 (71.67)	

Figure-I: Gender distribution of patients suffering from over active bladder.

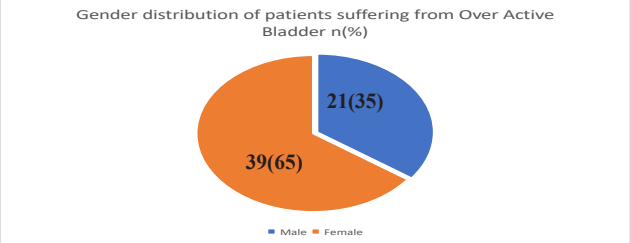

Table-II: Change in micturition frequency per 24 hours among different treatment groups (p<0.001)*with independent t test applied.

Variables	Solifenacin + behavioral therapy (n=30)	Mirabegron (n=30)	P -value
Baseline	9.872 ± 0.215	9.800 ± 0.278	0.265
First visit (6th week)	7.665 ± 0.224	8.213 ± 0.267	≤0.001
Second visit (12th week)	4.760 ± 0.129*	6.283 ± 0.029	≤0.001

Table-III: Change in nocturia per 24 hours among different treatment groups (p<0.01) ** with independent t test applied.

Variables	Solifenacin + behavioral therapy (n=30)	Mirabegron (n=30)	P -value
Baseline	2.065±0.33	2.410±0.48	0.002
First visit (6th week)	1.210±0.26	1.780±0.31	≤0.001
Second visit (12th week)	0.520±0.16	0.150±0.21	≤0.001

Table-IV: Change in urgency per 24 hours among different treatment groups (p<0.001)* with independent t test applied.**

Variables	Solifenacin + behavioral therapy (n=30)	Mirabegron (n=30)	P -value
Baseline	2.065±0.331	2.410±0.482	=0.002
First visit (6th week)	1.010±0.21	1.670±0.29	≤0.001
Second visit (12th week)	0.180±0.078	0.520±0.162	≤0.001

DISCUSSION

This study evaluated the comparative efficacy of Solifenacin combined with behavioral therapy versus Mirabegron in managing overactive bladder (OAB) symptoms. The findings demonstrated that while both treatment groups showed improvement, the combination therapy significantly outperformed Mirabegron alone across all measured outcomes, including micturition frequency, nocturia, and urgency. The reduction in micturition frequency was notably greater in the Solifenacin group. This suggests that combining pharmacological treatment with behavioral strategies addresses not only the physiological but also the behavioral components of OAB.

Behavioral therapy likely enhances bladder control through training mechanisms that complement the anticholinergic effects of Solifenacin. A systematic review conducted by Reisch et al has also suggested that behavioral therapy leads to phenomenal improvement in symptoms of overactive bladder [11]. Similarly, a randomized controlled trial has reported a significant difference of 12.6 points (95% CI, 6.6-18.6 points; P<.001) after 13 weeks of treatment between two groups receiving pharmacological treatment plus behavioral therapy versus pharmacological treatment alone. Maximum improvement was confirmed for the frequency of micturition and urgency in the pharmacological treatment plus behavioral therapy group [12].

Despite the proven benefits of Behavioral therapy in patients suffering from overactive bladder, the compliance rate is less than 30% after one year. Barriers to the long-term compliance of behavioral therapy in patients with overactive bladder (OAB) include the time and effort required to practice these techniques consistently, a lack of immediate symptom relief compared to medications, and insufficient support or follow-up from healthcare providers [13].

Another study has revealed that 30% to 50% of patients who did not attempt one or more levels of overactive bladder (OAB) therapy reported that they were never offered behavioral therapy as a treatment option. This highlights a significant issue in patient education and communication between healthcare providers. Despite being a cornerstone of OAB management, behavioral therapy is often overlooked or not emphasized during consultations, leaving patients unaware of its potential benefits [14]. The study's results also suggest that a combination of Solifenacin and behavioral therapy should be prioritized for patients seeking more effective OAB symptom relief. While Mirabegron remains a valuable option, especially for patients who cannot tolerate anticholinergics, the superior outcomes with combination therapy indicate its potential as a first-line treatment [15].

While this study provides valuable insights into the comparative effectiveness of Solifenacin combined with behavioral therapy versus Mirabegron alone in managing overactive bladder (OAB), several limitations exist. The study involved a relatively small sample size, and a larger sample would provide more robust and generalizable results, particularly for diverse patient populations across different settings. The study relied on clinical measures that may be influenced by the subjective interpretation of researchers or the participants themselves. Future studies should incorporate objective measures, such as bladder diaries or urodynamic testing, to reduce potential bias [16].

CONCLUSION

The combination of Solifenacin and behavioral therapy offers a more effective and holistic approach to managing OAB symptoms compared to Mirabegron alone. By addressing both the physiological and behavioral dimensions of the condition, this dual approach enhances symptom relief and has the potential to improve patient adherence and overall quality of life.

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Muhammad Sajjad: Substantial contributions to the conception and design of the work.

Syed Atif Hussain: The acquisition and analysis of data for the work.

Muhammad Saddiq Haris: Interpretation of data for the work.

Aqib Shahzad: Drafting the work.

Shafi Ghouri: Reviewing it critically for important intellectual content.

Muhammad Zohaib Fazal : Final approval of the version to be published.