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Original Research Article

Effectiveness and safety in behavioural and pharmacological interventions in patients of overactive bladder in real-world settings in India

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ABSTRACT

Background: Overactive bladder (OAB) is a urinary bladder condition causing bladder dysfunction. OAB commonly presents the symptoms of nocturia, incontinence, increased urinary frequency, and urinary urgency with a prevalence of 15.5 % among the Indian population.
Methods: This retrospective observational study assessed the efficacy and safety of combined behavioral and pharmacotherapy in managing OAB in the elderly adult population. Data was collected from digital and paper-based medical records of patients aged 40 years or older. Enrolled patients reported symptoms of OAB for at least 3 months. Efficacy and safety outcomes were assessed using overactive bladder symptom score (OABSS) measured at baseline and after an 8-week follow-up period.
Results: The mean OABSS reduced from 12.39±2.4 at baseline to 8.06±3.46 at 8 weeks post-intervention. A mean difference of 4.33 points ($p<0.0001$) was observed in OABSS scores between baseline and the 8-week follow-up. During the follow-up, no adverse events were observed.
Conclusions: A mean reduction of 4.33 points in OABSS scores was observed between baseline and the 8-week follow-up, showing a significant decrease in symptom severity with combined behavioral and pharmacological therapy. To assess the long-term efficacy and safety of combined behavioral and pharmacological interventions in OAB patients, studies with large sample sizes are required. This will provide a better understanding to healthcare professionals to optimize OAB management and overcome side effects seen with conventional medications.

Keywords: Combined therapy, Efficacy, Overactive bladder, Overactive bladder symptom score, Real-world

INTRODUCTION

Overactive bladder (OAB) is a chronic condition causing functional impairment of the urinary bladder. This condition commonly manifests as nocturia, urinary urgency, increased urinary frequency and incontinence without the presence of underlying infection or other significant pathology.[1] OAB affects daily activities and negatively impacts psychological well-being, sleep quality, work productivity and social interactions and lowers self-esteem. The global prevalence of OAB highly varies across different epidemiological studies, ranging from 3% to 43%.[2] OAB is prevalent in approximately 15.5 % of the Indian adult population with 6.9% affected males and 8.6% affected females, thereby suggesting higher prevalence among the female population compared to male counterparts.[3] Advanced age is a common risk factor associated with developing OAB. The prevalence rate of

OAB in the elderly is approximately 51.4%, which is significantly greater than the prevalence rate among the general population (3-43%).[2,4] The geriatric female population is at increased risk for developing OAB due to the smaller urethra and sphincter anatomy.[5]

Emergence of comorbidities such as diabetes, benign prostatic hyperplasia, hypertension and cardiovascular conditions in elderly patients increases the risk of OAB development.[6] These comorbidities impact lower urinary tract function, consequently increasing the chances of OAB development. Due to the weakening of pelvic floor muscles, elderly females face a higher risk of stress urinary incontinence. However, most of the patients report experiencing mixed incontinence.

The primary therapeutic strategy in OAB patients includes behavioral therapies.[1] Behavioral therapies include a broad spectrum of strategies involving patient education and adherence. Patient education regarding lower urinary tract physiology, emphasizes the distinct phases of bladder filling, storage and voiding to enhance understanding and improve management of urinary symptoms. A study recommended the use of bladder diaries to facilitate the identification and adjustment of voiding patterns.[7]

Other behavioral modifications including appropriate fluid intake such as avoiding caffeine, maintaining enough hydration, timing of fluid intake and managing constipation are effective strategies for treating OAB.[8] Furthermore, bladder training which includes an initial urinating frequency of 30 minutes, extending to 3 to 4 hours once the patient can control urinary urge is also a helpful approach for improving bladder function.[9] Lastly, kegel exercises improve urgency by the controlled contraction and relaxation of the pelvic floor muscle using anal palpation are a part of behavioral therapy.[1]

The second line of treatment includes pharmacological interventions. The most commonly used pharmacological agents include antimuscarinic drugs and β3-adrenoreceptor agonists.[1] The mechanism of action of β3-adrenoreceptor agonists involves the reduction of muscular tension in the urinary bladder and subsequent expansion in its capacity for storage.[10] The antimuscarinic drugs act by inhibiting muscarinic M3 activity and blocking detrusor contractions. However, they have various side effects such as constipation, cognitive dysfunction, cardiac conditions and dry mouth.[1]

While both behavioral and pharmacological interventions have demonstrated efficacy in mitigating OAB symptoms, neither approach alone can achieve complete symptom resolution when administered individually.[11]According to Xu et al. (2018), patients with OAB experienced a lower quality of life, which was highly correlated with the severity of their symptoms.[12] Therefore, OAB impairs the health-related quality of life (HRQOL) of patients necessitating timely management of this chronic condition.

Various tools are available to measure OAB symptoms including Urgency Severity Scale (USS), and Overactive Bladder Symptom Score (OABSS).[13] OABSS is a unique tool that employs a questionnaire for subjective assessment of the symptoms and quantifying OAB symptomology into one score between 0 and 25. OABSS analysis provides points for each symptom and collectively measures the frequency of daytime voiding (5 points), night time voiding (5 points), urgency (5 points), incontinence (5 points), and urgency incontinence (5 points). Comprehensive assessment of the bladder function using OABSS makes it a valuable tool for assessing OAB severity.

While behavioral therapies improve urodynamics and bladder function, pharmacological treatments increase bladder volume. Therefore, a combination of behavioral and pharmacological therapy presents as a better option with additive effects.[10] Recent studies have shown that combining behavioral and pharmacological therapies improves symptom severity and HRQOL.[1] However, due to limited evidence on the safety and efficacy of a combination approach, real-world implementation is lacking in OAB patients. Therefore, the objective of the present investigation is to assess the efficacy and safety outcome of combining behavioral and pharmacotherapy in the management of OAB.

METHODS

Study design

An observational, retrospective study was conducted to determine the efficacy of behavioral and pharmacotherapy in the treatment of adult subjects with OAB. The present study analyzed patient's digital medical records and paper-based medical records from healthcare facilities. The enrolled patients were diagnosed with OAB at the physician's discretion.

Study place

The study was conducted in a private clinic (Wagholikar Kidney Hospital, Sangamner) in Maharashtra.

Study duration

This study was conducted between May 2023 to December 2023.

Inclusion criteria

The study participants' inclusion criteria for the present study were 1) Adult participants of the age ≥40 years presenting with lower urinary tract dysfunction consistent with OAB, 2) ≥3 months of documented OAB symptoms such as urinary urgency, increased urinary frequency, with/without urinary incontinence, before study enrollment and 3) Availability of complete medical records for the specified period.

Exclusion criteria

Patients with incomplete medical records or missing data about any of the study outcome measures were excluded from data analysis.

Out of 25 patients, 18 patients satisfied the inclusion criteria thus included in the study.

Data collection

Retrospective data was collected by the urologists in the OAB study electronic case report form (eCRF). The choice of patient selection was purely based on the physician's discretion who provided the treatment. No additional evaluation or investigation was conducted to capture data in this form.

Baseline data was collected for all patients using medical records. The data was collected at baseline and recorded in the eCRF by the physicians. Patient demographics and clinical characteristic data were collected including weight, height, gender, age, body mass index (BMI), vital signs, OAB symptoms, OABSS (0-25), family history of lower urinary tract symptoms, existing comorbidities and medication history.

Lifestyle factors were documented at baseline including fluid intake, dietary habits, smoking status and physical activity level. A description of the prescribed pharmacological treatment was recorded.

Behavioral therapy was adopted according to the OAB Partnership Programme (OAB PP) which was prepared by Alkem Laboratories Ltd. The OAB PP offers a comprehensive interactive digital platform developed to facilitate the management of OAB through various tools. Some of the tools include educational materials, instructional videos for pelvic floor (Kegel) exercises, an OAB diary for the documentation of daily urinary frequency, a symptom score tracker for assessing OAB severity, and a washroom locator to provide timely access to nearby washrooms.

The primary objective of the program was to enhance patient knowledge and promote self-management strategies, contributing to more effective management of OAB symptoms. Therefore, the OAB PP serves as a holistic tool facilitating the delivery of continuous and integrated patient care over the long term. Post-intervention data collection was performed at 8 weeks after patients followed behavioral therapy and pharmacotherapy. The data was collected using eCRFs by the physicians. OABSS (0-25) post-intervention was measured to determine the impact of pharmacological and behavioral therapy. Physicians recorded the adherence of the patient to behavioral therapy and determined the ease of access. Evaluation of study medication intake compliance, adverse events and concomitant medication use was performed.

Outcome assessment

The primary outcome of the present study was the efficacy of the combination therapy. Efficacy analysis was performed by assessing the reduction of mean OABSS from baseline to 8 weeks post adherence to the combined therapy. Statistical analysis was performed to determine mean parameters. Statistical tests compared the data at baseline and at post-interventional time points. The secondary outcome of the present study is the safety of the combined treatment. All treatment-emergent adverse events, both collected through patient reporting or physician observation are summarized in the eCRFs. Safety analysis was performed descriptively in all the participants administered with at least one dose of the combined therapy.

Ethical Consideration

This retrospective study was conducted according to the ethical guidance. As per ICMR's "Ethical Guidelines for Biomedical Research on Human Participants", the study presents less than minimal risk, hence ethics committee approval was not obtained. Since it is a retrospective study where the participants were de-identified or cannot be contacted, consent was not obtained. The patient's details were kept confidential.

RESULTS

Patient demographics

Patient demographics are presented in Table 1. The mean age of the participants is 67.4±11.8 years. A total of 18 study participants out of 25 were included with 15 male patients and 3 female patients. The mean height of the study participants is 165.2±5.4 cm and the mean weight of the participants is 75.6±6.8 kg. The major comorbidities present in the study sample include hypertension, diabetes, and other bladder issues. All participants exhibited comorbidities including bladder dysfunction in six patients, hypertension in the other six patients, and diabetes mellitus in the remaining six patients. None of the patients had a family history of OAB or related conditions ruling out genetic predisposition. Pharmacological treatment was administered as monotherapy with Mirabegron (50 mg or 25 mg) in 12 patients. Fixed-dose combination therapy with Mirabegron and Solifenacin (5 mg) was prescribed for 6 patients. All 18 participants were recommended for similar behavioral therapy including fluid intake, dietary changes, alcohol reduction, kegel exercises, and an OAB diary through the OAB PP (Table 1).

Study outcomes

The OABSS is a symptom assessment questionnaire designed to quantify OAB symptoms. OABSS employs a scale of 0-25, where 0 attributes the absence of any symptoms and 25 attributes the highest presence of

symptoms. Individual OABSS scores are outlined in Figure 1.

OABSS was reported by the physicians for each patient at two time points, at baseline and at 8 weeks after recommending behavioral and pharmacological therapy. The OABSS was used to assess changes in the OAB symptoms (Figure 2). The patients showed a significant improvement in OABSS scores after eight weeks of intervention. The mean OABSS decreased from 12.39±2.4 at baseline to 8.06±3.46 post-intervention, indicating a 35% reduction in OAB symptoms from baseline. A mean difference of 4.33 points was observed in OABSS scores between baseline and the 8-week follow-up, indicating a reduction in symptom severity. This difference was statistically significant ($p<0.0001$), with a 95% confidence interval ranging from 2.90 to 5.77, suggesting a robust effect of the intervention on mitigating OAB symptoms. The combined therapeutic strategy of behavioral and pharmacotherapy for OAB demonstrated a favorable safety profile in this study. During the 8-week follow-up, no adverse effects or events were observed by the primary physician or reported by the patients.

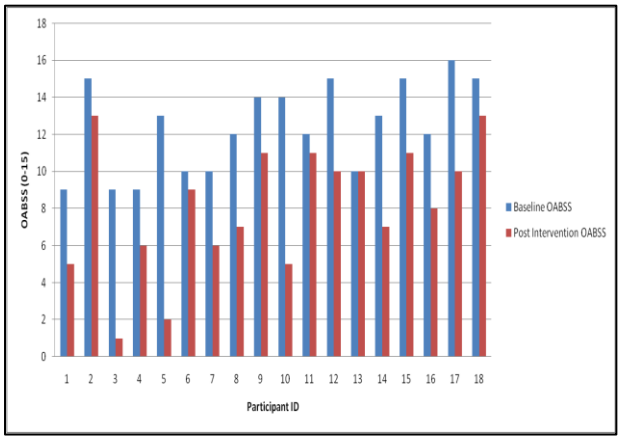

Figure 1: Individual patient OABSS at baseline and 8-week follow-up.

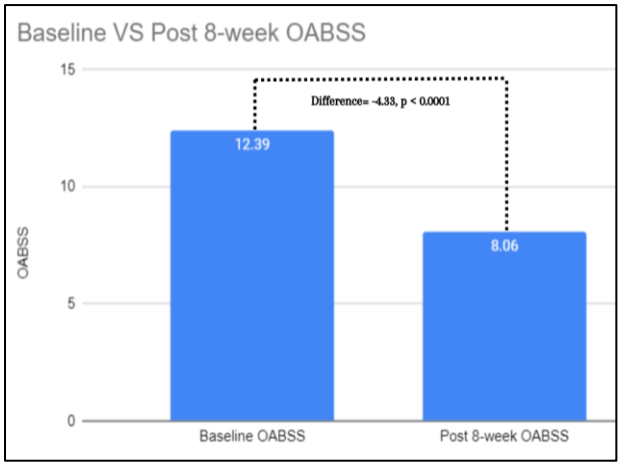

Figure 2: Baseline Vs 8-week post-intervention OABSS comparison.

Table 1: Patient demographics and administered therapy of the study population (n=18).

Parameter	Mean (SD)
Age (years)	67.4 (11.8)
Height (cm)	165.2 (5.4)
Weight (kg)	75.6 (6.8)
Medical history (N)	
Diabetes	6
Hypertension	6
Bladder diseases	6
Pharmacotherapy (N)	
Monotherapy with Mirabegron	12
Combination therapy with mirabegron and solifenacin	6
Behavioral strategies (N)	
Fluid intake	18
Dietary changes	18
Alcohol consumption	18
Kegel exercises	18
Oab diary	18

SD-Standard Deviation.

DISCUSSION

The present retrospective study showed a statistically significant difference ($p<0.001$) in reducing OAB symptoms following the treatment with behavioral therapy and pharmacotherapy after 8 weeks as assessed using the OABSS score. The majority of the patients reported improvement in clinical symptoms of OAB highlighting the therapeutic efficiency of the combined therapy. Furthermore, no adverse event was reported during the study period demonstrating the safety outcome of the treatment. These findings indicate that a combination of behavioral and pharmacological therapy not only effectively manages OAB symptoms but also maintains a strong safety profile, making it a promising treatment strategy for OAB management.

The present study had a higher proportion of male patients compared to females, which contrasts with previous studies that included a higher number of female patients.[3,14] Qudah et al, reported the presence of OAB in 32.4% of the females, while 22% in the males whereas Pal et al, mentioned the rate of prevalence of OAB among the male and female patients as 6.9% and 8.6% respectively.[3,14] The mean age of the study participants was 67.4 years, denoting that the majority of them were elderly. This aligns with other studies suggesting an increased risk of OAB with advancing age.[1,4] Similarly, Burgio et al, reported that the mean age of OAB male patients was approximately 64 years.[1] Przydacz et al, reported the prevalence of OAB as 51.4% in the elderly participants with a mean age of 72.5 years.[4] Due to the presence of comorbidities and weakening of sphincter muscle with increasing age, age can be considered a significant risk factor for OAB development.

In the present study, one-third of the participants had a medical history of diabetes which is in alignment with previous literature.[15] Xu et al, observed that the prevalence of OAB was greater in individuals with type 2 diabetes, exceeding that of the general population by a factor of two.[16] This underscores the significance of diabetes as a clinically relevant comorbidity in OAB patients. While the mechanism behind this association is not well defined it is hypothesized that hyperglycaemia resulting in elevated glycosylated haemoglobin levels, deteriorates the condition in OAB patients.[15]

Behavioral interventions are particularly recommended for patients with diabetes such as improving toileting behaviors, reducing premature voiding and preventing straining during voiding, as these behaviors can contribute to the onset or progression of OAB.[16] Additionally, evidence reveals a positive correlation between the frequency of unhealthy voiding behaviors and the increased incidences of developing OAB in the diabetic population.[16] Therefore, patient education is important in regulating urinary behavior in diabetic patients suffering from OAB.

In the present study, 33% of the participants had a medical history of hypertension. Although there is limited evidence demonstrating the association between hypertension and OAB, there may be a correlation between the two conditions.[17] Patients presenting with OAB demonstrate hyperactivity of the sympathetic nervous system while suppressing the parasympathetic system.[17] This causes a higher sensitivity to bladder filling, urge, and voiding as a result dysautonomia may contribute to elevated blood pressure in OAB patients.[18,19] An empty bladder is recommended during blood pressure measurements, recognizing the potential impact of bladder distension on hemodynamic parameters.[20] As β blockers, calcium channel blockers and diuretics used for hypertension impact OAB symptoms, it is important to consider the use of concomitant antihypertensive medications when managing OAB patients.[17]

There was a significant reduction in OABSS from baseline to 8-week follow-up when patients underwent treatment with pharmacotherapy and behavioral modifications. There are limited studies assessing the real-world efficacy of the combined approach. Previous studies have reported improved patient outcomes by combining behavioral strategies with pharmacotherapy.[1,21] Burgio et al, studied the efficacy of behavioral therapy with kegel exercises in combination with tolterodine and tamsulosin in male OAB patients.[1] The results showed a 30.5% mean reduction in the overactive bladder questionnaire score with the combined therapy, while the improvement in the scores with the behavioral therapy and drug therapy alone was 24.7% and 12.7% respectively. This indicates that improvement in OAB symptoms was greater when pharmacotherapy and behavioral modifications were used compared to monotherapy. The patients in the present study were administered either Mirabegron alone or in combination with Solifenacin to manage OAB symptoms. Both of these pharmacological strategies reduced OAB symptoms at the 8-month follow-up. Mirabegron is an FDA-approved β3-receptor antagonist with previous studies reporting the manifestation of therapeutic efficacy within four to eight weeks of initiation.[22,23] On the other hand, Solifenacin is an antimuscarinic agent with high clinical efficacy. A study reported that 25% of patients experienced urgency resolution, 50% achieved continence and 33% achieved normal micturition frequency with eight or fewer voids daily.[24] While Mirabegron exhibits a significantly lower incidence of dry mouth than Solifecanin, additional adverse reactions include increased heart rate, headache, backache, dizziness, palpitations, arrhythmia, urticarial reactions, arthralgia and edema.[25,26] However, randomized controlled trials have reported that combination therapy with Mirabegron and Solifenacin offers superior efficacy in alleviating urinary urgency and urgency incontinence compared to either agent alone.[27–29]

In the present study, behavioral therapies were recommended to OAB patients including 4 major aspects, fluid Intake, dietary changes, alcohol consumption and kegel exercises. The association between fluid intake and urinary incontinence has been established for over four decades.[30] Inadequate fluid consumption, leading to dehydration, may contribute to bladder wall inflammation through the production of hyperosmolar urine, which increases the risk of OAB and urge incontinence. Few of the patients with OAB instinctively reduce fluid intake as a self-management strategy to mitigate urgency.[31] However, studies have demonstrated that maintaining adequate hydration, especially in geriatric populations, can lead to improved outcomes in OAB management.[32,33] An additional method to track OAB-related measures is the OAB diary where the patient documents the intensity of urgency during the day/night, voided volume, frequency of voiding and nocturia documented for a period of 24 hours. For example, Hagovska et al. (2021) used an OAB diary as an outcome measure to assess patient compliance and tracking of symptoms.[5]

Kegel exercises were recommended as part of the treatment regimen to lower the OABSS. These exercises, which strengthen pelvic muscles, have been shown to reduce urinary leakage and improve OAB symptoms by enhancing the muscular support of the urethra and pelvic organs, particularly under conditions of increased intra-abdominal pressure.[34] Despite the non-invasive nature of these interventions, their effectiveness can be compromised by inconsistencies in exercise techniques and varying levels of patient adherence.[35] Dietary changes also play a crucial role in behavioral therapy for OAB. The rationale behind these recommendations lies in the direct influence of diet on urinary output. Since urine is composed of electrolytes, acid-base components, toxins, and fluid intake, dietary intake directly affects diuresis and voiding frequency.[36] Therefore, dietary modifications are an integral part of behavioral therapy.[36] Additionally, reducing alcohol consumption was advised as part of

behavioral therapy. Alcohol intake triggers vasopressin release, leading to increased diuresis, which subsequently heightens bladder activity and urinary urgency.[37] The present study used the OABSS tool for assessing clinical outcomes in OAB patients. This tool was opted for due to its simplicity and holistic assessment of OAB symptoms. Furthermore, OABSS is an effective measure as it provides an aggregate score of the 4 crucial symptoms of OAB.

Various studies have used OABSS to score the severity of OAB symptoms.[12,38,39] Chun et al used OABSS to assess the clinical efficacy of Solifenacin in reducing OAB symptoms.[38] Xu et al, assessed the HRQOL and symptom severity in diabetic OAB patients using OABSS.[12] Funada et al used the OABSS as a criterion to define the patient population with severe OAB.[39] Therefore, OABSS works as a simple and effective tool to evaluate OAB symptoms severity and track the improvement or deterioration over time

The present study according to the author's knowledge is the first Indian study assessing the efficacy and safety of combined pharmacological and behavioral therapies in OAB patients. The absence of any adverse event signifies the safety profile, laying the foundation for future large-scale clinical trials. The study highlights the role of patient education and awareness in reducing OAB symptoms in combination with a pharmacological approach.

There are certain limitations in the present study that should be acknowledged. Firstly, the study had a small sample size. Secondly, the follow-up period of the study participants is particularly short at 8 weeks. Further long-term studies can be conducted to elucidate the long-term efficacy and safety of the combined approach. Thirdly, OABSS assessment may have limited the evaluation of OAB symptoms, excluding factors like HRQOL and patient satisfaction. Fourthly, there is an absence of a comparator arm including patients treated with pharmacological therapy alone. Nonetheless, reporting rigor and ethical standards were maintained throughout the study.

CONCLUSION

A significant reduction in OABSS was observed from baseline to the 8-week follow-up following treatment with the combination therapy including pharmacological and behavioral modifications. This demonstrates the efficacy and safety of the combination approach in managing OAB symptoms. However, limited studies have evaluated the real-world effectiveness of this combined therapeutic approach. To assess the long-term efficacy and safety of combined behavioral and pharmacological interventions in OAB patients, studies with large sample sizes are required. This will provide a better understanding to healthcare professionals to optimize OAB management and overcome side effects observed with conventional medications.

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