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Original Article

Assessment of Combined Behavioural and Pharmacotherapy for Overactive Bladder Management (BEP study)

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ABSTRACT

Background: Overactive bladder (OAB) is a chronic weakening syndrome characterized by urinary urgency (with or without urgency incontinence), usually with urinary frequency and nocturia, often resulting in impaired quality of life. Although behavioural and pharmacotherapy are frequently used in OAB management, real-world evidence on their combined usage in Indian adults remains limited. This study assessed the effectiveness and adherence of combined therapy in adults with OAB.

Methods: This was a retrospective, multicentre, observational study conducted across multiple health care centres in India. Adults aged over 40 years with lower urinary tract symptoms suggestive of OAB for at least 3 months were included. Retrospective data were collected from medical records and case record forms. Demographic characteristics, comorbidities, treatment details, OAB symptom severity, and follow-up OAB symptom scores were recorded. Changes in OAB symptom scores from baseline to week 4, 8, and 12 were analysed using repeated-measure ANOVA.

Results: A total of 961 participants were included in this study. The mean age of the participants was 64.27 ± 9.09 years, and most of them were male (91.9%). Diabetes mellitus (28.8%) and hypertension (22.1%) were the most common comorbidities. Solifenacin and Mirabegron were commonly prescribed pharmacotherapy, while OAB diary use, Kegel's exercises, dietary changes, and fluid regulation were frequently recommended. Mean OAB symptom score declined significantly from 12.06 ± 0.11 at baseline to 10.12 ± 0.10, 8.55 ± 0.08, and 6.90 ± 0.08 at weeks 4, 8, and 12, respectively, representing a 42.8% reduction by week 12 ($p<0.001$).

Conclusion: Combined behavioural and pharmacological treatment was associated with significant reductions in OAB symptom severity over 12 weeks.

Keywords: *Overactive bladder, Behavioural Therapy, Pharmacotherapy, Real-world Evidence, Overactive Bladder Symptom Score.*

INTRODUCTION

Overactive bladder (OAB) is a common, often debilitating syndrome characterized by urinary urgency (with or without urgency incontinence), usually with urinary frequency and nocturia(1,2). Over the past 20 years, the prevalence of OAB has increased drastically, rising from 18.1% to 23.9% globally (3). It affects approximately 12% of adults (both sexes), growing radically with advanced age (70–80% by age 80)(1). OAB is more prevalent in males than in females, but females commonly have incontinence due to the small urethra and sphincter anatomy(4). It's more common in elderly people and individuals with comorbid illnesses such as benign prostate hyperplasia, diabetes mellitus, hypertension, and cardiovascular disease(1). OAB strongly impairs quality of life and has significant psychological, social, and economic impacts. Leading guidelines, including the American Urological Association (AUA), the European Association of Urology (EAU), National Institute of Health and Care Excellence (NICE), etc., consistently recommend first-line conservative therapies (5,6). These therapies include lifestyle modifications and structured behavioural interventions (bladder and pelvic floor muscle training, training, fluid regulations) before advancing to pharmacological intervention. These traditional

measures can be highly effective for many patients. for example, about 50% of patients achieve satisfactory control using lifestyle and behavioural strategies alone, but these approaches are often underutilized or insufficiently implemented in practice (5,6).

When medical intervention is required, oral pharmacotherapy with antimuscarinic agents (e.g., oxybutynin, tolterodine) or β_3-agonists (mirabegron) is a first-line strategy(7). These pharmacotherapies can reduce OAB symptoms but carry deleterious side effects such as dry mouth, dry eyes, constipation, heart palpitations, tachycardia etc., and poor long-term adherence(8,9). As a result, treatment effectiveness in the real world remains suboptimal.

Combining behavioral therapy with pharmacotherapy is a logical next step. This dual approach targets both voluntary control (via bladder retraining and pelvic floor exercises) and bladder excitability (via receptor blockade)(10). Recent randomized trials and meta-analyses suggest that combined treatment may yield greater symptom improvement than either modality alone(11,12). For example, Burgio et al. found significantly better symptom scores with lower OAB questionnaire scores in patients receiving combined therapy versus behavioural or drug therapy alone(11). Similarly, stepwise studies showed that adding oxybutynin to patients already doing bladder training markedly increased incontinence reduction, and vice versa(12).

Despite these encouraging results, existing data are limited. Most trials have been relatively small, often in Western populations, and focus on short-term outcomes in controlled settings. There is a lack of large, multi-centre, real-world evidence examining combined therapy, especially in diverse settings such as in India. This gap motivates the current BEP (Behavioural + Pharmacotherapy) study.

In this retrospective multicentre observational BEP study, we evaluate the effectiveness of combined behavioural and pharmacologic therapy for adults with idiopathic OAB. The primary objective is to assess symptom outcomes (frequency, urgency, incontinence episodes, quality of life) with combined therapy. The secondary objective is to examine adherence and tolerability. We hypothesize that integrated therapy will lead to significant improvements in OAB symptoms and quality-of-life measures, with acceptable adherence, compared to that of monotherapy.

METHODOLOGY

2.1. Study Design

This study was designed as a retrospective, multicentre, observational study conducted across multiple healthcare centres in India. The study aimed to evaluate the efficacy and adherence of combined behavioural therapy and pharmacotherapy in the management of OAB. Since this was a retrospective study that did not involve identifiable patient information, a waiver of consent was sought from the ethics committee (EC). The identify of any participant was not revealed through the study. Participants' data were collected retrospectively from electronic health records (EHRs) and medical records maintained at participating hospitals, clinics, and urology centres.

2.2. Patient Population

A total of 961 participants from multiple centres across India were enrolled in this study. The study included all adult male and female participants aged 40 years or older who were diagnosed with lower urinary tract symptoms indicative of overactive bladder. Participants who had symptoms of OAB, including urinary urgency and frequency with or without urinary incontinence, persisting for at least 3 months before assessment, were included in the study. Participants with missing or incomplete medical records were excluded from the study. Participant selection was completely at the discretion of the treating physician in routine practice.

2.3. Study Assessments

Data extracted from medical records included demographic characteristics such as age, gender, weight, and height. Relevant medical records, such as previous diagnosis of OAB, family history of OAB, co-existing urological disorder, and associated comorbidities, including hypertension, ischemic heart disease, heart failure, diabetes mellitus, obesity, and other urological conditions, were also documented. Pharmacological treatment and recommended behavioural therapy taken by the participants were also documented. Pharmacological treatment included monotherapy, combination therapy, surgical intervention, and other treatment recommendations, while behavioural therapy included fluid intake modification, dietary changes, reduction in alcohol consumption, Kegel’s exercises, and maintenance of the OAB diary. Efficacy assessments were performed using data available in the medical records and case record forms (CRFs). OAB symptom severity was evaluated using the overactive bladder symptom score (OABS), which included assessment of urgency, urgency incontinence, and urinary incontinence, urinary frequency, and nocturia. Baseline OABSS scores and follow-up scores at 4, 8, and 12 weeks after initiation of combined therapy were recorded. Additional assessment included uroflowmetry findings if available, adherence to the therapy, medication compliance, and recording of adverse events.

2.4. Study Flow and conduct

The study was conducted post approval from the appropriate ECs. Participating physicians provided consent for participation before initiation of data collection. Standardized eCRFs were circulated to participating investigators for data

abstraction from source document. Retrospective data from the last 12 months were collected and entered into the eCRFs by treating physicians, general practitioners, or urologists.

2.5. Statistical Analysis

The data analysis was conducted utilizing IBM SPSS Statistics. The continuous variables were summarized in terms of mean and SD, and the categorical variables in terms of frequency and percentage. Descriptive analyses were conducted to evaluate the baseline demographics, co-morbid disorders, pharmacological treatment regimes, support measures, and distribution of the severity of symptoms. In order to examine the intra-individual differences across time, the primary outcome scores obtained in each follow-up visit were subjected to Repeated Measures ANOVA. The estimated marginal means (SE) at each follow-up visit were computed. The LSD post hoc pairwise comparison was done among the follow-ups. Additionally, the percent change from baseline at each follow-up visit was calculated. A two-sided level of significance of less than 0.05 was considered for all the statistical tests.

2.6. Ethical Considerations

Approval from the appropriate EC was obtained prior to the study. The study followed the "Ethical guidelines for Biomedical research on Human participants' outlined by the Indian Council of Medical Research (ICMR).

RESULTS

3.1. Baseline Demographics and Clinical Characteristics

The sample size in this study was 961 participants. The average age of participants was 64.27 ± 9.09 years. Most participants were males (91.9%), while 8.1% of participants were females. The mean body weight and height were 70.73 ± 9.60 kg and 165.84 ± 7.51 cm, respectively. There were previous cases of OAB in 19.8% of participants, while 16.0% of participants had a history of OAB in their families. Other related urinary diseases were recorded in 10.4% of participants **(Table 1).**

Table 1. Demographic and Clinical Characteristics of the Study Population

Variable	Value
N	961
Age (years), mean ± SD	64.27 ± 9.09
Weight (kg), mean ± SD	70.73 ± 9.60
Height (cm), mean ± SD	165.84 ± 7.51
Male gender, n (%)	883 (91.9)
Female gender, n (%)	78 (8.1)
Previous diagnosis of OAB, n (%)	190 (19.8)
Family history of OAB, n (%)	154 (16.0)
Other urological conditions, n (%)	100 (10.4)

3.2. Comorbid Conditions

In terms of other diseases, diabetes was the most prevalent at 28.8%, followed by hypertension at 22.1% and obesity at 16.1%. Participants with ischemic heart disease and heart failure comprised 3.0% and 1.7%, respectively **(Table 2).**

Table 2. Co-morbid Conditions Among Study Participants

Co-morbid Condition	n (%)
Diabetes mellitus	277 (28.8)
Hypertension	212 (22.1)
Obesity	155 (16.1)
Other comorbidities	36 (3.7)
Ischemic heart disease	29 (3.0)
Heart failure	16 (1.7)

3.3. Treatment Details

In regard to pharmacotherapy, solifenacin 5 mg once daily was the most common anticholinergic combination in 94.1% of the subjects who received anticholinergics. The mirabegron 25 mg once daily and mirabegron 50 mg once daily regimens were used in 53.0% and 42.9% of the subjects, respectively. As for the alpha reductase inhibitors, the dutasteride 0.5 mg once daily regimen was the most common (93.8%). The silodosin 8 mg once daily regimen was the most frequent among the alpha blockers in 67.0% of the patients. Botulinum therapy was utilized in 18.3% of the subjects in the study **(Table 3).**

As for non-pharmacological and supportive treatments, they were also frequently employed. OAB diary and Kegel exercises were reported in 83.9% and 83.8% of the subjects, respectively. Dietary and fluid intake changes and abstinence from alcohol were observed in 77.3%, 73.7%, and 70.6% of the subjects, respectively **(Table 4).**

Table 3. Pharmacotherapeutic Regimen, Dosage, and Administration Frequency Among Study Participants

Drug Class	Regimen	n (%)
Anticholinergics	Solifenacin 5 mg once daily	904 (94.1)
	Solifenacin 5 mg twice daily	14 (1.5)
	Solifenacin 7.5 mg once daily	3 (0.3)
	Solifenacin 7.5 mg twice daily	1 (0.1)
	Solifenacin 10 mg once daily	28 (2.9)
	Solifenacin 10 mg twice daily	1 (0.1)
	Solifenacin 15 mg once daily	2 (0.2)
	Darifenacin 5 mg once daily	1 (0.1)
	Darifenacin 7.5 mg once daily	6 (0.6)
	Oxybutynin 5 mg once daily	1 (0.1)
Beta-3 agonists	Mirabegron 25 mg once daily	509 (53.0)
	Mirabegron 25 mg twice daily	37 (3.9)
	Mirabegron 50 mg once daily	412 (42.9)
	Mirabegron 50 mg twice daily	3 (0.3)
Botulinum therapy	Botulinum therapy administered	176 (18.3)
	Botulinum therapy not administered	785 (81.7)
Alpha reductase inhibitors	Dutasteride 0.5 mg once daily	901 (93.8)
	Dutasteride 0.5 mg twice daily	8 (0.8)
	Dutasteride 1 mg once daily	1 (0.1)
	Dutasteride 5 mg once daily	41 (4.3)
	Dutasteride 10 mg once daily	1 (0.1)
	Finasteride 0.5 mg once daily	4 (0.4)
	Finasteride 1 mg once daily	1 (0.1)
	Finasteride 5 mg once daily	4 (0.4)
Alpha blockers	Silodosin 0.4 mg once daily	19 (2.0)
	Silodosin 0.8 mg once daily	70 (7.3)
	Silodosin 4 mg once daily	118 (12.3)
	Silodosin 4 mg twice daily	1 (0.1)
	Silodosin 8 mg once daily	644 (67.0)
	Silodosin 8 mg twice daily	3 (0.3)
	Tamsulosin 0.4 mg once daily	99 (10.3)
	Tamsulosin 0.8 mg once daily	2 (0.2)
	Tamsulosin 4 mg once daily	2 (0.2)
	Tamsulosin 8 mg once daily	3 (0.3)

Table 4. Non-pharmacological and Supportive Interventions Among Study Participants

Intervention	n (%)
OAB diary	806 (83.9)
Kegel's exercise	805 (83.8)
Dietary changes	743 (77.3)
Fluid intake modification	708 (73.7)
Reduced alcohol consumption	678 (70.6)
Kegel's exercise	7 (0.7)

3.4. Symptom Severity Distribution

Assessment of baseline symptom severity was found to indicate that the vast majority of patients experienced moderate to severe symptom severity in all assessed dimensions. The most commonly reported severity scores of 3 and 4 for urgency symptoms, urgency incontinence, incontinence, urinary frequency, and nocturnal walks for urination were identified. For the dimension of urgency symptoms, severity scores of 4 and 3 were indicated by 31.9% and 31.4% of patients, respectively. This was seen in relation to other dimensions such as urgency, incontinence and urinary frequency as well **(Table 5).**

Table 5. Symptom Severity Distribution Among Participants at Baseline

Severity Score	Urgency n (%)	Urgency Incontinence n (%)	Incontinence n (%)	Frequency n (%)	Nocturnal Walking to Urinate n (%)
0	26 (2.7)	28 (2.9)	38 (4.0)	8 (0.8)	53 (5.5)
1	50 (5.2)	46 (4.8)	49 (5.1)	41 (4.3)	92 (9.6)

2	142 (14.8)	182 (18.9)	167 (17.4)	140 (14.6)	182 (18.9)
3	302 (31.4)	352 (36.6)	360 (37.5)	357 (37.1)	316 (32.9)
4	307 (31.9)	257 (26.7)	244 (25.4)	256 (26.6)	224 (23.3)
5	134 (13.9)	96 (10.0)	103 (10.7)	159 (16.5)	94 (9.8)

3.5. Changes in Primary Outcome

The repeated measures analysis indicated a statistically significant decrease in the OABSS at all post-treatment evaluations (overall $p < 0.001$). The estimated marginal means of the OABSS scores showed a consistent decline from a baseline value of 12.06 ± 0.11 to 10.12 ± 0.10, 8.55 ± 0.08, and 6.90 ± 0.08 at Week 4, Week 8, and Week 12, respectively. The corresponding percentage decreases were 16.1%, 29.1%, and 42.8% at Weeks 4, 8, and 12, respectively, when compared with baseline values. Post hoc pairwise comparisons using LSD (Least Significant Difference) tests indicated statistically significant differences at all post-treatment evaluations as compared with the baseline level ($p < 0.001$) **(Table 6).**

Table 6. Changes in Primary Outcome Scores Across Follow-up Visits

Visit	n	Estimated Mean	SE	% Change from Baseline	Overall p – value	p-value
Baseline	951	12.06	0.11	-	<0.001	-
Week 4	951	10.12	0.10	−16.1%		<0.001
Week 8	951	8.55	0.08	−29.1%		<0.001
Week 12	951	6.90	0.08	−42.8%		<0.001

SE: Standard error. The percentage change was calculated with reference to baseline estimated mean values. The overall p-value was assessed using repeated measures analysis of variance (Repeated Measures ANOVA). Post hoc pairwise comparisons between visits were performed using the Least Significant Difference (LSD) test. All follow-up visits demonstrated statistically significant reductions in primary outcome scores compared to baseline ($p < 0.001$). Estimated means represent estimated marginal means derived from the repeated measures model.

DISCUSSION

This retrospective study reported that the combined behavioural and pharmacotherapy showed substantial improvement in OAB symptoms over 12 weeks' duration. In this cohort, mean OAB symptom scores fell significantly from baseline to the end of treatment, and no serious adverse events (SAEs) were documented. These findings align well with previous studies that combined behavioural and pharmacotherapy interventions and ascertain that the combination therapy has no inherent risks and that the drug-related AEs tend to be mild(13,14).

The considerable decrease in OAB symptom scores suggests that the combination therapy was effective in this mixed population. The magnitude of reduction in OAB scores was comparable to that observed in previous studies of combined therapy. For instance, Wagholikar et al observed a mean OAB symptom score reduction of 4.33 points after 8 weeks in a similar real-world population (From 12.39 to 8.06)(14). Our findings extend these observations to 12 weeks and a larger sample (N=951 versus N=91). The consistent and highly significant improvements suggest that patients had fewer urgency episodes, voids, and incontinence episodes, even though exact diary counts were not provided. Similarly, Burgio et al conducted a randomised trial in older men and concluded that combination therapy produced a significantly greater decrease in 24 h voiding frequency than drug therapy alone(13). In this study mean voids per 24 hours fell from 11.8 to 8.2 with combination therapy compared to that drug alone (11.8 to 10.3). Our findings are also well aligned with the various guidelines that emphasize step wise approach for OAB management, suggesting behavioural therapy as the first-line therapy followed by pharmacological intervention when needed(5,6).

Mechanistically, behavioural interventions increase functional bladder capacity and reduce urgency sensations, while pharmacotherapy relaxes the bladder muscle. Their effects are additive. For instance, evidence shows that behavioural approaches alone can often reduce OAB urgency and incontinence rates substantially, and adding a pharmacological intervention may aid patients who only partially responded(13).

Our data also represent real-world practice in older adults, with a majority of male participants in our sample. The very high male predominance with possible benign hyperplasia (BPH) is notable, as many OAB studies focus on women. In older men, OAB often coexists with BPH and pelvic floor issues, and combination therapy is frequently used. The findings of this study also suggest that solifenacin and mirabegron were the most used drugs, alongside pelvic floor training and fluid regulation in most patients. This treatment mix aligns with the expert recommendations and previous clinical trials(15). The lack of reported AEs in our cohort is reassuring; prior trials note that most adverse effects of antimuscarinics (dry mouth, constipation) are mild and often dose-adjustable, and that β3-agonists (mirabegron) have a favourable safety profile(12,15).

A main strength of this retrospective study is the large multicentre real-world cohort, enhancing generalizability to routine clinical practice. The retrospective design captured actual physician treatment patterns and outcomes. However, the

absence of randomization or a control arm limits causal interpretation. Since this was an observational study, selection bias is possible. Moreover, the absence of pharmacotherapy only comparator prevents evaluation of comparative efficacy.

CONCLUSION

The BEP study concludes that combined behavioural and pharmacotherapy was associated with significant improvement in OAB symptoms in real-world clinical practice. These findings support the practical logic of integrating lifestyle modification, bladder training, pelvic floor exercise, and pharmacological treatment for better symptom control. However, prospective controlled studies are required to validate therapy effects, compare combination therapy with monotherapy, and evaluate long-term outcomes. Future studies should involve a broader patient population, adherence data, and quality-of- life outcomes.

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