Am J Clin Exp Urol 2025;13(3):215-224
www.ajceu.us /ISSN:2330-1910/AJCEU0165294

Original Article

Efficacy and safety of pelvic floor magnetic stimulation combined with mirabegron in men with benign prostatic hyperplasia and overactive bladder in a prospective randomized controlled trial

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Received April 13, 2025; Accepted June 10, 2025; Epub June 15, 2025; Published June 30, 2025

Abstract: Objective: This study aimed to evaluate the therapeutic efficacy and safety profile of pelvic floor magnetic stimulation (PFMS) in combination with mirabegron in male patients diagnosed with benign prostatic hyperplasia (BPH) and overactive bladder (OAB). Patients and methods: Eighty-six patients were prospectively randomized into two cohorts. The control group received oral mirabegron (50 mg daily), whereas the experimental group underwent combined PFMS and mirabegron therapy. Primary endpoints included variations in urinary frequency and urgency intensity, measured through a 3-day voiding diary. Secondary endpoints included changes in the International Prostate Symptom Score (IPSS), Overactive Bladder Questionnaire (OAB-q) Health-Related Quality of Life (HRQoI) index, and symptom burden, assessed at weeks 6 and 12. Results: Among the participants, 42 received the combination therapy and 44 received mirabegron monotherapy. At both time points, the combination group demonstrated significantly reduced lower urinary tract symptoms (LUTS) - including urgency, frequency, and incontinence - relative to the monotherapy group ($P < 0.05$). Moreover, OAB-q HRQoI scores were consistently higher in the combination group ($P < 0.05$). Significant improvements were also observed in the IPSS, OAB-q symptom bother index, and Overactive Bladder Symptom Score (OABSS) within the combination cohort ($P < 0.05$). The incidence of drug-associated adverse events did not differ significantly between groups ($P > 0.05$). Conclusion: PFMS combined with mirabegron markedly alleviated BPH and OAB symptoms and improved patient-reported quality of life, without increasing the risk of adverse events compared to mirabegron monotherapy.

Keywords: Pelvic floor magnetic stimulation, overactive bladder, benign prostatic hyperplasia, mirabegron

Introduction

Benign prostatic hyperplasia (BPH), a prevalent age-associated disorder of the male urinary system, frequently coexists with overactive bladder (OAB), driven by bladder adaptations to urethral obstruction and prostate enlargement, compounded by localized inflammation, dysregulated neural pathways, and hormonal imbalances that precipitate detrusor overactivity [1]. This overlap presents clinically with increased urinary frequency, urgency, nocturia, and incontinence, collectively impairing patients' quality of life [2]. Epidemiological data reveal that BPH affects over 50% of men aged above 50, escalating to nearly 80% in those over 70 [3], with 30% to 50% concurrently experiencing OAB symptoms [4]. Current pharmacotherapies predominantly target α-adrenergic and muscarinic receptors, exemplified by agents such as tamsulosin and silodosin [5], yet treatment adherence remains suboptimal due to limited efficacy and common adverse reactions, including xerostomia and constipation. β3-adrenergic receptor agonists, particularly mirabegron, offer enhanced receptor specificity and a more favorable side effect profile, marking a notable advancement in OAB man-

https://doi.org/10.62347/TMQG2381

agement [6]. Simultaneously, non-invasive modalities like pelvic floor magnetic stimulation (PFMS) have attracted attention for their therapeutic potential and safety profile [7]. Despite these developments, the inherent limitations of monotherapies have prompted a shift toward integrative treatment strategies combining pharmacological and physical modalities.

PFMS, a non-invasive method based on electromagnetic induction, modulates pelvic floor neuromuscular activity to improve bladder sensory perception and urinary control [8]. Its key advantages include substantial tissue penetration, the elimination of active patient cooperation, and concurrent stimulation of deep pelvic floor musculature, rendering it applicable to conditions such as urinary incontinence, OAB, and chronic pelvic pain [9]. Clinical data indicate that PFMS significantly mitigates OAB symptoms by suppressing detrusor overactivity and strengthening urethral sphincter performance, with high levels of patient tolerability [10]. The refinement of magnetic stimulation parameters - particularly frequency and intensity - alongside the integration of intelligent technologies, has broadened its role in urinary rehabilitation, reinforcing its position as a complementary strategy to pharmacologic and surgical interventions. Prospective studies are expected to prioritize individualized treatment algorithms and explore combined approaches with other therapeutic options.

This study aims to evaluate the feasibility and therapeutic effectiveness of combining PFMS with mirabegron for managing BPH accompanied by OAB. Mirabegron can modulate bladder function by suppressing detrusor overactivity via β3 receptor activation [11], whereas PFMS aims to restore storage and voiding dynamics through neuromuscular modulation and pelvic floor muscle remodeling. The concurrent application of these modalities may enhance symptom resolution by targeting both receptor-level mechanisms and structural-functional rehabilitation pathways. This integrative approach offers a potential alternative for patients with suboptimal responses to conventional therapies. The novelty of this investigation lies in its initial exploration of PFMS in combination with mirabegron in this context, addressing both therapeutic outcomes and mechanistic underpinnings, and contributing to a broadened framework for the multimodal treatment of lower urinary tract dysfunction.

Patients and methods

Study design

This prospective, controlled, single-center study was conducted between January and December 2024 and registered with the Chinese Clinical Trial Registry (ChiCTR22000-56752, registration date: 13/02/2022). The study protocol was approved by the Clinical Research Ethics Committee of the Affiliated Jiangning Hospital of Nanjing Medical University (approval number: 202200137). All procedures involving human participants conformed to the ethical guidelines of the Affiliated Jiangning Hospital and aligned with the principles of the 1964 Helsinki Declaration. Written informed consent was obtained from each participant after providing detailed information regarding the study's objectives, procedures, potential risks, and anticipated benefits.

A total of 98 men met the inclusion criteria and consented to participate (**Figure 1**). Participants were randomly allocated in a 1:1 ratio to a 12-week maintenance intervention. Before enrollment, a thorough baseline assessment was performed, including demographic profiling, medical history, physical and laboratory evaluations, and imaging diagnostics.

Inclusion and exclusion criteria

Eligible participants met the following inclusion parameters: 1. Male individuals aged ≥ 50 years. 2. Clinical diagnosis of LUTS, OAB, and BPH. 3. Persistent OAB symptoms - including urinary frequency and urgency, with or without incontinence - lasting a minimum of 3 months. 4. An IPSS of 8 or higher. 5. Mean daily micturition frequency of ≥ 8 over a 3-day bladder diary. 6. Mean daily urgency episodes of ≥ 2, graded as 3 or 4, during the same observation period.

Exclusion criteria included the following conditions: 1. Post-void residual volume > 200 mL, current urinary tract infection, hematuria, recurrent UTIs, or stress urinary incontinence. 2. Administration of anticholinergics or β3-adrenergic agonists within 4 weeks prior to enrollment, or prior treatment with botulinum toxin or chronic neuromodulation for OAB within the past 12 months. 3. History of lower urinary tract surgery or intermittent catheterization. 4. Presence of malignancies involving the lower urinary tract or prostate, or diagnosis of neuro-

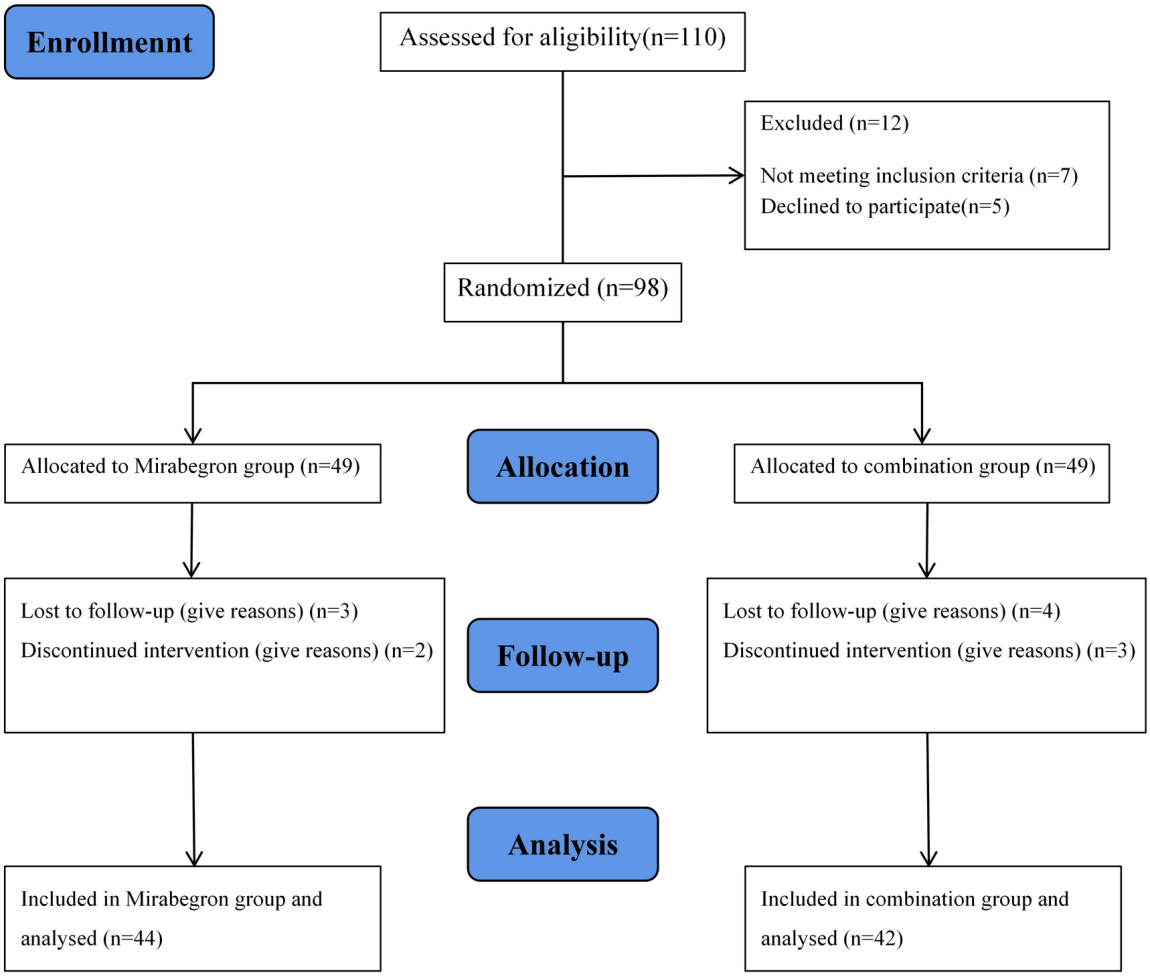

Figure 1. Flowchart for case selection.

genic bladder. 5. Anatomical abnormalities including urethral stricture, bladder neck stenosis, or urolithiasis. 6. Confirmed diagnosis of diabetes mellitus.

Randomization

Eligible participants who provided informed consent were randomly allocated to treatment or control groups via a computer-generated randomization code. Allocation concealment was maintained using sealed envelopes to preserve the integrity of the assignment procedure.

Study procedure

Patients in the mirabegron group received a fixed daily dose of 50 mg, whereas the combination group was administered the same dosage alongside PFMS therapy twice weekly (**Figure 2**). Magnetic stimulation was delivered using the Magneuro 30F device (Weisi, Nanjing). During treatment, participants remained fully clothed and seated, selecting the overactive bladder protocol via the interface (**Figure 3**). Stimulation intensity was modulated in 5% increments based on individual sensory thresholds, initiated upon detection of anal sphincter contraction. The stimulation protocol comprised a frequency of 10 Hz, 4-second stimulation intervals, 6-second rest periods, and a total duration of 20 minutes per session.

Hydration guidelines recommended a daily urine output exceeding 1500 mL. Participants completed real-time questionnaires to document any drug-related adverse effects and to monitor clinical indicators such as urinary urgency, frequency, and incontinence. Supplementary assessments were conducted at fol-

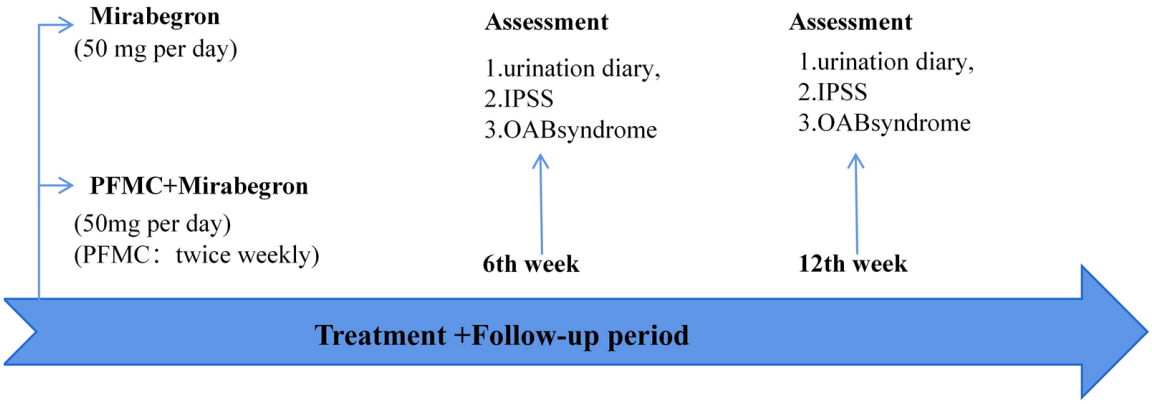

Figure 2. Study procedures.

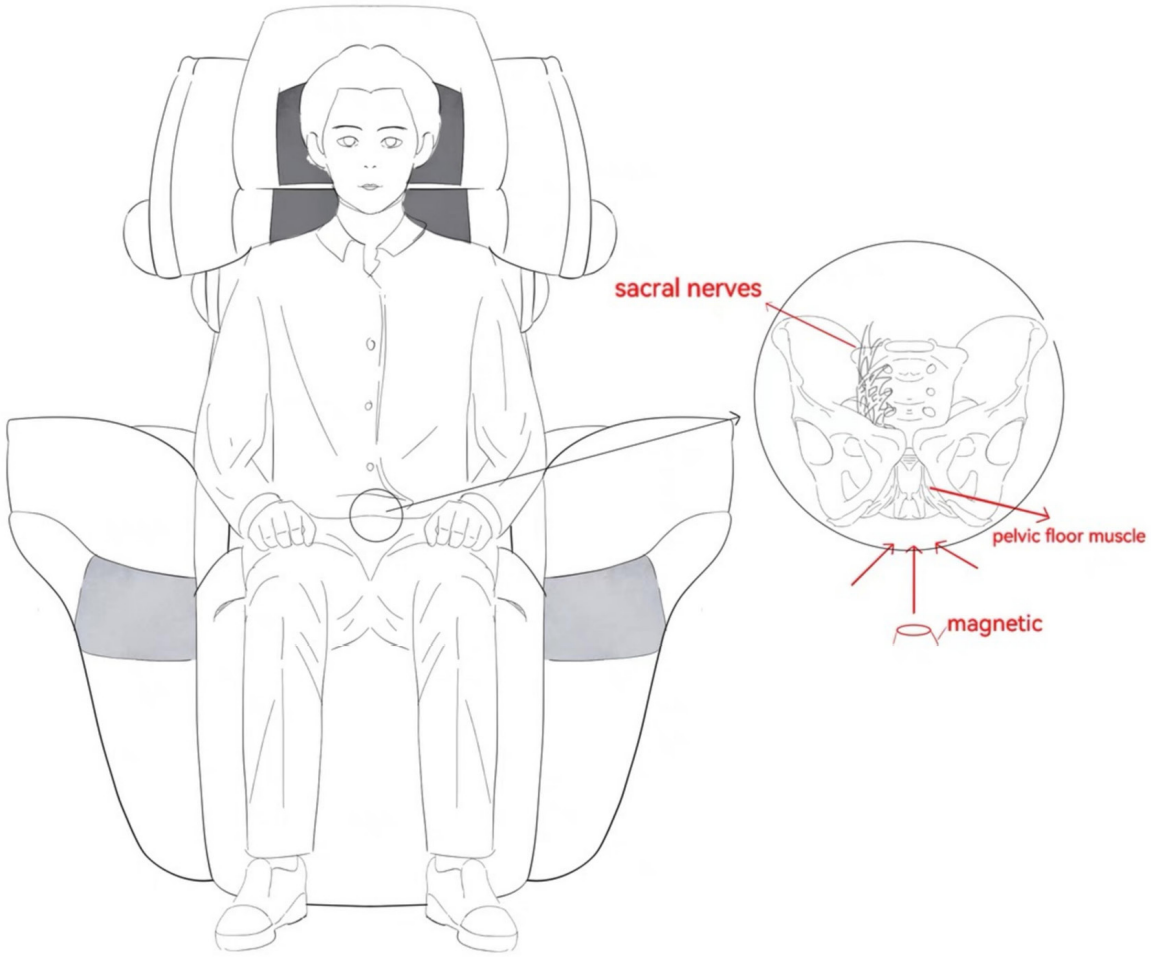

Figure 3. Diagram for pelvic floor magnetic stimulation.

low-up. Communication with attending physicians was encouraged for any treatment-related issues. In cases of persistent discomfort or suboptimal therapeutic response by the end of follow-up, additional supportive interventions were considered.

Outcome measures

Primary outcomes: Primary outcomes comprised alterations in voiding frequency and urgency severity, assessed via a 3-day voiding diary. This diary recorded the number of urina-

tions, episodes of urgency, and instances of urgency urinary incontinence (UUI).

Urinary urgency refers to a sudden, compelling need to void that is difficult to postpone. Its severity was measured using the Overactive Bladder Symptom Score (OABSS), which classifies urgency frequency as follows: 1 for fewer than once per week, 2 for more than once weekly, 3 for once daily, 4 for two to four times per day, and 5 for more than five times daily. This validated scale offers a consistent and standardized approach to quantifying the severity and frequency of urgency.

Secondary outcomes: Secondary outcomes included the International Prostate Symptom Score (IPSS), Overactive Bladder Questionnaire (OAB-q), Health-Related Quality of Life (HRQol), and OABSS scores, completed by participants during study visits. The IPSS categorized BPH-related symptom severity as mild (0-7), moderate (8-19), or severe (20-35) [12]. The OAB-q assessed symptom burden (ranging from 0 = asymptomatic to 100 = most severe) and quality of life (100 = optimal, 0 = poor) over the preceding four weeks [13]. The OABSS evaluated symptom intensity across seven items, yielding a composite score between 0 (no symptoms) and 28 (maximum severity) [14]. All adverse events, including serious complications, were rigorously monitored and documented throughout the study period.

Sample size and statistical analysis

Estimates derived from prior magnetic stimulation (MS) studies indicate a symptom improvement rate of 60% in OAB patients undergoing MS, compared to 30% in those receiving sham MS [15]. Under a one-sided hypothesis framework, with α set at 0.05 and β at 0.20 (power = 80%), a minimum of 40 subjects per group is required. To account for potential attrition during follow-up, the total enrollment target was adjusted to 110 participants.

Statistical analyses were performed using SPSS v.22.0 for Windows (IBM Corp., Armonk, NY, USA). Categorical data were evaluated using the Chi-square test, and continuous variables were analyzed via Student's t-test. A two-tailed *p*-value < 0.05 was adopted as the threshold for statistical significance.

Results

Demographics and clinical characteristics

A total of 98 eligible patients were enrolled and randomly allocated into two cohorts: one receiving mirabegron monotherapy (n = 49) and the other administered a combined regimen of PFMS and mirabegron (n = 49). Throughout the intervention and follow-up period, 12 participants discontinued, yielding 86 subjects for the final analysis of the primary endpoint (**Figure 1**).

Baseline demographic and clinical variables, including age, body mass index (BMI), symptom duration, and comorbid conditions such as hypertension, diabetes, and constipation, demonstrated no statistically significant intergroup differences (all $P > 0.05$), as summarized in **Table 1**. Furthermore, subgroup evaluations stratified by OAB subtype indicated comparable distributions across both groups.

OAB-S clinical symptoms and complications

Table 2 presented a comparative overview of bladder diary metrics across study intervals. Baseline assessments revealed no statistically significant variation in voiding frequency, urgency episodes, or urinary incontinence between groups (all $P > 0.05$). By weeks 6 and 12, the combination therapy group demonstrated more pronounced declines in urgency, frequency, and incontinence events relative to the mirabegron-only group ($P < 0.05$), indicating superior therapeutic efficacy over time.

IPSS score and OAB symptom severity score

Marked improvements were observed in the combination group across multiple evaluation metrics, including IPSS, OAB-q symptom score, OAB-q HRQoL, and OABSS (**Table 3**). At weeks 6 and 12, the combination therapy yielded significantly lower IPSS scores relative to mirabegron alone [10.2 ± 1.9 vs. 14.8 ± 3.0 ($P = 0.012$) and 8.4 ± 2.4 vs. 12.9 ± 3.5 ($P < 0.001$)]. Correspondingly, OAB-q HRQoL scores were significantly elevated in the combination group at both time points [79.0 ± 4.4 vs. 75.0 ± 4.9 ($P = 0.045$) and 88.5 ± 4.7 vs. 84.0 ± 5.1 ($P < 0.001$)]. OABSS scores also demonstrated greater reduction with the combined intervention [5.3 ± 2.2 vs. 6.7 ± 2.3 ($P = 0.015$) and 2.2

Table 1. Comparisons of patients' demographics and clinical characteristics between two groups

Variables, mean ± SD or n (%)	Mirabegron group (n = 44)	Combination group (n = 42)	*P*-value
Age (years)	64.8 ± 5.6	65.1 ± 6.0	0.385
BMI (kg/m^2)	24.6 ± 3.2	25.0 ± 2.9	0.409
Duration of symptoms (months)	72.5 ± 10.6	75.6 ± 12.4	0.435
Hypertension history			
No	28 (63.6)	25 (59.5)	-
Yes	16 (36.4)	17 (40.5)	0.702
Diabetes history			
No	21 (47.7)	19 (45.2)	-
Yes	23 (52.3)	23 (54.8)	0.835
Constipation			
No	32 (72.7)	33 (78.6)	-
Yes	12 (27.3)	9 (21.4)	0.512
Type of OAB			
Mixed urinary incontinence	12 (27.3)	9 (21.4)	0.571
OAB-wet	30 (68.2)	31 (73.8)	0.522
OAB-dry	2 (4.5)	2 (4.8)	1.000

BMI: body mass index; OAB: overactive bladder; SD: standard deviation. P < 0.05 is considered statistically significant.

Table 2. OAB-S clinical symptoms and complications

Dependent variable	Mirabegron group (n = 44)	Combination group (n = 42)	*P*-value
Micturitions			
Baseline	12.5 ± 4.30	14.2 ± 3.75	0.280
6 weeks	9.80 ± 2.50	8.10 ± 1.80	0.012*
12 weeks	8.60 ± 3.20	5.80 ± 2.50	< 0.001***
Episodes of urgency			
Baseline	4.10 ± 1.60	4.25 ± 2.20	0.610
6 weeks	3.20 ± 1.40	1.80 ± 1.10	0.008**
12 weeks	2.20 ± 1.70	1.00 ± 0.70	< 0.001***
Episodes of UUI			
Baseline	1.74 ± 1.31	1.93 ± 1.40	0.080
6 weeks	1.52 ± 1.13	0.92 ± 0.51	0.025*
12 weeks	1.41 ± 0.92	0.65 ± 0.35	< 0.001***
Related adverse events			
Tachycardia	3 (6.8%)	2 (4.5%)	-
Nausea	2 (4.5%)	1 (2.3%)	-
Constipation	2 (4.5%)	1 (2.3%)	-
Dizziness	1 (2.3%)	1 (2.3%)	-
Urinary retention	0 (0%)	0 (0%)	-

SD: standard deviation; OAB-S: overactive bladder symptoms; UUI: urgency urinary incontinence. P < 0.05 is considered statistically significant, *P < 0.05, **P < 0.01, ***P < 0.001.

± 1.4 vs. 2.9 ± 1.5 (*P* = 0.001)]. In addition, the OAB-q symptom scores declined more substantially in the combination group at both assessments [34.9 ± 3.2 vs. 37.5 ± 4.0 (*P* = 0.025) and 22.7 ± 3.5 vs. 25.0 ± 3.6 (*P* = 0.004)]. Tachycardia, nausea, and constipation emerged as the most commonly reported adverse events. However, no significant intergroup differences were identified in the incidence of drug-related adverse events (*P* > 0.05).

Table 3. Comparisons of IPSS score and OAB symptom severity score

Variables, mean ± SD or n (%)	Mirabegron group (n = 44)	Combination group (n = 42)	*P*-value
IPSS score			
Baseline	18.1 ± 2.6	18.2 ± 2.8	0.412
6 weeks	14.8 ± 3.0	10.2 ± 1.9	0.012
12 weeks	12.9 ± 3.5	8.4 ± 2.4	< 0.001***
OAB-q symptom score			
Baseline	48.0 ± 4.2	46.5 ± 3.9	0.165
6 weeks	37.5 ± 4.0	34.9 ± 3.2	0.025*
12 weeks	25.0 ± 3.6	22.7 ± 3.5	0.004**
OAB-q HRQoL score			
Baseline	57.5 ± 5.3	58.2 ± 5.0	0.388
6 weeks	75.0 ± 4.9	79.0 ± 4.4	0.045*
12 weeks	84.0 ± 5.1	88.5 ± 4.7	< 0.001***
OABSS			
Baseline	9.3 ± 2.1	9.0 ± 1.9	0.513
6 weeks	6.7 ± 2.3	5.3 ± 2.2	0.015*
12 weeks	2.9 ± 1.5	2.2 ± 1.4	0.001

SD: standard deviation; IPSS: International Prostate Symptom Score; OAB-q: overactive bladder questionnaire; HRQol: health-related quality of life; OABSS: overactive bladder syndrome score. *P < 0.05, **P < 0.01, ***P < 0.001.

Discussion

This study evaluated the therapeutic effectiveness and safety profile of PFMS combined with mirabegron in male patients diagnosed with BPH and OAB. Compared with mirabegron monotherapy, the combination regimen produced a significantly greater reduction in urgency, frequency, and incontinence at both 6- and 12-week follow-up intervals ($P < 0.05$). Notable improvements were also recorded in IPSS, OAB-q HRQoL, and OABSS metrics. The incidence of drug-related adverse events remained comparable between groups, indicating acceptable tolerability. Collectively, the data support the clinical utility of PFMS plus mirabegron in ameliorating LUTS and improving HRQol without increasing safety concerns.

BPH accompanied by OAB constitutes a leading etiology of LUTS in aging male populations [16]. The underlying pathophysiology reflects the combined influence of bladder outlet obstruction (BOO), secondary to prostatic enlargement, and detrusor overactivity (DO) [17]. BOO induces adaptive changes within the bladder wall, including hypertrophy, increased collagen deposition, and neuroplastic alterations, primarily mediated by sustained mechanical compression and chronic ischemia. These structural modifications impair storage function and contribute to symptom progression [18, 19]. Simultaneously, DO arises from enhanced afferent nerve excitability and dysregulated M2/M3 receptor activity, generating urgency, frequency, and urge incontinence [20]. Epidemiological data reveal that 50% to 75% of individuals with BPH exhibit concurrent OAB symptoms, with the intensity of LUTS inversely associated with quality of life (QoL) metrics [21]. The symptomatic burden frequently results in psychological distress, including anxiety, depressive states, and social disengagement, particularly driven by daytime frequency and nocturnal polyuria [22]. Standard pharmacotherapy typically involves alpha-1 adrenergic antagonists (e.g., tamsulosin) and anticholinergic compounds (e.g., sorixin). Alpha-1 blockers attenuate BOO by inducing relaxation of prostatic smooth muscle, while anticholinergics mitigate DO-related symptoms through suppression of involuntary detrusor activity. Nevertheless, their clinical application is often constrained by adverse effects, including orthostatic hypotension for alpha-1 blockers and CNS-related events (e.g., cognitive dysfunction), as well as peripheral complications (e.g., xerostomia, constipation), in the case of anticholinergics [23]. Mirabegron, a selective β3 receptor agonist, has recently gained attention for OAB management due to its capacity to induce detrusor relaxation with a more favor-

able side effect profile compared to conventional anticholinergic agents [24]. Despite these therapeutic advances, monotherapy yields response rates of only 40% to 60% in moderate-to-severe presentations, and efficacy in ameliorating BOO-associated symptoms remains limited [25].

In this context, non-invasive interventions such as PFMS have attracted increasing clinical interest. PFMS has shown therapeutic potential by attenuating detrusor overactivity and improving urethral sphincter function through targeted stimulation of deep pelvic floor musculature and modulation of the sacral nerve reflex arc [26]. A randomized controlled trial (n = 80) reported a statistically significant decrease in urgency and nocturia after 8 weeks of PFMS, with favorable tolerability profiles [27]. Despite these outcomes, evidence regarding combined treatment strategies for BPH and OAB comorbidities remains scarce, warranting further investigation into potential synergistic interactions and sustained efficacy of PFMS when integrated with pharmacotherapy.

The therapeutic mechanism of PFMS operates through electromagnetic induction, generating alternating magnetic fields that induce rhythmic contractions and relaxations in pelvic floor musculature and associated neural circuits. This neuromodulatory process contributes to the bidirectional regulation of urinary storage and voiding. Two primary mechanisms have been identified: (1) Suppression of detrusor muscle activity: Low-frequency PFMS (10-15 Hz) activates inhibitory interneurons within the pelvic floor, resulting in attenuated excitability of bladder afferent pathways and subsequent suppression of involuntary detrusor contractions during the storage phase [28]. (2) Enhancement of urethral sphincter function: Clinical studies have demonstrated that PFMS increases urethral closure pressure and enhances sphincter control by stimulating the pudendal nerve through the sacral Onuf nucleus pathway [29]. Compared to conventional pelvic floor electrical stimulation, PFMS offers the advantage of non-invasive penetration into deeper pelvic musculature, such as the levator ani and obturator internus, without requiring voluntary muscular engagement. This feature enhances its applicability in elderly patients or individuals with reduced pelvic muscle strength.

The outcomes observed align with previous research. A multicenter randomized controlled trial (n = 160) demonstrated a 43.7% reduction in urinary urgency episodes following biweekly PFMS over 4 weeks in individuals with OAB. Combination therapy further decreased urgency episodes by 67.5% [30], consistent with the 50% reduction observed in the combination group at the 12-week follow-up in the current analysis. Additionally, a meta-analysis by Magdalena et al. [31] reported significantly greater symptom improvement with PFMT combined with pharmacotherapy compared to monotherapy, corroborating the IPSS differences identified in this study (IPSS: 8.4 in the combination group vs. 12.9 in the monotherapy group).

Additionally, the stimulation frequency of 10 Hz applied here is consistent with current mechanistic evidence indicating that lower frequencies suppress detrusor overactivity, whereas higher frequencies primarily target muscle strengthening [32]. These observations point to the potential utility of tailoring stimulation parameters to individual pathophysiological profiles for enhanced therapeutic outcomes.

The combined application of PFMS and mirabegron demonstrates a synergistic therapeutic effect in alleviating LUTS in men concurrently diagnosed with BPH and OAB. The observed improvements in urgency, frequency, and incontinence significantly exceeded those achieved with mirabegron monotherapy, aligning with the distinct but complementary mechanisms of action: PFMS modulates neuromuscular activity within the pelvic floor and bladder, whereas mirabegron induces detrusor relaxation through β3-receptor activation. The integration of these modalities may be particularly advantageous in cases where monotherapy yields suboptimal responses. As indicated by the present findings, this dual approach has the potential to support more tailored, multidimensional treatment strategies. Despite its clinical relevance, the study presents several limitations. The relatively limited sample size (n = 86) and single-center design may restrict the external validity of the results. Additionally, the 12-week observation period precludes evaluation of sustained therapeutic effects and long-term safety. Parameter optimization for PFMS - such as frequency and session duration

- remains unaddressed, potentially constraining the reproducibility and scalability of treatment protocols. Future investigations should incorporate larger, multi-center cohorts, extend follow-up durations to 6-12 months, and include both PFMS monotherapy and sham stimulation control arms to enhance comparative interpretation. Further mechanistic insights may be obtained through integration of objective assessments, including urodynamic studies and pelvic floor EMG signal analysis. Exploration of PFMS in combination with adjunctive therapies such as behavioral interventions or electrical stimulation may offer additional avenues for advancing individualized, comprehensive management of BPH/OAB.

Conclusion

Compared to mirabegron monotherapy, the combined intervention of PFMS and mirabegron can achieve superior symptom relief for BPH and OAB, accompanied by greater improvements in quality of life, without a corresponding rise in adverse events.

Disclosure of conflict of interest

The authors report no commercial or financial relationships that could be interpreted as potential conflicts of interest.

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