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Voiding Dysfunction

Effectiveness and Safety of Mirabek Sustained-release 50 mg Tablets in Korean Patients with Overactive Bladder: A Multicenter Observational Study at Tertiary General Hospitals

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Abstract

Background and objective: Mirabegron, a first-in-class β_3-adrenergic agonist, is a key therapy for overactive bladder (OAB). This study aimed to evaluate the real-world effectiveness and safety of generic mirabegron (Mirabek) in Korean patients with OAB through a multicenter, prospective, noninterventional observational study at tertiary general hospitals.

Methods: Adult patients with OAB newly prescribed Mirabek sustained-release 50 mg tablets were enrolled from 46 tertiary general hospitals. Assessments were performed at baseline and follow-up visits at 3 and 6 mo. Data collected included the OAB Symptom Score (OABSS), bladder diaries, uroflowmetry results, and adverse events.

Key findings and limitations: Among the 4009 participants analyzed, 81.3% completed 6 mo of treatment. At 3 and 6 mo, 35.3% and 43.4% of participants, respectively, achieved a $\geq$3-point reduction in total OABSS ($p < 0.0001$), with the mean score improving from 6.9 to 4.6. All seven bladder diary parameters, including urgency and incontinence, showed significant improvement. Treatment satisfaction increased, and 67.3% of participants continued Mirabek at 6 mo. Adverse events occurred in 5.5% of participants, with 1.8% being drug related; all were mild.

Conclusions and clinical implications: Mirabek (generic mirabegron) demonstrated effective symptom relief and was well tolerated in Korean patients with OAB, with sustained efficacy up to 6 mo. The introduction of Mirabek substantially reduced treatment costs and expanded access to mirabegron therapy.

Patient summary: In this study, we looked at the effect of Mirabek, a generic medication for overactive bladder (OAB), in >4000 Korean patients treated in large hospitals. We found that Mirabek improved bladder symptoms such as urgency and frequent urination over 6 mo, with very few side effects. Most patients stayed on the treatment and reported feeling better, suggesting that this affordable medication can help more people manage their OAB effectively.

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1. Introduction

Overactive bladder (OAB), a syndrome defined by the International Continence Society [1], is characterized by symptoms such as urinary urgency with or without incontinence and affects approximately 10–15% of the general population [2,3]. Management of OAB typically includes behavioral interventions and pharmacotherapy [4,5], with anticholinergic medications and β_3-adrenergic agonists as the primary pharmacological options [4,6]. Anticholinergics mitigate involuntary bladder contractions by antagonizing muscarinic receptors; however, long-term use is frequently limited by adverse effects such as dry mouth, constipation, dizziness, blurred vision, and cognitive impairment [7–11].

Mirabegron, the first β_3-adrenergic receptor agonist approved for OAB, promotes detrusor muscle relaxation by targeting β_3 receptors in the bladder and may also modulate bladder afferent signaling [12,13]. Clinical guidelines recommend mirabegron as a first-line pharmacotherapy alternative to anticholinergics due to its efficacy in alleviating OAB symptoms and its lower incidence of anticholinergic-related side effects [14,15].

Substitution of brand-name drugs with generic alternatives is a widely adopted strategy to curb rising health care costs [16,17]. Generic drugs, which are bioequivalent to their brand-name counterparts, are typically priced approximately 80–85% lower [18]. Mirabek, a generic form of mirabegron (reference product: Betmiga; Astellas Pharma Inc.), is manufactured by Hanmi Pharmaceutical Co. (Seoul, Republic of Korea) and has rapidly gained a substantial share of the mirabegron market in Korea. Despite its widespread use, real-world clinical data on the effectiveness and safety of Mirabek remain limited. Furthermore, large-scale observational studies involving Korean patients with OAB are scarce. Previous postmarketing surveillance of mirabegron and other OAB treatments has primarily focused on long-term safety, often without a thorough evaluation of therapeutic outcomes.

A previous multicenter observational study of Mirabek conducted in local clinics found that short-term (8-wk) administration improved OAB symptoms significantly, with a low incidence of adverse events and favorable tolerability in real-world primary care settings [19]. While informative, this study was limited by its short follow-up period and lack of detailed urodynamic or diary-based outcome measures, which are often challenging to collect in local clinics [19].

To address these limitations, we conducted a large-scale, prospective observational study in tertiary general hospitals across Korea to evaluate the sustained (6-mo) effectiveness and safety of Mirabek. Importantly, while the efficacy and tolerability of the originator mirabegron (Betmiga) have been documented extensively in randomized controlled trials, there is a lack of robust real-world evidence specifically for its generic counterpart. This study is the first multicenter, long-term investigation of generic mirabegron in a tertiary care setting, enrolling over 4000 patients and incorporating detailed bladder diary parameters, uroflowmetry, treatment persistence, and patient-reported satisfaction—measures that have rarely been captured in previous studies. Beyond confirming clinical effectiveness, our findings also highlight the potential health care implications of generic substitution, particularly its ability to provide comparable efficacy and safety to the originator mirabegron, while improving affordability and access to therapy. Together, these aspects establish the novelty and added value of our study within the current evidence base.

2. Patients and methods

2.1. Study design

This multicenter, prospective, noninterventional observational study was conducted in South Korea across 46 tertiary general hospitals (including large community and academic hospitals) between June 2021 and August 2023. As an observational study, all treatment decisions were made by the attending physicians as part of routine care; no additional interventions were required beyond data collection. This study adhered to the ethical principles of the Declaration of Helsinki and local regulations for observational research. Institutional review board approval and written informed consent were obtained at each site before data collection.

2.2. Participants

Eligible participants were adults (aged $\geq$18 yr) diagnosed with OAB, clinically defined as urinary urgency with or without urge incontinence, typically accompanied by increased frequency and nocturia, after excluding urinary tract infection or other identifiable causes. Patients were enrolled at the time their physician decided to initiate treatment with Mirabek sustained-release (SR) 50 mg (Hanmi Pharmaceutical Co.). Patients could be treatment naïve or have previously used OAB medications; those on other OAB therapies could either switch to or add Mirabek at the physician's discretion. The key exclusion criteria included contraindications to mirabegron (eg, severe uncontrolled hypertension or hypersensitivity) and OAB symptoms due to neurogenic bladder or anatomical obstruction requiring alternate treatment.

2.3. Study flow

At baseline, demographic information (age and sex), medical history (including duration of OAB symptoms and prior OAB treatments), and concomitant medications were recorded. Baseline symptom severity was assessed using the Overactive Bladder Symptom Score (OABSS), a validated four-item questionnaire evaluating daytime frequency,

night-time frequency, urgency, and urge incontinence, with total scores ranging from 0 to 15. OAB severity was categorized as mild (total OABSS: 0–5), moderate (6–11), or severe (12–15). Patients also completed a voiding diary (typically over 3 d) and a baseline treatment satisfaction assessment, if applicable, before initiating Mirabek. All patients started on Mirabek SR 50 mg once daily. Concomitant OAB treatment (eg, an antimuscarinic agent) was permitted and documented; no placebo or control group was included.

2.4. Follow-up and outcome measures

Follow-up assessments were scheduled at approximately 3 and 6 mo after starting Mirabek. At each visit, symptom severity and treatment outcomes were reassessed. The primary effectiveness outcome was the proportion of patients achieving a reduction of ≥3 points in total OABSS from baseline, considered a clinically meaningful improvement. The primary endpoint was assessed at 3 mo.

The secondary endpoints included the following: (1) change in total OABSS from baseline to 6 mo; (2) treatment persistence at 6 mo, defined as continued Mirabek use without discontinuation; (3) patient-reported satisfaction measured by a Treatment Satisfaction Visual Analog Scale (TS-VAS; 0–10 scale) at 3 and 6 mo; and (4) safety outcomes, including all treatment-emergent adverse events (TEAEs), regardless of causality. Adverse drug reactions (ADRs) were defined as TEAEs considered possibly or definitely related to Mirabek. Serious adverse events—those that were life threatening, resulted in hospitalization or disability, or were otherwise medically significant—were specifically noted, and any suspected serious ADRs were reported immediately. Additional safety data included vital signs (particularly blood pressure and pulse, due to mirabegron's pharmacology).

Objective urinary metrics, including postvoid residual volume and maximum urinary flow rate (Qmax) from uroflowmetry, were recorded when available in routine clinical care to monitor for urinary retention or voiding difficulty.

2.5. Subgroup analyses

Subgroup analyses were conducted to examine the effect of concomitant therapies. Patients were stratified into two groups: (1) Mirabek monotherapy (no concurrent antimuscarinic agent), including both treatment-naïve and switch patients, and (2) combination therapy (Mirabek plus another OAB-active drug). Efficacy (OABSS improvement) and safety outcomes were compared across these subgroups to evaluate differential benefit or risk profiles.

2.6. Statistical analysis

Baseline characteristics were summarized using descriptive statistics. Continuous variables (eg, age, OABSS, and diary measures) are presented as mean ± standard deviation or median (range), as appropriate. Categorical variables (eg, sex, severity categories, and improvement rates) are presented as frequencies and percentages.

Changes in continuous outcomes from baseline were analyzed using paired *t* tests (for normally distributed data) or Wilcoxon signed-rank tests (for nonparametric data). McNemar's test was used for paired binary comparisons (e., improvement rates at 3 vs 6 mo). The primary endpoint (≥3-point OABSS reduction) was calculated with 95% confidence intervals. Changes in OAB severity categories were assessed using the marginal homogeneity test.

For subgroup comparisons, chi-square or Fisher's exact tests were used for categorical outcomes, and analysis of variance or Kruskal-Wallis tests were used for continuous outcomes. No imputation was performed for missing data; analyses at each time point included only patients with available data. Patients lost to follow-up or who discontinued early were excluded from subsequent analyses, except for persistence, where noncompletion was counted as nonpersistence. A two-sided p value of <0.01 was considered statistically significant. Given the large sample size, clinical relevance was also considered in interpreting results. We selected a more stringent significance threshold ($p < 0.01$) to reduce the risk of false-positive findings due to the large sample size. All statistical analyses were conducted using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA) and SPSS version 25 (IBM Corp., Armonk, NY, USA), under the supervision of a biostatistician.

3. Results

3.1. Participant characteristics

Among 5254 patients enrolled, 5244 were included in the safety set for an adverse event analysis. Baseline demographics and clinical characteristics are summarized in Table 1. The mean age was 68.1 (10.7) yr, with 66.9% aged ≥65 yr. The cohort included a higher proportion of males (69.7% male vs 30.3% female). The mean duration of OAB symptoms before enrollment was 13.8 (34.5) mo.

The full analysis set comprised 4009 patients who had at least one follow-up efficacy assessment. Among them, 3993 had baseline efficacy data, 3889 completed the 3-mo follow-up, and 3249 (81.3%) completed the 6-mo follow-up while continuing Mirabek treatment. Baseline OAB severity was moderate in most patients, with 53.8% categorized as having moderate and 10.2% as severe OAB (Table 2). The mean total OABSS at baseline was 6.9 (3.3; Table 2).

Table 1 – Baseline patient characteristics (*N* = 5244)

Variables	
Age, yr (SD)	68.1 (10.7)
<65, *n* (%)	1736 (33.1)
≥65, *n* (%)	3508 (66.9)
Sex, *n* (%)	
Male	3657 (69.7)
Female	1587 (30.3)
BMI, kg/m^2 (SD)	24.5 (3.4)
Duration of OAB, mo (SD)	13.8 (34.5)

BMI = body mass index; OAB = overactive bladder; SD = standard deviation.
BMI = weight (kg)/(height [m])^2. Duration of OAB (mo) = consent date – diagnosis date (after unit conversion from day to month, round to the second decimal place).

Table 2 – Therapeutic efficacy of Mirabek at 3 and 6 mo after treatment measured by OABSS (*N* = 4009)[a]

Baseline	3993
Mild, *n* (%)	1438 (36.0)
Moderate, *n* (%)	2147 (53.8)
Severe, *n* (%)	408 (10.2)
OABSS, *n* (SD)	6.9 (3.3)
3 mo	3889
Mild, *n* (%)	2244 (57.7)
Moderate, *n* (%)	1479 (38.0)
Severe, *n* (%)	166 (4.3)
OABSS, mean (SD)	5.2 (3.2)
Participants with symptom improvement [b] for OAB, *n* (%)	1369 (35.3)
Change of OABSS from baseline, *n* (SD)	−1.7 (3.1)
6 mo	3249
Mild, *n* (%)	2244 (57.7)
Moderate, *n* (%)	1479 (38.0)
Severe, *n* (%)	166 (4.3)
OABSS, *n* (SD)	5.2 (3.2)
Participants with symptom improvement [b] for OAB, *n* (%)	1406 (43.4)
Change of OABSS from baseline, *n* (SD)	−2.2 (3.3)
Change of OABSS from 3 mo, *n* (SD)	−0.6 (2.5)
Completed 6-mo treatment, *n* (%)	2696 (67.2)

OAB = overactive bladder; OABSS = Overactive Bladder Symptom Score; SD = standard deviation.

[a] Mild: total OABSS ≤5; moderate: 6 ≤ total OABSS ≤ 11; severe: total OABSS ≥12.

[b] Symptom improvement is defined as total OABSS decreased by more than 3 points compared with the total OABSS at baseline.

Regarding prior OAB treatments, approximately 87% of patients were not using any OAB medication at the time of initiating Mirabek.

3.2. Therapeutic efficacy outcomes

Mirabek treatment resulted in significant improvement in OAB symptom severity over 6 mo. At 3 mo, 1369 of 3889 patients (35.3%) showed a ≥3-point reduction in total OABSS compared with baseline (Table 2). By 6 mo, this proportion increased to 1742 of 4009 patients (43.4%; Table 2). The increase from 35.3% to 43.4% was statistically significant ($p < 0.0001$), indicating that some patients experienced delayed improvement (Fig. 1A). The 95% confidence interval for the 6-mo response rate was approximately 41.3–45.4%, supporting the robustness of this finding.

Fig. 1B illustrates the shift in OABSS distribution: many patients transitioned from moderate or severe categories to mild. The proportion rated as mild increased from 36.0% at baseline to 57.7% at 3 mo and 65.4% at 6 mo. Nearly half of the patients experienced a noticeable reduction in symptom burden with Mirabek in real-world settings. In terms of absolute change, the mean total OABSS declined from 6.9 at baseline to 5.2 at 3 mo and 4.6 at 6 mo (Table 2), indicating a mean improvement of approximately 2.2 points ($p < 0.0001$). This suggests that while not all patients achieved the predefined response (≥3-point improvement), many experienced partial improvements and shifted to less severe categories. A key finding was the relatively high persistence with Mirabek in this real-world cohort. At 6 mo, 67.3% of patients remained on treatment (Table 2).

All seven key voiding diary parameters improved significantly from baseline at both 3 and 6 mo (Table 3). The 24-h micturition frequency declined significantly ($p < 0.0001$) without a change in total urine volume. Episodes of urinary incontinence, nocturia, and urgency also decreased significantly ($p < 0.0001$). Patients reported fewer urgency events and experienced milder urgency severity following treatment.

Consistent with reduced voiding frequency, the mean voided volume per micturition increased by approximately 30–50 ml by 6 mo (eg, from ∼170 ml at baseline to ∼210 ml at 6 mo, $p < 0.0001$), reflecting improved bladder capacity. The maximum single voided volume also increased, suggesting enhanced ability to hold urine without urgency. These improvements were significant at 3 mo, and either sustained or enhanced further at 6 mo.

Treatment satisfaction improved alongside symptom reduction (Table 4). Based on the TS-VAS (0–10 scale), participants reported a mean increase of 1.2 (2.4) points at 3 mo and 1.7 (2.4) points at 6 mo compared with baseline—both statistically significant ($p < 0.0001$ for both).

Uroflowmetry showed no significant change in postvoid residual volume, indicating preserved bladder emptying. The mean Qmax increased slightly by 0.4 ml/s at 3 mo and 0.5 ml/s at 6 mo.

3.3. Subgroup analysis

After treatment initiation, 14.3% of patients received Mirabek in combination with another OAB medication (primarily an antimuscarinic), while 85.7% used Mirabek alone. In the *monotherapy subgroup*, the ≥3-point OABSS improvement rate at 6 mo was approximately 44%, similar to the overall rate. The *combination therapy group* had a response rate of approximately 45%, with no statistically significant differences between groups. There was a trend toward slightly greater absolute improvement in some diary metrics with combination therapy, although differences were not substantial.

3.4. Safety profile

Mirabek was generally safe and well tolerated. Among 5244 patients in the safety analysis, 289 (5.51%) experienced at least one TEAE during the 6-mo period. Most events were mild and required no specific intervention. Importantly, only 93 patients (1.77%) had ADRs considered to be related to Mirabek.

4. Discussion

In this large real-world study of Korean patients with OAB, Mirabek, a generic formulation of mirabegron, demonstrated significant efficacy in relieving OAB symptoms over 6 mo, alongside a favorable safety profile. These results support and extend findings from randomized trials of mirabegron into routine clinical practice.

The symptom improvements observed with Mirabek are consistent with established mirabegron efficacy from clinical trials. In phase 3 RCTs, mirabegron 50 mg reduced average daily micturitions by approximately 1.5–2 times and incontinence episodes by fewer than one per day versus placebo, while also improving patient perception of bladder

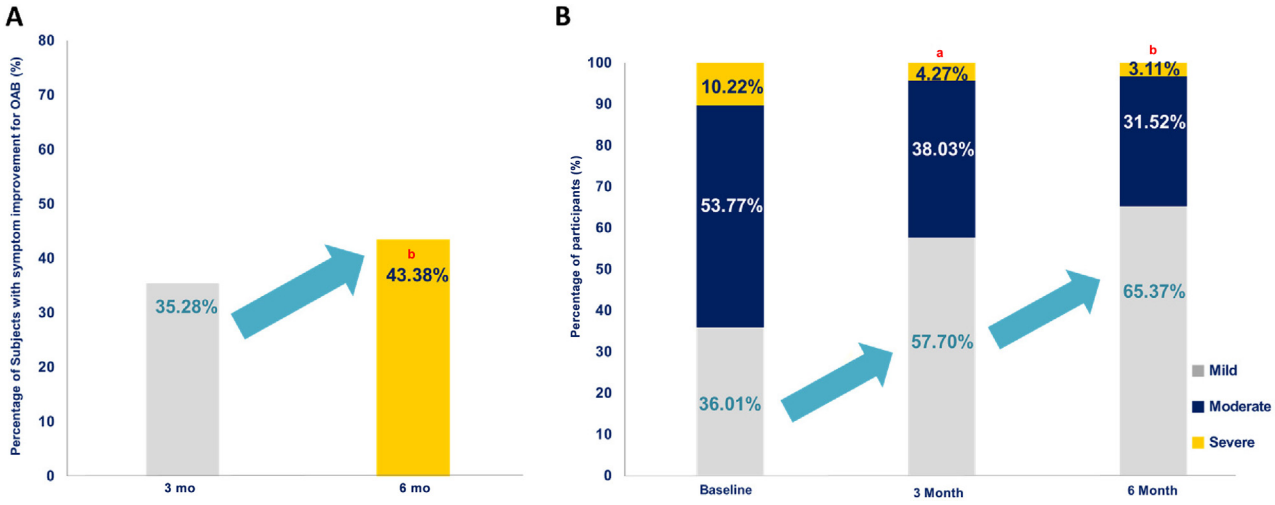

Fig. 1 – Therapeutic efficacy of Mirabek in patients with overactive bladder (OAB), assessed at 3 and 6 mo after treatment compared with those at baseline. (A) Proportion of participants with symptom improvement, defined as a reduction of >3 points in the total overactive bladder symptom score (OABSS) after treatment, and (B) proportion of participants categorized by OAB symptom severity based on total OABSS (0–5: mild; 6–11: moderate; and 12–15: severe) following treatment. [a] Significant differences between baseline and 3 mo using McNemar's test ($p < 0.0001$). [b] Significant differences between 3 and 6 mo using McNemar's test ($p < 0.0001$).

Table 3 – Changes in voiding diary measures at 3 and 6 mo after Mirabek treatment

	Baseline	3 mo	6 mo	*p* value [a]
Number of Urination, *n* (SD)	10.1 (3.7)	8.8 (3.1)	8.5 (2.8)	<0.0001
Volume of urination, ml (SD)	1652.9 (661.7)	1682.8 (553.6)	1671.4 (509.2)	0.0188
Urinary incontinence, *n* (SD)	0.7 (1.6)	0.5 (1.7)	0.3 (1.1)	<0.0001
Urinary urgency, *n* (SD)	4.4 (5.1)	3.7 (4.2)	3.2 (4.1)	<0.0001
Degree of urinary urgency [b], points (SD)	3.1 (1.6)	2.5 (1.4)	2.4 (1.5)	<0.0001
Number of nocturia, *n* (SD)	1.9 (1.2)	1.3 (1.1)	1.1 (0.9)	<0.0001
Average urine volume per urination, ml (SD)	177.2 (77.2)	205.6 (72.3)	210.7 (68.9)	<0.0001

SD = standard deviation.
[a] The *p* values indicate comparisons between baseline and 6-mo outcomes. Statistical tests for 3-mo changes were not performed separately.
[b] The degree of urgency was recorded on a 5-point scale (0 = no urgency and 5 = severe urgency that is difficult to defer) in the bladder diary.

Table 4 – Change of treatment Satisfaction by Mirabek at 3 and 6 mo after treatment

	TS-VAS [a], points (SD)
Baseline	5.2 (2.2)
3 mo	6.3 (2.1)
Change of TS-VAS from baseline	1.2 (2.4)
6 mo	6.8 (2.1)
Change of TS-VAS from baseline, points (SD)	1.7 (2.4)
Change of TS-VAS from 3 mo, points (SD)	0.5 (2.0)

SD = standard deviation; TS = treatment satisfaction; VAS = Visual analog scale.
[a] The TS-VAS scores range from 0 (no, not at all) to 10 (yes, completely).

condition [20,21]. Although our study lacked a placebo group, the observed before-after improvements in frequency (1.6/d) and urgency incontinence (many participants becoming dry) align closely with these findings, suggesting that Mirabek conferred genuine therapeutic benefit beyond placebo. While direct comparisons are limited by differing endpoints, our finding that 43% of participants achieved a ≥3-point OABSS improvement at 6 mo offers a practical measure of treatment impact. Similarly, a Finnish 6-mo prospective study of mirabegron (n = 170) reported that 45.2% of participants experienced symptom relief [22].

The mean reduction in OABSS in our study was slightly lower than in some shorter-term trials [5,23], likely due to our inclusion of many participants with mild baseline symptoms and limited room for numeric improvement. Nearly half of the cohort began with mild OAB severity, whereas clinical trials typically enroll individuals with more severe symptoms.

A notable finding was the continued symptom improvement between 3 and 6 mo of treatment. Some participants improved only after prolonged therapy, with response rates increasing during this period. This suggests that mirabegron's therapeutic effects may build over time in certain individuals or that delayed responders may still benefit from extended treatment. Clinically, this supports maintaining therapy for 3–6 mo before concluding that it is ineffective. The sustained effect through 6 mo supports

mirabegron's utility in long-term OAB management and raises the possibility that benefits persist with continued use [24,25]. This delayed maximal response is consistent with clinical experience and may involve progressive central or peripheral nervous system adaptation [26]. It also underscores the importance of continued treatment beyond the initial few weeks to achieve optimal outcomes.

Treatment persistence of two-thirds of patients at 6 mo indicates a notably higher persistence rate than previously reported for OAB medications, which typically range from 30% to 50% at 6 mo [27–32]. This suggests that most participants found Mirabek both effective and tolerable. Persistence data provide meaningful insights into real-world adherence. In contrast to antimuscarinic agents—often discontinued within 6 mo due to side effects or limited efficacy, mirabegron generally shows better persistence, likely due to its more favorable safety profile [9,33]. Our observed persistence supports this trend, indicating that the low rate of anticholinergic-like side effects helped participants remain on treatment.

Mirabek was well tolerated, and no new safety concerns emerged. The 1.8% rate of ADRs was low, and all were mild. This aligns with the established safety profile of mirabegron from clinical trials and long-term studies, where common ADRs such as hypertension, headache, and tachycardia affect only a small proportion of patients [21,23]. In our cohort, no significant changes were observed in blood pressure or cases of acute urinary retention, consistent with prior findings that mirabegron minimally impacts blood pressure and does not negatively affect voiding dynamics [34,35]. The slight increase in Qmax observed may reflect relief of OAB-related bladder outlet obstruction through reduced urgency and detrusor overactivity.

The key strengths of this study include its large sample size and multicenter design, enhancing generalizability. A broad range of outcomes was assessed—from symptom scores to voiding diary measures and patient satisfaction—providing a comprehensive evaluation of treatment effectiveness. However, limitations inherent to observational studies must be acknowledged. The absence of a control group precludes definitive attribution of improvements solely to mirabegron, although the magnitude and consistency of symptom improvement across endpoints support a genuine treatment effect. The absence of a control group in this nonrandomized, open-label study represents an important limitation and necessitates cautious interpretation of our findings. Some degree of improvement may reflect natural symptom fluctuation or regression to the mean, as patients often initiate therapy when their symptoms are most severe. In addition, placebo effects are well documented in OAB trials, where patients in placebo arms frequently report meaningful reductions in urgency, frequency, and incontinence episodes. In a large pooled analysis of randomized controlled trials, Chapple et al. [24] confirmed that placebo responses in OAB are substantial and must be considered when interpreting real-world data. These effects are thought to arise from patients' treatment expectations and the increased clinical attention associated with study participation.

While we cannot exclude such nonspecific effects, several aspects of our data suggest that the therapeutic benefits observed here are unlikely to be explained by placebo alone. First, improvements were sustained over 6 mo, with a persistence rate of approximately 72%, a durability that is not easily attributed to placebo effects, which typically exert their greatest influence during the initial weeks to months. This finding is consistent with the COMPOSUR study, an open-label real-world investigation of vibegron, which reported high patient satisfaction and a 6-mo persistence rate of 73.9% [25]. Second, improvements in our study were concordant across both subjective outcomes (OABSS and treatment satisfaction) and objective measures (bladder diary parameters and uroflowmetry), the latter being less susceptible to an expectancy bias. Taken together, these considerations suggest that Mirabek provided meaningful therapeutic benefit in this real-world cohort, although we acknowledge that placebo contributions cannot be ruled out completely. Future studies with randomized controlled designs or active comparators will be needed to confirm these findings definitively.

In addition to the lack of a control group, the observational design without randomization may have introduced potential confounding factors, such as differences in patient characteristics, baseline symptom severity, or concomitant treatments. Although no formal statistical adjustment was performed, the large sample size, inclusion of diverse tertiary care centers, and consistent treatment effect across subgroups (eg, monotherapy vs combination therapy) help mitigate concerns regarding a selection bias. Nevertheless, the possibility of unmeasured confounding cannot be ruled out and should be considered when interpreting the findings. Additionally, more than one-quarter of participants did not complete the 6-mo follow-up, which may have introduced an attrition bias if their outcomes differed from completers. To address this, we conservatively treated noncompleters as nonpersistent in the persistence analysis, and a sensitivity perspective assuming them as nonresponders still showed significant overall improvement. Importantly, the observed persistence of about 72% in our study is consistent with the findings from the COMPOSUR trial of vibegron, which reported a 6-mo persistence rate of 73.9% with a similar discontinuation rate [25]. These results suggest that our attrition is in line with other large real-world studies in this therapeutic area. The follow-up duration of 6 moths also warrants consideration. While randomized controlled trials of OAB pharmacotherapy often extend to 12 mo or longer, conducting longer-term follow-up in large, multicenter observational studies poses substantial challenges. Notably, the COMPOSUR trial also reported 6-mo interim outcomes, underscoring that this timeframe is used widely and accepted for real-world investigations of β_3-adrenergic receptor agonists [25]. Thus, although longer-term data are ultimately desirable, our study provides robust and clinically meaningful evidence on the real-world effectiveness, persistence, and safety of generic mirabegron within a feasible and relevant timeframe. Lastly, reliance on self-reported adherence and diary data may introduce a reporting bias, although these reflect real-world clinical assessment practices.

In summary, this study provides robust real-world evidence that Mirabek, a generic mirabegron, effectively alleviates OAB symptoms with minimal side effects in a broad Korean population. These findings reinforce the role of β_3-agonist therapy in OAB management, particularly for patients who cannot tolerate anticholinergics. The data also underscore the importance of accessible generic options in improving treatment uptake and persistence. Future research should explore outcomes beyond 6 mo, assess patient-reported measures in greater depth, and compare combination therapy (mirabegron plus anticholinergic) with monotherapy in real-world settings.

5. Conclusions

Mirabek improved OAB symptoms significantly and was well tolerated in a large cohort of Korean patients over 6 mo. Most participants experienced symptom relief, and no serious adverse effects were reported. These findings support mirabegron's value as a real-world treatment for OAB and demonstrate that cost-effective generic formulations can improve access without compromising efficacy or safety.

***Author contributions*:** Won Sik Jang had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: J.S. Park, M.-H. Park.
Acquisition of data: J.S. Park, Kim, Jang.
Analysis and interpretation of data: J.S. Park.
Drafting of the manuscript: J.S. Park.
Critical revision of the manuscript for important intellectual content: M.-H. Park, Jang.
Statistical analysis: J.S. Park, M.-H. Park.
Obtaining funding: Jang.
Administrative, technical, or material support: Kim, M.-H. Park.
Supervision: Jang.
Other: None.

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Data sharing statement: The dataset used and/or analyzed during the current study are available from the corresponding author on reasonable request.

***Ethics statement*:** This study protocol was reviewed and approved by the Yonsei University Health System (4-2021-0256). The study was performed in accordance with the approved guidelines and regulations for medical research in the Declaration of Helsinki. Informed consent was obtained from all participants.

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