Poster #445

Presented at the
2023 Annual Meeting of
International Continence Society
September 27–29, 2023
Toronto, ON, Canada

Real-World Adherence and Persistence of Vibegron Versus Mirabegron and Anticholinergics in Patients With Overactive Bladder: A Retrospective Claims Analysis

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Background

- Overactive bladder (OAB) syndrome is a common, chronic disorder defined by urinary urgency, usually with urinary frequency and/or nocturia, with or without urinary incontinence, and in the absence of urinary tract infection or other detectable disease[1]
- Anticholinergics and β_3-adrenergic receptor agonists have shown efficacy in the treatment of OAB; however, management of OAB symptoms with pharmacotherapy is limited by low real-world adherence and persistence[2]
  - Persistence over 12 months with anticholinergic therapy is low, typically reported between 5%–25%[3]
  - The use of β_3-adrenergic receptor agonists has shown improved persistence compared with anticholinergics[4]
- Vibegron, a β_3-adrenergic receptor agonist approved by the US Food and Drug Administration in December 2020 for OAB, was shown to be efficacious and safe in the 12-week EMPOWUR trial[5] and its 40-week extension[6]
- In the US, there are no comparative data available on real-world adherence and persistence with vibegron vs mirabegron or anticholinergics

Objective

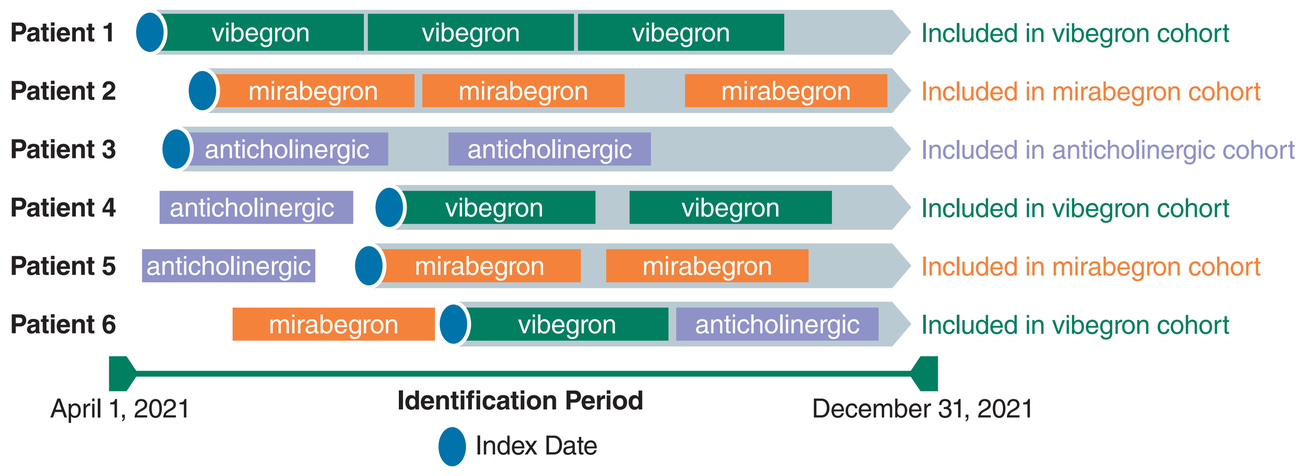
- To assess vibegron adherence and persistence compared with mirabegron and anticholinergics in a real-world population of patients with OAB in the US

Methods

Study Design and Patient Identification

- This retrospective study used pharmacy claims data from the Optum Research Database (ORD) to identify patients ≥18 years old with ≥1 pharmacy claim for vibegron, mirabegron, or an anticholinergic (darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine, trospium) from April 1, 2021, to December 31, 2021 (identification period) (**Figure 1**)
  - The ORD comprises deidentified medical and pharmacy claims data from >76 million patients in the US and is compliant with the Health Insurance Portability and Accountability Act
  - The index date was defined as the first date for a fill of vibegron, mirabegron, or an anticholinergic, set hierarchically, during the identification period
- Additional inclusion criteria were continuous enrollment in a commercial or Medicare Advantage health plan with pharmacy and medical benefits for 3 months preindex (fixed-length baseline) and ≥2 months postindex (variable-length follow-up period) and no index medication during baseline

Figure 1. Patient Identification and Cohort Entry Example



Patients in the mirabegron cohort have no claims for vibegron during the identification period; patients in the anticholinergic cohort have no claims for vibegron or mirabegron during the identification period.

Patient Matching

- 2 independent propensity-score models were used to match patients treated with (1) vibegron vs mirabegron and (2) vibegron vs anticholinergics with the closest available propensity score in a 1:2 ratio for each comparison group
  - Patient characteristics collected and used for propensity-score matching included demographics, variables related to prescription coverage, and baseline clinical characteristics

Assessments and Statistical Analysis

- Adherence was assessed using the proportion of days covered (PDC) from index to end of follow-up and was calculated as:

$$\text{PDC} = \frac{\text{total days' supply received}}{\text{length of follow-up}}$$

- Persistence was defined as days from index date to discontinuation of index medication (first 30-d gap) or end of follow-up
- Adherence was analyzed descriptively; *P* values were calculated with *z*-tests using robust standard errors in an ordinary least squares regression for continuous measures and Rao-Scott test for binary measures
- Persistence was analyzed using Kaplan-Meier analysis; *P* values were calculated with Wald chi-square tests using robust standard errors from a Cox proportional hazard model testing for equality in hazard rates
  - Patients were censored at the end of study follow-up if they did not discontinue

Results

Patient Identification

- 1655 and 3310 patients were included in the matched vibegron and mirabegron cohorts, respectively, and 1595 and 3190 patients were included in the matched vibegron and anticholinergic cohorts
- Owing to propensity-score matching, the cohorts were generally well balanced with respect to patient demographics, prescription coverage–related variables, and baseline comorbid medical conditions (**Table 1**)
  - Mean age in the anticholinergic cohort was lower than in the vibegron cohort (*P*<0.001); mean age for the mirabegron and vibegron cohorts were comparable
  - Index copays were higher in the vibegron cohorts compared with the matched mirabegron and anticholinergic cohorts (*P*<0.05 and *P*<0.001, respectively)
  - Index fill days' supply significantly differed between vibegron and the matched anticholinergic cohort (*P*=0.008)

Table 1. Patient Demographics and Baseline Clinical Characteristics

Characteristic	Vibegron (Matched With Mirabegron) (N=1655)	Mirabegron (N=3310)	Vibegron (Matched With Anticholinergic) (N=1595)	Anticholinergic (N=3190)
Mean (SD) age, y	74.7 (10.6)	74.2 (10.3)	74.5 (10.7)	73.4 (11.0)***
Female, n (%)	1153 (69.7)	2275 (68.7)	1102 (69.1)	2220 (69.6)
Race, n (%)				
White	1180 (71.3)	2335 (70.5)	1134 (71.1)	2241 (70.3)
Black/African American	194 (11.7)	392 (11.8)	186 (11.7)	399 (12.5)
Hispanic	141 (8.5)	287 (8.7)	134 (8.4)	283 (8.9)
Asian	32 (1.9)	59 (1.8)	32 (2.0)	56 (1.8)
Other/missing	108 (6.5)	237 (7.2)	109 (6.8)	211 (6.6)
Region, n (%)				
South	718 (43.4)	1454 (43.9)	686 (43.0)	1411 (44.2)
Midwest	379 (22.9)	768 (23.2)	369 (23.1)	729 (22.9)
Northeast	341 (20.6)	655 (19.8)	330 (20.7)	646 (20.3)
West/Other	217 (13.1)	433 (13.1)	210 (13.2)	404 (12.7)
Provider specialty, n (%)				
Urology	745 (45.0)	1477 (44.6)	694 (43.5)	1411 (44.2)
Allied health professional	347 (21.0)	752 (22.7)	343 (21.5)	663 (20.8)
Primary care provider	267 (16.1)	482 (14.6)	267 (16.7)	542 (17.0)
Other/unknown	296 (17.9)	599 (18.1)	291 (18.2)	574 (18.0)
Insurance type, n (%)				
Medicare	1505 (90.9)	3069 (92.7)*	1443 (90.5)	2867 (89.9)
Commercial	150 (9.1)	241 (7.3)	152 (9.5)	323 (10.1)
Low-income subsidy, n (%)	474 (28.6)	959 (29.0)	453 (28.4)	912 (28.6)
Mean (SD) index copay, US$	56.40 (63.75)	52.44 (68.50)*	56.36 (63.80)	16.02 (21.68)***
Mean (SD) index fill supply, d	42.3 (26.8)	41.5 (26.2)	42.7 (27.1)	40.7 (27.9)*
Index fill supply, n (%)				
1–21 d	162 (9.8)	300 (9.1)	158 (9.9)	496 (15.6)***
22–42 d	1105 (66.8)	2273 (68.7)	1052 (66.0)	1947 (61.0)***
≥43 d	388 (23.4)	737 (22.3)	385 (24.1)	747 (23.4)
Mean (SD) length of follow-up, d	160.6 (64.4)	159.9 (63.3)	161.5 (64.6)	166.5 (69.4)*
Mean (SD) Charlson Comorbidity Index score	1.34 (1.70)	1.35 (1.73)	1.32 (1.70)	1.38 (1.82)
Comorbidities of interest, n (%)				
Hypertension	1003 (60.6)	2019 (61.0)	960 (60.2)	1942 (60.9)
Coronary artery disease	289 (17.5)	580 (17.5)	275 (17.2)	552 (17.3)
Chronic heart failure	171 (10.3)	326 (9.9)	162 (10.2)	321 (10.1)
Mean (SD) medication count	9.2 (5.3)	9.0 (5.1)	9.1 (5.3)	8.8 (5.1)*

*P<0.05 vs matched vibegron cohort. ***P<0.001 vs matched vibegron cohort.

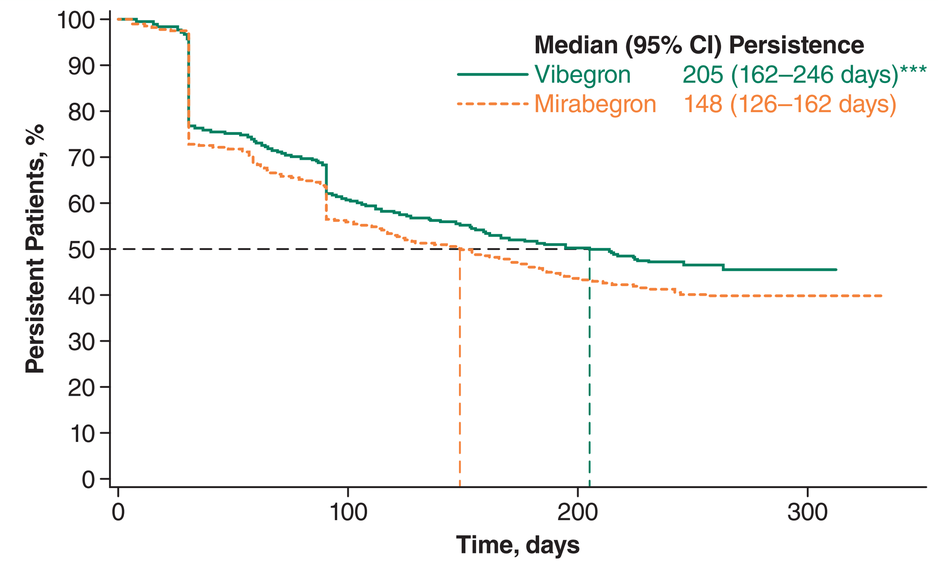
Adherence With Vibegron

- Patients receiving vibegron had greater adherence vs patients receiving mirabegron (mean [SD] PDC: 0.71 [0.31] vs 0.68 [0.32], respectively; *P*=0.004) and vs patients receiving anticholinergics (mean [SD] PDC: 0.71 [0.31] vs 0.61 [0.35]; *P*<0.001)
- A greater percentage of patients receiving vibegron were adherent (PDC ≥80%) vs those receiving mirabegron (53.4% vs 49.2%, respectively; *P*=0.005) and vs those receiving anticholinergics (53.7% vs 43.2%; *P*<0.001)

Persistence With Vibegron

- Median persistence was longer with vibegron vs mirabegron (**Figure 2**) and vs anticholinergics (**Figure 3**)
  - Reductions in persistence were observed at 30 and 90 days, corresponding with the most common days' supplies
- A greater percentage of patients receiving vibegron remained persistent through the end of the study period vs patients in the matched mirabegron cohort (56.8% vs 50.8%, respectively; *P*<0.001) and matched anticholinergics cohort (56.9% vs 42.9%; *P*<0.001)
- The mean (SD) number of fills during persistence was similar for patients in the vibegron and mirabegron cohorts (3.2 [2.8] vs 3.0 [2.8], respectively; *P*=0.083) but significantly greater for patients in the vibegron vs anticholinergic cohort (3.2 [2.8] vs 2.5 [2.0], respectively; *P*<0.001)

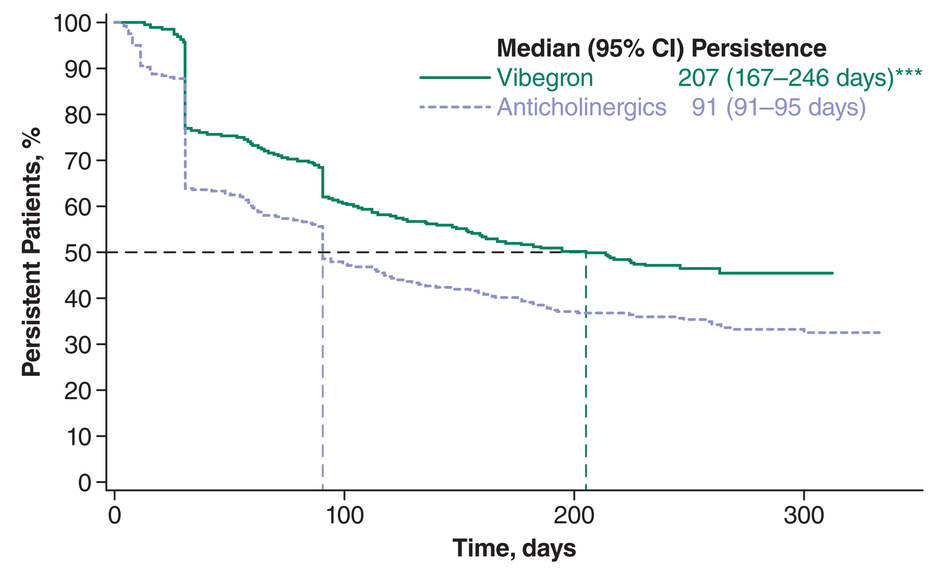
Figure 2. Persistence With Vibegron vs Mirabegron



Day	0	30	60	90	120	150	180	210	240	270
No. at Risk										
Vibegron	1655	1596	1202	911	600	434	287	171	93	38
Mirabegron	3310	3231	2266	1739	1132	840	557	330	172	52

***P<0.001; A Wald chi-square test using robust standard errors in a proportional hazard model was used for assessing equality of hazard rates.

Figure 3. Persistence With Vibegron vs Anticholinergics



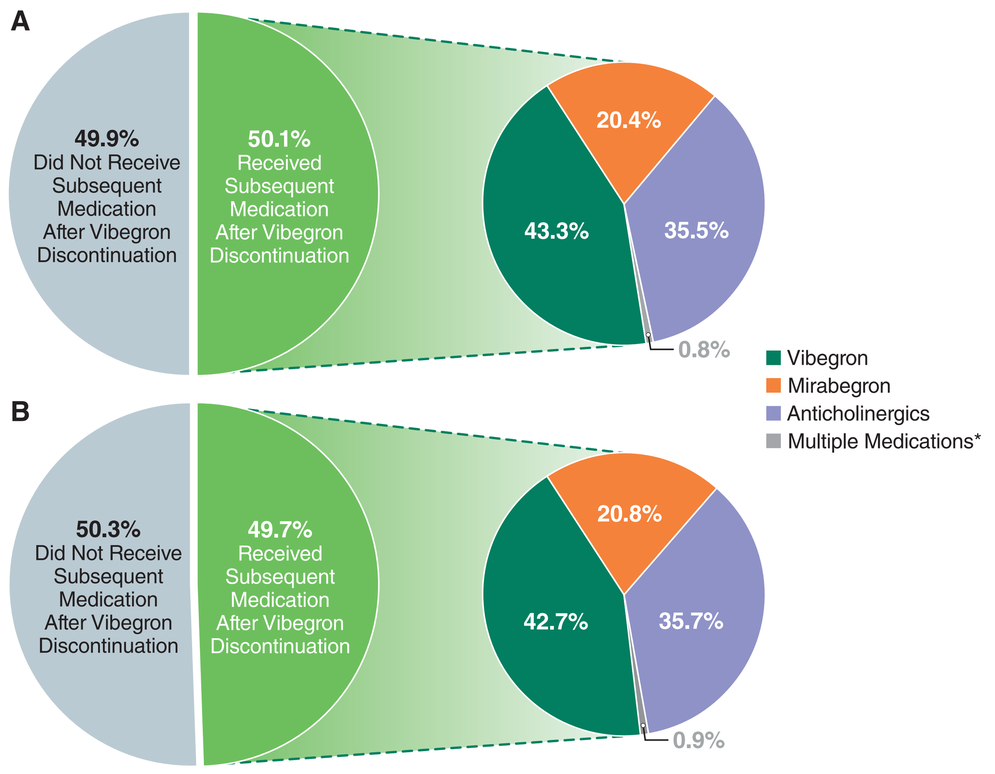
Day	0	30	60	90	120	150	180	210	240	270
No. at Risk										
Vibegron	1595	1540	1165	884	584	427	282	166	93	38
Anticholinergics	3190	2799	1907	1501	968	678	504	354	203	117

***P<0.001; A Wald chi-square test using robust standard errors in a proportional hazard model was used for assessing equality of hazard rates.

First Medication After Discontinuation

- Of patients in the vibegron matched with mirabegron and anticholinergic cohorts who received subsequent oral OAB medication after discontinuation of index treatment during the study, 43.3% and 42.7% reinitiated vibegron, respectively (**Figure 4**)

Figure 4. First Oral OAB Medication Used After Discontinuation of Vibegron in the (A) Vibegron Matched With Mirabegron Cohort and (B) Vibegron Matched With Anticholinergic Cohort



*Patients with claims for 2 or more OAB medications.

Discussion

Limitations

- Interpretation of results is limited by the inability to confirm whether patients who were prescribed medications took the medication or whether behavioral therapy was implemented
- This study is limited by the analysis time frame, which began in April 2021 and coincided with the launch of vibegron, likely biasing index fill dates
- As with retrospective datasets, these results may not be generalizable to all patients with OAB

Conclusions

- In this retrospective analysis, real-world adherence and persistence was higher in patients initiating vibegron compared with patients initiating mirabegron or anticholinergics when matched on baseline characteristics
  - A robust propensity score–matching model was used to control for confounding variables among baseline characteristics
  - Improved adherence and persistence with vibegron was observed despite association with characteristics typical of lower adherence and persistence (eg, large copays)

Acknowledgments Medical writing and editorial support were provided by The Curry Rockefeller Group, LLC (Tarrytown, NY), and funded by Sumitomo Pharma America, Inc. (formerly Urovant Sciences; Marlborough, MA).

Funding This study was funded by Sumitomo Pharma America, Inc. (formerly Urovant Sciences; Marlborough, MA).

Disclosures **Benjamin Chastek**, **Christina Landis**, and **Tim Bancroft** are employees of Optum. **Adam Carrera** is an employee of Sumitomo Pharma America (formerly Urovant Sciences) and Duke Health. **Daniel Snyder**, **Laleh Abedinzadeh**, and **Jeffrey Nesheim** are employees of Sumitomo Pharma America (formerly Urovant Sciences). **David Staskin** is an advisor for Astellas, Sumitomo Pharma America (formerly Urovant Sciences), and UroCure; a meeting participant, lecturer, and investigator for Astellas and Sumitomo Pharma America (formerly Urovant Sciences); and a board member of AzuraBio, Quillitin, and UroCure.

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