Research Article ISSN 2639-9342

Gynecology & Reproductive Health

Trends in Overactive Bladder Prescriptions from 2020 to 2022

Sarah Ashmore MD[1], Margaret G Mueller MD[1], Kimberly Kenton MD[1], Jinxuan Shi MA[1], Prottusha Sarkar MD[2] and Oluwateniola Brown MD[3]

[1]*Section of Urogynecology and Reconstructive Pelvic Surgery, University of Chicago, Chicago, IL, USA.*

[2]*Northwestern University Feinberg School of Medicine, Chicago, IL, USA.*

[3]*Division of Female Pelvic Medicine and Reconstructive Surgery, Northwestern Medicine, Chicago, IL, USA.*

***Correspondence:**
Sarah Ashmore, MD, Section of Urogynecology and Reconstructive Pelvic Surgery, University of Chicago, Chicago, IL, USA, Tel: (970) 581-1554.

Received: 07 Jan 2026; **Accepted:** 28 Feb 2026 **Published:** 11 Mar 2026

Citation: Sarah Ashmore, Margaret G Mueller, Kimberly Kenton, et al. Trends in Overactive Bladder Prescriptions from 2020 to 2022. Gynecol Reprod Health. 2026; 10(3): 1-6.

ABSTRACT

Importance: *There is growing concern regarding the risk of cognitive impairment with anticholinergics to treat overactive bladder (OAB). In 2021, updated clinical guidelines cautioned the use of anticholinergic especially in elderly patients and vibegron became the second available Beta-3 agonist medication.*

Objective: *The primary objective of this study was to examine OAB prescribing patterns from 2020 to 2022.*

Study Design: *This was a retrospective study at two academic centers between January 2020 and December 2022. Female patients at least 18 years old diagnosed with OAB and newly prescribed anticholinergic or Beta-3 for OAB were included. OAB diagnosis was identified using ICD-10 codes and the electronic medical record was queried for new OAB medication prescriptions in the health system. Patient demographics and provider specialty were abstracted from the medical record.*

Results: *Between 2020 and 2022, 12,162 patients were prescribed a new anticholinergic or Beta-3 medication. Older, white patients were more likely to be prescribed Beta-3 medications ($p<0.001$). Publicly insured patients were more likely to receive a Beta-3 prescription while patients with private insurance were more likely to receive an anticholinergic prescription ($p<0.001$). Provider specialty was significantly different between Beta-3 and anticholinergic prescriptions ($p<0.001$). Urogynecologists were the leading prescribers of Beta-3 (33.8%), while PCPs prescribed the most anticholinergic (38.6%). When comparing 2020 and 2022 OAB prescriptions by provider specialty, percentage of Beta-3 prescriptions increased for all specialties and percentage of anticholinergic prescriptions decreased ($p<0.001$).*

Conclusion: *Consistent with updated guidelines, Beta-3 prescriptions for OAB increased while anticholinergic prescriptions decreased substantially between 2020 and 2022.*

Keywords

Bladder, Urogynecologists, Beta-3 medication, Anticholinergic.

Introduction

Overactive bladder (OAB) is a prevalent, debilitating condition affecting 12-17% of the general population [1-5]. The American Urological Association (AUA) and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) recommend anticholinergic or Beta-3 agonists as pharmacotherapy for OAB [6]. Anticholinergic pharmacotherapies block muscarinic receptors, thereby inhibiting bladder contraction. Muscarinic receptors are located throughout the body leading to a broad range of potential side effects: dry mouth, blurred vision, constipation, and impaired cognition [7]. Beta-3 pharmacotherapies have a more favorable side effect profile compared to anticholinergics [8].

Anticholinergic medications cross the blood-brain barrier resulting in an increased risk for undesirable cognitive effects. There is growing concern regarding the associated risk of cognitive impairment, dementia, and Alzheimer disease with anticholinergic pharmacotherapy [9-16]. In February 2021, the American Urogynecology Society (AUGS) released an updated clinical consensus statement highlighting the associated risks of cognitive impairment with anticholinergic medications [17]. AUGS recommends reducing anticholinergic burden by prescribing the lowest effective dose and considering Beta-3 medications as alternatives. In women older than 70 years old with OAB, AUGS recommends avoiding anticholinergic medications completely. Beta-3 alternatives include mirabegron and vibegron. Mirabegron and vibegron stimulate adrenergic receptors on the bladder wall resulting in relaxation. Vibegron received approval by the United States Food and Drug Administration (FDA) in December 2020, however, was not available for use until April 2021. Vibegron more selectively binds Beta-3 receptors compared to mirabegron mitigating some of the undesirable effects of mirabegron [18].

Previous studies have evaluated OAB medication prescribing patterns within the US [19-25]. Even though Beta-3 prescriptions increased, anticholinergic pharmacotherapies are consistently prescribed at a higher rate especially by clinicians outside of gynecology and urology specialties. All prior literature is limited to a single Beta-3 prescription (i.e. mirabegron) as vibegron was not yet FDA approved. Two major events occurred in 2021: updates to the AUGS clinical consensus statement and the FDA approval of vibegron. We aimed to determine how OAB prescription patterns changed following these events at two academic tertiary care centers.

Materials and Methods

We performed a retrospective review at two large, academic tertiary care centers of women prescribed OAB medications between January 2020 and December 2022. Our study was deemed exempt by the Institutional Review Boards at both sites. Adult women with a diagnosis of OAB and newly prescribed anticholinergic or Beta-3 pharmacotherapy were included. The primary objective was to identify OAB medication prescription trends between 2020 and 2022. Secondary objectives were to identify differences in patient demographics and clinician specialty by type of OAB medication prescribed. Prescriptions trends by clinician specialty were also evaluated.

OAB diagnosis was identified utilizing ICD-10 codes: Urge incontinence N39.41 Frequency of micturition R35.0, Urgency of urination R39.15, and Overactive bladder N32.81. The electronic medical record was queried to identify the first time anticholinergic and Beta-3 prescriptions were documented in the health record. Anticholinergic prescriptions included oxybutynin, trospium, solifenacin, tolterodine, fesoterodine, and darifenacin. Beta-3 medications included mirabegron and vibegron. Clinician specialty and patient age, race, ethnicity, and insurance were abstracted from the medical record. Specialties were grouped as urogynecology, urology, obstetrics and gynecology, and primary care.

Statistical analysis was performed using IBM SPSS Statistics version 28 (SPSS Inc, Chicago, IL). We compared demographic variables of patients with independent student's t-test for continuous variables and Chi-square test for categorical variables. We examined prescription trends between 2020 and 2022 using student's t-test and examined trends by prescriber specialty.

Results

Between January 2020 and December 2022, 12,162 women were newly prescribed OAB medications. 4,329 (35.6%) patients were prescribed Beta-3 medications while 7,833 (64.4%) were prescribed anticholinergic pharmacotherapies (Table 1). Majority of women were white (47.0%) with government insurance (60.4%) and a mean ($\pm$ SD) age of 68 ($\pm$ 0.53) years. Primary care physicians prescribed the majority of OAB medications (32.8%) followed by obstetrics and gynecology (24.2%), urogynecology (21.8%), and urology (21.2%) respectively.

Important differences existed in patients receiving anticholinergic medication and those receiving Beta-3 agonists. Women who received Beta-3 agonists were older than those who received anticholinergics (69 ± 0.58 vs 67 ± 0.51, $p<0.001$). Race, ethnicity, and insurance coverage also differed significantly between OAB medication cohorts (Table 1). White patients were more likely to be prescribed Beta-3 agonist while Black patients were more likely to be prescribed anticholinergic medications ($p<0.001$). Only 50.8% of white patients were prescribed anticholinergic medications compared to 83.2% of Black patients. Patients with private insurance were more likely prescribed anticholinergic mediations, and Beta-3 agonists were more likely prescribed for patients with government insurance ($p<0.001$). 37.6% of patients with government insurance were prescribed Beta-3 medications. 67.6% of patients with private insurance were prescribed anticholinergic medications.

Differences also existed in prescribing practices by physician specialty. Urogynecologists were more likely to prescribed Beta-3 agonists compared to urologists, obstetrician and gynecologists, and primary care physicians ($p<0.001$), while anticholinergic medications were more likely to be prescribed by primary care physicians. Fifty-five percent of OAB prescriptions written by a urogynecologist were for Beta-3 agonists compared to 38% of those by urologists, 31% of those by obstetrician-gynecologists, and 24% of those by primary care physicians (Table 1).

When comparing 2020 to 2022, total OAB prescriptions increased from 3,194 to 4,718 (Table 2). Overall Beta-3 prescriptions increased while anticholinergic prescriptions decreased ($p<0.001$). This remained a consistent trend when breaking down OAB prescriptions by clinician specialty ($p<0.001$). Total Beta-3 prescriptions increased by 137% between 2020 and 2022 while anticholinergic prescriptions only increased by 16% ($p<0.001$). For

urogynecologists, urologists, obstetricians and gynecologists, and primary care physicians, Beta-3 prescriptions increased by 343%, 98%, 53%, and 115% respectively. Anticholinergic prescriptions increased by 106%, 11%, and 38% for urogynecology, urology, and primary care physicians respectively. Anticholinergic prescriptions decreased by 31% between 2020 and 2022 for obstetrics and gynecology. Figure 1 displays the number of Beta-3 and anticholinergic medication prescriptions in 2020, 2021, and 2022. Figure 2 and 3 shows Beta-3 and anticholinergic prescriptions over the 3 years by clinician specialty respectively.

Table 1: Patient demographics and clinician specialty.

	Entire Cohort (n=12162)	**Beta-3 Agonist (n=4329)**	**Anticholinergic (n=7833)**	***p***
Age, *years*	68 (±0.53)	69 (±0.58)	67 (±0.51)	<0.001
Race				
White	5724 (47.0%)	2816 (65.1%)	2908 (37.1%)	<0.001
Black/African American	4105 (33.8%)	688 (15.9%)	3417 (43.6%)	
Asian	183 (1.5%)	67 (1.5%)	116 (1.5%)	
None of the above	2150 (17.7%)	758 (17.5%)	1392 (17.8%)	
Ethnicity				
Hispanic	742 (6.1%)	237 (5.4%)	505 (6.4%)	<0.001
Not Hispanic	9388 (77.2%)	3468 (80.1%)	5920 (75.6%)	
None of the above	2032 (16.7%)	624 (14.5%)	1408 (18.0%)	
Insurance				
Medicaid/Medicare	7346 (60.4%)	2766 (63.9%)	4580 (58.5%)	<0.001
Private	4773 (39.2%)	1547 (35.7%)	3226 (41.2%)	
Self-pay	43 (0.4%)	16 (0.4%)	27 (0.3%)	
Clinician Specialty				
Urogynecology	2647 (21.8%)	1463 (33.8%)	1184 (15.1%)	<0.001
Urology	2586 (21.2%)	995 (23.0%)	1591 (20.3%)	
Obstetrics/Gynecology	2944 (24.2%)	910 (21.0%)	2034 (26.0%)	
Primary Care	3985 (32.8%)	961 (22.2%)	3024 (38.6%)	

Table 2: Overactive bladder prescription trends 2020 to 2022.

	2020 (n=3194)	**2022 (n=4718)**	***p***	***% change in prescriptions 2020 versus 2022***
All prescriptions				
Beta-3 Agonist	838 (26.2%)	1984 (42.1%)	<0.001	+137%
Anticholinergic	2356 (73.9%)	2734 (57.9%)		+16%
Urogynecology				
Beta-3 Agonist	164 (38.9%)	727 (57.8%)	<0.001	+343%
Anticholinergic	258 (61.1%)	531 (42.3%)		+106%
Urology				
Beta-3 Agonist	226 (31.4%)	448 (45.1%)	<0.001	+98%
Anticholinergic	493 (68.6%)	546 (54.9%)		+11%
Obstetrics/Gynecology				
Beta-3 Agonist	248 (23.5%)	380 (40.6%)	<0.001	+53%
Anticholinergic	809 (76.5%)	555 (59.4%)		-31%
Primary Care				
Beta-3 Agonist	200 (20.1%)	429 (28.0%)	<0.001	+115%
Anticholinergic	796 (79.9%)	1102 (72.0%)		+38%

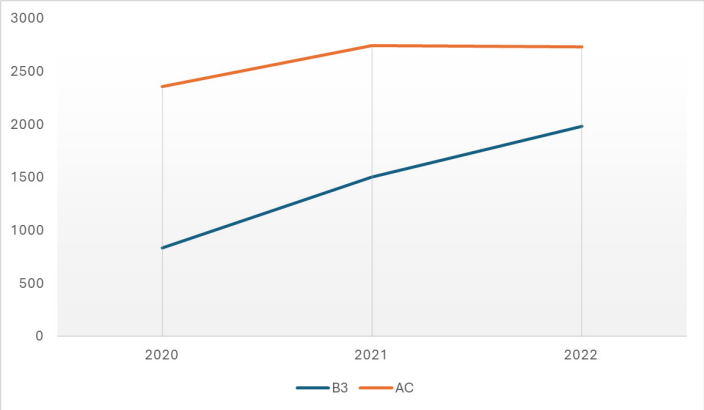

Figure 1: Number of beta 3 agonists (B3) and anticholinergic (AC) medication prescription between 2020 to 2022.

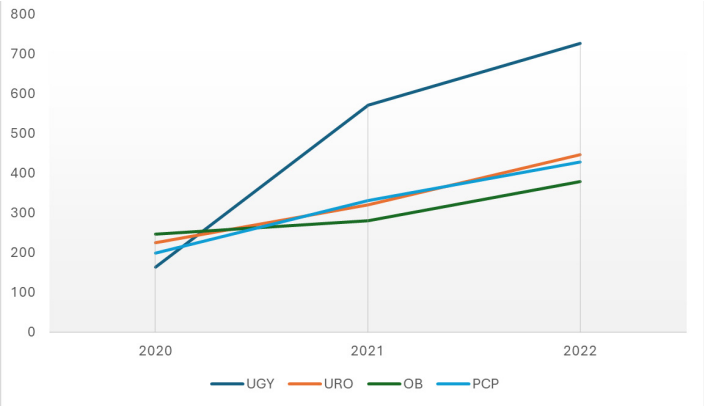

Figure 2: Number of beta 3 agonist prescriptions for urogynecology (UGY), urology (URO), obstetrics/gynecology (OBG), and primary care (PCP) clinicians between 2020 to 2022.

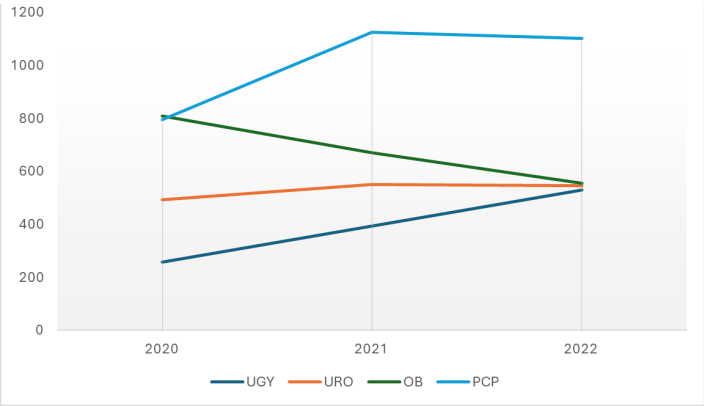

Figure 3: Number of anticholinergic prescriptions for urogynecology (UGY), urology (URO), obstetrics/gynecology (OBG), and primary care (PCP) clinicians between 2020 to 2022.

Discussion

While Beta-3 agonist prescriptions for OAB increased by approximately 140% between 2020 and 2022 at two large academic medical centers, anticholinergic medications still accounted for nearly two thirds of all OAB medications prescribed during the three-year period. Given the mounting data associating anticholinergic medications for OAB with dementia [9-16], we anticipated the proportion of patients receiving Beta-3 agonists overall would be higher but were optimistic regarding the significant increase in prescribing rates over time. We also found demographic and provider specialty difference in prescribing patterns that can be used to target future education and interventions. Older, white patients with government insurance were more likely to be prescribed Beta-3 pharmacotherapy, while Black patients and those with private insurance were more likely to receive anticholinergic prescriptions. The slightly higher age may reflect provider and/or patient awareness of the cognitive effects of anticholinergic medication, while lack of private insurance coverage of the newer Beta-3 agonists may limit their availability to some patients.

More concerning was our finding that 83% of Black women received an anticholinergic prescription compared to only 51% of white women suggesting race may influence prescribing practices. Previous literature reports that black patients have lower dementia prevalence compared to white counterparts, however, black participants with dementia have more dementia risk factors and greater cognitive impairment and neuropsychiatric symptom severity [26]. Our data are consistent with Bowman et al. who reported that compared to white patients, Asian, Black, and other races were less likely to receive a Beta-3 agonist prescription using the American Urological Association Quality (AUAQ) Registry from 2014 to 2020 [24]. In a multivariable logistic regression to account for potential confounding factors, Bowman et al. found that Black patients were at 0.87 lower odds of receiving a Beta-3 prescription compared to white patients. Unlike our data the AUAQ Registry is limited to a single specialty (urologists), so our data expands this racial disparity in prescribing practices to other specialties. Other studies have also found that race and ethnicity independently affect the treatment of patients with OAB [27,28]. There may be a direct racial disparity in the diagnosis and management of OAB. Further research is needed to assess this potential health disparity and promote equity amongst patients with OAB and mitigate the risk of anticholinergic pharmacotherapy.

Our data showed that urogynecologists were the leading prescribers for Beta-3 medications, and primary care physicians prescribed anticholinergic medications at the highest rate compared to other specialties. In 2021, American Urogynecologic Society (AUGS) released an updated clinical statement addressing the association of anticholinergic pharmacotherapy with cognitive impairment in women with OAB [17]. There is growing evidence that anticholinergic medications are associated with an increased risk of cognitive impairment, dementia, and Alzheimer disease [9-16]. Gray et al. performed a prospective cohort study of 3,434 patients to examine the association between cumulative anticholinergic use and dementia [9]. Higher cumulative anticholinergic use corresponding to oxybutynin 5 mg daily for more than 3 years was associated with an increased risk for dementia (HR 1.54,

95% CI 1.21-1.96). In a retrospective cohort study, 47,324 new anticholinergic users were matched with 23,662 new Beta-3 agonist users to determine the increased risk of dementia among patients with OAB [16]. Anticholinergic users were at increased risk for dementia compared to Beta-3 users (HR 1.23, 95% CI 1.12-1.35). Given the growing body of literature, AUGS recommends reducing overall anticholinergic burden and encourages clinicians to consider using Beta-3 alternatives instead [17]. Anticholinergic medications should be avoided in women older than 70 years old. In our study, older patients were more likely to be prescribed Beta-3 pharmacotherapy for OAB treatment which is consistent with these recommendations.

Similar to other studies [20], we found that primary care physicians accounted for the highest proportion of OAB prescriptions written at our institutions, and anticholinergic medications accounted for three quarters of the prescriptions written by primary care physicians. This is consistent with older studies which showed that mirabegron accounted for only 16% of OAB prescriptions written by primary care physicians. The high rate of anticholinergic medications prescribed by primary care physicians compared to specialists may reflect insurance coverage challenges for Beta-3 agonists. Many private and government insurance plans require that a patient trial 1-2 anticholinergic medications before they will cover a Beta-3 agonist. However, these differences may also reflect differences in awareness of updated AUGS guidelines and evolving scientific literature regarding long-term risks of anticholinergic OAB medications. The difference in OAB medication prescribing patterns by clinician specialty highlights a need for further investigation to promote better OAB care.

Despite the growing concern regarding undesirable cognitive effects of anticholinergic pharmacotherapy, there are significant barriers to accessing Beta-3 medications for OAB treatment. Beta-3 and anticholinergic pharmacotherapy are equally effective OAB treatments, however, long-term adherence is better for Beta-3 medications compared to anticholinergics [29,30]. Improved Beta-3 adherence rates are likely due to differences in side effect profiles. Even with these findings, Beta-3 medications are prescribed at significantly lower rates compared to anticholinergics [19-25]. This may be attributed to the prohibitive cost of Beta-3 medications and variations in insurance coverage. A 30-day supply of mirabegron 25 milligram tablets costs $397.54 out-of-pocket on GoodRx.com compared to $10.73 for a month supply of oxybutynin 5 milligram tablets [31]. Co-pays and out-of-pocket costs may still be expensive even when medications are covered by insurance. Expenses may prohibit patients from accessing medications that are proven to be ultimately safer. Currently, there is limited research investigating underlying reasons for OAB medication prescribing patterns and further investigation is needed. Our study found that patients with government insurance were more likely to be prescribed Beta-3 medications and anticholinergic prescriptions were more commonly prescribed for patients with private insurance. We suspect this is likely due to differences in medication coverage amongst insurance plans.

Our study has several strengths and limitations. To the best of our knowledge, this is the first study to evaluate OAB medication prescribing patterns since the FDA approval of vibegron and the AUGS clinical consensus statement update in 2021. Prior studies are limited to one Beta-3 medication (mirabegron) and all were performed prior to 2021. We also stratified obstetricians and gynecologists further to highlight the practice patterns of urogynecologists specifically given the recommendations from urogynecology professional societies. Our study was performed at two high volume tertiary care centers with strong referral patterns and a diverse patient population. The major limitations of our study is the inability to perform a multivariable logistic regression due to the available data for statistical analysis. Our study found that there were significant difference in OAB medication prescriptions by race and ethnicity. We are unable to control for potential confounding factors to further analyze this significance; however, we intend to address this in future directions of this study. In our study, we did not account for multiple OAB medication prescriptions for a single patient. We identified the first OAB prescription within the study period and did not include subsequent prescriptions thereafter. The electronic medical recorded was also searched for prescriptions placed; however, it was not confirmed that prescriptions were filled and initiated.

While we found a substantial increase in prescriptions for Beta-3 agonists over the study period, nearly two-thirds of OAB prescriptions were for anticholinergic medications despite evolving data and guidelines about cognitive and dementia risks with their usage.

The increase in Beta-3 prescriptions was primarily driven by urogynecologists who were likely influenced by the AUGS clinical consensus statement. More than 4 out of 5 black women were given an anticholinergic medications rather than Beta-3 agonists suggesting a concerning racial disparities in prescribing practices to a group already at higher dementia risk. Future studies are needed to identify more recent prescribing patterns on a national scale and motivations influencing prescribing patterns given the risk of cognitive impairment with anticholinergic pharmacotherapy.

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