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Retrospective study of utilization patterns of overactive bladder therapy in men in a commercially-insured population: the early US mirabegron experience

Daniel Ng[1], Di Wei[1], Linyi Fan[1], Jeremy Shelton[2]

[1]Medical Affairs, Americas; Astellas Pharma Global Development, Northbrook, IL, USA; [2]Skyline Urology, Torrance, CA, USA

INTRODUCTION

- Bladder outlet obstruction (BOO) is often treated with α-blockers or 5-α reductase inhibitors (5ARIs). However, overactive bladder (OAB) symptoms may coexist with BOO, in which case drugs targeting both storage and voiding symptoms may be required
- There are two distinct classes of OAB therapy, the antimuscarinic (AM) agents and the β3-adrenoceptor agonists, of which mirabegron is the only one available
- Understanding the patient demographics and baseline characteristics associated with utilization of particular OAB therapies and medications used concomitantly to treat BOO, may help to predict long-term healthcare resource allocation in the male OAB population and thereby help ensure that patients receive the most appropriate treatment

OBJECTIVES

- The primary objective of this study was to describe the baseline characteristics of men according to the oral OAB therapies (mirabegron or AMs) that they are prescribed
- Secondary objectives were to describe the level of usage of other urologic medication classes over the long-term, the combinations that were used and the order in which they were combined

METHODS

Data source

- The Optum database is a large, nationally representative, commercial prescription and medical claims database comprised of United Healthcare beneficiaries in the United States
- Data from the Optum database were analyzed to identify men with a first claim for any OAB therapy (the drug index date) between 10/01/12 and 12/31/13 and who had an insurance coverage eligibility period of at least 12 months pre-index and 3 months post-index

Study design

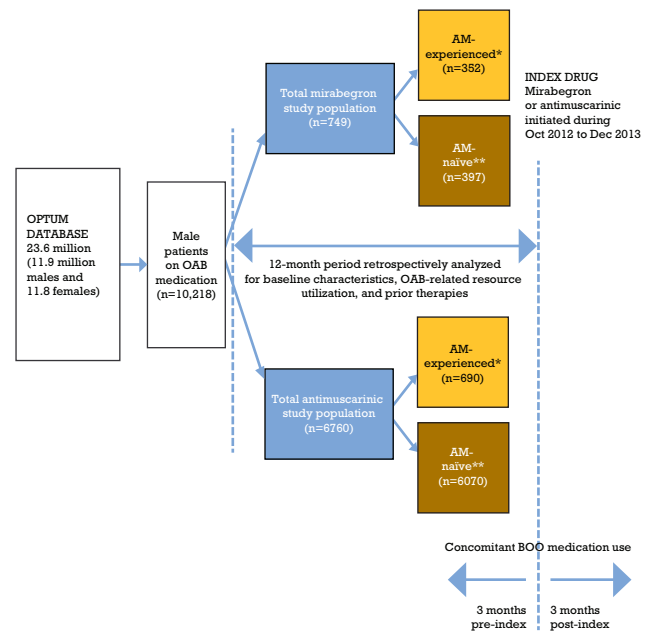
- Men were grouped according to whether they initiated mirabegron or an AM on the drug index date
- A 12-month retrospective analysis was conducted, with patients defined as AM-experienced or AM-naïve depending on whether they did or did not have a claims record of any listed AM agent in the 12-month period prior to the index date
- Demographics and comorbid conditions of the four groups on the index date (mirabegron and AMs, naïve or experienced) were compared
- Use of concomitant BOO medications (5ARIs, α-blockers, AMs or phosphodiesterase type 5 [PDE-5] inhibitors), in use on the index date, or initiated or discontinued during the 90-day period pre- and post-index date, was summarized

RESULTS

Study population

- Of 10,218 male patients in the Optum commercial claims database who were receiving OAB medication, the 7,509 who were initiated on mirabegron or AMs between 10/01/12 and 12/31/13 were included in the 12-month retrospective analysis
  - 749 started mirabegron, of whom 397 were AM-naïve and 352 were AM-experienced
  - 6,760 started AMs, of whom 6,070 were AM-naïve and 690 were AM-experienced (Figure 1)

Figure 1. Study design and patient population



*Use of antimuscarinic drug during 12-month period prior to first index drug
**No claims records of any listed AM drugs in the 12-month period prior to first index drug

- Mirabegron patients were older (mean age of 64 vs 59 years) and had a higher incidence of comorbidities (as reflected by a higher mean Elixhauser comorbidity index [4.7 vs 4.0]) than AM patients (Table 1)
  - Mirabegron patients were more likely to have underlying benign prostatic hyperplasia/lower urinary tract symptoms than AM patients (65.6% vs 48.7%; Table 1)
  - AM-naïve patients had less comorbidity than AM-experienced patients in both the mirabegron cohort (mean Elixhauser scores of 4.4 and 5.0, respectively) and AM cohort (mean Elixhauser scores of 4.0 and 4.6, respectively)

Health resource utilization

- In the 12 months prior to the index date, health resource utilization was higher in mirabegron patients than AM patients (Table 2):
  - 75.4% vs 35.2% visited a urologist at least once
  - 57.8% vs 28.9% had undergone urodynamic testing
  - 24.8% vs 18.6% had undergone cystoscopy
  - Received an average of 10.4 vs 8.2 unique prescriptions
  - Overall mean number of outpatient visits of 11.4 vs 8.5
- Mirabegron patients were more likely than AM patients to have had a prostate (7.6% vs 5.8%) or OAB (3.9% vs 0.7%) surgical procedure over the 12 months prior to index (Table 3)
- AM patients were more likely than mirabegron patients to have used no prior urologic prescription therapy (48.4% vs 21.9%)
- Mirabegron patients were more likely than AM patients to have previously used drugs from any of the four classes of urologic drugs (Table 4)
  - α-blockers either as monotherapy or in combination (44.3% vs 37.4%)
  - AMs either as monotherapy or in combination with another medication (47.0% vs 10.2%)
- Mirabegron patients were more likely than AM patients to have used a combination medication in the 12 months prior to index (Table 4)
  - The use of two or three urologic therapies in combination was higher among AM-experienced than AM-naïve users in both the mirabegron and AM cohorts
- The continued use of combination therapy for 3 months pre- and post-index was higher among mirabegron than AM patients: 7.4% vs 4.0% for 5ARIs; 10.4% vs 1.2% for AMs; 25.9% vs 16.6% for α-blockers; and 5.9% vs 4.0% for PDE-5 inhibitors (Table 5)

Table 1. Demographics and OAB-related comorbidities of men (AM-experienced and AM-naïve) on the drug index date

	mirabegron			AM		
	AM-experienced (n=352)	AM-naïve (n=397)	Total (n=749)	AM-experienced (n=690)	AM-naïve (n=6070)	Total (n=6760)
Mean age, years (SD)	65.4 (14.1)	62.4 (13.3)	63.8 (13.7)	64.5 (12.9)	57.8 (14.3)	58.5 (14.3)
Number (%) aged <65 years	173 (49.1%)	234 (58.9%)	407 (54.3%)	349 (50.6%)	4261 (70.2%)	4610 (68.2%)
Health plan region, n (%)						
Midwest	73 (20.7%)	58 (14.6%)	131 (17.5%)	204 (29.6%)	1712 (28.2%)	1916 (28.3%)
Northeast	43 (12.2%)	34 (8.6%)	77 (10.3%)	62 (9.0%)	555 (9.1%)	617 (9.1%)
South	189 (53.7%)	246 (62.0%)	435 (58.1%)	299 (43.3%)	2801 (46.1%)	3100 (45.9%)
West	47 (13.4%)	59 (14.9%)	106 (14.2%)	124 (18.0%)	995 (16.4%)	1119 (16.6%)
NA	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)	7 (0.1%)	8 (0.1%)
Insurance plan description, n (%)						
Exclusive Provider Organization	38 (10.8%)	56 (14.1%)	94 (12.6%)	84 (12.1%)	659 (10.9%)	743 (11.0%)
HMO	22 (6.3%)	15 (3.8%)	37 (4.9%)	53 (7.7%)	568 (9.4%)	621 (9.2%)
Indemnity	52 (14.8%)	45 (11.3%)	97 (13.0%)	90 (13.0%)	445 (7.3%)	535 (7.9%)
Point of Service	221 (62.8%)	267 (67.3%)	488 (65.2%)	431 (62.5%)	4190 (69.0%)	4621 (68.4%)
Preferred Provider Organization	18 (5.1%)	14 (3.5%)	32 (4.3%)	32 (4.6%)	197 (3.2%)	229 (3.4%)
Other	1 (0.3%)	0 (0%)	1 (0.1%)	0 (0%)	11 (0.2%)	11 (0.2%)
Elixhauser comorbidity score	5.0 (3.3)	4.4 (3.3)	4.7 (3.3)	4.6 (3.1)	4.0 (2.8)	4.0 (2.9)
OAB-related comorbidities, n (%)						
Neurologic diseases	76 (21.6%)	65 (16.4%)	141 (18.8%)	156 (22.6%)	670 (11.0%)	826 (12.2%)
Mobility deficits	35 (9.9%)	23 (5.8%)	58 (7.7%)	46 (6.7%)	235 (3.9%)	281 (4.2%)
Medically complicated/uncontrolled diabetes	38 (10.8%)	39 (9.8%)	77 (10.3%)	102 (14.8%)	491 (8.1%)	593 (8.8%)
Fecal motility disorders	9 (2.6%)	6 (1.5%)	15 (2.0%)	7 (1.0%)	48 (0.8%)	55 (0.8%)
Chronic pelvic pain	55 (15.6%)	51 (12.8%)	106 (14.2%)	89 (12.9%)	588 (9.7%)	677 (10.0%)
Urinary tract infections	132 (37.5%)	112 (28.2%)	244 (32.6%)	196 (28.4%)	1492 (24.6%)	1688 (25.0%)
Gross hematuria	100 (28.4%)	67 (16.9%)	167 (22.3%)	133 (19.3%)	1330 (21.9%)	1463 (21.6%)
Sleep disorder	88 (25.0%)	78 (19.6%)	166 (22.2%)	149 (21.6%)	996 (16.4%)	1145 (16.9%)
Genital skin infections	0 (0%)	0 (0%)	0 (0%)	1 (0.1%)	5 (0.1%)	6 (0.1%)
Sexual disorder*	7 (2.0%)	8 (2.0%)	15 (2.0%)	10 (1.4%)	62 (1.0%)	72 (1.1%)
Prostate cancer	104 (29.5%)	85 (21.4%)	189 (25.2%)	172 (24.9%)	1252 (20.6%)	1424 (21.1%)
Bladder cancer	19 (5.4%)	13 (3.3%)	32 (4.3%)	28 (4.1%)	252 (4.2%)	280 (4.1%)
BPH/LUTS	228 (64.8%)	263 (66.2%)	491 (65.6%)	407 (59.0%)	2882 (47.5%)	3289 (48.7%)
Urinary retention	112 (31.8%)	112 (28.2%)	224 (29.9%)	179 (25.9%)	1076 (17.7%)	1255 (18.6%)
Catheter placement	16 (4.5%)	18 (4.5%)	34 (4.5%)	22 (3.2%)	189 (3.1%)	211 (3.1%)
Erectile dysfunction	125 (35.5%)	131 (33.0%)	256 (34.2%)	234 (33.9%)	1369 (22.6%)	1603 (23.7%)

*Excluding erectile dysfunction
AM=antimuscarinic; BPH=benign prostatic hyperplasia; HMO=health maintenance organization; LUTS=lower urinary tract symptoms; NA=not available; OAB=overactive bladder; SD=standard deviation

Table 2. Medical resource utilization of men (AM-experienced and AM-naïve) over the 12 months preceding the drug index date

	mirabegron			AM		
	AM-experienced (n=352)	AM-naïve (n=397)	Total (n=749)	AM-experienced (n=690)	AM-naïve (n=6070)	Total (n=6760)
≥1 urologist visit, n (%)	286 (81.2%)	279 (70.3%)	565 (75.4%)	430 (62.3%)	1952 (32.2%)	2382 (35.2%)
Incidence of hospitalization, n (%)	63 (17.9%)	74 (18.6%)	137 (18.3%)	125 (18.1%)	1127 (18.6%)	1252 (18.5%)
Outpatient physician office visits						
Mean (SD)	11.9 (8.0)	11.0 (8.4)	11.4 (8.2)	9.9 (7.5)	8.3 (6.8)	8.5 (6.9)
Median (min, max)	10 (0, 66)	9 (0, 63)	10 (0, 66)	8 (0, 66)	7 (0, 74)	7 (0, 74)
Emergency department visits						
Mean (SD)	0.4 (0.9)	0.4 (1.0)	0.4 (0.9)	0.4 (1.4)	0.6 (1.1)	0.5 (1.2)
Median (min, max)	0 (0, 5)	0 (0, 8)	0 (0, 8)	0 (0, 28)	0 (0, 21)	0 (0, 28)
Urodynamics, n (%)	218 (61.9%)	215 (54.2%)	433 (57.8%)	245 (35.5%)	1707 (28.1%)	1952 (28.9%)
Cytoscopy, n (%)	98 (27.8%)	88 (22.2%)	186 (24.8%)	122 (17.7%)	1135 (18.7%)	1257 (18.6%)
Surgical procedures, n (%)	20 (5.7%)	16 (4.0%)	36 (4.8%)	10 (1.4%)	81 (1.3%)	91 (1.3%)
Polypharmacy (unique no. of prescriptions)						
Mean (SD)	11.5 (5.6)	9.5 (5.8)	10.4 (5.8)	10.6 (5.6)	7.9 (5.5)	8.2 (5.6)
Median (min, max)	11 (1.0, 37.0)	8 (0.0, 29.0)	10 (0.0, 37.0)	10 (1.0, 35.0)	7 (0.0, 42.0)	7 (0.0, 42.0)

AM=antimuscarinic; SD=standard deviation

Table 3. Surgical procedures undergone by men (AM-experienced and AM-naïve) over the 12 months preceding the drug index date

	mirabegron			AM		
	AM-experienced (n=352)	AM-naïve (n=397)	Total (n=749)	AM-experienced (n=690)	AM-naïve (n=6070)	Total (n=6760)
Total prostate surgical procedures performed	**34 (9.7%)**	**23 (5.8%)**	**57 (7.6%)**	**37 (5.4%)**	**352 (5.8%)**	**389 (5.8%)**
Surgery for BOO	34 (9.7%)	21 (5.3%)	55 (7.3%)	34 (4.9%)	276 (4.5%)	310 (4.6%)
General prostatectomy	2 (0.6%)	0 (0%)	2 (0.3%)	0 (0%)	13 (0.2%)	13 (0.2%)
TURP/TUMT/TUNA	21 (6.0%)	17 (4.3%)	38 (5.1%)	25 (3.6%)	187 (3.1%)	212 (3.1%)
Laser enucleation	18 (5.1%)	5 (1.3%)	23 (3.1%)	10 (1.4%)	95 (1.6%)	105 (1.6%)
Radical prostatectomy	0 (0%)	2 (0.5%)	2 (0.3%)	2 (0.3%)	70 (1.2%)	72 (1.1%)
Other prostate surgical procedures	1 (0.3%)	0 (0%)	1 (0.1%)	1 (0.1%)	8 (0.1%)	9 (0.1%)
Total OAB surgical procedures performed	**16 (4.5%)**	**13 (3.3%)**	**29 (3.9%)**	**8 (1.2%)**	**42 (0.7%)**	**50 (0.7%)**
Surgical neuromodulation of the bladder	15 (4.3%)	13 (3.3%)	28 (3.7%)	6 (0.9%)	17 (0.3%)	23 (0.3%)
Sacral neuromodulation	1 (0.3%)	6 (1.5%)	7 (0.9%)	1 (0.1%)	1 (0.0%)	2 (0.0%)
Peripheral tibial nerve stimulation	6 (1.7%)	9 (2.3%)	15 (2.0%)	2 (0.3%)	3 (0.0%)	5 (0.1%)
Intradetrusor onabotulinumtoxin A	8 (2.3%)	1 (0.3%)	9 (1.2%)	5 (0.7%)	14 (0.2%)	19 (0.3%)
Urethral suspension	1 (0.3%)	0 (0%)	1 (0.1%)	2 (0.3%)	20 (0.3%)	22 (0.3%)
Augmentation cystoplasty or urinary diversion	0 (0%)	0 (0%)	0 (0%)	0 (0.0%)	5 (0.1%)	5 (0.1%)

AM=antimuscarinic; BOO=bladder outlet obstruction; TUMT=transurethral microwave thermotherapy; TUNA=transurethral needle ablation; TURP=transurethral resection of the prostate

Table 4. Urological medication utilization over the 12 months prior to index date (i.e. whether single therapy or in combination) for men (AM-experienced and AM-naïve) who initiated mirabegron or an AM on the drug index date

	mirabegron			AM		
	AM-experienced (n=352)	AM-naïve (n=397)	Total (n=749)	AM-experienced (n=690)	AM-naïve (n=6070)	Total (n=6760)
No other previous urological prescription medication	--	164 (41.3%)	164 (21.9%)	--	3274 (53.9%)	3274 (48.4%)
All uses† of:						
5ARI	49 (13.9%)	60 (15.1%)	109 (14.6%)	79 (11.4%)	532 (8.8%)	611 (9.0%)
α-blocker	143 (40.6%)	189 (47.6%)	332 (44.3%)	256 (37.1%)	2275 (37.5%)	2531 (37.4%)
AM	352 (100.0%)	na	352 (47.0%)	690 (100.0%)	--	690 (10.2%)
PDE-5 inhibitors	66 (18.8%)	58 (14.6%)	124 (16.6%)	112 (16.2%)	675 (11.1%)	787 (11.6%)
Monotherapy						
Any monotherapy	153 (43.5%)	168 (42.3%)	321 (42.9%)	340 (49.3%)	2168 (35.7%)	2508 (37.1%)
5ARI	--	15 (3.8%)	15 (2.0%)	--	129 (2.1%)	129 (1.9%)
α-blocker	--	125 (31.5%)	125 (16.7%)	--	1671 (27.5%)	1671 (24.7%)
AM	153 (43.5%)	--	153 (20.4%)	340 (49.3%)	--	340 (5.0%)
PDE-5 inhibitor	--	28 (7.1%)	28 (3.7%)	--	368 (6.1%)	368 (5.4%)
Two in combination						
Any two	142 (40.3%)	56 (14.1%)	198 (26.4%)	260 (37.7%)	570 (9.4%)	830 (12.3%)
5ARI + α-blocker	--	35 (8.8%)	35 (4.7%)	--	321 (5.3%)	321 (4.7%)
5ARI + AM	14 (4.0%)	--	14 (1.9%)	32 (4.6%)	--	32 (0.5%)
5ARI + PDE-5 inhibitor	--	1 (0.3%)	1 (0.1%)	--	24 (0.4%)	24 (0.4%)
α-blocker + PDE-5 inhibitor	--	20 (5.0%)	20 (2.7%)	--	225 (3.7%)	225 (3.3%)
AM + α-blocker	92 (26.1%)	--	92 (12.3%)	168 (24.3%)	--	168 (2.5%)
Antimuscarinic + PDE-5 inhibitor	36 (10.2%)	--	36 (4.8%)	60 (8.7%)	--	60 (0.9%)
Three in combination						
Any three	55 (15.6%)	9 (2.3%)	64 (8.5%)	83 (12.0%)	58 (1.0%)	141 (2.1%)
5ARI + α-blocker + PDE-5 inhibitor	--	9 (2.3%)	9 (1.2%)	--	58 (1.0%)	58 (0.9%)
5ARI + AM + α-blocker	27 (7.7%)	--	27 (3.6%)	38 (5.5%)	--	38 (0.6%)
5ARI + AM + PDE-5 inhibitor	6 (1.7%)	--	6 (0.8%)	2 (0.3%)	--	2 (0.0%)
AM + α-blocker + PDE-5 inhibitor	22 (6.3%)	--	22 (2.9%)	43 (6.2%)	--	43 (0.6%)
Four in combination						
Any four	2 (0.6%)	--	2 (0.3%)	7 (1.0%)	--	7 (0.1%)
5ARI + α-blocker + AM + PDE-5 inhibitor	2 (0.6%)	--	2 (0.3%)	7 (1.0%)	--	7 (0.1%)

†Monotherapy or combination
5ARI=5α-reductase inhibitor; AM=antimuscarinic; PDE-5=phosphodiesterase type 5

Table 5. Use of concomitant BOO therapy over the 3 months pre- and/or post-index date by men (AM-experienced and AM-naïve)

	mirabegron			AM		
	AM-experienced (n=347)	AM-naïve (n=421)	Total (n=768)	AM-experienced (n=659)	AM-naïve (n=6702)	Total (n=7361)
5ARI						
Only prior to index date, n (%)	11 (3.2%)	9 (2.1%)	20 (2.6%)	10 (1.5%)	142 (2.1%)	152 (2.1%)
Only post-index date, n (%)	8 (2.3%)	10 (2.4%)	18 (2.3%)	10 (1.5%)	122 (1.8%)	132 (1.8%)
Continued therapy, n (%)	24 (6.9%)	33 (7.8%)	57 (7.4%)	50 (7.6%)	248 (3.7%)	298 (4.0%)
Total 5ARI	**43 (12.4%)**	**52 (12.4%)**	**95 (12.4%)**	**70 (10.6%)**	**512 (7.6%)**	**582 (7.9%)**
AM						
Only prior to index date, n (%)	155 (44.7%)	0 (0%)	155 (20.2%)	329 (49.9%)	0 (0%)	329 (4.5%)
Only post-index date, n (%)	16 (4.6%)	32 (7.6%)	48 (6.3%)	21 (3.2%)	297 (4.4%)	318 (4.3%)
Continued therapy, n (%)	80 (23.1%)	0 (0%)	80 (10.4%)	92 (14.0%)	0 (0%)	92 (1.2%)
Total AM	**251 (72.3%)**	**32 (7.6%)**	**283 (36.8%)**	**442 (67.1%)**	**297 (4.4%)**	**739 (10.0%)**
α-blocker						
Only prior to index date, n (%)	23 (6.6%)	46 (10.9%)	69 (9.0%)	25 (3.8%)	841 (12.5%)	866 (11.8%)
Only post-index date, n (%)	13 (3.7%)	18 (4.3%)	31 (4.0%)	37 (5.6%)	610 (9.1%)	647 (8.8%)
Continued therapy, n (%)	81 (23.3%)	118 (28.0%)	199 (25.9%)	140 (21.2%)	1084 (16.2%)	1224 (16.6%)
Total α-blockers	**117 (33.7%)**	**182 (43.2%)**	**299 (38.9%)**	**202 (30.7%)**	**2535 (37.8%)**	**2737 (37.2%)**
PDE-5 inhibitor						
Only prior to index date, n (%)	22 (6.3%)	11 (2.6%)	33 (4.3%)	18 (2.7%)	145 (2.2%)	163 (2.2%)
Only post-index date, n (%)	13 (3.7%)	22 (5.2%)	35 (4.6%)	20 (3.0%)	357 (5.3%)	377 (5.1%)
Continued therapy, n (%)	21 (6.1%)	24 (5.7%)	45 (5.9%)	37 (5.6%)	254 (3.8%)	291 (4.0%)
Total PDE-5 inhibitor	**56 (16.1%)**	**57 (13.5%)**	**113 (14.7%)**	**75 (11.4%)**	**756 (11.3%)**	**831 (11.3%)**

5ARI=5α-reductase inhibitor; AM=antimuscarinic; BOO=bladder outlet obstruction; PDE-5=phosphodiesterase type 5

CONCLUSIONS

- In the 12-month period preceding initiation of mirabegron or AM, demographic and baseline differences were evident among male patients. For example, male patients prescribed mirabegron were older, had more comorbidities, greater baseline healthcare resource utilization, and had more visits to the urologist compared with male patients who received AMs
- Male patients receiving mirabegron were more likely to use other urological therapies such as 5ARIs, α-blockers, PDE-5 inhibitors, than those receiving AMs
- Additional studies to model the impact of patient characteristics on outcomes in those prescribed mirabegron and AMs may be helpful in predicting long-term healthcare resource allocation

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