Characteristics of men with untreated LUTS interested in over-the-counter tamsulosin

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Introduction: *Treatment for lower urinary tract symptoms (LUTS) is often delayed, as it is considered a natural progression of aging. We described baseline demographic and clinical characteristics of men currently not using prescription medications for benign prostatic hyperplasia (BPH) but interested in self-directed use of over-the-counter (OTC) tamsulosin and who had participated in OTC tamsulosin–simulated studies.*

Materials and methods: *Pooled baseline data from four OTC tamsulosin–simulated studies were analyzed for men who were currently not using BPH prescription medication and who believed that OTC tamsulosin was appropriate for use or were interested in purchasing it. Data from the OTC-simulated studies for men using BPH prescription medication and from the BPH registry, which included men diagnosed with BPH, were used for comparison.*

Results: *Overall, 3285 non–prescription-using men (mean age ± standard deviation [SD], 60.6 ± 11.6 years) were included. Average American Urological Association Symptom Index (AUA-SI) total score was 17.6; 25.5% reported urinary symptoms for > 5 years. Overall, 46.7% of these men had > 1 visit/year with their physicians. Baseline characteristics of prescription users from the OTC-simulated studies (n = 364; mean age ± SD, 68.3 ± 9.1 years; mean AUA-SI score, 18.5) and of men from the BPH registry (n = 5042; 64.8 ± 10 years; 11.6) were similar to those of non-prescription users.*

Conclusions: *Non-prescription users had long term moderate-to-severe male LUTS, yet remained untreated; self-management may be a viable alternative strategy for this population. Disease characteristics of men not using BPH prescription medication and interested in using OTC tamsulosin were similar to those using BPH medication or diagnosed with BPH.*

Key Words: lower urinary tract symptoms, benign prostatic hypertrophy, over-the-counter medications, tamsulosin

Introduction

Lower urinary tract symptoms (LUTS) increase in frequency and severity with age, affecting 80% of men over the age of 70 years.[1] LUTS are often seen secondary to benign prostatic hyperplasia (BPH) (here onwards referred to as male LUTS) but can have multiple etiologies, and not all men with BPH will go on to develop LUTS.[2]

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LUTS comprise voiding symptoms such as slow/poor stream and hesitancy; storage symptoms such as urgency and nocturia; and post-micturition symptoms including post-void dribble.[3,4] As the degree of bother increases, these symptoms can adversely affect quality of life (QoL) and impair work productivity.[5-7] Mild LUTS (as measured by an American Urological Association Symptom Index [AUA-SI] total score of < 8) are typically managed with watchful waiting and lifestyle modifications.[8] As LUTS progress, however, pharmacologic treatment options or surgery may be necessary. Voiding symptoms are usually treated with α1-adrenergic receptor blockers and/or 5-α-reductase inhibitors, while storage symptoms are treated with antimuscarinic agents.[8]

However, despite available treatment options, LUTS is often underdiagnosed and untreated.[9,10] Many men do not discuss them with a healthcare provider

(HCP) possibly because of a lack of knowledge of the condition and available treatment options in addition to either embarrassment or presuming their symptoms to be a part of the aging process.[11] In this context, an over-the-counter (OTC) supply model could improve QoL in men reluctant to approach an HCP to seek treatment for their LUTS.[12] Tamsulosin, an α1-adrenergic receptor blocker prescribed for the signs and symptoms of BPH, has a well-established safety and efficacy profile[13] and has been proposed as a potentially viable OTC option for treatment of male LUTS.[14] As required by the United States Food and Drug Administration, several OTC-simulated studies have been conducted to assess the use of tamsulosin in an OTC setting.[14-17] Self-selection and actual-use studies have shown that consumers interested in treating their LUTS are able to correctly decide whether OTC tamsulosin is appropriate for them to use and are able to use it as per the instructions and directions in the drug facts label accompanying the medication.[14-17]

The OTC-simulated studies focused on users who were not currently using any prescription medication for their BPH (nonRx users), as they represented prospective OTC users whose decisions and behaviors were not influenced by knowledge or guidance given by a prescribing HCP about the use of the product and/or the condition it is meant to treat. In order to better understand the profiles of men willing to seek self-care options for their untreated LUTS, this study was conducted to describe the demographic and clinical characteristics of nonRx users who were interested in self-directed use of OTC tamsulosin and had participated in the relevant OTC-simulated studies.

Materials and methods

Study design and participants

Data were obtained from four observational clinical studies, namely, a pilot self-selection study (SS1),[14] a pivotal self-selection study (SS2),[15] an 8-week pilot actual-use study (AUS8),[16] and a 24-week pivotal actual-use study (AUS24),[17] simulating OTC use of tamsulosin using a passive recruitment method. Study participants were consumers who self-identified as potential study candidates by responding to simulated OTC mass advertising. Recruitment advertisements were similar throughout the studies and mimicked the way a consumer might hear about a new OTC product; however, the advertising was kept simple—with few clues to the consumer about the product or its intended use. No active recruitment by HCPs was allowed.

In all four studies, men who responded to the recruitment advertising by calling a toll-free number underwent centralized screening to confirm eligibility. Study eligibility criteria were broad, and men ≥ 18 years old and able to speak, read, and understand English were included. Trained pharmacy staff conducted a baseline, standardized, scripted interview and were not permitted to provide any unsolicited advice to participants. Information on demographics, targeted medical history, medication use, and healthcare utilization habits was collected, and tests assessing health literacy (Rapid Estimate of Adult Literacy in Medicine)[18] and symptoms (self-administered AUA-SI) were administered.

Statistical analyses

Baseline data were pooled and analyzed for participants who were currently not using an α-blocker or a prescription medicine for BPH and who believed that the OTC product was appropriate for them to use or were interested in purchasing this product (nonRx users).

Additionally, a cohort of men in AUS24 with a prescription BPH medication (Rx users) at study initiation were included for comparison with the pooled nonRx users, as, by definition, the prescribing HCP had determined that these Rx users have male LUTS and/or are appropriate users of BPH prescription medication.

Baseline demographic and clinical characteristics were also compared with baseline data from a previously published BPH observational study, the BPH registry.[19] Briefly, the BPH registry was a prospective, multicenter, longitudinal, observational disease registry that enrolled men (from January 2004 to February 2005) diagnosed with male LUTS that was untreated or presently/recently treated with an α-adrenergic blocker, a 5-α-reductase inhibitor, a combination of an α-adrenergic blocker and a 5-α-reductase inhibitor, or anticholinergics.[20,21] Descriptive statistics were used to summarize and assess the results.

Results

Baseline demographic characteristics

Based on the pooled data from the four OTC-simulated studies, a total of 3285 men were not using an α-blocker or a prescription medicine for BPH at the time of the study and expressed an interest in using or purchasing the OTC study product. In AUS24, a cohort of 364 men reported using a prescription medication for BPH.

Overall, baseline demographic characteristics of study participants were balanced across all pooled nonRx users, and were similar to those of Rx users. Mean (standard deviation [SD]) age of all pooled nonRx users was 60.6 (11.6) years, with 92.7% of the participants aged 45 years or older, Table 1. Rx users were slightly older (mean age [SD], 68.3 [9.1] years), with 99.2% of the participants aged

TABLE 1. **Baseline characteristics of study participants**

	Rx users			nonRx users		
	AUS24	**AUS8**	**SS1**	**AUS24**	**SS2**	**Total**
Number of men	364 (100.0)	473 (100.0)	1185 (100.0)	1157 (100.0)	470 (100.0)	3285 (100.0)
Age (years), mean (SD)	68.3 (9.1)	64.4 (12.8)	56.9 (11.1)	62.3 (11.0)	61.7 (10.5)	60.6 (11.6)
Age group						
< 45 years	1 (0.3)	28 (5.9)	135 (11.4)	61 (5.3)	16 (3.4)	240 (7.3)
≥ 45 years	361 (99.2)	445 (94.1)	1050 (88.6)	1096 (94.7)	454 (96.6)	3045 (92.7)
Race						
White	260 (71.4)	403 (85.2)	713 (60.2)	715 (61.8)	287 (61.1)	2118 (64.5)
Black/African American	70 (19.2)	59 (12.5)	427 (36.0)	334 (28.9)	131 (27.9)	951 (28.9)
Asian	5 (1.4)	6 (1.3)	16 (1.4)	5 (0.4)	11 (2.3)	38 (1.2)
American Indian/ Alaska Native	3 (0.8)	2 (0.4)	12 (1.0)	15 (1.3)	1 (0.2)	30 (0.9)
Hawaiian/Pacific Islander	0 (0.0)	0 (0.0)	1 (0.1)	6 (0.5)	2 (0.4)	9 (0.3)
Multiple	3 (0.8)	0 (0.0)	0 (0.0)	17 (1.5)	3 (0.6)	20 (0.6)
Other	20 (5.5)	0 (0.0)	0 (0.0)	61 (5.3)	33 (7.0)	94 (2.9)
Refused to answer/ missing	3 (0.8)	3 (0.6)	16 (1.4)	4 (0.3)	2 (0.4)	25 (0.8)
Ethnicity						
Hispanic or Latino	24 (6.6)	34 (7.2)	114 (9.6)	86 (7.4)	37 (7.9)	271 (8.2)
Not Hispanic or Latino	338 (92.9)	439 (92.8)	1058 (89.3)	1068 (92.3)	432 (91.9)	2997 (91.2)
Not reported	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.3)	1 (0.2)	4 (0.1)
Missing	2 (0.5)	0 (0.0)	13 (1.1)	0 (0.0)	0 (0.0)	13 (0.4)
Literacy (REALM test score profile)						
Low literacy (0-60)	82 (22.5)	76 (16.1)	247 (20.8)	272 (23.5)	82 (17.4)	677 (20.6)
Normal literacy (61-66)	280 (76.9)	392 (82.9)	938 (79.2)	880 (76.1)	388 (82.6)	2598 (79.1)

Data are expressed as n (%) unless stated otherwise.
AUS8 = 8-week pilot actual-use study; AUS24 = 24-week pivotal actual-use study; BPH = benign prostatic hyperplasia; nonRx users = currently not treating their urinary symptoms; Rx users = using a prescription medicine for BPH; REALM = Rapid Estimate of Adult Literacy in Medicine; SS1 = pilot self-selection study; SS2 = pivotal self-selection study; SD = standard deviation

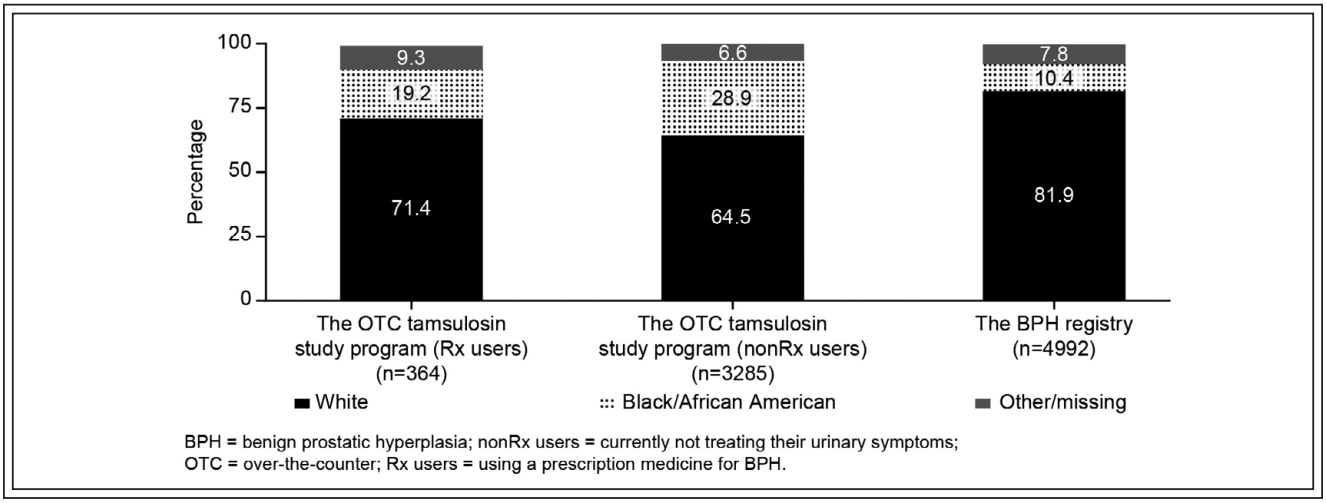

Figure 1. Racial diversity in the OTC self-selection study versus BPH registry.[19]

45 years or older. The baseline characteristics of men in the BPH registry were representative of men diagnosed with LUTS and were similar to those of nonRx users (mean age [SD], 64.8 [10.0] years).[19]

Racial diversity was greater in the OTC-simulated study program (nonRx and Rx users) compared with that observed in the BPH registry, Figure 1. While the non-Caucasian population was underrepresented in the BPH registry, a relatively higher percentage of the African-American population was represented in the OTC tamsulosin study program (19.2% of Rx users and 28.9% of nonRx users versus 10.4% in the BPH registry) [19], possibly reflecting how the BPH registry was set up.

Baseline clinical characteristics

In contrast to the nonRx user group, Rx users had a much higher frequency of comorbidities—hypertension (43.9% versus 63.4%), high cholesterol (33.7% versus 52.9%), erectile dysfunction (20.4% versus 41.8%), heart problems (16.3% versus 20.3%), and diabetes (14.4% versus 21.6%), respectively, Table 2.

The mean AUA-SI total score for nonRx users was 17.6, Table 2, with almost equal storage (AUA-SIS = 8.6) and voiding (AUA-SIV = 8.4) subscores, Figure 2a. However, upon classifying participants as having predominant failure to void (defined as AUA-SIV / AUA-SIS > 1) or predominant failure to store (AUA-SIV / AUA-SIS ≤ 1) symptoms, it was found that nonRx users with predominant failure to void reported a higher AUA-SI total score compared to nonRx users with predominant failure to store (21.2 versus 14.7), Figure 2b. NonRx users with predominant failure to void were also likely to report both storage and voiding symptoms, while men with predominant failure to store were less likely to report voiding symptoms based on the contribution of subscores relative to their potential maximum subscore in the AUA-SI total score (storage, 57%; void, 42%; Figure 2c).

The eighth question in the AUA-SI assessed disease-specific QoL on a continuous scale of 0 (delighted) to 6 (terrible). It was found that the disease-specific QoL score was the same for nonRx and Rx users (4.0), but was

TABLE 2. **Clinical characteristics of study participants**

	Rx users		**nonRx[a] users**		
	AUS24	**SS1**	**AUS24**	**SS2**	**Total**
Number of men	153 (100.0)	1185 (100.0)	1157 (100.0)	470 (100.0)	2812 (100.0)
Mean AUA-SI total score	18.5	18.7	16.9	16.5	17.6[b]
Number of men who have BPH (enlarged prostate)	112 (73.2)	207 (17.5)	324 (28.0)	134 (28.5)	665 (23.6)
Men with existing or previously diagnosed targeted medical conditions (as told by their HCPs)					
Hypertension	97 (63.4)	490 (41.4)	556 (48.1)	188 (40.0)	1234 (43.9)
High cholesterol	81 (52.9)	368 (31.1)	434 (37.5)	145 (30.9)	947 (33.7)
Erectile dysfunction	64 (41.8)	229 (19.3)	262 (22.6)	82 (17.4)	573 (20.4)
Heart problems	31 (20.3)	184 (15.5)	211 (18.2)	62 (13.2)	457 (16.3)
Diabetes	33 (21.6)	156 (13.2)	187 (16.2)	61 (13.0)	404 (14.4)
Depression	29 (19.0)	181 (15.3)	169 (14.6)	51 (10.9)	401 (14.3)
Kidney stones	22 (14.4)	100 (8.4)	146 (12.6)	44 (9.4)	290 (10.3)
COPD or chronic bronchitis	23 (15.0)	55 (4.6)	68 (5.9)	22 (4.7)	145 (5.2)
Stroke	6 (3.9)	48 (4.1)	65 (5.6)	16 (3.4)	129 (4.6)
Bladder infection	13 (8.5)	52 (4.4)	45 (3.9)	14 (3.0)	111 (3.9)
Prostate cancer	9 (5.9)	32 (2.7)	57 (4.9)	16 (3.4)	105 (3.7)
Poor kidney function	4 (2.6)	17 (1.4)	30 (2.6)	8 (1.7)	55 (2.0)
Serious liver damage	4 (2.6)	21 (1.8)	19 (1.6)	8 (1.7)	48 (1.7)
Chronic prostatitis	6 (3.9)	15 (1.3)	16 (1.4)	4 (0.9)	35 (1.2)
Neurogenic bladder	0	6 (0.5)	7 (0.6)	1 (0.2)	14 (0.5)

Data are expressed as n (%).

[a]Data are not included for the AUS8 study, as this study did not assess comorbidities. [b]Total AUA-SI score is based on N = 3285.

AUA-SI = American Urological Association Symptom Index; AUS24 = 24-week pivotal actual-use study; BPH = benign prostatic hyperplasia; COPD = chronic obstructive pulmonary disease; HCP = healthcare provider; nonRx users = currently not treating their urinary symptoms; Rx users = using a prescription medicine for BPH; SS1 = pilot self-selection study; SS2 = pivotal self-selection study; SD = standard deviation

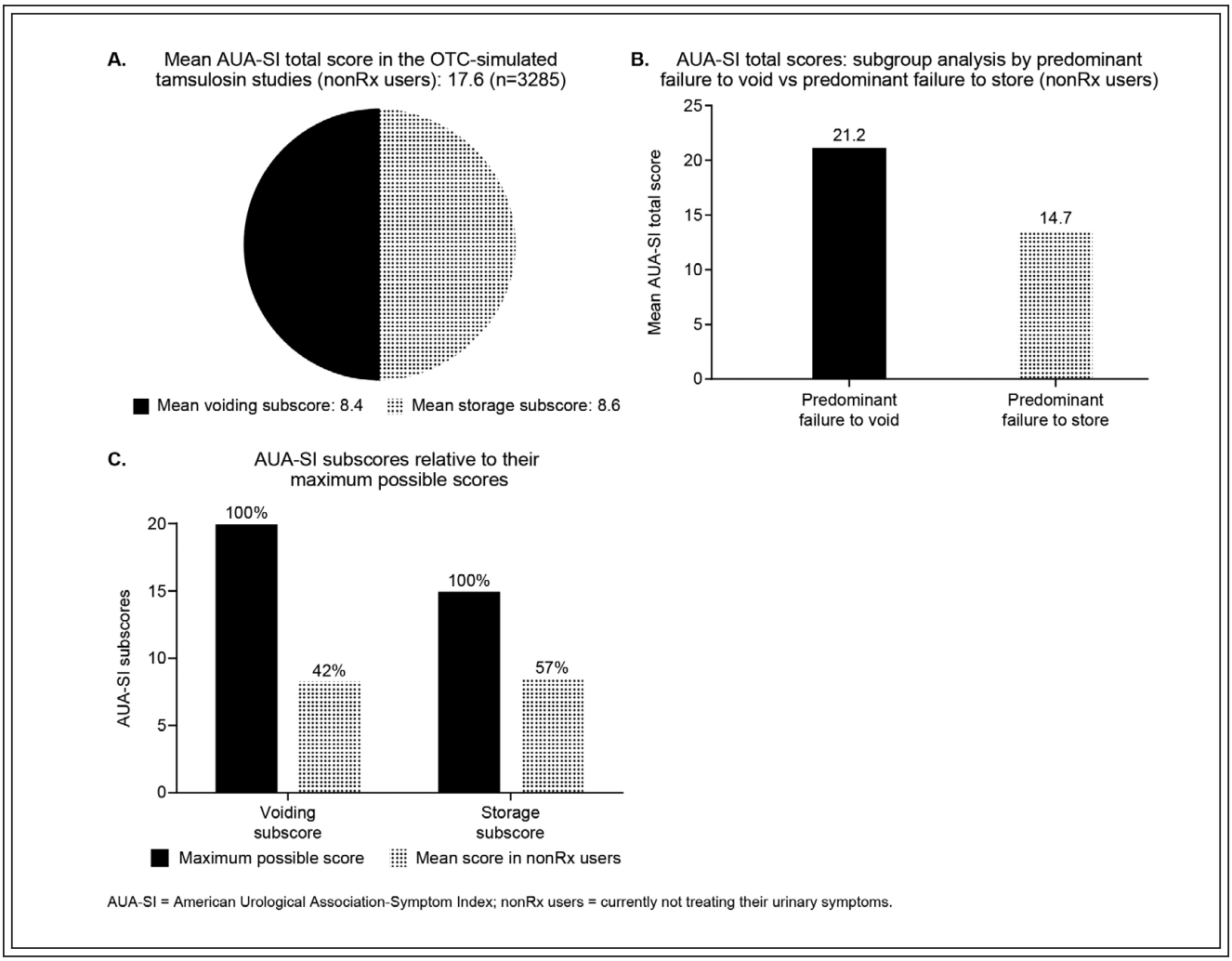

Figure 2. AUA-SI scores. **A)** Mean AUS-SI voiding and storage subscores of nonRx users; **B)** Subgroup analysis by predominant failure to void versus storage symptoms; **C)** AUA-SI voiding and storage subscores relative to their maximum possible subscores.

greater than that reported in the BPH registry (4.0 versus 2.5), indicating that nonRx users in the OTC-simulated studies had a greater degree of bother, Figure 3a. Additionally, nonRx users with predominant failure to void had a mean score of 4.1, while nonRx users with predominant failure to store had a slightly lower and better score of 3.9 on the AUA-SI QoL question, Figure 3b.

Healthcare-seeking behavior

Most nonRx users (83%) had visited an HCP within a year of their respective study initiations, with 46.7% reporting an HCP visit more than once a year, Table 3. However, many of the nonRX users (41.2%) had never discussed their urinary symptoms with their HCPs, despite a majority of them (n = 2550; 77.6%) experiencing symptoms for at least a year.

Discussion

We analyzed baseline characteristics of men with untreated LUTS who were currently not taking any prescription medication for BPH but who were interested in treating their symptoms with OTC tamsulosin and had participated in OTC-simulated studies for tamsulosin. Although data collected for the non-interested nonRx users were available and potentially informative, these data are not reported because these men were not prospective OTC users of tamsulosin.

Pooled analysis of the four observational studies in the OTC-simulated tamsulosin study program showed that many nonRx users interested in self-directed care with OTC tamsulosin had bothersome urinary symptoms for at least a year (with approximately one

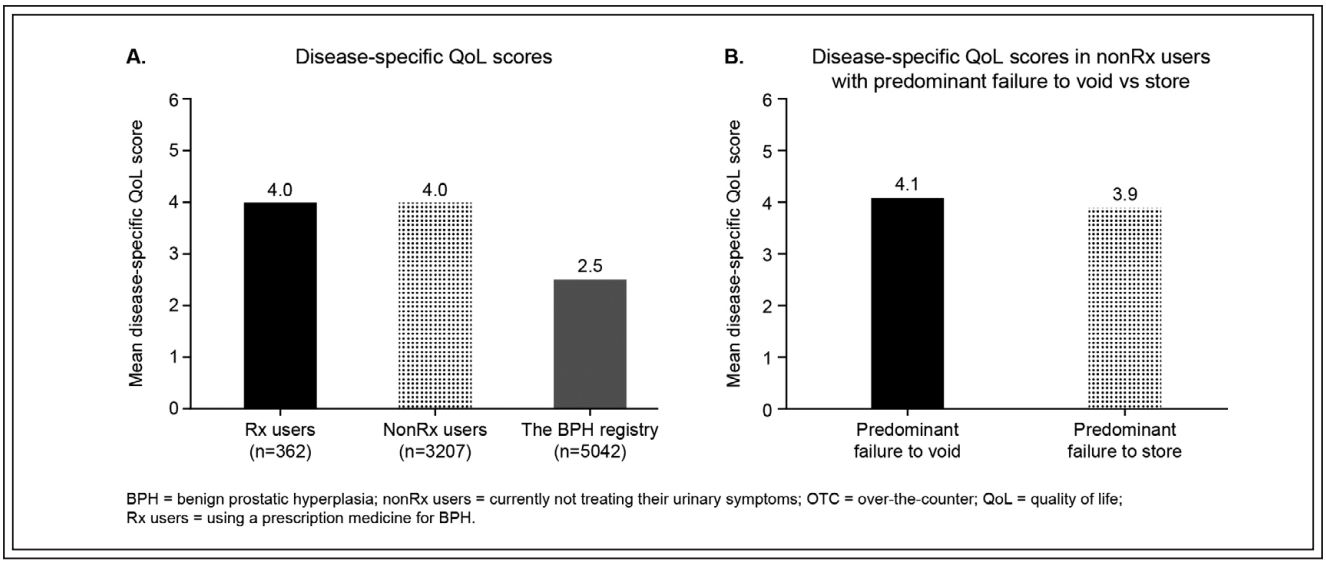

Figure 3. QoL scores. **A)** Disease-specific QoL scores in the OTC-simulated tamsulosin study program and BPH registry[19]; **B)** Subgroup analysis by predominant failure to void versus storage symptoms.

TABLE 3. **Healthcare-seeking behavior of study participants**

	Rx users			**nonRx[a] users**		
	AUS24	**AUS8**	**SS1**	**AUS24**	**SS2**	**Total**
Number of men	364 (100.0)	473 (100.0)	1185 (100.0)	1157 (100.0)	470 (100.0)	3285 (100.0)
Last visit to HCP						
Within 1 year	360 (98.9)	423 (89.4)	875 (73.8)	1027 (88.8)	403 (85.7)	2728 (83.0)
More than 1 year and up to 3 years ago	2 (0.5)	36 (7.6)	158 (13.3)	95 (8.2)	0 (0.0)	289 (8.8)
More than 3 years ago	0	14 (3.0)	80 (6.8)	35 (3.0)	66 (14.0)	195 (5.9)
Missing	2 (0.5)	0 (0.0)	72 (5.6)	0 (0.0)	1 (0.2)	73 (2.2)
Frequency of visiting an HCP						
Never	0	4 (0.8)	25 (2.1)	26 (2.2)	7 (1.5)	62 (1.9)
Only when sick	17 (4.7)	91 (19.2)	351 (29.6)	231 (20.0)	97 (20.6)	770 (23.4)
Regularly: once a year	72 (19.8)	129 (27.3)	261(22.0)	316 (27.3)	142 (30.2)	848 (25.8)
Regularly: more than once a year	273 (75.0)	249 (52.6)	477 (40.3)	584 (50.5)	223 (47.4)	1533 (46.7)
Discussed urinary symptom(s) with their HCP						
Yes	NA	320 (67.7)	593 (50.0)	505 (43.6)	268 (57.0)	1686 (51.3)
No		153 (32.3)	515 (43.5)	486 (42.0)	200 (42.6)	1354 (41.2)
Missing		0 (0.0)	77 (6.5)	166 (14.3)	2 (0.4)	245 (7.5)
Duration of urinary symptoms						
Between 1 year and 5 years[a]	203 (55.8)	227 (48.0)	535 (45.1)	677 (58.5)	272 (57.9)	1711 (52.1)
More than 5 years	140 (38.5)	152 (32.1)	314 (26.5)	265 (22.9)	108 (23.0)	839 (25.5)

Data are expressed as n (%).
[a]For nonRx users this is at least 1 year and less than 5 years.
AUS8 = 8-week pilot actual-use study; AUS24 = 24-week pivotal actual-use study; BPH = benign prostatic hyperplasia; HCP = healthcare provider; NA = not applicable; nonRx users = currently not treating their urinary symptoms; Rx users = using a prescription medicine for BPH; SS1 = pilot self-selection study; SS2 = pivotal self-selection study

quarter of the participants reporting urinary symptoms for more than 5 years) and were yet untreated. This finding confirms existing data on the delay in seeking treatment for LUTS[9,10] and suggests that an OTC treatment option may be a viable alternative for this untreated population. One of the concerns with the availability of OTC tamsulosin is the potential for misdiagnosis of the underlying disease.[12] However, we observed that despite their apparent reluctance to discuss LUTS with HCPs, many nonRx users reported visiting their HCPs once a year or more, indicating that these men are already part of the healthcare system, which can act as a safety net in the event of a misdiagnosis. Moreover, α blockers as a class are generally well-tolerated.[13,14] In addition, FDA mandates that an OTC drug meets safety standards applicable to a prescription drug, ensuring overall safety of the drug prior to approval.[14] Furthermore, health authorities like FDA require manufacturers of approved OTC products to have pharmacovigilance reporting systems in place and the requirements of safety reporting and monitoring are the same as those for prescription drugs.

Baseline demographic and clinical characteristics were generally similar between BPH Rx and nonRx users in the OTC tamsulosin program, except that Rx users were slightly older (68.3 versus 60.6 years) and a smaller proportion were black/African American (19.2% versus 28.9%). Baseline characteristics of nonRx users were also similar to those seen in the BPH registry,[19] which represents men with LUTS typically seen by HCPs; the mean ages of the men included were similar between the two groups (60.6 and 64.8 years, respectively). However, compared with the BPH registry, the OTC tamsulosin studies included a more diverse population; African Americans constituted 10.0% of the BPH registry, while 28.9% of African-American nonRx users entered the OTC-simulated tamsulosin studies. This suggests that the option of self-managing LUTS with an OTC medication may be advantageous to currently underserved and undertreated populations in providing relief from symptoms and improvement in QoL.[22]

The mean AUA-SI score for nonRx users was 17.6, indicating moderate-to-severe LUTS, and although storage and voiding subscores in the AUA-SI total score were similar (8.6 versus 8.4, respectively), storage symptoms were likely to be more severe based on the contribution of subscores relative to their maximum possible subscore in the AUA-SI total score (storage, 57%; void, 42%).

While the AUA-SI total score for nonRx users was 17.6, men included in the BPH registry had a lower AUA-SI total score (11.6),[19] implying that untreated men interested in an OTC were more symptomatic. Men in the OTC-simulated study program also showed a greater degree of bother with their mean disease-specific QoL score being higher compared to that of men in the BPH registry data (4.0 versus 2.5).[19]

The frequency of cardiovascular disease and diabetes was higher in men diagnosed with BPH (BPH registry)[19] compared with nonRx users in the OTC-simulated tamsulosin studies (hypertension, 51.1% versus 43.9%; high cholesterol, 44.4% versus 33.7%; diabetes, 17% versus 14.4%, respectively). A comparatively higher incidence of comorbidities was also observed among Rx users in the OTC-simulated tamsulosin studies. This could have possibly been because the prevalence of such conditions generally increases with age and the nonRx users were slightly younger than the Rx users and men in the BPH registry. Men with a high comorbidity burden are more likely to visit their HCP regularly. This may in turn have increased the prospect of an HCP diagnosing their LUTS and prescribing a BPH medication.

A few limitations of this study should be considered while interpreting the findings. First, all study analyses were descriptive in nature; however, this study drew from a large body of data and these findings highlight trends in the treatment of LUTS that warrant further consideration. Second, the OTC tamsulosin–simulated studies and the Rosen et al[19] observational study, which used the BPH registry data, relied on self-reported data, which are sensitive to various forms of bias. Finally, differences in recruitment strategies should also be acknowledged while comparing baseline data across these studies.

Conclusions

In summary, analysis of the pooled data demonstrates that prospective users of OTC tamsulosin had similar demographic characteristics as current users of a BPH prescription medication. Many interested nonRx users reported visiting their HCP once a year or more, which allows for the possibility that their health could be monitored by an HCP during self-directed use of an OTC medication. However, despite many of the interested nonRx users visiting their HCPs regularly, their reported moderate-to-severe LUTS, often of long duration, went untreated. A self-management strategy using tamsulosin may be a viable alternative for this interested yet untreated population. Further, underserved populations, such as African-American men, could stand to benefit the most from the OTC availability of tamsulosin.

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Disclosure

CGR, FCL, and MG are consultants/advisors for BIPI; JMW is an employee of the sponsor and AEV was an employee when the study was conducted. □

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