Feasibility of an Alternative Option for the Management of Male Lower Urinary Tract Symptoms

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Purpose: We determine if men with self-reported lower urinary tract symptoms can make a correct decision to use an over-the-counter alpha-1 blocker. Furthermore, we assess the frequency of medically significant conditions presenting with urinary symptoms in these consumers.

Materials and Methods: Subjects reviewed a mock-up of an over-the-counter product for male lower urinary tract symptoms (part 1). Subjects who selected the product underwent urine dipstick testing and male subjects completed the AUA Symptom Index (part 2). Urological assessment was conducted in women; in men younger than 45 years; men 45 years old or older who reported "Do Not Use" symptoms listed on the over-the-counter label; who had glucose, leukocytes and/or blood in their urine; or had an AUA-SI score of 20 or greater.

Results: Of the 1,967 subjects enrolled 1,953 completed part 1 (men/women 1,697/256), 1,311 (1,294/17) entered part 2 and 1,289 (1,274/15) were evaluated. Frequently reported baseline medical conditions were hypertension (45.8%/46.7%) and dyslipidemia (36.4%/60.0%). Lower urinary tract symptoms were present for more than 3 years in 47.6% of men and 40% of women. Mean AUA-SI score was 18.9. Urine dipstick results were positive in 20.9% of men. Overall 729 men and 12 women underwent urological assessment, and 517 (70.9%) men had urologist confirmed lower urinary tract symptoms while 200 (27.4%) did not. Newly diagnosed medically significant conditions causing/contributing to lower urinary tract symptoms were identified in 21 (2.9%) men and 2 (16.7%) women.

Conclusions: Most men correctly selected the over-the-counter product for the management of lower urinary tract symptoms/benign prostatic hyperplasia, while most women correctly deselected to use the product. Since few men had undiagnosed medically significant conditions causing/contributing to urinary symptoms, the risk of harm due to incorrect selection was low.

Key Words: prostatic hyperplasia, lower urinary tract symptoms, self care

Abbreviations and Acronyms

AUA = American Urological Association

AUA-SI = AUA symptom index

BPH = benign prostatic hyperplasia

DFL = drug facts label

DNU = do not use

HCP = health care provider

LUTS = lower urinary tract symptoms

MSC = medically significant condition

OTC = over-the-counter

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Male lower urinary tract symptoms are often perceived as a normal consequence of aging. Therefore, many men do not discuss these symptoms with their HCPs.[1,2] Consequently, symptoms often remain untreated and can considerably affect individuals' quality of life.[3,4] In men LUTS have traditionally been attributed to urethral obstruction caused by benign prostatic hyperplasia, a highly prevalent, slowly progressive disorder.[5]

It is well-known that the prevalence of BPH increases as men age.[6]

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The United States census projects 83.7 million individuals 65 years old or older in 2050 (44.9% of men), which is almost double the 2013 estimate of 44.5 million.[7,8] In contrast, an approximate 30% decrease in urologists is projected by 2025,[9] primarily because of retirement, decreased American Board of Medical Specialties urology certifications and threats to the graduate medical education fund.[9] In addition, a substantial number of men are currently self-managing BPH with herbal supplements,[10] none of which have proven efficacy.[11,12] Therefore, alternative models of care are of interest from a public health perspective and worthy of exploration, including self-management.

As BPH can only be confirmed histologically, which is impractical, and as the bladder also has a key role in male LUTS,[13,14] a symptom oriented approach has been developed to guide the scientific understanding and management of male LUTS. The 2010 AUA guidelines on the management of male LUTS recommend alpha-1 blockers for men with moderate to severe symptoms (AUA-SI score 8 or greater) and bothersome symptoms.[15] Used for almost 2 decades, these drugs have proven safety and efficacy for the treatment of BPH.[16] Together the symptom oriented approach to male LUTS management, the established modality to manage these symptoms with alpha-1 blockers and the growing need for an alternative model of care allow for the exploration of the feasibility of an OTC medication. Of concern when considering the possible self-management of male LUTS with a pharmacological agent is the potential for men to confuse urinary symptoms caused by medically significant nonBPH conditions (ie diabetes mellitus, infections or malignancies of the lower urinary tract including the prostate, and urolithiasis) with those of BPH, thereby masking the diagnosis and delaying treatment. Furthermore, other conditions that may be detected by a care provider based on a guideline algorithm driven evaluation of male LUTS may be undiagnosed in an OTC model. Moreover, availability of OTC alpha-1 blockers may induce women to purchase this product.

In this study we assessed the feasibility of conducting a clinical study program that would explore a self-care model for male LUTS treatment with an OTC alpha-1 blocker. A self-selection study design was used as it allowed for the identification of men with self-reported urinary symptoms who were interested in self-managing their symptoms with an OTC product. A preliminary drug facts label was developed for this study. Thus, the primary objective was to determine whether men with self-reported urinary symptoms could make a correct decision to use the study product based on their relevant health history and DFL printed on the mock-up of the proposed OTC product. The secondary objective was to assess whether consumers choosing to use the OTC product might be masking the diagnosis and delaying treatment of a medically significant condition. Although the proposed OTC product is targeted for use in men, an OTC product can be purchased by anyone and, as such, the study population for this self-selection study includes an all-comers population of adult men and women.

METHODS

Study Design

This study was conducted at 43 urology research centers across the United States. Subjects who responded to an advertisement regarding urinary symptoms were referred to the study sites where they reviewed a mock-up of a potential OTC product and determined its suitability for their personal use (part 1). Subjects who chose not to use the product or reported an allergy to the ingredients listed on the product mock-up were considered to have completed the study. Subjects who chose to use the product entered part 2 of the study, regardless of whether their decision was in alignment with the product information.

In part 2, subjects underwent baseline assessments and dipstick urinalysis. The criteria for referral to the study urologists were defined a priori in the study protocol. Subjects who did not meet these criteria were considered to have completed the study. The criteria used to identify subgroups were female gender; men younger than 45 years; and men 45 years old or older who reported 1 or more of self-assessed cannot urinate at all, dysuria, extreme thirst, gross hematuria or urethral discharge (referred to as "Do Not Use" symptoms); trace levels or more of glucose, leukocytes or blood in the urine sample; or an AUA-SI score of 20 or greater. Subjects not referred for urological assessment were men 45 years old or older who did not meet any of the aforementioned criteria, since it was unlikely that these men would have an undiagnosed MSC. All subjects provided written informed consent for study participation. The study was conducted in compliance with the protocol and the principles in the Declaration of Helsinki and the ICH Harmonised Tripartite Guidelines for Good Clinical Practices, and relevant Boehringer Ingelheim Standard Operating Procedures.

Study Participants

The study population comprised men and women 18 years old or older who responded to a recruitment advertisement regarding urinary symptoms. The key exclusion criteria are shown in the supplementary material (http://jurology.com/).

Assessments

A priori diagnostic algorithms based on current medical care standards and national guidelines developed by the AUA and the American Diabetes Association[15,17] were developed. The study urologists used standard approved diagnostic methods for the assessment of subjects