

## AN ALTERNATIVE MODEL FOR THE MANAGEMENT OF LOWER URINARY TRACT SYMPTOMS PRESUMED TO BE DUE TO BENIGN PROSTATIC HYPERPLASIA

### Hypothesis / aims of study

Cases of benign prostatic hyperplasia (BPH) are projected to increase, whereas the number of urologists will decrease, making alternative models of care imperative. This study evaluated consumer's ability to correctly self-identify male lower urinary tract symptoms associated with BPH (LUTS/BPH). The magnitude of undiagnosed medically significant conditions (MSC)—like diabetes, urinary tract infections, urolithiasis, and possible/confirmed malignancies—presenting with urinary symptoms, which can be confused with LUTS/BPH, were assessed.

### Study design, materials and methods

Subjects who believed that an over-the-counter (OTC) product was appropriate to self-manage their LUTS underwent dipstick urinalysis and completed the AUA Symptom Index (AUA-SI). Sub-groups for urologic assessment included men < 45 years; and men ≥ 45 years who reported symptoms listed on the OTC label as reasons not to use the product; or were found to have a trace or more of glucose, leukocyte, and/or blood in their urine; or had an AUA-SI score ≥ 20. Urologic assessment was not conducted in men ≥ 45 years who did not meet any of these criteria.

### Results

A total of 1274 men self-selected and had a urine dipstick performed. The mean AUA-SI total score was 18.9. Positive urine dipstick results were obtained from 266 (20.9%) men. A total of 729 men underwent urologic assessment; 517 (70.9%) had urologist confirmed LUTS/BPH, whereas 200 (27.4%) did not. The mean AUA-SI total score was 22.5 and 21.2 in men with and without LUTS/BPH, respectively. Urologists identified newly diagnosed MSC causing or contributing to urinary symptoms in 11 men with LUTS/BPH and 10 men without (Table).

### Interpretation of results

Men can identify LUTS likely to be associated with BPH. The risk of potential harm due to incorrect self-identification is low as few men had an undiagnosed MSC.

### Concluding message

Although most men have regular contact with an HCP, they are not diagnosed with BPH; their urinary symptoms are not generally discussed during HCP interactions and are not treated. With an OTC product, men can safely manage their condition with low medical risk.

### **Table**

	≥ 45 years, n (%) <sup>*</sup>				Total
	< 45 years, n (%)	'Do not use' symptoms	Positive urine dipstick	Severe AUA-SI	
Number of men who self-selected	131 (100)	244 (100)	168 (100)	285 (100)	828 (100)
Discussion of urinary symptoms with HCP	55 (42.0)	145 (59.4)	93 (55.4)	194 (68.1)	487 (58.8)
Symptom duration >3 years	50 (38.2)	117 (48)	79 (47.0)	149 (52.3)	395 (47.7)
On prescription medication	18 (13.7)	84 (34.4)	54 (32.1)	107 (37.5)	263 (31.8)
Men who underwent urological assessment	112 (100)	208 (100)	148 (100)	261 (100)	729 (100)
Confirmed LUTS/BPH	30 (26.8)	164 (78.8)	108 (73.0)	215 (82.4)	517 (70.9)
Men without LUTS/BPH	82 (73.2)	40 (19.2)	32 (21.6)	46 (17.6)	200 (27.4)
Newly diagnosed MSC causing/contributing to urinary symptoms	5 (4.5)	7 (3.4)	3 (2.0)	6 (2.3)	21 (2.9)

AUA-SI, AUA Symptom Index; BPH, benign prostatic hyperplasia; LUTS, lower urinary tract symptoms; MSC, medically significant conditions

<sup>\*</sup> The table does not include the number of patients ≥ 45 years who did not report a Do Not Use condition, had a normal urine dipstick and had a mild or moderate AUA score (n = 446)

### Disclosures

**Funding:** This study was funded by Boehringer Ingelheim Pharmaceuticals, Inc. **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Local Institutional Review Board (IRB) or Independent Ethics Committee (IEC) **Helsinki:** Yes **Informed Consent:** Yes