Tamsulosin Treatment Affecting Patient-reported Outcomes in Benign Prostatic Hyperplasia-associated Depressive Symptoms

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OBJECTIVE To investigate the effect of tamsulosin on LUTS and depressive symptoms among depressed and nondepressed individuals previously diagnosed with benign prostatic hyperplasia.

MATERIALS AND METHODS The study conducted from July 2013 to June 2014 included outpatient participants with benign prostatic hyperplasia presenting with lower urinary tract symptoms (LUTS). One tablet of tamsulosin (0.2 mg) was administered to patients daily. We divided participants with geriatric depression scale (GDS) scores of 0-17 into the nondepressive symptom group (group 1) and those with GDS scores of 18-30 into the depressive symptom group (group 2). At the first visit (V1), 4th week (V2), and 12th week (V3), the International Prostate Symptom Score (IPSS), quality of life (QoL), patient perception of bladder condition, overactive bladder syndrome symptom score, and GDS questionnaires were administered.

RESULTS IPSS (17.35 ± 7.11 vs 14.61 ± 6.04, $P = .10$) as well as GDS scores (20.97 ± 3.07 vs 8.84 ± 4.50, $P < .01$) were higher among those with depressive symptoms than those without, and difference between the two groups was not represented. After taking tamsulosin, on the V2 and V3, both groups had improved overactive bladder syndrome symptom scores, patient perception of bladder condition, IPSS, QoL, and GDS. Comparing the first visit with the V2 and V3, group 2 showed significant changes in GDS, but group 1 did not.

CONCLUSION Treatment with tamsulosin is associated with improved LUTS and decreased depressive symptoms, which could enhance QoL. UROLOGY 87: 172–177, 2016. © 2015 Elsevier Inc.

Depression is a relatively common disease, with prevalence rates ranging from 2% to 15%.[1] Depression affects an individual's overall health, family life, and personal economic life.[2] Depression plays an important role in chronic diseases, such as chronic obstructive lung disease, inflammatory bowel disease, arthritis, asthma, diabetes, and congestive heart failure.[3] Depression is also associated with urologic diseases such as ureter stone, incontinence, overactive bladder, and lower urinary tract symptoms (LUTS).[4]

LUTS related to benign prostatic hyperplasia (BPH) and other urologic diseases have a negative effect on an individual's quality of life (QoL), nocturia in particular.[5] Recent studies show that BPH with LUTS has a negative association with QoL, overall general condition, and mental health.[6] Additionally, the clinical course and treatment of BPH are chronic and are difficult for patients to manage by themselves.

Many studies suggest a significant association between depression and BPH.[7] Also, LUTS or BPH is strongly related with anxiety and stress vulnerability.[8,9] Nocturia is one of the symptoms of LUTS that was revealed to have close connection with depression. Presence of nocturia is a risk factor for depression and depression can contribute to nocturia.[10] Additionally, the presence of nocturia causes insomnia, which contributes to depressive symptoms.[11]

There are some studies exploring the relationship between depression and LUTS, although few address the changes in depressive symptoms that occur in the course of managing LUTS. However, there is no study that shows that improvement of LUTS affects depressive symptoms. In this study, we investigated the effect of tamsulosin on LUTS and depressive symptoms among depressed and nondepressed individuals previously diagnosed with BPH.

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MATERIALS AND METHODS

Study Design

This is a prospective study conducted at the Department of Urology of Hanyang University Guri Hospital from July 2013 to June 2014 that included outpatient participants with BPH presenting with LUTS, with 93 patients enrolled in the study. The institutional review board of Hanyang University Guri Hospital reviewed and approved this study, and data were collected after obtaining informed consent from all participants.

This study targeted male patients greater than 40 years old, demonstrating LUTS, with an International Prostate Symptom Score (IPSS) over 8 points, prostate size over 20 cc via examination of transrectal ultrasonography, and with no history of taking 5-alpha-reductase inhibitors (5ARI), including dutasteride and finasteride, in the past 3 months. All participants included expressed an intention to participate in the clinical test and provided informed consent.

Individuals were excluded from the study if they met any of the following criteria: a medical history of prostate operation, urinary tract tumor, neurogenic bladder, or urethral stricture; over 150 mL of residual urine; acute urinary tract infection during the registration period; an inserted urinary tract catheter or training for intermittent self-catheterization; a prostate-specific antigen level of more than 10 ng/mL (cases with a prostate-specific antigen level of between 4 and 10 ng/mL and no prostatic cancer as confirmed on prostate biopsy were included in the study); abnormalities on digital rectal examination; hypersensitivity to medications, severe liver disorders (glutamate-oxaloacetate transaminase, glutamate-pyruvate transferase over 100 IU/L), or renal disorders (creatinine over 3 mg/dl); or previous treatment for depression or treatment for depression scheduled to be performed. Based on these criteria, the patients took one tablet of tamsulosin (0.2 mg) , which is the recommended therapeutic dose of tamsulosin in Korea, 30 minutes before going to bed, with BPH showing LUTS once a day, and questionnaires were administered at the first visit (Visit 1 – V1), as well as on the 4th (Visit 2 – V2) and 12th (Visit 3 – V3) weeks of the study. We divided participants with geriatric depression scale (GDS) scores of 0-17 into the nondepressive symptom group (group 1) and those with GDS scores of 18-30 into the depressive symptom group (group 2).

Rating Scales

Urinary Scales. Questionnaire measures included the IPSS,[12] which evaluates the severity of urinary tract symptoms; the overactive bladder syndrome symptom (OABSS) score,[13] which diagnoses overactive bladder syndrome symptoms; and the patient perception of bladder condition (PPBC),[14] which assesses self-bladder condition.

Depression Scale. The GDS[15] is a tool for evaluating depressive symptoms among older individuals. The reliability and validity of GDS have been addressed in many studies, and it is a commonly used tool in evaluating depressive symptoms.[16] From the GDS questionnaire, scores of 0-17 are diagnosed as not depressed, 18-21 indicate mild depression, 22-25 points indicate moderate depression, and 26-30 indicate severe depression. Given that LUTS accompanying BPH is a chronic disease and may co-occur with depressive symptoms, depression levels based on the GDS were identified.

Statistical Analysis

All data were recorded and analyzed in standard form. Using a Student *t* test, the standard record of the two groups was comparatively analyzed. The divided data were analyzed using chi-square tests. All statistical analyses were performed using SPSS (IBM SPSS version 22.0, IBM, Armonk, NY) software and values of $P < .05$ were considered significant.

RESULTS

Ninety-three patients were enrolled in this study; in the enrollment session, patients who had been diagnosed with depression or treated for depression in the past were excluded. Twenty-three were lost to follow-up (11 refused, whereas we lost contact in 12) and five patients discontinued because of adverse drug events (three because of retrograde ejaculation, two because of decreased blood pressure). Thus, a total of 65 patients completed the study. Participant characteristics and mean scores on measures are described in Table 1. After participants were divided into two groups based on depressive symptoms, notable

Table 1. Basic participant characteristics

	Total (n = 65)	Group 1 (n = 31)	Group 2 (n = 34)	*P* Value
Age	62.74 ± 8.84	62.16 ± 9.42	63.26 ± 8.39	.62
TRUS (cc)	32.39 ± 8.59	31.75 ± 7.95	32.97 ± 9.21	.57
PSA (ng/dL)	1.57 ± 1.73	1.64 ± 1.42	1.50 ± 2.00	.74
Total IPSS	16.05 ± 6.71	14.61 ± 6.04	17.35 ± 7.11	.10
Voiding IPSS*	9.71 ± 4.75	8.48 ± 3.91	10.82 ± 5.21	.04
Storage IPSS†	6.34 ± 3.31	6.13 ± 3.10	6.53 ± 3.53	.63
PPBC	3.71 ± 1.13	3.58 ± 1.18	3.82 ± 1.09	.39
QoL	3.80 ± 0.85	3.61 ± 0.96	3.97 ± 0.72	.09
OABSS	5.34 ± 3.43	5.03 ± 3.27	5.62 ± 3.60	.50
OABSS No.3‡	2.28 ± 1.80	2.32 ± 1.72	2.24 ± 1.89	.85
GDS	15.18 ± 7.18	8.84 ± 4.50	20.97 ± 3.07	<.01

GDS, geriatric depression scale; IPSS, International Prostate Symptom Score; OABSS, overactive bladder syndrome symptom; PPBC, patient perception of bladder condition; PSA, prostate-specific antigen; QoL, quality of life; TRUS, transrectal ultrasonography.

* Sum of questions 2, 4, and 7 of the IPSS.

† Sum of questions 1, 3, 5, and 6 of the IPSS.

‡ Question No. 3 (Urgency) of the OABSS.