

## **Efficacy and Safety of Tadalafil 5 mg Administered Once Daily in Men with Erectile Dysfunction and Lower Urinary Tract Symptoms**

**Introduction and Objective:** Recent data suggest that there may be an association between erectile dysfunction (ED) and lower urinary tract symptoms (LUTS). Increasing evidence also indicates that the clinical use of phosphodiesterase type 5 (PDE5) inhibitors provides relief from LUTS. The purpose of our study is to investigate the safety and effects of Tadalafil 5mg once daily in men with ED and LUTS.

**Materials and Methods:** This study included a total of 89 patients who complained of ED and LUTS and treated with tadalafil 5mg once daily for eight weeks between September 2009 and February 2011. The International Prostate Symptom Score (IPSS) and the International Index of Erectile Function (IIEF)-5 questionnaire information were obtained prior to treatment (V1), and again following treatment with Tadalafil 5mg once a day (weeks 4 (V2) and 12 (V3) after treatment began). We also evaluated any adverse effects of Tadalafil 5mg when it was administered once daily during the follow-up period.

**Results:** A total, of 60 patients (67.4%) completed the eight-week clinical study. The mean patient age was  $57.0 \pm 9.2$  years. Regarding subjective symptoms, there were 48 patients (80.0%) who experienced improvement of their ED and 43 patients (71.7%) who experienced the improvement of their LUTS. The IPSS values were  $15.33 \pm 8.32$  (V1),  $11.78 \pm 7.69$  (V2), and  $9.91 \pm 7.77$  (V3), with significant improvement (V1 vs. V2,  $p=0.042$ , V1 vs. V3,  $p=0.006$ ). The IIEF-5 values were  $8.34 \pm 5.33$  (V1),  $15.74 \pm 8.99$  (V2), and  $18.72 \pm 19.58$  (V3), with significant improvement (V1 vs. V2,  $p=0.001$ , V1 vs. V3,  $p=0.001$ ). A total of three patients (5.0%) reported adverse effects, i.e. two patients experienced facial flushing and one patient had mild chest discomfort.

**Conclusions:** Treatment with Tadalafil 5mg once daily was beneficial for the treatment of both ED and LUTS. Adverse effects on the cardiovascular system were minimal in our study. Therefore, we believe that taking Tadalafil 5mg once daily is safe for patients with ED and LUTS.