ORIGINAL RESEARCH—ERECTILE DYSFUNCTION

Effectiveness of Tadalafil 5 mg Once Daily in the Treatment of Men with Lower Urinary Tract Symptoms Suggestive to Benign Prostatic Hyperplasia With or Without Erectile Dysfunction: Results from Naturalistic Observational TadaLutsEd Study

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ABSTRACT

Introduction. Naturalistic clinical trials provide data on the effectiveness of drugs in nonexperimental and everyday situations and are extremely helpful for decision-making purposes and for confirming experimental findings in clinical trials. No data have been published from naturalistic studies performed in patients with lower urinary tract symptoms suggestive of benign prostatic hyperplasia (LUTS/BPH) with or without erectile dysfunction (ED) and treated with phosphodiesterase type 5 inhibitors.

Aim. The aim of this study (TadaLutsEd Study) was to assess, in the context of medical practice, the effectiveness of tadalafil 5 mg once daily in patients with LUTS/BPH with or without erectile dysfunction.

Methods. The study was a 6-week uncontrolled, prospective, open-label, multicentric, observational study.

The patient population involved sexually active males aged ≥50 years, diagnosed with LUTS/BPH with or without concomitant ED, and treated with tadalafil 5 mg daily in accordance with standard urological practice.

Main Outcome Measures. Effectiveness was assessed through the self-administered International Prostate Symptom Score (IPSS) questionnaire; quality of life was evaluated through the IPSS quality of life section (IPSS-QoL). The patients were also evaluated with the International Index of Erectile Function (IIEF-5). Adverse events were recorded. Statistical analyses using paired data samples was applied (Wilcoxon signed-ranks test).

Results. Sixty-two patients (mean age 62.2 years) completed the treatment, of whom 85.5% showed improvement in their urinary symptoms. Pre- and post-treatment differences in the IPSS, IPSS-QoL, and IIEF-5 scores were statistically significant at 4.4, 1, and 5.4 points, respectively ($P < 0.0001$). Tadalafil was well tolerated, and adverse events were mild, with a discontinuation rate of 1.6%.

Conclusion. According to study results, the use of tadalafil 5 mg once daily in a nonselected patient population with LUTS/BPH with or without ED led to improvements in terms of symptoms and quality of life and exhibited a safety profile similar to that obtained in controlled tadalafil clinical trials. **Bechara A, Casabe A, Rodriguez Baigorri G, and Cobreros C. Effectiveness of tadalafil 5 mg once daily in the treatment of men with lower urinary tract symptoms suggestive to benign prostatic hyperplasia with or without erectile dysfunction: Results from naturalistic observational TadaLutsEd Study. J Sex Med 2014;11:498–505.**

Key Words. Benign Prostatic Hyperplasia; Erectile Dysfunction; Lower Urinary Tract Symptoms; Phosphodiesterase 5 Inhibitor; Tadalafil; IIEF; IPSS

Introduction

Various epidemiological studies have revealed a high prevalence of lower urinary tract symptoms secondary to benign prostatic hyperplasia (LUTS/BPH) and their impact on the quality of life of patients [1–5]. Treatment approaches are aimed at improving symptoms and quality of life, stopping BPH progression, and avoiding BPH-related complications [6,7].

Drugs such as alpha blockers and 5-alpha reductase inhibitors have proven to be very effective both in controlled clinical trials and in clinical practice [8–14]. Recently, tadalafil—a phosphodiesterase type 5 inhibitor of proven efficacy in the treatment of erectile dysfunction (ED)—was proven to be effective in several controlled clinical trials including patients with LUTS/BPH with or without ED. This has led to its approval as a therapeutic product for this population of patients [15–19].

Controlled clinical trials are experimental and provide safety and efficacy data related to a given intervention obtained under exclusively experimental circumstances in a concrete and homogeneous population representative of the general population, though this is not always possible; supplementary data are also needed for application across the general population.

Naturalistic clinical trials provide data on the effectiveness of drugs under nonexperimental everyday situations and have proven to be extremely useful for decision-making purposes as well as for confirming the experimental findings of clinical trials [20–23].

Clinical trials are designed to assess efficacy (whether a drug is fit to produce the effects proposed in Phase II studies) and efficiency (comparative efficacy between the new drug and a known drug—Phase III studies). However, effectiveness is assessed vis-à-vis a comparator drug of proven efficiency and efficacy in a population of regular patients. It is for this reason that our study intends to assess effectiveness in terms of improvement in symptoms and quality of life.

We were unable to find data in the literature on studies of this nature performed on patients with LUTS/BPH with or without ED treated with phosphodiesterase type 5 inhibitors such as tadalafil.

As a result, our objective has been to carry out a naturalistic and observational study (TadaLutsEd Study) in order to evaluate the effectiveness of tadalafil 5 mg once daily in the treatment of LUTS/BPH with or without ED.

Aim

The primary objective of this study is to assess the effectiveness of tadalafil 5 mg once daily in the improvement of LUTS, in the context of standard urological practice, in patients with LUTS/BPH with or without concomitant ED. The secondary objective is to assess treatment effectiveness in terms of quality of life and drug safety.

Materials and Methods

This study was a 6-week uncontrolled (naturalistic), prospective, open-label, multicentric, longitudinal, observational study.

In accordance with the design of naturalistic observational studies, diagnosis and treatment type were based on the universal criteria accepted in standard practice; therefore, assessments and treatment were not conditioned in any way. All patients completed questionnaires related to sexual health, urinary symptoms, and quality of life, both before and after treatment.

Based on medical history and the opinion of the intervening physician, the study's inclusion criteria accepted sexually active male patients of 50 years or more who complained of symptoms of LUTS, ED, or both, and who had been prescribed tadalafil 5 mg daily in accordance with standard urological practice. The exclusion criteria excluded patients with contraindications for tadalafil therapy as established by the drug's package insert.

Prostate adenoma diagnosis was performed through a physical examination, and the presence and severity of LUTS/BPH and ED were evaluated through a series of self-administered questionnaires (International Prostate Symptom Score [IPSS] and International Index of Erectile Function -5 [IIEF-5]) [24–27]. Quality of life (IPSS-QoL) was also determined.

The severity of LUTS was classified according to IPSS as mild (0–7), moderate (8–19), or severe (20–35). The severity of ED was classified according to IIEF-5 score as mild (17–21), mild to moderate (12–16), moderate (8–11), or severe (5–7).

Treatment satisfaction was evaluated by means of a visual analogue scale ranging from 1 (very bad) to 10 (very good) [28,29].

Patients completing at least 4 weeks of treatment were taken into consideration for effectiveness analysis purposes, and adverse events were recorded.