Treatment Satisfaction of Men and Partners Following Switch from On-Demand Phosphodiesterase Type 5 Inhibitor Therapy to Tadalafil 5 mg Once Daily

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ABSTRACT

Introduction. Treatment satisfaction of men receiving phosphodiesterase 5 inhibitors (PDE5) for erectile dysfunction (ED) and their partners is essential to successful long-term therapy.
Aim. This study aims to assess treatment satisfaction, in men with a partial response to on-demand (PRN) PDE5 and their female partners, following tadalafil 5 mg once daily or placebo.
Methods. The study was randomized, double-blind, parallel, and placebo-controlled in men primarily with mild to moderate ED. Treatment satisfaction was assessed following a 4-week maximum dose PRN lead-in, 4-week nondrug washout, and treatment through 12 weeks. Men were ≥18 years old with ED for ≥3 months and International Index of Erectile Function Erectile Function score of ≥17 and <26 at screening and <26 following PRN lead-in.
Main Outcome Measures. Treatment satisfaction was assessed using the Treatment Satisfaction Scale (TSS) for patients and partners. TSS domain scores range from 0 to 100, with higher values indicating greater satisfaction. Statistical comparisons were made using analysis of covariance.
Results. Treatment satisfaction was significantly greater with tadalafil once daily vs. placebo across all TSS domains for both patients and their partners (all $P < 0.001$). For patients, mean scores for the TSS domains Confidence to Complete Sexual Activity and Satisfaction with Orgasm ranged from 53.7 to 57.8 after the PRN lead-in and 26.7 to 31.9 following the nondrug washout. Following randomized treatment, scores for tadalafil and placebo were 55.4 and 32.6, respectively, for Confidence to Complete Sexual Activity and 57.5 and 37.9, respectively, for Satisfaction with Orgasm. Results were comparable for other TSS domains and between men and their partners.
Conclusions. Treatment satisfaction was comparable for tadalafil 5 mg once daily and PRN PDE5 for both patients and female partners, suggesting that tadalafil once daily is a viable therapy option for men with ED who had a partial response to PRN PDE5 therapy. **Burns PR, Rosen RC, Dunn M, Baygani SK, and Perelman MA. Treatment satisfaction of men and partners following switch from on-demand phosphodiesterase type 5 inhibitor therapy to tadalafil 5 mg once daily. J Sex Med 2015;12:720–727.**

Key Words. Erectile Dysfunction; Tadalafil; Treatment Satisfaction; Partner; Couples

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Introduction

Phosphodiesterase type 5 inhibitors (PDE5) are recommended as first-line therapy in the treatment of erectile dysfunction (ED) [1,2]. Although PDE5's are generally effective, many couples discontinue treatment within the first year [3,4]. Notably, ED is a multifactorial experience, including difficulty with physical aspects such as ease of erection and successful completion of intercourse, as well psychosocial aspects such as sexual confidence, impact on relationship, and partner satisfaction [5]. Fully evaluating treatment response should similarly encompass both evaluation of sexual functioning and sexual satisfaction of patients and partners, as well as assessing the impact of treatment on the sexual relationship, self-confidence, and overall satisfaction [6]. Ultimately, treatment satisfaction of patients and their partners is of central importance in evaluating successful outcomes, and thus in providing the most effective and satisfying therapies [4].

In terms of the degree of erectile function improvement, men undergoing ED therapy have rated a return to normal erectile function as highly desirable [7]. However, earlier reports indicate that only approximately 50% of men treated with an on-demand (PRN) PDE5 therapy achieve a return to normal function, as defined by an International Index of Erectile Function-Erectile Function (IIEF-EF) domain score of ≥26 [8,9]. The ability of tadalafil once daily at doses up to 5 mg to provide a return to normal erectile function in men who had a partial response to PRN PDE5 therapy was recently assessed [10]. Overall efficacy and safety results were reported previously; however, data on treatment satisfaction of both patients and partners, as assessed by the Treatment Satisfaction Scale (TSS) [11–13], have not been presented.

Aims

Here we report on treatment satisfaction in men who had a documented partial response to PRN PDE5 therapy and their female partners following treatment with tadalafil once daily vs. placebo for up to 12 weeks.

Methods

Study Design and Methods

The present post hoc analyses were based on data from a randomized, double-blind, parallel-group, placebo-controlled study of tadalafil 5 mg once daily for up to 12 weeks. That study evaluated return to normal erectile function (IIEF-EF ≥26) in men who previously had a partial response to the maximum dose of a PRN PDE5 therapy. The study design and methods have been described previously [10]. In brief, patients were eligible if they were ≥18 years of age, had at least a 3-month history of ED, and had been taking the maximum dose of sildenafil citrate, vardenafil, or tadalafil PRN for at least 1 month prior to study entry. The study periods included a 4-week maximum dose PRN PDE5 lead-in period and a 4-week nondrug washout period, followed by randomization of eligible patients in a 1:1:1 ratio to tadalafil 2.5 mg titrated to 5 mg, tadalafil 5 mg, or placebo once daily for 12 weeks (Figure 1).

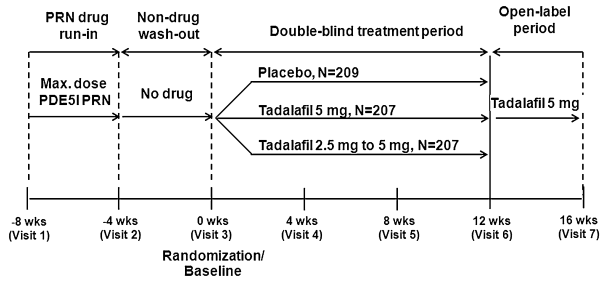

Figure 1 Study design
Note: The open-label study period was not addressed herein

The study was conducted in accordance with the ethical principles originating in the Declaration of Helsinki, good clinical practices, and all applicable laws and regulations. The institutional review board at each site approved the study, and all men provided written informed consent before undergoing any study procedure or receiving any study therapy.

Study Population

This study assessed men who had been taking the maximum dose of sildenafil citrate (100 mg), vardenafil (20 mg), or tadalafil (20 mg) PRN for at least 1 month prior to study entry and had an IIEF-EF domain score of ≥17 and <26 at screening (visit 1) [10]. Exclusion criteria included prior ineffective PDE5 treatment per the opinion of the investigator, no successful intercourse attempts during the 30 days prior to visit 1, an IIEF-EF domain score ≥26 at visit 2; or a female partner who was unwilling to complete the TSS. Other exclusion criteria were as previously described in studies of tadalafil once daily for ED [14–16].