

Association between the Erectile Dysfunction Inventory of Treatment Satisfaction and the Self-Esteem and Relationship Questionnaire Following Treatment with Sildenafil Citrate for Men with Erectile Dysfunction

Joseph C. Cappelleri, PhD,¹ Stanley E. Althof, PhD,² Richard L. Siegel, MD,³ Vera J. Stecher, PhD,³ Li-Jung Tseng, PhD,³ Sandeep Duttgupta, PhD³

¹Pfizer Inc, Global Research & Development, Groton, CT, USA; ²Center for Marital and Sexual Health, Case Western Reserve University, Beachwood, OH, USA; ³Pfizer Inc, New York, NY, USA

ABSTRACT

Objectives: Research is lacking on the correlation between treatment satisfaction and confidence, self-esteem, and relationships for men receiving treatment for erectile dysfunction (ED). We sought to correlate scores between the validated Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) index and the validated Self-Esteem And Relationship (SEAR) questionnaire following treatment with sildenafil citrate (VIAGRA).

Methods: This study was based on an open-label, flexible-dose trial of 93 sildenafil-naïve patients with ED. Pearson correlation coefficients between EDITS index and SEAR questionnaire scores, each of which can range from 0 to 100 (most favorable), were calculated at end of treatment (EOT). An analysis of covariance model was applied to associate changes from baseline to EOT in SEAR scores with EDITS score at EOT, controlling for baseline SEAR score.

Results: Significant and sizable Pearson's correlations between SEAR and EDITS scores ($P \leq 0.0001$; range:

0.49–0.84) were observed. A 10-point higher EDITS scores at EOT corresponded to a significant and tangible average improvement in SEAR scores from baseline to EOT ($P \leq 0.0001$; range: 6.6–8.7). Average SEAR scores at EOT were markedly different between patients with greater treatment satisfaction at EOT (EDITS score \geq median EDITS score of 88.6; $n = 50$) and those with lesser treatment satisfaction at EOT (EDITS score < 88.6 ; $n = 43$).

Conclusions: The data add to the validity of the SEAR questionnaire, suggest a tangible relationship between treatment satisfaction and psychosocial benefit among men with ED treated with sildenafil, and highlight the importance of assessing the psychosocial impact of ED in men undergoing treatment.

Keywords: confidence, erectile dysfunction, psychometrics, quality of life, relationships, self-esteem, sildenafil citrate, Viagra.

Introduction

Erectile dysfunction (ED) is defined as the inability to achieve or maintain an erection sufficient for sexual intercourse [1], and is a prevalent condition affecting as many as 50% of men over the age of 40 years [2]. The incidence of ED increases substantially with age, approximately doubling with each decade of life after 50 years [2]. ED is a common complication of spinal cord injury and prostate sur-

gery [3,4]; is often a comorbid condition of diabetes, depression, and other diseases [5–9]; and may be a symptom of underlying, chronic systemic vascular disease [10–12]. Nevertheless, ED is often undertreated [13]. Moreover, men are often reluctant or embarrassed to discuss sexual issues [14], making diagnosis and treatment a challenge for health-care providers.

Sexual and erectile function are considered important components of men's overall health [15]. The psychosocial impact of ED can lead to depression, loss of self-esteem, and relationship and marital difficulties [16]. A review of clinical trials showed that successful ED treatment was associated with improved sexual, relational, and emotional aspects of the lives of patients with ED, regardless

Address correspondence to: Joseph C. Cappelleri, Pfizer Inc, Global Research & Development, MS 8260-2222, Eastern Point Road, Groton, CT 06340-8030, USA. E-mail: joseph.c.cappelleri@pfizer.com

doi:10.1111/j.1524-4733.2005.00072.x

of the specific therapy used [16]. Three of these studies assessed the impact of sildenafil in a double-blind placebo-controlled setting [3,17,18]. Sildenafil was significantly associated with clear improvements in several components of sexual function (ability to achieve and maintain an erection, sexual satisfaction), mental health (well-being, depression, anxiety), and “quality of life” after successful treatment of ED [18,19]. Thus, assessing the psychosocial impact of ED is relevant toward understanding and measuring sexual, relationship, and emotional domains of treatment outcomes of interest to patients.

More recently, three independent clinical trials with sildenafil—one an open-label trial [20] and two double-blind placebo-controlled studies [21,22]—have demonstrated major psychosocial gains in self-esteem, confidence, and relationships as measured by the Self-Esteem and Relationship (SEAR) questionnaire, an ED-specific instrument that has undergone rigorous development and validation [20,23]. Focus groups of men with ED, their female partners, and physicians, along with the clinical literature, have provided testimony that improved self-esteem, confidence, and relationships add value to health in men with ED [23]. The three studies [20–22] also demonstrated uniformly large gains in erectile and sexual functioning. For example, in the open-label trial [20], mean scores for the erectile function domain of the International Index of Erectile Function (IIEF) (range: 1 [lowest] to 30 [highest]) increased significantly from 15.5 (SD 6.4) at baseline to 25.6 (SD 6.8) at end of treatment (EOT) ($P = 0.0001$); the remaining four domains on the IIEF also showed considerable improvement. Changes in Erectile Function domain score correlated moderately with changes in SEAR domain and subscale scores (Sexual Relationship, $r = 0.69$; Confidence, $r = 0.48$; Self-Esteem, $r = 0.47$; Overall Relationship, $r = 0.35$; $P \leq 0.001$).

The Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS), another well-validated ED-specific instrument, was developed to assess satisfaction with ED therapies and to explore the impact of patient and partner satisfaction on treatment continuation [24]. EDITS has been used to evaluate patients’ satisfaction with therapies such as sildenafil, apomorphine, intracavernosal injections, and penile prosthesis [25–27] for the treatment of ED of varied etiologies, including Peyronie’s disease [28] and following therapy for prostate cancer [29].

To fully assess how ED therapy affects a patient’s condition, we need to consider different questionnaires each intended to measure a different aspect of

how ED therapy affects a patient’s profile. Efficacy assessments of ED therapies like the IIEF primarily focus on the patient’s erection and associated sexual functioning. Treatment satisfaction measures like the EDITS focus on treatment satisfaction, a characteristic feature of ED therapy. Measures like the SEAR questionnaire focus on the broader psychosocial impact of the condition.

Research is lacking, however, on the association between treatment satisfaction and improvements in psychosocial factors following a beneficial intervention for ED. Treatment satisfaction is critical in helping to prevent therapy discontinuation for patients with ED [30,31]. A tangible association between treatment satisfaction and psychosocial factors like self-esteem, confidence, and relationships may suggest that these factors are also relevant for treatment adherence. We therefore investigated the relationship between the EDITS index and the SEAR questionnaire in patients treated with a beneficial intervention for ED.

Methods

Study Design

The current study was part of a larger investigation to assess the responsiveness of change scores on the SEAR questionnaire—and especially its self-esteem subscale—in a multicenter, open-label, flexible-dose (25–100 mg) clinical trial in sildenafil-naïve men with ED [20]. Patients were 18 years or older, in a stable relationship with a single partner, and had clinically documented ED. Following a 2-week screening phase, patients received sildenafil (initial dose 50 mg, adjustable to 100 mg or 25 mg based on efficacy and tolerability) to be taken as needed for 10 weeks. Patients were excluded if they had sitting hypotension (blood pressure $<90/50$ mm Hg) or severe hypertension (blood pressure $>170/110$ mm Hg) or significant cardiovascular disease. Patients were excluded if they were taking nitrates or nitric oxide donors or CYP3A4 inhibitors, were previously treated with sildenafil, or were currently taking any other treatment for ED. The study was approved by an Institutional Review Board, was conducted in accordance with Good Clinical Practice requirements, and in full compliance with the most recent amendments of the World Medical Assembly Declaration of Helsinki.

Efficacy Measures

In this report we focused on the association between treatment satisfaction as measured by the EDITS index and psychosocial factors as measured

Download English Version:

<https://daneshyari.com/en/article/10485400>

Download Persian Version:

<https://daneshyari.com/article/10485400>

[Daneshyari.com](https://daneshyari.com)