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PSYCHOMETRICS

Enriching the Interpretation of the Erectile Dysfunction Inventory of Treatment Satisfaction: Characterizing Success in Treatment Satisfaction

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ABSTRACT

Background: Patient-reported outcomes, such as the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) index, are essential for successful evaluation and treatment of patients with erectile dysfunction.

Aim: To enrich interpretation of the EDITS index score and to complement the existing 0 to 100 scoring.

Methods: This supplemental analysis evaluated EDITS questionnaire data (11 items; index score range = 0−100; higher scores indicate more treatment satisfaction) after completion of an 8-week double-blinded trial of 279 men 18 to 65 years old with erectile dysfunction randomized to sildenafil 100 mg, sildenafil 50 mg, or placebo. Response options for each EDITS item were grouped into "success" (the 2 most satisfied or favorable responses) and "no success" (the remaining 3 responses). The binary response (success or no success) for each item was expressed as a function of overall EDITS score in a simple logistic regression model with all treatments combined.

Outcomes: Odds ratios and success probabilities (using Wald χ^2 tests) were calculated for specified point differences and total EDITS index scores, respectively.

Results: EDITS index score increases corresponded with significant increases in odds of success in different EDITS aspects ($P < .0001$ for all comparisons). For instance, a 10-point EDITS index score difference was associated with odds ratios of 11.3, 42.0, 17.7, and 6.8 for overall treatment satisfaction, treatment meeting expectations, satisfaction with treatment quickness, and satisfaction with how long treatment lasts, respectively. For a given EDITS index score, likelihood of success was determined for different aspects of treatment satisfaction. For example, a mean EDITS index score of 78 (sildenafil 100 mg; SD = 18) corresponded to 96%, 88%, 94%, and 88% chances of success for the 4 EDITS items referenced earlier, respectively. Corresponding probabilities for a mean EDITS index score of 50 (placebo; SD = 18) were 3%, less than 0.1%, 1%, and 4%, respectively.

Clinical Implications: Interpretation of the EDITS index score can be augmented using key aspects of treatment satisfaction as reported by the patient.

Strengths and Limitations: This analysis used a well-established anchor-based approach to interpret EDITS index scores. The methodology used and corresponding results are appropriate for clinical practice and clinical trial settings. Limitations include data evaluation only for the Patient EDITS and not the complementary Partner EDITS and use of data from a clinical trial enrolling a well-defined patient population only in stable relationships.

Conclusion: These results enable a meaningful interpretation of EDITS index scores, facilitating decision making by stakeholders for better-informed health care choices. **Cappelleri JC, Tseng L-J, Stecher V, Goldstein I. Enriching the Interpretation of the Erectile Dysfunction Inventory of Treatment Satisfaction: Characterizing Success in Treatment Satisfaction. J Sex Med 2018;15:732−740.**

Key Words: Erectile Dysfunction; Patient-Reported Outcome; Erectile Dysfunction Inventory of Treatment Satisfaction; Sildenafil

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INTRODUCTION

The successful evaluation and treatment of patients with erectile dysfunction (ED) rely on patient-reported outcomes (PROs).[1−3] A PRO is "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else."[4] Objective outcomes are available to measure sexual function; however, to fully and accurately assess ED, direct evaluation from the patient is required.

Several validated and reliable PROs have been developed to assess the different aspects of ED.[3] These PROs are the preferred efficacy end points in clinical trials to assess the benefits of treatments for ED.[1] As a result, PRO data are often used and reviewed by a large number of stakeholders, including clinicians, regulatory bodies, health policymakers, reimbursement agencies, and, ultimately, patients. PROs are central to evidence-based practice for the treatment of ED, and each stakeholder must be able to meaningfully interpret the data. However, translating a PRO score into a meaningful and tangible measurement of a patient's health status can be challenging, because the scores are often not well understood owing to insufficient data, lack of experience, or lack of clinical understanding.[5]

The Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) is a validated 11-item questionnaire used to assess treatment satisfaction and the likelihood of treatment continuation in patients with ED.[3,6] The EDITS is often used in clinical trials to assess and compare satisfaction with treatments and in clinical practice when considering treatment alternatives.[3,7] The EDITS has patient and partner components; the patient component is a collection of 11 questions that cover items such as overall treatment satisfaction, degree to which the treatment met expectations, ease of use, likelihood of treatment satisfaction, and naturalness of the erection (Table 1). For each question, the patient scores the treatment from 0 (no or low satisfaction or dissatisfaction) to 4 (high satisfaction).[3,6] Then, the mean satisfaction value is calculated and multiplied by 25, giving a final index score range of 0 to 100, with higher scores representing higher treatment satisfaction. The resulting score must be interpreted in a clinical context, a process that can be particularly cumbersome and challenging in practice.

The purpose of this analysis is not to replace the existing interpretation of the EDITS index score based on a scale of 0 to 100, but rather to enrich and complement it by demonstrating how interpretation can be augmented and illustrating the advantages of using the EDITS in clinical practice. A central question regarding clinical implementation of the EDITS is, "What does an EDITS index score represent and what do differences in scores actually mean?" For example, what does a score of 50 indicate and how does it compare with a score of 80? This topic is addressed by testing hypotheses assuming that each EDITS item is related to the overall EDITS index score and characterizing the extent or magnitude of that relation.

METHODS

Trial Design

Data used in this extended analysis were collected from a multicenter, parallel-group, randomized trial, which was designed to assess the efficacy and tolerability of initiating the starting dose of sildenafil at 100 mg rather than initiating a dose of 50 mg and titrating upward (ClinicalTrials.gov NCT00245258).[8] The study was conducted at 19 centers in the Republic of Korea (6 centers), the Russian Federation (5 centers), Spain (4 centers), and Sweden (4 centers). The 14-week trial included a 2-week screening phase; an 8-week double-blinded, placebo-controlled, fixed-dose treatment phase; and a 4-week open-label phase with sildenafil.[8] This supplemental analysis evaluated EDITS data from the aforementioned 8-week double-blinded trial of men 18 to 65 years old with ED who were randomized to receive sildenafil 100 or 50 mg or placebo in the treatment phase.

To be included in the study, adult men (18−65 years old) had to have a diagnosis of ED (International Index of Erectile Function erectile function domain [IIEF-EF] score $\leq$ 25) and be in a stable sexual relationship for the duration of the study. Key exclusion criteria were treatment with more than 6 doses of sildenafil or another phosphodiesterase type 5 inhibitor in total and treatment with any phosphodiesterase type 5 inhibitor in the 4 weeks before screening. Patients were randomized 1:1:1 to sildenafil 50 mg, sildenafil 100 mg, or placebo taken as needed for sexual activity but not more than once a day.

Randomization numbers were created by an independent randomization group with a block size of 6 and 1:1:1 ratio to the sildenafil 100 or 50 mg or placebo treatment group. Each subject was allocated a subject identification number only after the informed consent had been signed (screening visit 1, ie, week −2). For subjects who had met all protocol criteria and were eligible to receive study medication, the randomization number (which appeared on the study medication label) was allocated to the subject at visit 2 (week 0). All subject identification numbers and randomization numbers were assigned sequentially, in ascending order, beginning with the lowest number available.

Men were encouraged to attempt sexual activity at least twice a week. During the open-label phase, all patients received the sildenafil 50-mg dose, with the option to uptitrate to 100 mg to improve efficacy. Men taking sildenafil 100 mg could adjust the dose to 50 mg for safety and tolerability between visits; those patients who could not tolerate the 50-mg dose were discontinued from the study.

For the original investigation, the primary trial end point was change in IIEF-EF score from baseline to the end of the double-blinded treatment phase. As stated in the primary publication of the original study,[8] the sample size was determined based on the expected difference in the mean change from baseline to end