

A Systematic Review of the Psychosocial Outcomes Associated with Erectile Dysfunction: Does the Impact of Erectile Dysfunction Extend Beyond a Man's Inability to Have Sex?

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ABSTRACT

Aim. The aim of this study was to report and analyze the published data from randomized controlled trials (RCTs) for (i) the psychosocial outcomes associated with erectile dysfunction (ED) before treatment with a phosphodiesterase type 5 (PDE5) inhibitor; and (ii) the change in psychosocial outcomes after the use of a PDE5 inhibitor in men with ED.

Methods. The method used was a prospectively designed systematic literature review of publications reported in MEDLINE via PubMed, EMBASE, the Cochrane Library, Science Citation Index Expanded, and PsychINFO from January 1, 1995 to May 14, 2012.

Main Outcome Measures. The main outcome measures were scores on psychosocial measures in men who were treated for ED with a PDE5 inhibitor before and after treatment.

Results. A total of 1,714 publications were retrieved; 1,674 publications were excluded because they did not meet the design requirements of the review, and 40 publications (32 RCTs) were retained. Before treatment, men who participated in clinical trials reported relatively good quality of life and overall relationships, but poor sexual relationships and sexual satisfaction, diminished confidence, low self-esteem, and symptoms of depression. After treatment, there were significant improvements from baseline in most of these measures, except for overall life satisfaction and overall relationship satisfaction.

Conclusions. ED and the treatment of ED are associated with substantially broader aspects of a man's life than just erectile functioning. This review demonstrates the importance of evaluating the psychosocial factors associated with ED and its treatment, and the importance of using standardized scales to conduct this evaluation. Further research is needed to better understand the mechanisms underlying the reciprocal relationships among physical and psychological functioning in men with ED. **McCabe MP and Althof SE. A systematic review of the psychosocial outcomes associated with erectile dysfunction: Does the impact of erectile dysfunction extend beyond a man's inability to have sex? J Sex Med 2014;11:347–363.**

Key Words. Clinical Trial; Erectile Dysfunction; Mood; PDE5i; Psychology; Psychosocial; Quality of Life; Sexual Confidence; Review

Introduction

Erectile dysfunction (ED) is a common problem worldwide that affects men as they age, with 22.5% of men aged between 40 and 80 years reporting to have ED in the United States [1–3]. As well as the inability to achieve or maintain an erection, there is increasing evidence that the impact of ED extends beyond the immediate

inability to have sex and negatively affects men's emotional and psychological well-being [4,5], their relationships [6], and their partner's sexual and emotional life [7,8]. However, evaluation of pharmacological treatments for ED has, until recently, focused primarily on physical measures of erectile function, not the psychosocial aspects. For example, the International Index of Erectile Function (IIEF), which encompasses erectile and

orgasmic function (eight items), sexual desire (two items), overall satisfaction and satisfaction with intercourse (four items), and confidence (one item), is the gold standard measure that is most often used to assess erectile function and response to treatment in clinical trial settings [9,10]. Although the goals of pharmacological treatment are generally to improve erectile function and the sexual aspects of quality of life and life satisfaction (e.g., feelings of being less of a man, embarrassment, and guilt and worry that the partner feels hurt or rejected [11]), the IIEF was not designed to assess the impact of ED and treatment on broader psychosocial outcomes.

Oral phosphodiesterase type 5 (PDE5) inhibitors are recommended as first-line therapy for pharmacological treatment of men with ED [12]. PDE5 inhibitors can be taken as needed (e.g., sildenafil, tadalafil, vardenafil, avanafil) or daily (tadalafil), depending on patients' medical history, preferences, and previous experiences [12,13]. The treatment of ED is not simply about addressing the physical aspects of sexual function. In addition to the IIEF, broader psychological and relationship outcome measures, such as confidence, relationship satisfaction, depression, and performance anxiety, have recently been included in the assessment of PDE5 inhibitors as treatment for ED in clinical trial settings [14–19].

Collation of clinical study data that explore the reciprocal relationship between ED and psychosocial measures, and any change in psychosocial measures associated with treatment with oral PDE5 inhibitors, may be of assistance to clinicians when managing men with ED. The aim of this systematic review was to summarize the published data from randomized controlled trials (RCTs) for (i) the psychosocial outcomes associated with ED before treatment with a PDE5 inhibitor; and (ii) the change in psychosocial outcomes after the use of a PDE5 inhibitor in men with ED.

Methods

Search Strategy

A prospectively designed literature search strategy was developed to retrieve articles published from January 1, 1995 to May 14, 2012 that met the predefined inclusion and exclusion criteria.

The following databases were searched: MEDLINE via PubMed; EMBASE; The Cochrane Library, including the Cochrane Database of Systematic Reviews and Cochrane Central

Register of Controlled Trials; Science Citation Index Expanded (SCI-EXPANDED); and PsychINFO®.

Search terms selected to search each database were medical subject headings (MeSH) wherever applicable. The ED terms were erectile dysfunction (MeSH) and male impotence. The PDE5 inhibitor terms were phosphodiesterase inhibitors (MeSH), phosphodiesterase type 5 inhibitor, PDE5 inhibitor, PDE-5 inhibitor, PDE 5 inhibitor, mirodenafil, sildenafil, tadalafil, udenafil, vardenafil. The psychosocial terms were enjoyment and satisfaction questionnaire, patient satisfaction (MeSH), psychology (MeSH), psychological, psychological and interpersonal relationship scale, PAIRS, quality of life (MeSH), QOL, self concept (MeSH), self-esteem, self-esteem and relationship, SEAR, self perception, sexual quality of life, SQOL, sexual life quality questionnaire, and SLQQ.

Search terms within each category were separated by the Boolean operator OR, and categories were separated by the operator AND. The search was limited to publications written in English and studies in humans wherever possible. Additional database-specific limits were used. For MEDLINE, the search was limited to clinical trials, meta-analyses, RCTs, clinical trials (Phase I, Phase II, Phase III, Phase IV), comparative studies, and multicenter studies. For EMBASE and SCI-EXPANDED, the search excluded abstracts and review articles. For PsychINFO, the search was limited to longitudinal studies, meta-analyses, prospective studies, quantitative studies, RCTs, and systematic reviews.

Inclusion Criteria

Retrieved publications were included if they were (i) published from January 1, 1995 to the search date and reported psychosocial measures in men who were treated for ED with a PDE5 inhibitor; (ii) reported numerical data from the following widely used instruments that have been validated or designed specifically for use in men with ED or are general measures of quality of life, mental health, and well-being: the Self-Esteem and Relationship (SEAR) questionnaire, the Psychological and Interpersonal Relationship Scale (PAIRS), the Sexual Life Quality Questionnaire (SLQQ), the Sexual Quality of Life (SQOL) questionnaire, and the Quality of Life Enjoyment and Satisfaction Questionnaire; (iii) reported numerical data from other measures of self-concept or relationship

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