

Combination of Psychological Intervention and Phosphodiesterase-5 Inhibitors for Erectile Dysfunction: A Narrative Review and Meta-Analysis

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ABSTRACT

Introduction. Erectile dysfunction (ED) is an increasing health problem that demands effective treatment. There is evidence that phosphodiesterase-5 inhibitors (PDE5-Is) and psychological intervention (PI) are effective treatment options; however, little is known about their comparative efficacy and the efficacy of combined treatments.

Aim. The aim of this systematic review and meta-analysis is to evaluate the comparative efficacy of PI, PDE5-Is, and their combination in the treatment of ED.

Main Outcome Measures. Primary outcome was ED symptoms, and secondary outcome was sexual satisfaction of the patient.

Methods. A systematic literature search was conducted in order to identify relevant articles published between 1998 and 2012. We included randomized controlled trials and controlled trials comparing PI with PDE5-I treatment or one of them against a combination of both.

Results. Eight studies with a total number of 562 patients were included in the meta-analysis. The results of the included studies are inconclusive, though they show a trend towards a larger effect of combined treatment compared with PI or PDE5-I treatment alone. The meta-analysis found that, overall, combined treatment was more efficacious for ED symptoms than PDE5-I treatment or PI alone. Combined treatment was more efficacious than PDE5-I use alone on sexual satisfaction. No differences were found between PDE5-Is and PI as stand-alone treatments. None of the moderators (treatment duration, methodological quality, or researcher allegiance) altered the effects.

Conclusions. The combination of PI and PDE5-Is is a promising strategy for a favorable outcome in ED and can be considered as a first-choice option for ED patients. Stronger RCTs are required to confirm this initial finding. **Schmidt HM, Munder T, Gerger H, Frühauf S, and Barth J. Combination of psychological intervention and phosphodiesterase-5 inhibitors for erectile dysfunction: A narrative review and meta-analysis. J Sex Med 2014;11:1376–1391.**

Key Words. Erectile Dysfunction Therapy; Health Services Research; Impotence; Male; Sexual Dysfunction; Phosphodiesterase Inhibitor; Sex Counseling; Systematic Review; Meta-Analysis; Intervention; Randomized Controlled Trial; Patient Satisfaction

Introduction

Erectile dysfunction (ED) is a frequently occurring disorder in men, with increasing prevalence rates among all age groups, ranging from 2% under the age of 40 to more than 80% in

men over 80 years [1]. Due to demographic shifts in the age pyramid, an increase in ED rates for the general population can be expected in the future [2]. ED is associated with low quality of life [3,4], marital problems [5], and psychological distress and disorders, as well as low self-esteem [6]. Such

functional limitations often lead to a vicious cycle resulting in chronic problems [7], and both medical and psychological treatments seem appropriate [8–10].

With the introduction of sildenafil (Viagra) in 1998, phosphodiesterase-5 inhibitors (PDE5-Is) became the medical treatment of choice. They are efficacious and safe [11] and can be applied easily [12–14]. A meta-analysis of 130 randomized controlled trials (RCTs) on the efficacy of PDE5-Is in patients with ED revealed that PDE5-Is were more efficacious than placebo, with higher rates of successful sexual intercourse attempts (69% vs. 35%) [13]. Despite the high efficacy and easy administration of PDE5-Is in general, several challenges of using them for a comprehensive treatment of ED have to be considered. Rates of discontinuation are usually high, with discontinuation rates ranging from 14% to 50% [8]. Dissatisfaction with treatment may also be caused by inadequate application of the PDE5-Is (e.g., too early medication or insufficient sexual stimulation) and unrealistically high expectations. A second reason might be unrecognized psychological or interpersonal issues as the cause of erectile dysfunction that are not targeted by the medical treatment [15].

Psychological intervention (PI), such as sex therapy or counseling, addresses the underlying psychosocial causes of ED. Examples of such causes are performance anxiety, physical or mental health problems (of the partner), the couple relationship, and current life stress [16–18]. “By understanding the medical, psychological, interpersonal, and cultural factors that contribute to the problem, a sex therapist can design an individualized treatment plan for the patient or couple” (Althof, 2011, p. 1,828) [17]. Despite the wide use of PI in clinical practice, randomized studies on its efficacy are rather scarce. Earlier reviews on PI found efficacy compared with no-treatment control groups, but conclusions were limited due to the low quality of studies [19]. A recent meta-analysis on four RCTs comparing ED patients receiving PI with those on the waiting list for treatment found a non-significant, moderate effect size of $d = 0.53$ (95% CI [-0.08, 1.14]) for symptom severity and a non-significant, moderate effect size of $d = 0.38$ (95% CI [-0.17, 0.94]) for sexual satisfaction [20].

As PDE5-Is and PI supplement each other, some authors recommend a conjoint medical and psychosocial treatment [8–10]. This integrated treatment approach is based on the assumption

that the binary model (in which ED is either psychogenic or organic) is insufficient to explain a complex disorder like ED, and therefore a treatment should rely on a biopsychosocial model that integrates all predisposing, precipitating, maintaining, and contextual factors [16–18,21]. “The clinician’s interventions are then focused on the predominant factors, although not ignoring the others” (Perelman, 2006, p. 105) [21]. The combination of medical and psychosocial treatments is not a novel concept. It is successfully employed in the treatment of mental disorders, as well as organic diseases such as diabetes and breast cancer [16,21]. However, studies on the efficacy of a combined treatment for ED are rare. One recent review [22] found a larger effect of a combined treatment of PDE5-Is and PI, as well as a larger effect of PI alone, vs. PDE5-Is alone. However, this review was based on only two studies, and thus the generalizability of the findings is very limited. Moreover, the review did not report on comparisons between PI and a combination of PI and PDE5-Is.

The aim of this systematic review and meta-analysis is to evaluate the comparative efficacy of PI, PDE5-Is and their combination in the treatment of ED.

Methods

Inclusion and Exclusion Criteria

We included controlled studies that compared PI for men suffering from ED with either PDE5-I treatment or a combination of PDE5-I and PI treatment. Neither an explicit diagnostic procedure nor randomization of patients to treatments was required for study inclusion.

PI included psychotherapy and psychoeducation (i.e., counseling, sexual education, and workshops). We set no restrictions with respect to treatment modalities (i.e., individual, couple, or group) or formats (i.e., face-to-face therapy, Internet therapy, self-help materials). All pharmaceutical agents based on the PDE-5I mechanism were considered eligible. The included studies reported on ED symptoms and/or sexual satisfaction. Studies in any language and from any cultural background were considered eligible for inclusion.

Literature Search and Data Sources

The initial literature search for studies that were published between 1998 (the year of the release of Viagra) and 2012 was conducted in the context of

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