ORIGINAL RESEARCH

The Combination of Dapoxetine and Behavioral Treatment Provides Better Results than Dapoxetine Alone in the Management of Patients with Lifelong Premature Ejaculation

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ABSTRACT

Introduction. It is not known whether the efficacy of dapoxetine, the only drug approved for the on-demand treatment of premature ejaculation (PE), can be increased by the addition of sexual behavioral treatment (SBTx).
Aim. To test the hypothesis that combined dapoxetine and SBTx provide better result than dapoxetine alone in the management of patient with lifelong PE.
Methods. After a 4-week run-in period, 50 patients with lifelong PE entered a 24-week, open-label, prospective study with a 1:1 assignment. Twenty-five patients (group A) received on-demand dapoxetine 30 mg alone, and the remaining 25 patients (group B) combined on-demand dapoxetine 30 mg and SBTx. The CONSORT 2010 statement was adhered to where possible.
Main Outcome Measures. The intravaginal ejaculatory latency time (IELT), the premature ejaculation diagnostic tool (PEDT) score, and the treatment-emergent adverse events (TEAEs) were analyzed.
Results. Mean age was 34.16 years in group A and 34.44y in group B. From baseline to 4-, 12- and 24-week evaluation, both groups experienced a significant ($P < 0.0001$) increase in mean IELT and decrease in mean PEDT score, but patients in group A showed a significantly lower increase in mean IELT (85.0; 84.8; 130.7; 160.0 vs. 92.0; 137.9; 232.7; 370.7 seconds, respectively; $P < 0.0001$) and a significantly lower decrease in mean PEDT score (20.4; 18.16; 15.88; 14.68 vs. 19.56; 16.0; 11.96; 7.92, respectively; $P < 0.0001$) than those in group B. At 24-week evaluation, no patient in group A reached a PEDT score ≤8 (absence of PE) as opposed to 80% of patients in group B. There was no difference between groups in TEAEs rate (16% vs. 16%; $P = 1.00$). Limitations included the absence of a group receiving SBTx alone or group crossover.
Conclusions. Combined dapoxetine and SBTx proved to be more effective than dapoxetine alone in treating patients with lifelong PE, up to restoring a normal ejaculatory function in most of them. **Cormio L, Massenio P, La Rocca R, Verze P, Mirone V, and Carrieri G. The combination of dapoxetine and behavioral treatment provides better results than dapoxetine alone in the management of patients with lifelong premature ejaculation. J Sex Med 2015;12:1609–1615.**

Key Words. Dapoxetine; Behavioral Therapy; Premature Ejaculation; Sexual Dysfunction

Introduction

Premature ejaculation (PE) is one of the most common male sexual disorders, affecting up to 30% of all men [1]. It involves both physiologic disturbances and psychological concerns over ejaculatory latency, control over ejaculation, and ensuing distress [2,3]. Recently, the International Society for Sexual Medicine (ISSM) has proposed the first evidence-based definition of PE [4].

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According to this new definition, PE (lifelong and acquired) is a male sexual dysfunction characterized by the following:

1. Ejaculation that always or nearly always occurs prior to or within circa 1 minute of vaginal penetration (lifelong PE) or a clinically significant and bothersome reduction in latency time, often to about 3 minutes or less (acquired PE).
2. The inability to delay ejaculation in all or nearly all vaginal penetrations.
3. Negative personal consequences such as distress, bother, frustration, and/or the avoidance of sexual intimacy. Various treatment options are commonly used in clinical practice, including selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCAs), tramadol, phospfodiesterase 5 inhibitors (PDE5-Is), alpha 1-adrenoceptor antagonists, topical anaesthetics, and sex behavioral therapy [5].

Among pharmacological agents, the rapidly acting SSRI dapoxetine hydrochloride is the only currently approved drug for the on-demand treatment of PE [6]. In the pooled dataset of more than 6,000 subjects [7], on-demand administration of 30 or 60 mg dapoxetine resulted in a 2.5- and 3.0-fold (respectively) increase in the intravaginal ejaculatory latency time (IELT) and in significantly better scores than placebo in the four items of the Premature Ejaculation Profile questionnaire. Dapoxetine hydrochloride also provided benefits for female partner-reported outcomes [7] and had similar efficacy in primary (lifelong) and acquired PE, and across different geographic areas as well [8].

Sex behavioral and sex counseling therapies have been widely used around the world since early reports by Masters and Johnson [9] and Semans [10], respectively. According to the ISSM guidelines for PE [11–14], there is a 2b level of evidence regarding the efficacy of such PE treatments; however, the only two studies using contemporary assessment methods (IELT) showed that sex behavioral therapy was more effective than no treatment (wait-list control group) but less effective than pharmacological treatment with either paroxetine or lidocaine-based spray [12,13].

The possibility of combining pharmacological and behavioral treatment, though recommended in the ISSM guidelines for PE with a 2a level of evidence [11], has received little attention. The ISSM guidelines recommendation is based on three Chinese studies [14–16] comparing pharmacological treatment alone: sildenafil, clomipramine, citalopram with combined pharmacological and behavioral treatment. In all three studies, combination therapy was superior to pharmacotherapy alone on both the Chinese Index for Premature Ejaculation and/or the IELT [11]. These finding provide grounds for assuming that sex behavioral treatment might improve the results of pharmacotherapy by improving the psychological and physical control of ejaculation. In spite of such evidence and with dapoxetine being the only approved pharmacological treatment for PE, no study has been published that determines whether the addition of sex behavioral therapy improves the efficacy of dapoxetine or not.

Aims

The present study was designed to test the hypothesis of combined dapoxetine and sex behavioral treatment providing better results than dapoxetine alone in the management of patients with lifelong PE.

Patients and Methods

Men between the ages of 18 and 70 years with a history of lifelong PE who met the ISSM definition criteria were considered eligible for the study [4]. The Consolidated Standards of Reporting Trials (CONSORT) 2010 statement was adhered to where possible. Study inclusion criteria was the following: (i) a stable, heterosexual relationship with a single sexually active female partner for at least 6 months and with at least four intercourses per month; (ii) Premature Ejaculation Diagnostic Tool (PEDT) score ≥11 [17]; and (iii) no previous or concurrent treatments for PE. Exclusion criteria were: (i) a history of medical or psychiatric illness; (ii) use of SSRIs, TCAs, and PDE5-Is or other medications potentially interfering with dapoxetine; (iii) erectile dysfunction (ED) as determined by an International Index of Erectile Function five items (IIEF-5) score <22; and (iv) any form of sexual dysfunction in the female partner as assessed by interview.

After the preliminary evaluation for eligibility including medical and sexual history, physical examination, and self-administration of IIEF-5 and PEDT questionnaires, enrolled patients underwent a 4-week baseline period during which couples were encouraged to experience sexual intercourse at least four times and record the IELT for each event using the stopwatch technique. At

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