Efficacy and tolerability of dapoxetine in treatment of premature ejaculation: an integrated analysis of two double-blind, randomised controlled trials

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Lancet 368:929-937, 2006

**Background.**—No drugs are approved for treatment of premature ejaculation. Our aim was to determine the efficacy and tolerability of on-demand dapoxetine in patients with severe premature ejaculation.

**Methods.**—We determined the efficacy of dapoxetine in a prospectively predefined integrated analysis of two 12-week randomised, double-blind, placebo-controlled, phase III trials of identical design done independently, in parallel, at 121 sites in the USA. Men with moderate-to-severe premature ejaculation in stable, heterosexual relationships took placebo (n=870), 30 mg dapoxetine (874), or 60 mg dapoxetine (870) on-demand (as needed, 1-3 h before anticipated sexual activity). The primary endpoint was intravaginal ejaculatory latency time (IELT) measured by stopwatch. Safety and tolerability were assessed. All analyses were done on an intention-to-treat basis. The trials are registered at ClinicalTrials.gov, numbers NCT00211107 and NCT00211094.

**Findings.**—672, 676, and 610 patients completed in the placebo, 30 mg dapoxetine, and 60 mg dapoxetine groups, respectively. Dapoxetine significantly prolonged IELT (p<0.0001, all doses vs placebo). Mean IELT at baseline was 0.90 (SD 0.47) minute, 0.92 (0.50) minute, and 0.91 (0.48) minute, and at study endpoint (week 12 or final visit) was 1.75 (2.21) minutes for placebo, 2.78 (3.48) minutes for 30 mg dapoxetine, and 3.32 (3.68) minutes for 60 mg dapoxetine. Both dapoxetine doses were effective on the first dose. Common adverse events (30 mg and 60 mg dapoxetine, respectively) were nausea (8.7%, 20.1%), diarrhoea (3.9%, 6.8%), headache (5.9%, 6.8%), and dizziness (3.0%, 6.2%).

**Interpretation.**—On-demand dapoxetine is an effective and generally well tolerated treatment for men with moderate-to-severe premature ejaculation.

Premature ejaculation (PE) has been reported to be the most common male sexual dysfunction. Despite this, as of March 2007, there are no therapies approved by the US Food and Drug Administration for this condition. The problem stems in part from conflicting notions of what constitutes PE and difficulty with adequately quantitating the condition, thus making therapeutic trials challenging to design and conduct. Selective serotonin reuptake inhibitors are known to have ejaculation-delaying effects, and this side effect has been used for the therapy of PE. Dapoxetine is a short-acting selective serotonin reuptake inhibitor that is currently under investigation as an oral therapy for PE. The authors of this study combine results from two double-blind, placebo-controlled trials of dapoxetine at 30 mg and 60 mg doses on demand for the treatment of men with PE. Average IELT at baseline was less than a minute for all of the men studied. Improvement in mean IELT was noted in all three
groups, but the improvements were significantly greater in the dapoxetine groups; average IELT at 12 weeks or at the last follow-up visit was 1.75 minutes, 2.78 minutes, and 3.32 minutes for placebo, dapoxetine 30 mg, and dapoxetine 60 mg, respectively. The improvement in IELT as well as the patient’s reported sense of control over ejaculation and his perception of longer intercourse duration was significantly greater in both dapoxetine groups as compared with placebo. Side effects included nausea, diarrhea, headache, and dizziness. Dapoxetine offers promise as a potential therapy for PE, but US Food and Drug Administration approval is still pending at the time of this printing.

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Psychobiologic Correlates of the Metabolic Syndrome and Associated Sexual Dysfunction

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*Eur Urol* 50:595-604, 2006

**Objectives.**—The association of low testosterone level and erectile dysfunction (ED) with metabolic syndrome (MS) is receiving increasing attention. The present study determined the psychobiologic characteristics of sexual dysfunction (SD) associated with MS (as defined by the National Cholesterol Education Program’s Adult Treatment Panel III criteria) in a series of 803 consecutive male outpatients.

**Methods.**—Several hormonal, biochemical, and instrumental (penile Doppler ultrasound [PDU]) parameters were studied, along with general psychopathology scores (Middlesex Hospital Questionnaire modified [MHQ]). The Structured Interview on Erectile Dysfunction (SIEDY) was also applied.

**Results.**—Among the 236 patients (29.4%) diagnosed as having a MS, 96.5% reported ED, 39.6% hypoactive sexual desire (HSD), 22.7% premature ejaculation, and 4.8% delayed ejaculation. Patients with MS were characterised by greater subjective (as assessed by SIEDY) and objective (as assessed by PDU) ED and by greater somatised anxiety than the rest of the sample. The prevalence of overt hypogonadism (total testosterone <8 nM) was significantly higher in patients with MS. Among MS components, waist circumference and hyperglycaemia were the best predictors of hypogonadism. Hypogonadal patients with MS showed higher gonadotropin and lower free testosterone levels, suggesting a primary hypogonadism. Among patients with MS, hypogonadism was present in 11.9% and 3.8% in the rest of the sample (p < 0.0001) and was associated with typical hypogonadism-related symptoms, such as hypoactive sexual desire, low frequency of sexual intercourse, and depressive symptoms.

**Conclusions.**—Our data suggest that MS is associated with a more severe ED and induces somatisation. Furthermore, MS is associated with a higher prevalence of hypogonadism in patients with SD. The presence of hypogo-
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