

**Conclusions:** treatment with mirtazapine was effective in both depressed women and men and no effect on sexual function.

**Key words:** mirtazapine, depression, posttraumatic stress disorder (PTSD), sexual dysfunction, outpatients.

## P0054

An integrated analysis of the efficacy of desvenlafaxine succinate compared with placebo in the treatment of major depressive disorder

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**Objective:** To assess the efficacy of desvenlafaxine succinate (DVS) treatment in patients with major depressive disorder (MDD).

**Methods:** Seven randomized, double-blind, placebo-controlled, short-term studies were pooled to evaluate the efficacy of DVS in MDD. Adult outpatients with DSM-IV MDD were enrolled in all studies. Eligible patients were randomly assigned to DVS (n=1186) at doses of 100–400 mg/d, or placebo (n=797) for 8 weeks. The 17-item Hamilton Depression Rating Scale (HAM-D17) was the primary efficacy variable. Other efficacy variables were the Clinical Global Impressions scale (CGI), HAM-D6, Montgomery Åsberg Depression Rating Scale (MADRS), Covi Anxiety scale, Sheehan Disability Scale (SDS), WHO-5 Well-Being Index, and the Visual Analog Scale–Pain Intensity (VAS-PI). A mixed-effect model for repeated measures (MMRM) analysis was used to analyze continuous variables. Logistic regression was used to analyze response and remission rates.

**Results:** An adjusted mean difference of –2.8 points on HAM-D17 total score at end point for DVS vs placebo (95% confidence limits: –2.2, –3.4; P<0.001) was demonstrated. Response and remission rates were significantly elevated for DVS-treated patients compared with placebo (P<0.001) across rating scales (HAM-D17, MADRS, and CGI). For other secondary measures at end point, including the CGI, HAM-D6, MADRS, Covi, SDS, WHO-5, and VAS-PI, significant differences from placebo were also observed. No additional benefit was observed for DVS doses above 100 mg/d in analyses of fixed-dose studies.

**Conclusions:** DVS was efficacious in treating MDD based on standard depression rating scales and measures of anxiety, global severity/improvement, functioning, well being, and pain.

## P0055

Prolactin inhibition by SSRI'S

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The relationship between selective serotonin reuptake inhibitors (SSRI'S) is presented.

The SSRI dependent side effects are mostly characterized by serotonin potentiation.

Both SSRI'S and tricyclic antidepressants can also cause extrapyramidal side effects.

The occurrence of movement disorders such as akathisia, dystonia and Parkinsonism after use of SSRI'S was reported.

Furthermore descriptions of deterioration of Parkinson's disease after use of fluoxetine, fluvoxamine and paroxetine can be found in the literature.

Medication having a serotonergic effect can cause a prolactin level elevation through an indirect mechanism.

Prolactin elevation may cause galactorrhea.

Two mechanisms are considered to explain the prolactin release induced by the serotonergic system: the presynaptic inhibition of dopamine discharge by the serotonergic receptors or the direct stimulation of the hypothalamic postsynaptic receptors.

## P0056

Reduction of anxiety symptoms in patients with major depressive disorder treated with Desvenlafaxine Succinate: A pooled analysis

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**Objective:** To assess the efficacy of desvenlafaxine succinate (DVS) treatment in reducing symptoms of anxiety in patients with major depressive disorder (MDD).

**Methods:** Data were pooled from 7 randomized, double-blind, placebo-controlled, 8-week DVS trials. All studies enrolled adult outpatients with DSM-IV MDD. Patients were excluded if an anxiety disorder was the primary diagnosis. Eligible patients were randomly assigned to treatment with 100–400 mg/d DVS (n=1186) or placebo (n=797) for 8 weeks. The primary efficacy outcomes in this analysis were the 17-item Hamilton Rating Scale for Depression (HAM-D17) item 10 (Anxiety/Psychic) and the Covi Anxiety total score (measured in 6 of the 7 trials). Patients with a Covi Anxiety score >9 or whose Covi score exceeded their Raskin Depression total score were not enrolled. Changes from baseline were analyzed using a mixed-effects model for repeated measures (MMRM) analysis, which included the fixed, categorical effects of treatment, protocol, visit, and the treatment-by-visit interaction, as well as the continuous, fixed covariate of baseline score. Secondary analyses evaluated changes from baseline to end point using analysis of covariance (ANCOVA), using last-observation-carried-forward [LOCF] and observed cases [OC] analyses.

**Results:** Improvement from baseline at week 8, the study end point, was significantly greater for the DVS group than for the placebo group on both the HAM-D17 Anxiety/Psychic item and Covi Anxiety total scores in both the MMRM and ANCOVA (LOCF and OC) analyses.

**Conclusion:** In this pooled analysis, DVS was significantly superior to placebo in the treatment of anxiety symptoms associated with depression.