

Background: We evaluated the efficacy of eszopiclone (ESZ) and concurrent escitalopram oxalate (EO) in patients with insomnia and co-morbid GAD.

Methods: Patients meeting DSM-IV-TR criteria for GAD and insomnia received 10 weeks of EO 10mg and co-therapy with ESZ 3mg or placebo (PBO) for 8 weeks. For the last 2 weeks, ESZ was replaced with single-blind PBO to evaluate discontinuation effects. Sleep, daytime functioning and anxiety measures were captured during the study.

Results: ESZ+EO improved sleep and daytime functioning at each week and the double-blind period average ($p < 0.05$). At Week 8, significantly more ESZ+EO patients had no clinically meaningful insomnia based on ISI ≤ 7 . Significant improvements with ESZ+EO (relative to PBO+EO) were observed in HAM-A total scores each week, and Weeks 4–10 excluding the insomnia item. ESZ+EO was significantly better at every timepoint on CGI-I ($p < 0.02$); CGI-S was not different between treatments after Week 1. Median time to anxiolytic response was reduced with ESZ+EO based on HAM-A and CGI-I. HAM-A response and remission rates at Week 8 were higher with ESZ+EO, and HAM-D17 scores were improved at all timepoints ($p < 0.004$). After eszopiclone discontinuation, there was no evidence of rebound insomnia, and no treatment differences in sleep or daytime function. Significant treatment differences in anxiety and mood were maintained after discontinuation.

Conclusion: In this study, ESZ+EO was well tolerated and associated with improved sleep and daytime function without evidence of tolerance. Improvements in anxiety and mood were observed with ESZ+EO.

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P062

Prevalence, incidence and risk of depression in the Spanish cohort within the predict study

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Background: Depression occurs in a quarter of general practice attendees, relapse is frequent five to 10 years from first presentation and residual disability is common. Estimating overall risk across a range of putative risk factors is fundamental to prevention of depression.

Methods: This is a prospective study. As part of the European Predict study, in Málaga (Spain), 9 general practices were recruited. Consecutive attendees aged 18 to 75 were recruited and undertook a detailed interview. Subjects were administered the Composite International Diagnostic Interview (CIDI) depression subscale allowing diagnoses using ICD-10 criteria for depressive episode. For risk factors the interviews included individual-level risk factors and environmental risk factors. All participants completed baseline and follow up assessments at six and 12 months.

Results: A total of 1276 patients were interviewed in the first assessment of the PREDICT study, in Málaga, (Spain) and the response rate of the study one year later was 88%. Out of 1276, 70.5% of the sample is women whilst only 29.5% were men. The sample's mean age was 49 years (SD=15.3). Depression was common amongst

this sample of primary care attendees, although point prevalence values varied slightly according to the diagnostic criteria used. The prevalence of ICD-10 Depressive Episode was 38.2% while ICD-10 depressive episode of mild was 3.4% moderate 12% and severe intensity 22.8%.

Conclusions: The high prevalence we found shows that the depressive disorders are a very common problem with the primary care attendees in our area.

P063

Refractory pain—depression syndrome treated with tianeptine

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Chronic pain is strongly associated with anxiety and depression symptoms in advanced cancer patients. The comorbidity of pain and depression significantly difficulties symptom control and seems to create a noxious feedback mechanism in which: CHRONIC PAIN > DEPRESSION > more PAIN > DEPRESSION. We call this feedback circle as Pain-Depression Syndrome. Mr RA, is a 68-years-old male Caucasian. At the age of 66 an advanced prostatic adenocarcinoma was diagnosed. Bone metastases were concomitantly found. A mild bone pain was treated with tenoxicam 20 mg/day. The pain became more severe. We initially treated the pain with 400 mg/day of tramadol with partial response. A decision to start morphine was discussed. The patient had no history of mental disorder and his family had no history of mood or anxiety disorder. He was examined by a psychiatrist who diagnosed a major depressive episode (DSM-IV-TR) associated with chronic pain syndrome (Clinical Global Impression-GGI, severity = 5). He was prescribed with amitriptyline starting with 25 mg/day and increasing up to 75 mg/day, at which dose he experienced severe anticholinergic side effects and mild confusion. Then amitriptyline was thus halted, and he was prescribed with tianeptine 12.5 mg three times a day. After a 2 week period he described a remarkable improvement of pain control (7–3 on a analogue visual scale of pain), mood, anxiety and depressive symptoms were also improved (CGI severity = 2; CGI improvement = 1). At 6 months follow-up he had very mild pain complaints and no significant mood or anxiety symptoms.

P064

Two years of maintenance treatment with venlafaxine xr 75–225 mg/d: Efficacy in patients with recurrent unipolar major depression

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Background: The efficacy of venlafaxine extended-release (XR) at doses between 75 mg/d and 300 mg/d has been demonstrated in patients with recurrent major depressive disorder (MDD) over 2.5 years. This analysis evaluated the long-term efficacy of venlafaxine XR ≤ 225 mg/d, the approved dosage in many countries.

Methods: In the primary multicenter, double-blind trial, outpatients with recurrent MDD (N=1096) were randomized to receive 10-week acute-phase treatment with venlafaxine XR (75 mg/d to 300 mg/d) or fluoxetine (20 mg/d to 60 mg/d), followed by a 6-month continuation phase. Subsequently, at the start of 2 consecutive, double-blind, 12-month maintenance phases, venlafaxine XR responders were randomized to receive venlafaxine XR or placebo. Data from the 24 months of maintenance treatment were analyzed for the combined end point of maintenance of response (ie, no recurrence of depression and no dose increase above 225 mg/d), and each component individually. Time to each outcome was evaluated with Kaplan-Meier methods using log-rank tests for venlafaxine XR-placebo comparisons.

Results: The analysis population included 114 patients who had received venlafaxine XR doses less than or equal to 225 mg/d prior to maintenance phase baseline (venlafaxine XR: n=55; placebo: n=59). Probability estimates for maintaining response were 70% for venlafaxine XR and 38% for placebo (P=0.007), for no dose increase were 76% and 58%, respectively (P=0.019), and for no recurrence were 87% vs 65%, respectively (P=.099).

Conclusions: These data confirm venlafaxine XR is effective maintaining response at doses ≤ 225 mg/d for up to 2.5 years in patients with MDD.

P065

Predictors of clinical outcome in panic disorder: Analysis of venlafaxine XR short-term treatment studies

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Objective: This pooled analysis evaluated the predictors of clinical outcome in the short-term treatment of panic disorder.

Methods: Data were pooled from 4 randomized, placebo-controlled studies of venlafaxine XR in adult outpatients with Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) panic disorder with or without agoraphobia (n=1595). Patients were randomly assigned to 10 to 12 weeks' treatment with either placebo or venlafaxine (fixed or flexible dosing, range from 75 mg/d to 225 mg/d). The primary efficacy measure was the proportion of patients free of full-symptom panic attacks at end point. Predictors included panic severity (<8 or ≥ 8 full-symptom panic attacks during each 2 week period in the 4 weeks prior to baseline) and gender. Other predictors included panic disorder, clinical global impressions, anxiety, somatic and psychic anxiety, depression, mood, phobias, fear, and avoidance.

Results: In both the active treatment and placebo groups, males (65% and 50%, respectively) and those with low symptom severity (69% and 53%, respectively) were significantly (P<0.05) more likely to be panic-free at end point. For nearly all baseline ratings on clinical measures, greater symptom severity was associated with lower proportions of patients who were free from full-symptom panic attacks at end point. Change scores showing improvement in symptom severity following treatment were associated with higher proportions of patients who were free from full-symptom panic attacks at end point.

Conclusions: Panic-free status at end point was predicted by gender, panic disorder severity, and most baseline and change scores of clinical ratings scales.

P066

Efficacy of venlafaxine XR and placebo in social anxiety disorder: Effects of gender and physical symptoms

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Objective: This pooled analysis compared the efficacy of venlafaxine extended-release (XR) versus placebo in the treatment of social anxiety disorder (SAD).

Methods: Data were pooled from 5 randomized studies of patients with Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) SAD (N=1459) who were treated with venlafaxine XR 75 mg/d to 225 mg/d or placebo for 12 weeks (4 studies) or 28 weeks (1 study). Response and remission rates were calculated for the overall sample, as well as stratified by gender and level of physical symptom severity at baseline. Response was defined as a score of 1 or 2 on the Clinical Global Impressions–Improvement (CGI-I) scale. Remission was defined as a total score of <30 on the Liebowitz Social Anxiety Scale (LSAS).

Results: At baseline the mean LSAS score was 88.1 and 86.6 for the venlafaxine and placebo arms, respectively. Overall response rates at week 12 were 55% for venlafaxine XR and 33% for placebo (P<0.0001); remission rates were 25% and 12%, respectively (P<0.0001). Among patients with less severe physical symptoms, response rates were 52% and 32% for venlafaxine XR and placebo, respectively (P<0.0001); remission rates were 27% and 14%, respectively (P<0.0001). Response rates among patients with more severe physical symptoms were 56% for venlafaxine XR and 33% for placebo (P<0.0001); remission rates were 24% and 11%, respectively (P<0.0001).

Conclusions: Venlafaxine XR is effective in the treatment of SAD, regardless of gender or severity of physical symptoms.

P067

Recurrence prevention in patients with recurrent major depression receiving 12 months of treatment with venlafaxine XR

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Introduction: We report the results from the first 12 months of a 2-year maintenance phase of a study evaluating long-term efficacy and