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INSOMNIA AND QUALITY OF LIFE IN GENERALIZED ANXIETY DISORDER: IMPACT ON CLINICAL PRESENTATION AND RESPONSE TO PREGABALIN AND VENLAFAXINE-XR

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Aims: To assess the impact of insomnia on quality of life (QoL) and functioning in patients with generalized anxiety disorder (GAD), and evaluate the efficacy of pregabalin and venlafaxine-XR in improving sleep and QoL.

Methods: A double-blind trial in adults who met DSM-IV criteria for GAD, with a HAM-A total score ≥ 20 , randomized to 8-weeks of flexible-dose treatment with pregabalin (300-600 mg/d, N=121), venlafaxine-XR (75-225 mg/d, N=125), or placebo (N=128).

Results: At baseline, 64% of all subjects had insomnia (according to the Medical Outcomes Study Sleep scale [MOS]-Sleep Problems Index [SPI] criteria). While HAM-A total scores (minus the insomnia item) were similar for patients with and without baseline insomnia (25.7 vs. 25.0) those with reported significantly more impairment on the Quality of Life, Enjoyment, and Satisfaction Questionnaire (Q-LES-Q; 45.4 vs. 53.6; $p < 0.0001$) and Sheehan Disability Scale (SDS; 17.5 vs. 14.3; $p < 0.0001$) than those without. At endpoint, there was a significantly greater mean improvement in MOS-sleep disturbance factor and MOS-SPI with pregabalin (-29.0 and -21.1, respectively) than venlafaxine-XR (-14.7 and -11.0) or placebo (-15.2 and -12.5; all $p < 0.05$). In more pregabalin (64%) than venlafaxine-XR (51%) or placebo (52%) subjects, abnormal baseline sleep had normalized by endpoint. Endpoint change in MOS-SPI significantly correlated with improvement in both Q-LES-Q and SDS-total scores (Spearman r-values, -0.48 and 0.46, respectively; both $p < 0.0001$; all subjects).

Conclusion: Significantly greater impairment in QoL and functioning was observed in patients with high (vs. low) levels of insomnia. Pregabalin produced significantly greater improvement in insomnia than venlafaxine-XR or placebo.