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COMPARATIVE EFFECTS OF PREGABALIN ON ANXIETY AND SLEEP DISTURBANCE:
RESULTS OF A PATH ANALYSIS

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Introduction: Sleep disturbance is one of the key DSM-IV criteria for generalized anxiety disorder (GAD), and represents the chief complaint in approximately one-third of patients presenting in the primary care setting.

Objectives/aims: To evaluate the extent to which improvement in anxiety is a direct effect of treatment with pregabalin, or is an indirect effect mediated by improvement in sleep disturbance, and vice-versa.

Methods: Data were pooled from 4 double-blind, placebo-controlled (n=406) short-term trials of pregabalin (all doses combined; n=853) in the treatment of generalized anxiety disorder (GAD). The effect of treatment on anxiety was measured using the Hamilton Anxiety Rating Scale (HAM-A), effect of treatment on sleep disturbance was measured using the 3-item Hamilton Depression Rating Scale (HAM-D) sleep factor. Path analyses, using a set of multivariate regression models, were used to evaluate the reciprocal effects of pregabalin on improvement in anxiety in the presence of improvement in sleep disturbance, and vice-versa.

Results: Sleep disturbance was common in this GAD sample, with 51.2% (placebo) and 52.2% (pregabalin) of patients, respectively, reporting moderate-to-severe insomnia (HAM-D sleep factor score ≥ 3). The results of the path analysis indicated that 91.7% ($P < 0.0001$) of improvement in anxiety was a direct effect of treatment with pregabalin, while 8.3% of improvement in anxiety was an indirect effect, mediated by improvement in sleep disturbance.

Conclusions: In this pooled 4-study data set, the anxiolytic efficacy of pregabalin appears to be primarily a direct effect, with only a small (8.3%) indirect effect, mediated by improvement in sleep disturbance.