

A Study of an Herbal Anxiolytic in Generalized Anxiety Disorder

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Objective: *Piper methysticum* (Kava) is a phytomedicine which has demonstrated anxiolytic effects in both animal models and clinical samples. This is the first study to assess the safety and efficacy of kava vs. placebo in a homogeneous sample of subjects with generalized anxiety disorder (GAD).

Materials and Methods: Thirty-seven adult outpatients meeting DSM-IV criteria for GAD were recruited. Subjects were randomly assigned to 4 weeks of double-blind treatment with kava (up to 280 mg kavalactones/day) or matching placebo. Weekly assessments included the Hamilton Anxiety Scale (HAM-A), Hospital Anxiety and Depression Scale (HADS), Self-Assessment of Resilience and Anxiety (SARA), global measures of clinical change, adverse events, and withdrawal symptoms. A subsample was examined for differences in heart rate variability (HRV) pre and post treatment.

Results: Improvement was observed with both treatments and post hoc analysis revealed significant differences based on baseline anxiety severity, with kava being superior on the SARA in low anxiety. Assessment of heart rate variability revealed significant changes in baroreflex control with kava as compared to placebo ($p < 0.05$), and the magnitude of this change correlated with clinical improvement ($p < 0.05$). The treatments were well tolerated and there was no evidence of withdrawal.

Conclusions: While there was no difference in overall improvement between the treatments, kava demonstrated a favorable effect on reflex vagal control of heart rate in GAD. The herbal medicine was well tolerated and not associated with withdrawal at the doses administered.