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Efficacy of pregabalin in the treatment of generalized anxiety disorder: double-blind, placebocontrolled comparison of BID versus TID dosing.

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Abstract

Pregabalin is a new anxiolytic that acts as a presynaptic inhibitor of the release of excessive levels of excitatory neurotransmitters by selectively binding to the alpha2-delta subunit of voltage-gated calcium channels. The current study evaluated the anxiolytic efficacy of BID versus TID dosing of pregabalin in patients with generalized anxiety disorder. Outpatients with Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition generalized anxiety disorder and having baseline Hamilton Anxiety (HAM-A) total scores > or =20 were randomized to 6 weeks of double-blind treatment with pregabalin 200 mg/d (BID; N = 78), 400 mg/d (BID; N = 89), or 450 mg/d (TID; N = 88) or placebo (N = 86). Mean improvement in HAM-A total score at last observation carried forward end point was significantly greater on pregabalin 200 (P = 0.006), 400 (P = 0.001), and 450 mg/d (P = 0.005) compared with placebo. Pairwise comparisons of BID versus TID dosing found no difference in HAM-A change score at end point. All 3 pregabalin dosage groups showed significantly greater efficacy versus placebo at end point on the HAM-A psychic and somatic anxiety factor scores. Improvement on both factors was rapid: significance versus placebo was achieved as early as the first assessment at week 1, with > or =30% reduction in HAM-A severity and equal or greater improvement for every subsequent visit in > or =38% of patients in all 3 pregabalin dosage groups (P < or = 0.001). Pregabalin was well tolerated, and despite the fixed-dose study design, discontinuations caused by adverse events ranged from 9% to 13%--comparable with that observed with placebo (8%). This study demonstrates that pregabalin is an effective treatment of generalized anxiety disorder, with BID dosing showing similar efficacy and comparable tolerability with TID dosing.

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