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Evid. Based Ment. Health 2007;10;23-

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Does pregabalin or venlafaxine treatment reduce symptoms of generalised anxiety disorder compared with placebo?

**Methods**

- **Design:** Multicentre randomised controlled trial.
- **Allocation:** Unclear.
- **Blinding:** Double blind.
- **Follow up period:** Six weeks (treatment period only).
- **Setting:** Seventy six centres (52 primary care centres and 24 psychiatric centres) in five European countries, 1999–2001.
- **Patients:** 426 adults with DSM-IV generalised anxiety disorder (GAD; diagnosed using the Mini-International Neuropsychiatric Interview) with predominantly symptoms of anxiety rather than depression (Comorbid Anxiety Scale score > 9 and Raskin Depression Scale score < 7) and Hamilton Rating Scale for Anxiety (HAM-A) score > 20. Main exclusions: current Axis I disorders (except simple phobia, somatisation disorder, dysthymia, or depression not otherwise specified); antisocial, borderline, or avoidant personality disorder; recent alcohol or substance use disorder; risk of suicide; ongoing psychodynamic or cognitive-behavioural psychotherapy; or clinically relevant medical comorbidity.
- **Intervention:** Pregabalin (400 mg/day or 600 mg/day), venlafaxine (75 mg/day) or placebo for 6 weeks.
- **Outcomes:** Change in symptoms of generalised anxiety disorder (change in HAM-A total score from baseline).
- **Patient follow up:** 76% of randomised participants completed 6 weeks’ treatment; 99% were included in last observation carried forward analyses.

**Main Results**

Pregabalin (both 400 mg and 600 mg daily doses) and venlafaxine both significantly reduced symptoms of GAD compared with placebo at six weeks (reduction in HAM-A score: 14.7 with pregabalin 400 mg/day v 14.1 with pregabalin 600 mg/day v 14.1 with venlafaxine 75 mg/day v 11.6 with placebo; p = 0.008 for pregabalin 400 mg/day v placebo, p = 0.03 for pregabalin 600 mg/day v placebo, and p = 0.03 for venlafaxine 75 mg/day v placebo). Venlafaxine significantly increased withdrawals due to adverse events compared with pregabalin 400 mg/day, but no other statistical comparisons were reported (withdrawals: 6% with pregabalin 400 mg/day v 14% with pregabalin 600 mg/day v 20% with venlafaxine 75 mg/day v 10% with placebo; p < 0.01 for venlafaxine v pregabalin 400 mg/day).

**Conclusions**

Pregabalin and venlafaxine improved symptoms of generalised anxiety disorder compared with placebo over six weeks’ treatment.