Risperidone Improved PTSD-Related Nightmares

A retrospective study found low-dose risperidone (Risperdal) improved or relieved combat-related nightmares in veterans with posttraumatic stress disorder.

**Background:** Recurrent nightmares and other sleep disturbances are common in PTSD, and several atypical antipsychotics have been investigated, most frequently risperidone. However, data is insufficient to support evidence-based guidelines.

**Methods:** Patients with PTSD who were treated with open-label risperidone at a veterans affairs clinic (n=65) were retrospectively studied. Risperidone was initiated specifically to address combat-related nightmares in all patients, and dosages ranged from 0.5 to 4 mg/day. Other atypical antipsychotics were discontinued before risperidone initiation, but additional psychotropics were continued. Change in nightmare frequency and intensity were the primary outcomes.

**Results:** Duration of risperidone treatment ranged from 1 month to nearly 10 years. Complete resolution of nightmares was reported by 28 patients (43%), all beginning on the first night of treatment. An additional 27 patients (42%) reported reductions in both the frequency and intensity of combat-related nightmares. The large majority (93%) of patients who improved with treatment received ≤2 mg/day risperidone. Ten patients (15%) experienced no improvement.

Concurrent use of psychiatric medications and/or illicit substances did not appear to affect response. Risperidone-associated adverse events affected 11 patients and included hand tremors; headaches; nausea; vomiting; drowsiness; irritability; GI upset; enuresis; urine retention; and weight gain.

**Discussion:** Although the results are encouraging, this study is limited by its uncontrolled and retrospective design and by the relatively homogenous sample (95% male, 72% Caucasian).

Long-Term Venlafaxine Prevents GAD Relapse

Generalized anxiety disorder has a chronic, often debilitating course. Short-term efficacy of venlafaxine (Effexor) has been established, but the optimal duration of treatment has not. Results of a controlled trial now suggest venlafaxine treatment should be continued for at least 12 months to prevent relapse.

Methods: This 3-phase relapse-prevention study of venlafaxine in GAD was conducted at the University of Pennsylvania. Initially, 268 patients with at least moderate DSM-IV GAD and a Hamilton Rating Scale for Anxiety (HAM-A) score of >20 received up to 6 months of open-label, flexible-dose, extended-release venlafaxine (75–225 mg/day). At 6 months, 136 patients whose anxiety was controlled were randomized to continue venlafaxine or switched to placebo in a double-blind fashion for an additional 6 months. Patients who completed the 12-month protocol (n=59) were further randomized to venlafaxine or placebo for an additional 6 months. Relapse was defined as having a HAM-A score of ≥16, a Clinical Global Impression (CGI) Severity* score of ≥4, and a CGI Improvement* rating of ≥6 for at least 1 month.

Results: Anxiety symptoms responded to acute treatment with open-label venlafaxine in about half of the 268 patients who entered the study. In the 136 patients who continued treatment during the subsequent 6 months, relapse occurred in 54% of those switched to placebo, compared with 10% of those who continued venlafaxine (p<0.001).

Of the 59 patients who entered the third phase, 47 completed 18 months of treatment. Five patients were lost to follow-up and 3 withdrew because of adverse events. Relapse rates were 7% in patients who received venlafaxine for the full 18 months, compared with 32% for those who received venlafaxine for 12 months followed by placebo for 6 months, and 54% in those switched to placebo immediately after 6 months of acute treatment (p<0.03 for patients switched at 6 and 12 months). Because the group treated with venlafaxine for the full 18 months was small, comparisons were underpowered to achieve statistical significance.

Adverse effects were those typically associated with venlafaxine—dry mouth, drowsiness, lightheadedness, and headache—each of which affected >35% of enrolled patients. Rates dropped substantially after 6 months of treatment, when the most commonly reported adverse effects of venlafaxine were lightheadedness (18%) and dry mouth (17%).

Discussion: Although the study is limited by a high attrition rate and other factors, the results demonstrate an advantage of continuing venlafaxine treatment for at least 12 months in patients with chronic anxiety who adhere to long-term treatment. Patients who did experience a relapse after switching to placebo generally improved after restarting venlafaxine.

Study Rating*—17 (100%): This study met all criteria for a controlled trial.

Rickels C, Etemad B, Khalid-Khan S, Lohoff F, et al: Time to relapse after 6 and 12 months’ treatment of generalized anxiety disorder with venlafaxine extended release. Archives of General Psychiatry 2010;67 (December):1274–1281. From the University of Pennsylvania School of Medicine, Philadelphia. Funded by the U.S. Public Health Service; medication was provided by Wyeth Pharmaceuticals. Two study authors disclosed commercial relationships with pharmaceutical-industry sources.

*See Reference Guide.

Maintenance Therapy in Bipolar Disorder

A systematic review of controlled trials of maintenance treatment in bipolar disorder found all approved pharmacological options prevented mood episodes overall. However, important differences were found between the agents in terms of manic- and depressive-episode prevention.

Methods: Randomized controlled trials of pharmacotherapy for any stage of bipolar disorder were reviewed if they included adult patients and had a duration of ≥6 months. The 15 identified
studies included >5000 patients and investigated aripiprazole; olanzapine; quetiapine; risperidone long-acting injection; ziprasidone; lamotrigine; oxcarbazepine; lithium; and valproate (either as monotherapy or in combination with other agents). Based on the results of individual studies and pooled evaluations when possible, numbers needed to treat* (NNT) were calculated for any recurrence, manic recurrence, and depressive recurrence with each agent.

**Results:** All agents were effective at preventing any mood-episode recurrence. NNTs ranged from 3 with olanzapine and quetiapine monotherapies to 8 with ziprasidone as an adjunct to lithium or divalproex. Although several studies produced NNTs that were not statistically significant, these appeared to be associated with individual study limitations such as small sample sizes. No agent consistently produced an NNT of >10, which is considered the cut-off value for clinical significance.

Agents that were particularly effective at preventing manic episodes include aripiprazole (NNT, 7), olanzapine (NNT, 5), and long-acting risperidone injections monotherapy or as an adjunct to treatment as usual (NNTs, 4 and 8, respectively). Lamotrigine more effectively prevented depressive than manic episodes (NNT, 7). Quetiapine as monotherapy or in addition to a mood stabilizer appeared to prevent both manic and depressive episodes, with NNTs ranging from 3 to 9 for mania and from 4 to 7 for depression. Although it did not reach statistical significance (probably because few patients received the combination), oxcarbazepine added to lithium produced relatively low NNTs for both mania and depression: 9 and 6, respectively.

**Discussion:** Maintenance therapy is an important part of bipolar-disorder treatment because nearly 50% of patients experience a recurrence within 2 years of initial recovery. The present results offer some clinical guidance that may help clinicians choose among the available options for maintenance therapy in patients with bipolar disorder.

Popovic D, Reinares M, Amann B, Salamero M, et al: Number needed to treat analyses of drugs used for maintenance treatment of bipolar disorder. *Psychopharmacology* 2010; doi 10.1007/s00213-010-2056-8. From the University of Barcelona, Spain; and other institutions. Source of funding not stated. This early-release article did not include disclosure of potential conflicts of interest.

**Drug Trade Names:** aripiprazole—Abilify; lamotrigine—Lamictal; olanzapine—Zyprexa; oxcarbazepine—Trileptal; quetiapine—Seroquel; risperidone long-acting injection—Risperdal Consta; valproate—Depakene, Depakote; ziprasidone—Geodon

*See Reference Guide.

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**Preliminary Evidence for Olanzapine in Trichotillomania**

Trichotillomania is classified in the DSM as an impulse-control disorder and has been suggested to be part of an obsessive-compulsive spectrum. However, it more closely resembles tics in Tourette’s syndrome, but treatment with SSRIs, which are a first-line treatment for OCD, is generally unsuccessful. Olanzapine (*Zyprexa*) has shown efficacy in treating tics and was investigated in a small manufacturer-sponsored study of patients with trichotillomania.

**Methods:** Study participants (n=25; mean age, 33 years) with a primary diagnosis of trichotillomania were randomized to double-blind flexibly-dosed olanzapine (2.5–20 mg/day; mean, 11 mg/day) or placebo for 12 weeks. Patients with current major depression, OCD, psychosis, substance-use disorders, or bipolar disorder were excluded. Patients were evaluated biweekly, and symptom improvement was measured using the Yale-Brown Obsessive Compulsive Scale for Trichotillomania (TTM-YBOCS). Response was defined as a Clinical Global Impression-Improvement (CGI-I) rating of "much" or "very much improved."

**Results:** The mean baseline TTM-YBOCS score was 21 in both treatment groups. Olanzapine produced a significantly greater reduction to an endpoint score of 10, compared with 18 in the placebo group (p<0.01). The effect size* for improvement in TTM-YBOCS score with olanzapine was >1, and the number needed to treat* was 1.5. Response rate was also significantly higher.
with olanzapine than with placebo (85% vs 17%; p=0.001). Two olanzapine-treated patients achieved remission. The effects of olanzapine on secondary outcomes, including measures of disability, hair pulling, and quality of life, were not significant. Adverse effects were common, affecting 21 of the 25 participants (84%). Olanzapine was significantly associated with dry mouth (54%), fatigue (54%), and appetite increase (46%). None of these effects were reported by placebo-treated patients, in whom the most common adverse effect was headache (33%). No severe adverse events occurred.

Discussion: The small sample size and the exclusion of patients with many common comorbid disorders limit the generalizability of the study findings. In addition, olanzapine is associated with potentially serious metabolic effects such as hyperlipidemia, diabetes, and weight gain. The authors suggest that alternate atypical antipsychotics with more favorable metabolic profiles warrant investigation as another treatment option for trichotillomania.

Study Rating*—17 (100%): This study met all criteria for a randomized controlled trial.


Desvenlafaxine Exposure in Breast Milk

Levels of desvenlafaxine in breast-fed infants of treated mothers were similar to levels previously identified in offspring of women treated with the parent drug venlafaxine.

Methods: Exposure in newborns was investigated in 10 mother-infant pairs. Women were being treated for postnatal depression and had been receiving steady-state desvenlafaxine at dosages of 50, 100, or 150 mg/day for an average of 9 days (range, 4–35 days). Each woman provided up to 8 breast-milk samples during a 24-hour period, including immediately before the morning dose and immediately after the 24-hour dose interval. Blood samples were also collected from both mothers and infants at about 6.5 hours after the maternal desvenlafaxine dose. The infants were 38–41 weeks old and all were healthy and developmentally normal. Eight were exclusively breastfed, and 2 were receiving some solid foods.

Results: Maximum concentrations of desvenlafaxine in breast milk were reached about 3.25 hours after drug administration. The maximum concentration in milk was 785 mcg/L. The estimated infant dosage via milk was 85 mcg/kg/day, which corresponds to 6.8% of the weight-adjusted maternal dose. Mean infant-plasma levels of desvenlafaxine were about 5% of the maternal-plasma levels. Infants showed no acute adverse effects of desvenlafaxine exposure.

Discussion: Previous studies in women treated with venlafaxine showed similar levels of desvenlafaxine exposure in breastfed infants to those seen in this study. However, according to the authors, desvenlafaxine may be preferable to venlafaxine in postnatal depression because lower dosages are required to achieve comparable therapeutic levels.

Rampono J, Teoh S, Hackett L, Kohan R, et al: Estimation of desvenlafaxine transfer into milk and infant exposure during its use in lactating women with postnatal depression. *Archives of Women’s Mental Health 2010; doi 10.1007/s00737-010-0188-9. From King Edward Memorial Hospital, Subiaco, Australia; and other institutions. Laboratory tests funded by Wyeth Australia. The authors did not include disclosure of potential conflicts of interest.

Drug Trade Names:  desvenlafaxine—Pristiq;  venlafaxine—Effexor

Reference Guide

Clinical Global Impression Improvement (CGI-I) Scale: A 7-point rating of patient improvement. A score of 1 corresponds to a rating of very much improved; 2=much improved; 3=minimally improved; 4=no change; 5=minimally worse; 6=much worse; 7=very much worse.
Clinical Global Impression Severity (CGI-S) Scale: A 7-point rating of the severity of illness. A score of 1 corresponds to a rating of normal; 2=borderline mentally ill; 3=mildly ill; 4=moderately ill; 5=markedly ill; 6=severely ill; 7=extremely ill.

Effect Size: The effect size represents the amount of change in outcome that can be attributed to treatment, where 0.2 indicates a small effect, 0.5 a medium effect, and 0.8 a large effect. It is relatively independent of clinical significance and large effect sizes do not ensure treatment efficacy.

Number Needed to Treat (NNT): Indicates how many patients need to be treated for 1 to benefit. The ideal NNT is 1, where everyone improves with treatment. The higher the NNT value, the less effective is the treatment.

Study Rating: A measure of how well a study conforms to quality standards. The study rating uses a checklist system based on the comprehensive Strength of Evidence Report from the Evidence-based Practice Center Program of the Agency for Healthcare Research and Quality (AHRQ). The rating checklists have been posted at www.alertpubs.com.

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