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The effect of mirtazapine in patients with chronic pain and concomitant depression.

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Abstract

OBJECTIVE: To evaluate the safety, tolerability and efficacy of mirtazapine in patients with the primary diagnosis of chronic pain and concomitant depression in an open post-marketing surveillance study.

RESEARCH DESIGN AND METHODS: 594 patients with a primary diagnosis of at least one chronic pain syndrome (minimum duration of 3 months) and the diagnosis of concomitant depression, appropriately made by a neurologist or psychiatrist, were recruited at psychiatric and/or neurological outpatient facilities throughout Germany. The primary efficacy parameter was pain at baseline and endpoint using a patient self-assessment scale. Secondary analyses were performed at baseline, week 1 (day 7 +/- 2), week 4 (day 28 +/- 4) and at endpoint (day 42 +/- 4 or early termination) and included safety and tolerability assessments. Investigators rated the severity of different potential co-morbidities (including depression) with a four-step rating scale (not present, mild, moderate, severe).

RESULTS: 594 patients were enrolled and treated with mirtazapine (mean daily dose of 34.5 +/- 10.4 mg at study endpoint). A statistically significant ($p < 0.0001$; one sample sign test) reduction of pain from baseline to endpoint was found for the overall population. The percentage of patients free of pain or with only moderate pain increased significantly, irrespective of patients' age or pain syndromes. Furthermore, we found a substantial improvement from baseline to endpoint regarding co-morbidities such as sleep disturbance, irritability and exhaustion. The number of adverse events was low (<7%; n = 37), with fatigue (n = 13) and weight gain (n = 11) occurring most frequently. No previously-unknown side effects occurred. One hundred and six patients (18%) discontinued mirtazapine during the study. The main reason was lack of efficacy (6%, n = 33), which may be a reflection of sub-optimal response to the anti-depressant or analgesic effect of the drug, but no

appropriate rating scale was used to clarify this question. Only a small number of patients stopped the drug due to adverse events (3%; n = 15). At study endpoint, the majority of physicians and patients rated the overall efficacy and tolerability of mirtazapine as good or very good. Most patients (80%) continued the therapy after 6 weeks.

CONCLUSIONS: Despite the limitations of an open observational study, our findings suggest that mirtazapine is a safe and well-tolerated drug for use in daily clinical practice. It still remains unclear whether the reduction of pain, the enhancement of the depressed mood or the combination of both effects led to these results. Nevertheless, our data point to a potential beneficial effect of mirtazapine in the treatment of patients with pain and concomitant depression. However, more systematic research, including placebo-controlled studies, and further empirical testing are necessary.

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