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Antipsychotics for fibromyalgia in adults.

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Abstract

BACKGROUND: This review is one of a series on drugs used to treat fibromyalgia. Fibromyalgia is a clinically well-defined chronic condition of unknown aetiology characterised by chronic widespread pain that often co-exists with sleep problems and fatigue. It affects approximately 2% of the general population. Up to 70% of patients with fibromyalgia meet the criteria for a depressive or anxiety disorder. People often report high disability levels and poor health-related quality of life. Drug therapy focuses on reducing key symptoms and disability, and improving health-related quality of life. Antipsychotics might reduce fibromyalgia and associated mental health symptoms.

OBJECTIVES: To assess the efficacy, tolerability and safety of antipsychotics in fibromyalgia in adults.

SEARCH METHODS: We searched CENTRAL (2016, Issue 4), MEDLINE and EMBASE to 20 May 2016, together with reference lists of retrieved papers and reviews and two clinical trial registries. We also contacted trial authors.

SELECTION CRITERIA: We selected controlled trials of at least four weeks duration of any formulation of antipsychotics used for the treatment of fibromyalgia in adults.

DATA COLLECTION AND ANALYSIS: We extracted the data from all included studies and two review authors independently assessed study risks of bias. We resolved discrepancies by discussion. We performed analysis using three tiers of evidence. We derived first tier evidence from data meeting current best standards and subject to minimal risk of bias (outcome equivalent to substantial pain intensity reduction, intention-to-treat analysis without imputation for drop-outs, at least 200 participants in the comparison, eight to 12 weeks duration, parallel design), second tier evidence from data that failed to meet one or more of these criteria and that we considered at some risk of bias but with adequate numbers in the comparison, and third tier evidence from data involving small numbers of participants that we considered very likely to be biased or used outcomes of limited clinical utility, or both. We rated the quality of evidence using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach.

MAIN RESULTS: We included a total of four studies with 296 participants. Three studies with 206 participants compared quetiapine, an atypical (second-generation) antipsychotic, with placebo. One study used a cross-over design and two studies a parallel-group design. Study duration was eight or 12 weeks. Quetiapine was used in all studies with a bedtime dosage between 50 and 300 mg/day. All studies had one or more sources of potential major bias and we judged them to be at moderate risk of bias overall. The primary outcomes in this review were participant-reported pain relief of 50% or greater, Patient Global Impression of Change (PGIC) much or very much improved, withdrawal due to adverse events (tolerability) and serious adverse events (safety). Second tier evidence indicated that quetiapine was not statistically superior to placebo in the number of participants with a 50% or more pain reduction (very low quality evidence). No study reported data on PGIC. A greater proportion of participants on quetiapine reported a 30% or more pain reduction (risk difference (RD) 0.12, 95% confidence interval (CI) 0.00 to 0.23; number needed to treat for an additional benefit (NNTB) 8, 95% CI 5 to 100) (very low quality evidence). A greater proportion of participants on quetiapine reported a clinically relevant improvement of health-related quality of life compared to placebo (RD 0.18, 95% CI 0.05 to 0.31; NNTB 5, 95% CI 3 to 20) (very low quality evidence). Quetiapine was statistically superior to placebo in reducing sleep problems (standardised mean difference (SMD) -0.67, 95% CI -1.10 to -0.23), depression (SMD -0.39, 95% CI -0.74 to -0.04) and anxiety (SMD -0.40, 95% CI -0.69 to -0.11) (very low quality evidence). Quetiapine was statistically superior to placebo in reducing the risk of withdrawing from the study due to a lack of efficacy (RD -0.14, 95% CI -0.23 to -0.05) (very low quality

evidence). There was no statistically significant difference between quetiapine and placebo in the proportion of participants withdrawing due to adverse events (tolerability) (very low quality evidence), in the frequency of serious adverse events (safety) (very low quality evidence) and in the proportion of participants reporting dizziness and somnolence as an adverse event (very low quality evidence). In more participants in the quetiapine group a substantial weight gain was noted (RD 0.08, 95% CI 0.02 to 0.15; number needed to treat for an additional harm (NNT_H) 12, 95% CI 6 to 50) (very low quality evidence). We downgraded the quality of evidence by three levels to a very low quality rating because of limitations of study design, indirectness (patients with major medical diseases and mental disorders were excluded) and imprecision (fewer than 400 patients were analysed). One parallel design study with 90 participants compared quetiapine (50 to 300 mg/day flexible at bedtime) to amitriptyline (10 to 75 mg/day flexible at bedtime). The study had three major risks of bias and we judged it to be at moderate risk of bias overall. We downgraded the quality of evidence by two levels to a low quality rating because of indirectness (patients with major medical diseases and mental disorders were excluded) and imprecision (fewer than 400 patients were analysed). Third tier evidence indicated no statistically significant differences between the two drugs. Both drugs did not statistically significantly differ in the reduction of average scores for pain, fatigue, sleep problems, depression, anxiety and for limitations of health-related quality of life and in the proportion of participants reporting dizziness, somnolence and weight gain as a side effect (low quality evidence). Compared to amitriptyline, more participants left the study due to adverse events (low quality evidence). No serious adverse events were reported (low quality evidence). We found no relevant study with other antipsychotics than quetiapine in fibromyalgia.

AUTHORS' CONCLUSIONS: Very low quality evidence suggests that quetiapine may be considered for a time-limited trial (4 to 12 weeks) to reduce pain, sleep problems, depression and anxiety in fibromyalgia patients with major depression. Potential side effects such as weight gain should be balanced against the potential benefits in shared decision making with the patient.

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