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Dopamine agonists for restless legs syndrome.

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Author information

Abstract

BACKGROUND: According to clinical guidelines, dopamine agonists are the first-line treatment of restless legs syndrome (RLS).

OBJECTIVES: To evaluate efficacy and safety of dopamine agonists for RLS.

SEARCH STRATEGY: We searched the Cochrane Central Register of Controlled Trials (The Cochrane Library 2008, Issue 4), MEDLINE, EMBASE, PsycINFO and CINAHL, from January 1985 to December 2008, plus reference lists of articles. We contacted pharmaceutical companies.

SELECTION CRITERIA: We included double-blind randomised controlled trials (RCTs) of dopamine agonist treatment versus placebo or other treatment for a period of at least seven days in patients with RLS (≥ 18 years). Outcomes included the International RLS Severity Rating Scale (IRLS), Clinical Global Impressions (CGI-I), polysomnography and self rated sleep quality, quality of life, daytime functioning, and safety parameters.

DATA COLLECTION AND ANALYSIS: Two reviewers extracted data separately; assessed risk of bias; and contacted pharmaceutical companies and authors for additional information. We collected dropout rates due to adverse events and experience of adverse events.

MAIN RESULTS: We included 35 placebo controlled and three active controlled RCTs (N = 7365). The mean reduction on the IRLS was -5.7 points lower in dopamine agonist treatment compared to placebo (95% confidence interval (CI) -6.7 to -4.7). Periodic limb movements in sleep per hour of sleep (PLMS-Index; PLMSI) were -22.4/h lower than in placebo (95% CI -27.8 to -16.9). Self rated quality of sleep and disease specific quality of life were improved by a standardised mean difference (SMD) of 0.40 (95% CI 0.33 to 0.47) and 0.34 (95% CI 0.23 to 0.44), respectively. Patients were more likely to drop out (odds ratio (OR) 1.82, 95% CI 1.35 to 2.45) and experienced more adverse events under dopamine agonist treatment than with placebo (OR 1.82, 95% CI 1.59 to 2.08). Visual inspection of forest plots showed the highest efficacy in three studies investigating cabergoline and pergolide (N = 3). Active controlled trials investigated effects of cabergoline, pergolide, and pramipexole in a number of outcomes. The IRLS score was lower with cabergoline and pramipexole compared to levodopa (MD -5.3, 95% CI -8.4 to -2.1). Only four studies investigated treatment efficacy up to seven months. The most severe side effect, augmentation, was not assessed reliably.

AUTHORS' CONCLUSIONS: The meta-analyses show the superiority of dopamine agonists over placebo in RCTs up to seven months. Cabergoline and pramipexole showed larger efficacy compared to levodopa in some but not all outcomes.

Comment in

ACP Journal Club. Review: Dopamine agonists are effective for the restless legs syndrome but may be discontinued due to adverse events. [Ann Intern Med. 2011]

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