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Efficacy of Pramipexole for the Treatment of Primary Restless Leg Syndrome: A Systematic Review and Meta-analysis of Randomized Clinical Trials.

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Abstract

PURPOSE: The objective of this meta-analysis was to systematically evaluate the efficacy of pramipexole for the treatment of primary moderate-to-severe restless leg syndrome (RLS).

METHODS: Databases of PubMed, OVID, ScienceDirect, SpringerLink, Thomson Reuters Web of Science, the Cochrane Library, the Wiley Online Library, ArticleFirst, CALIS, Study, CNKI, and WanFang were searched to identify randomized controlled trials (RCTs) investigating pramipexole for the treatment of primary moderate-to-severe RLS. A meta-analysis was then conducted to pool results.

FINDINGS: Twelve RCTs involving 3286 participants were included in this study. The mean (SD) treatment duration was 11.12 (5.72) weeks/person. The meta-analysis found that the post-treatment change in the International Restless Leg Syndrome Study Group Rating Scale (IRLS) score of the pramipexole group was significantly superior to that of the placebo group (weighted mean difference [WMD] = -4.64; 95% CI, -5.95 to -3.33; n = 8). More patients in the pramipexole group reported at least a 50% reduction in the IRLS score after treatment (risk ratio [RR] = 1.57; 95% CI, 1.43 to 1.73; n = 8). In terms of the scores for the Clinical Global Impression of Improvement scale (RR = 1.48; 95% CI, 1.31 to 1.66; n = 11) and the Patient Global Impression scale (RR = 1.54; 95% CI, 1.31 to 1.81; n = 9), treatment outcomes of the pramipexole group were significantly superior to those of the placebo group. In terms of the change in quality of life (WMD = 5.39; 95% CI, 2.28 to 8.50; n = 4), the change in daytime tiredness (WMD = -0.61; 95% CI, -1.21 to -0.01; n = 4), the change in the number of periodic limb movements per hour of sleep (WMD = -35.95; 95% CI, -56.42 to -15.48; n = 3), and the change in the quality of sleep (WMD = 3.60; 95% CI, 1.69 to 5.50; n = 6), the treatment outcomes of the pramipexole group were significantly superior to those of the placebo group.

IMPLICATIONS: This meta-analysis study indicated that pramipexole could effectively improve the symptoms of patients with primary moderate-to-severe RLS, although the quality of evidence was relatively low. Future clinical trials focusing on the medium-term and long-term treatment outcomes and using mainly objective indicators for evaluation are warranted. It is also necessary to pay close attention to augmentation during medication.

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KEYWORDS: clinical trials; efficacy; pramipexole; restless leg syndrome (RLS)

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