

Synopsis, meta-analysis, quality assessment and synthesis of randomized trials of dopamine agonists for the treatment of restless legs syndrome

Elias Zintzaras and George Hadjigeorgiou, University of Thessaly, Greece

Background

The use of dopamine agonists (DAs) for the treatment of patients with restless legs syndrome (RLS) has been evaluated in numerous randomized clinical trials (RCTs).

Objectives

The aims of this synopsis were to evaluate the reporting quality of published RCTs according to the CONSORT (Consolidated Standards of Reporting Trials) statement and to synthesize the studies' results in terms of efficacy and safety in order to improve the clinical management of RLS.

Methods

PubMed and Cochrane Controlled Trials Register were searched for English-language RCTs examining efficacy of DAs in RLS. Quality of reporting was assessed using a 17-item questionnaire based on the CONSORT checklist. Pooled mean change from baseline ($\Delta\mu$) and relative risk (RR) of response with 95% confidence intervals (CIs) were calculated for the International Restless Legs Syndrome Study Group Scale (IRLS) and Clinical Global Impression-Improvement (CGI-I) outcomes, respectively. The pooled proportion of adverse events (PAE) was also estimated.

Results

Eighteen RCTs (n=2848 subjects) were included for review. Two of the 17 (12%) items were reported in less than 50% of the studies, whilst nine items (53%) were reported by all studies. The meta-analyses confirmed the superior efficacy of the DAs pramipexole, ropinirole, rotigotine and cabergoline, compared to placebo on both the IRLS and the CGI-I; there was non-significant heterogeneity among the studies. A significant difference between pramipexole ($\Delta\mu=-6.62$ [-9.15,-4.10]) and ropinirole ($\Delta\mu=-3.64$ [-4.76—2.51]) was seen on the IRLS (p=0.04). The comparison between pramipexole and rotigotine produced non-significant results (p=0.54). The comparisons between the drugs were based on trials that compared these drugs with placebo.

Conclusions

DAs are efficacious drugs for the treatment of RLS. Head-to-head comparisons are needed for determining the relative efficacy and safety profile of individual agents.