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Curr Med Res Opin. 2014 Nov;30(11):2267-78. doi: 10.1185/03007995.2014.946124. Epub 2014 Jul 31.

A mixed treatment comparison of gabapentin enacarbil, pramipexole, ropinirole and rotigotine in moderate-to-severe restless legs syndrome.

Sun Y[1], van Valkenhoef G, Morel T.

Author information

Abstract

OBJECTIVE: A mixed treatment comparison (MTC) was performed to investigate the relative efficacy and safety of licensed pharmaceuticals for moderate-to-severe restless legs syndrome (RLS).

METHODS: RLS trials published over the past 10 years were identified via systematic literature searches of MEDLINE, Embase, Cochrane CENTRAL, and manufacturers' websites. MTC was performed with WinBUGS software using a Bayesian approach. Identified primary outcomes: change in International RLS Study Group Rating Scale (IRLS) at week 12 and end of maintenance (EoM).

SECONDARY OUTCOMES: IRLS and Clinical Global Impression - Improvement Scale (CGI-I) responders, RLS-6 items and adverse events (AEs).

RESULTS: Twenty-eight clinical trials were identified. Fifteen were included in the primary analysis. Indirect comparisons were established among gabapentin enacarbil, pramipexole, ropinirole, rotigotine and placebo. Overall, the four active treatments showed similar efficacies as assessed by changes in IRLS scores, IRLS responders, CGI-I responders, and RLS-6 scores. The sole exception was change in IRLS at week 12, for which rotigotine was likely more efficacious than ropinirole (mean difference: -2.52 [95% CrI: -4.74, -0.40]). Indirect comparisons on safety endpoints indicated ropinirole was associated with a higher risk of nausea than the other agents, and was more likely to result in discontinuations due to lack of efficacy than pramipexole. Nausea was likely more frequent with pramipexole than gabapentin enacarbil, and rotigotine was more likely to result in discontinuation due to AEs than ropinirole and pramipexole.

CONCLUSIONS: This MTC confirmed the superiority of gabapentin enacarbil, pramipexole, ropinirole, and rotigotine above placebo in alleviating RLS symptoms. Compared to ropinirole, rotigotine showed some additional benefit in terms of change in IRLS at Week 12. Choice of RLS drugs requires careful evaluation of effectiveness and safety profiles in clinical practice. Due to lack of head-to-head trials, inconsistency could not be assessed in our analysis. Head-to-head trials on a more homogeneous population are needed to validate the MTC results.

KEYWORDS: Bayesian approach; Dopamine agonist; Mixed treatment comparison; Restless legs syndrome

PMID: 25050588 DOI: 10.1185/03007995.2014.946124

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