DSEN ABSTRACT

Efficacy of modified released methylphenidate linked to pharmacokinetic profile: A Rapid Systematic Review

Summary

- This systematic review includes nineteen publications.
- Extremely limited evidence was located to support the research questions.
- More research is required to assist knowledge users determining bio- and therapeutic equivalence of generic modified-release methylphenidate products.

Key messages

- There is limited evidence relating novel pharmacokinetic measures to drug efficacy for modified-release methylphenidate products taken by individuals with ADHD.

What is the issue?

- Methylphenidate is a commonly prescribed psychostimulant medication used to treat symptoms (inattention, hyperactivity and impulsivity) of attention deficit hyperactivity disorder (ADHD) in children, teens and adults.
- A variety of different formulations and release profiles are approved for use in Canada, however, recently, extended- or modified-release products are becoming increasing popular with prescribers as they are convenient, and eliminate the requirement for additional doses while individuals are at school or work.
- These complex, multiphasic products and the bioequivalence metrics traditionally used to assure comparable therapeutic effectiveness may not be adequate to compare innovator products to their generic equivalents.

What was the aim of the study?

- The aim of this rapid systematic review was to assess the evidence relating pharmacokinetic measures with the pharmacodynamics or clinical outcomes of modified-release methylphenidate (MRM) products in individuals with ADHD.

How was the study conducted?

- A comprehensive literature search was performed in multiple databases (August 2014) and grey literature to identify comparative studies evaluating MRM pharmacokinetics and a behavioural outcome of interest. A single reviewer selected studies, performed data extraction and Cochrane risk of bias assessments and results were validated by a second reviewer.

What did the study find?

- A total of 19 studies were included.
- There is very limited evidence regarding whether the efficacy of MRM products is dependent on specific pharmacokinetic criteria in addition to standard metrics. No conclusions could be made based on the included studies.
- There was one small study comparing children who switched to a generic MRM product after taking an innovator MRM, but pharmacokinetic data were not reported in relation to the studied benefits and harms.
- No studies reported additional informative pharmacokinetic data tied to efficacy. to inform therapeutic equivalence.

Authors: Shannon E. Kelly, Mirvat Osman, Ahmed Kotb, Becky Skidmore, George A. Wells

For more information, please contact George A. Wells
gawells@ottawaheart.ca

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UNIVERSITY OF OTTAWA HEART INSTITUTE
INSTITUT DE CARDIOLOGIE DE L'UNIVERSITÉ D'OTTAWA