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Review

Are meta-analyses of Chinese herbal medicine trials trustworthy and clinically applicable? A cross-sectional study

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ABSTRACT

Ethnopharmacological relevance: Meta-analysis (MA) on Chinese herbal medicine (CHM) trials is increasingly published and indexed in major international databases but their trustworthiness and clinical applicability is uncertain. We aimed to assess the characteristics and methodological quality of MA on CHM.
Materials and Methods: Cross-sectional study. MA published during 1993–2013 was sampled from MEDLINE, EMBASE, Cochrane Database of Systematic Reviews and Database of Abstracts of Reviews of Effect. Bibliographical characteristics were abstracted and methodological quality was assessed using the validated AMSTAR tool by two independent reviewers.
Results: Total of 201 MA were included and half were published in or after 2009. Only 7.5% being updates of previous reviews. Majority are published in journals with low or no impact factor, with a median of 1.5. These MA demonstrated methodological strengths in ensuring comprehensive literature search, providing characteristics of the included studies, assessing the scientific quality of included studies and appropriately using the scientific quality of included studies in formulating conclusions. Nevertheless, weaknesses in protocol provision, listing of included and excluded studies, inclusion of grey literature, use of appropriate meta-analytic technique as well as reporting of funding sources were prevalent. CHM and control interventions pooled in majority of MA are found to have substantial clinical heterogeneity in terms of composition, dosage form and route of administration.
Conclusions: There are rooms for improvement in methodological rigor, and in choosing clinically homogenous interventions and control for statistical pooling. These shortcomings limit the trustworthiness and clinical applicability of existing MA on CHM trials. To overcome the limitations of pair-wise meta-analysis in synthesizing trials comparing different CHM and control interventions, the potential of network meta-analysis should be explored.

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1. Introduction

The inclusion of traditional and complementary medicine (T&CM) in health system is encouraged by the recent World Health Organization Traditional Medicine Strategy 2014–2023 (WHO, 2013). Chinese medicine is considered the major form of T&CM used by Chinese populations worldwide (Chung et al., 2012), and it forms part of the healthcare delivery system in Greater China region (Griffiths et al., 2010). It is gaining recognition as well in the West, as reflected by the recent formal regulation of Chinese medicine practice in Australia (CMBA, 2014) and Ontario, Canada (CTCMPAO, 2014). For policy makers, clinicians and patients, evidence based decision making on using Chinese medicine requires consideration on their effectiveness and safety. Meta-analysis (MA) of randomized trials is considered to be one of the best approaches for summarizing evidence on the effectiveness and safety of Chinese medicine (CEBM, 2014). Nevertheless, methodological flaws in the conduction of MA could result in biased conclusions (Whittington et al., 2004; Turner et al., 2008).

Besides methodological quality, the appropriateness of using MA for synthesizing trials on Chinese herbal medicine (CHM) is particularly controversial. CHM is often prescribed as a formulae consisting of multiple herbs, and the effect of different formulae on the same disease is often assessed in multiple trials. In trials where Chinese medicine diagnostic theory is taken into account, CHM are prescribed to patients in an individualized manner (Shin et al., 2013). In addition, the dosage form and route of delivery of CHM intervention may differ. Diversity in CHM intervention raises question on whether pooling of trial results would provide results that are directly applicable to clinical decision making, although such variations also reflect clinical reality. It is advocated that evidence synthesis should take a broad approach and accommodate treatment variation but current approaches taken by CHM systematic reviewers are unknown (Haidich et al., 2013). Furthermore, in CHM trials, conventional drugs are often prescribed as control due to pragmatic and ethical reasons. Variations in control treatment could contribute to additional clinical heterogeneity, and thus further limit the clinical applicability of MA results.

1.1. Objective of this study

In recent years, MA of CHM trials are increasing published and they have become the main source of clinical evidence among policy makers, clinicians and patients internationally. Using a cross-sectional study design, this study aims to: i) describe the bibliographical characteristics of MA on CHM trials; ii) determine the degree of clinical homogeneity among treatment and control interventions; iii) evaluate the methodological quality of MA on CHM; and iv) examine the association between bibliographical characteristics and methodological quality.

2. Methods

2.1. Sampling of meta-analyses

We sampled MA by searching MEDLINE, EMBASE and Cochrane Database of Systematic Reviews (CDSR) and Database of Abstracts of Reviews of Effect (DARE), from their inception till Mar 2013. We performed a comprehensive search on each database using a full Boolean search strategy and details are reported in Appendix 1. The use of these databases allowed us to assemble a representative sample of MA that is most accessible by international readers.

2.2. Inclusion and exclusion criteria

To be included, the MA must include trials that evaluate at least one CHM indexed in the 2010 China Pharmacopeia Chinese herbal medicine index (Dan et al., 2010). Narrative reviews, etiology or diagnostics research, systematic reviews with no MA, or network MA were excluded.

2.3. Data extraction and assessment of methodological quality

Data related to bibliographical characteristics were extracted with a pre-designed data extraction form. We also assessed whether the authors pooled the same CHM or control interventions (defined as having the same composition, dosage form and route of administration) in the MA.

Assessing the Methodological Quality of Systematic Reviews (AMSTAR) is a validated tool for assessing the methodological quality of MA (Shea et al., 2007). Validation study showed that AMSTAR is a reliable critical appraisal tool with good agreement, construct validity and feasibility (Shea et al., 2009). In this study, this 11-items tool is used for methodological quality assessment. Judgment for each item was given as either 'yes' or 'no' for items 1, 3, and 5–11. For items 2 and 4, an option from 'yes', 'cannot answer or not reported' or 'no' were chosen. Detailed operational guide for AMSTAR can be found in Appendix 2. The processes of MA selection, data extraction and methodological quality assessment were performed by two authors independently. Discrepancies were discussed and resolved by consensus amongst authors.

2.4. Data analysis

Descriptive analysis was used for summarizing the bibliographical characteristics. Fisher's exact tests were used to compare performance of MA published before or after 2009 on each AMSTAR item. Kruskal–Wallis tests were used to evaluate performance across different disease categories. The associations between bibliographical characteristics and scoring on each AMSTAR item were analyzed using multivariate logistic regression or multi-nominal logistic regression. Hosmer and Lemeshow tests were performed to evaluate model fitting. All statistical analyses were conducted with SPSS 18.0, with a two-tailed significance level of 0.05.

3. Results

3.1. Searching and article selection

The search strategy identified a total of 3945 citations. After excluding duplicates and eligibility assessment, a total of 201 MA

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