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Clinical efficacy of Chinese Patent Medicines as adjuncts to Western medicines in the treatment of Systemic lupus erythematosus in adult : A Multiple treatment Meta-analysis with Meta-regression

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ADMINISTRATIVE INFORMATION

Support - No.

Review Stage at time of this submission - Data extraction.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 June 2024 and was last updated on 23 June 2024.

INTRODUCTION

Review question / Objective A multiple treatment meta-analysis (MTMA) and Meta-regression was conducted to evaluate the comparative efficacy CPMs adjuncts to Western medicines for the treatment of Systemic lupus erythematosus in adult and to identify the moderating effects of Chinese Patent Medicines-assisted treatment on Systemic lupus erythematosus and the presence of publication bias.

Condition being studied Studies investigating the clinical use of Chinese Patent Medicines (CPMs) as adjuncts to Western medicines in the treatment of SLE are increasing. However, evidence on the relative efficacy of these adjunctive therapies is still lacking.

Aim of the study: A multiple treatment meta-analysis (MTMA) and Meta-regression was conducted to evaluate the comparative efficacy CPMs adjuncts to Western medicines for the treatment of Systemic lupus erythematosus in adult and to identify the moderating effects of Chinese Patent Medicines-assisted treatment on Systemic lupus erythematosus and the presence of publication bias.

METHODS

Search strategy We conducted a comprehensive search of six English-language databases and four Chinese-language biomedical databases from inception to May 2024. Randomised controlled trials (RCTs) evaluating the efficacy of patent medicine-assisted western medicine in the treatment of systemic lupus erythematosus were identified.

Participant or population Participants aged ≥18 years, irrespective of gender, race, region, or nationality, were eligible if they had a primary diagnosis of Systemic lupus erythematosus without comorbidities , according to recognised diagnostic criteria (e.g.Chinese guidelines for the diagnosis and treatment of systemic lupus erythematosus [20]), American College of Rheumatology (ACR), European League Against Rheumatic Diseases (EULAR).

Intervention Trials investigating the use of Chinese Patent Medicines -assisted medication (glucocorticosteroids, immunosuppressants and biologic agents) to treat Systemic lupus erythematosus were included. Chinese patent medicines (CPMs) are ready-to-use medicines made from Chinese herbs, formulated according to specific treatment principles and characterised by multiple components and multiple targets.Trials combining herbal medicines with CPMs were excluded.

Comparator The control group comprised trials involving drug interventions with Western medicines alone.

Study designs to be included Included studies were RCTs published journals with no language restrictions (English or Chinese).

Eligibility criteria We structured our eligibility criteria using the PICOS (Population, Intervention, Comparison, Outcome, Study design) framework [18-19]. Inclusion in this Multiple treatment Meta-analysi required studies to meet the following criteria: (1) Participants aged ≥18 years, irrespective of gender, race, region, or nationality, were eligible if they had a primary diagnosis of Systemic lupus erythematosus without comorbidities , according to recognised diagnostic criteria (e.g.Chinese guidelines for the diagnosis and treatment of systemic lupus erythematosus [20]), American College of Rheumatology (ACR), European League Against Rheumatic Diseases (EULAR) [21-24]. (2) Trials investigating the use of Chinese Patent Medicines -assisted medication (glucocorticosteroids, immunosuppressants and biologic agents) to treat Systemic lupus erythematosus were included. Chinese patent medicines (CPMs) are ready-to-use medicines made from Chinese herbs, formulated according to specific treatment principles and characterised by multiple components and multiple targets.Trials combining herbal medicines with CPMs were excluded. (3) The control group comprised trials involving drug interventions with Western medicines alone. (4) The efficacy of CPMs-assisted medication intervention versus medication alone in alleviating Systemic lupus erythematosus was assessed before and after treatment using SLEDAI scale. (5) Included studies were RCTs published journals with no language restrictions (English or Chinese). Conference papers, reviews, or incomplete data were excluded. Additionally, in cases where data from the same study were published in multiple articles at different times, we selected the most recent publication.

Information sources We conducted electronic searches of the following databases: PubMed, MEDLINE, Scopus, Web of Science, Cochrane, Embase, China National Knowledge Infrastructure, Science and Technology Journal Database and Wanfang. Our searches spanned from the inception of these databases to May 2024, without language or date restrictions. Manual searches were also performed, and original authors were contacted via email for incomplete data or clarification; however, most did not respond and were consequently excluded. The search employed a comprehensive range of relevant terms to retrieve all potentially eligible results related to Chinese Patent Medicines-assisted interventions for Systemic lupus erythematosus (detailed search terms provided in the Supplementary Appendix Text). All manuscripts underwent review by at least two independent reviewers, with any discrepancies resolved through discussion or arbitration by a third reviewer.

Main outcome(s) Primary outcomes: (i), to compare the Total effective rate of Chinese Patent Medicines as adjuncts to Western medicines therapy with that of Western medicines alone, (ii), to assess the change in SLE symptoms from baseline to post-intervention SLEDAI scores.

Quality assessment / Risk of bias analysis The Cochrane Risk of Bias Tool 2.0 assessed the quality of included trials, using the GRADE system to evaluate the quality of evidence and the level of recommendation.

Strategy of data synthesis To compare all adjunctive interventions, we performed a multiple treatment meta-analysis using R4.3.5 and Stata MP17 (www.stata.com). The random-effects model was selected for our review due to its ability to account for expected heterogeneity. Effect size (ES) indicators, including relative risk (RR), standardised mean difference (SMD) and 95% confidence interval (CI), were used for various numerical outcomes [27-28]. All MTMA were conducted on an intention-to-treat basis, with significance set at $p < 0.05$ on both sides [29-31].

Linear meta-regression analyses were employed to explore potential moderators of Chinese Patent Medicines -assisted Western medicines treatment for Systemic lupus erythematosus [32-33] . Publication bias was assessed through visual inspection of funnel plots. We used the area under the cumulative ranking curve (SUCRA) and probability to rank the outcomes of each traditional Chinese patent medicines as adjuncts to Western medicines in the treatment of Systemic lupus erythematosus in adult. In addition, clustering analysis was used to compare interventions with two outcome indicators, allowing a better selection of outcomes.

Subgroup analysis No.

Sensitivity analysis No.

Language restriction No.

Country(ies) involved China.

Keywords multiple-treatments meta-analysis, Western medicines , Chinese patent medicines, Systemic lupus erythematosus, Adjuvant therapy.

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