INPLASY PROTOCOL

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Corresponding author: Jun Xiong

xiongjun196071@163.com

Author Affiliation:

Jiangxi University of Traditional Chinese Medicine

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INTRODUCTION

Review question / Objective: The aim of this overview is to comprehensive summary and critically evaluate the current evidence from systematic reviews (SR)/ Meta-analysis pertaining to risk of bias and

The efficacy of moxibustion and acupuncture therapy for Ankylosing spondylitis: a protocol for an overview of systematic reviews and meta-analysis

Chen, J¹; Lu, LB²; Tang, GH³; Xiong, J⁴.

Review question / Objective: The aim of this overview is to comprehensive summary and critically evaluate the current evidence from systematic reviews (SR)/Meta-analysis pertaining to risk of bias and quality of evidence and methodological quality of systematic reviews of moxibustion and acupuncture therapy for Ankylosing spondylitis.

Condition being studied: Ankylosing spondylitis (AS) is an chronic disease that the main pathological change place is the spine, involve sacroiliac joint, cause spinal rigidity and fibrosis, it is autoimmune disease. The clinical manifestations of ankylosing spondylitis mainly include pain in the lower back, back, neck, hip and hip as well as swelling and pain of joints, the person with serious illness can produce spinal deformity and joint ankylosis. The prevalence and disability rates of this disease are high, but the etiology of this disease is unknown and there is no cure. It can occur at all ages, with the peak of onset being 15-35 years old. The average age of onset is around 25 years old, and the incidence is relatively rare in people less than 8 years old and more than 40 years old. Suffering from ankylosing spondylitis will cause great inconvenience to the life of the patient. Acupuncture and moxibustion therapy, a traditional Chinese medicine treatment. Many existing studies have shown that acupuncture and moxibustion can effectively relieve pain in patients with ankylosing spondylitis.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 August 2020 and was last updated on 09 August 2020 (registration number INPLASY202080035).

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METHODS

Participant or population: Patients with physician-diagnosed AS according to any accepted diagnostic criteria will be included.The patients' age, race, and gender were not limited.

Intervention: Du-moxibustion combine with Acupuncture or Du-moxibustion, Dumoxibustion combine with western medicine. Any type of acupuncture combine with Du-moxibustion will be included (eg. electro-acupuncture, needle warming moxibustion, dry needling, Dumoxibustion, long snake moxibustion, etc.)

Comparator: As to the control interventions, any form of therapy that did not involve acupuncture and moxibustion were included like medication, sham acupuncture, usual care, or no intervention.

Study designs to be included: SR/Metaanalysis of randomized controlled trials(RCTs)/cross-controlled trials (CCTs)(if have).No language limitation was used. Eligibility criteria: Patients with AS, age and sex were not restricted.Acupuncture and Du-moxibustion therapy were used as intervention measures in the treatment group, and other non-acupuncture and non-moxibustion methods were used as control measures.

Information sources: Five international electronic databases(Web of Science, The Cochrane Library, PubMed, MEDLINE, and EMBASE) and 4 Chinese electronic databases (China National Knowledge Infrastructure (CNKI), the Chinese Science and Technology Periodical Database (VIP), China Biology Medicine disc (CBM), and Wan Fang Digital Journals).

Main outcome(s): 1. Bath Ankylosing Spondylitis Functional Index(BASFI) 2. Bath Ankylosing Disease Activity Index(BASDAI) 3.Visual Analogue Scale(VAS) 4.Total effective rate and ineffective rate.

Quality assessment / Risk of bias analysis: Assessment of Multiple Systematic Reviews 2 (AMSTAR-2) measurement tool. **PRISMA statement: The PRISMA Statement** for reporting quality consists of a 27-item checklist and a four-phase flow diagram. The checklist included items deemed essential for transparent reporting of a systematic review. Each item of the PRISMA form was graded with a "complete report" score of 1, a "partial report" of 0.5, and an "unreported" score of 0, with a total score of 27. When the literature score is 21 to 27, the report is considered relatively complete; when the score is 15 to 21, the report is considered to have some defects; when the score is less than 15, it is considered that there are relatively serious information defects. GRADE approach: The evidence quality of the included SR/Metaanalysis was evaluated by the GRADE approach. Two authors (CJ and TGH) independently assessed the evidence of the outcomes, and the downgraded or upgraded factors affecting the quality of evidence should be described in detail to guarantee the reliability and transparency of results. The overall quality of evidence was judged as high, moderate, low, or very low.

Strategy of data synthesis: We will provide a narrative description of the findings of the included systematic reviews (SRs). Tables will be produced to detail the included studies and their outcomes. In addition, we will synthesis these reviews and provide pooled treatment effects for all SRs which include the following outcomes: 1.Bath Ankylosing Spondylitis Functional Index(BASFI)2. Bath Ankylosing Disease Activity Index(BASDAI) 3.Visual Analogue Scale(VAS)4.Total effective rate and ineffective rate. If necessary, this study will use RevMan5.4 software for data integration and analysis. The measurement data will use the mean difference (MD) as the effect indicator, and the count data will use the odds ratio (OR) as the effect index. Each effect indicator will be given as a point estimate with 95% confidence interval. The heterogeneity and size of each study result will be judged using statistical methods. For studies with no statistical heterogeneity, the analysis will be performed using a fixed-effect model, whereas a randomized effects model will be applied if for studies with significant statistical heterogeneity.

Subgroup analysis: If the necessary data are available, subgroup analysis will be carried out according to different factors as follows: 1. Control interventions (eg, medication, sham acupuncture, usual care, or no intervention, etc.). 2.Type of acupuncture and moxibustion (eg, Dumoxibustion, electronic-acupuncture, auricular acupuncture, heat-sensitive moxibustion, warm needling moxibustion, suspended moxibustion or mild moxibustion, etc.).

Sensibility analysis: Sensibility analysis: To assess the influence of each individual study, leave-one-out sensitivity analysis was performed iteratively by removing one study at a time to confirm that the findings were not influenced by any single study.

Country(ies) involved: China.

Keywords: Ankylosing spondylitis; AS;Dumoxibustion; Moxibustion; Acupuncture.

Contributions of each author:

Author 1 - Jun Chen - The author drafted and improved the manuscript.

Author 2 - Lun-Bin Lu - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.

Author 3 - Geng-Hua Tang - Data collection; analysis of results.

Author 4 - Jun Xiong - The author read, provided feedback and approved the final manuscript.