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Meta-analysis of Acupuncture Treatment for Postmenopausal Osteoporosis

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ADMINISTRATIVE INFORMATION

Support - No.

Review Stage at time of this submission - The review has not yet started.

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 12 June 2024 and was last updated on 12 June 2024.

INTRODUCTION

Review question / Objective Comparison of bone mineral density and clinical efficacy between patients with postmenopausal osteoporosis receiving conventional treatment and those treated with acupuncture.

Condition being studied Postmenopausal osteoporosis (PMOP) is a systemic bone metabolic disease characterized by a sharp decline in estrogen secretion, significant bone loss, and a markedly increased risk of fractures. With the increasingly severe trend of population aging, the incidence of osteoporosis has also significantly increased. Epidemiological surveys indicate that the global prevalence of osteoporosis in the elderly is 21.7%, and the prevalence of postmenopausal osteoporosis in women is 34.7%. In China, the prevalence of PMOP can be as high as 38.8%, and it continues to increase with age and years since menopause. This not only seriously affects the quality of life of patients but also greatly increases the risk of fractures and their associated mortality rates. According to the World Health Organization, the risk of fractures in osteoporotic patients is 30% to 40%. The rising number of osteoporotic fractures also imposes a heavy burden on public health expenditures. In Germany alone, the annual cost of osteoporosis amounts to 13.8 billion euros.

METHODS

Participant or population The exclusion criteria are delineated as follows: (1) Review articles, expert experiences, medical case reports, theoretical discussions, animal experimental studies, and patent literature; (2) Cohort studies, cross-sectional studies, case-control studies, and other non-randomized controlled studies; (3) Only the most recently published article was included in cases of duplicate publications; (4) Studies with a sample size of less than 25 cases in a single group; (5) Studies in which the treatment disease is PMOP but is combined with other diseases.

Intervention Acupuncture is defined as needle stimulation of acupoints, we will include studies

using body acupuncture, scalp acupuncture, manual acupuncture, auricular acupuncture, electro-acupuncture, fire needling et al.

Comparator Control interventions will encompass any alternative treatment modalities employed for the management of a postmenopausal osteoporosis, with the exception of acupuncture.

Study designs to be included We will include all randomized controlled trials (RCTs) that pertain to the utilization of acupuncture in the treatment of postmenopausal osteoporosis.

Eligibility criteria (1) Study Type: Clinical randomized controlled trials (RCTs) using acupuncture therapy to treat PMOP; (2) Study Subjects: Patients diagnosed with PMOP based on authoritative diagnostic criteria or those that have clearly specified the criteria used for diagnosis (even if the source is not specified); (3) Interventions: The treatment method for the experimental group mainly involves acupuncture therapy, which may be combined with the control group's treatment methods. There are no restrictions or distinctions regarding the acupuncture techniques, selection of acupuncture points, or the materials of the needles. (4) Efficacy Indicators: The primary outcome measures are the total effective rate and bone mineral density (BMD). Secondary outcome measures include estrogen, visual analogue scale (VAS), and records of adverse events.

Information sources The system searched eight databases, including the Chinese National Knowledge Infrastructure, Wanfang Data, VIP Database (CQVIP), China Biomedical Literature Database (CBM), PubMed, Embase, Web of Science, and the Cochrane Library. The inclusion criteria for articles were randomized controlled trials (RCTs) that applied acupuncture therapy to postmenopausal osteoporosis, with the primary outcome indicator being the total effective rate and bone mineral density (BMD). The search covered studies up to May 2024.

Main outcome(s) The primary outcome measures are the total effective rate and bone mineral density (BMD).

Additional outcome(s) Secondary outcome measures include estrogen, visual analogue scale (VAS), and records of adverse events.

Data management Data extraction will be meticulously carried out by two independent researchers using a standardized template and tabulating all relevant information. In case of discrepancies, the original text will be consulted, and consensus will be sought through discussion with the principal investigator. The following detailed information will be extracted: first author's name, year of publication, diagnostic criteria, sample size, patient age, years since menopause, body mass index (BMI), course of disease, interventions, total treatment duration, and outcome indicators.

Quality assessment / Risk of bias analysis We will employ the Cochrane Collaboration's tools to appraise the risk of bias in the studies included. Our scrutiny will span several domains, which include sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other potential sources of bias. The evaluation of bias risk will be classified into three categories: low risk, high risk, and unclear. In instances where clarity is deficient, we will endeavor to contact the authors of the papers to obtain supplementary information.

Strategy of data synthesis The synthesis of data and the meta-analysis will be conducted using Review Manager software (RevMan) version 5.4. Quantitative data will be expressed through mean differences or standardized mean differences, accompanied by 95% confidence intervals (CIs), while dichotomous data will be conveyed using risk ratios and their respective 95% CIs. Statistical heterogeneity among the studies will be quantified using the I^2 statistic. An I^2 value of 50% or less will be indicative of homogeneity amongst the studies, prompting the use of a fixed-effect model for the meta-analysis. A meta-analysis will be undertaken when there is a sufficient number of studies that are homogenous in their combined results.

Subgroup analysis Subgroup analysis was conducted based on the following aspects: (1) Whether the acupuncture therapy in the trial group was combined with conventional therapy; (2) Average age of patients, categorized as <64 years or ≥64 years; (3) Number of acupuncture points selected, categorized as <5 or ≥5; (4) Methods of tonification and sedation, categorized as using only tonification, only sedation, or both; (5) Average duration of illness, categorized as 3 months.

Sensitivity analysis Sensitivity analysis was conducted to verify the robustness of the combined results by sequentially excluding each study.

Country(ies) involved China.

Keywords Acupuncture Therapy; Postmenopausal Osteoporosis; Randomized Controlled Trials; Meta-Analysis.

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