

INPLASY PROTOCOL

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submission:** Data analysis.

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None declared.

INTRODUCTION

Review question / Objective: Cancer-induced bone pain (CIBP) is one major symptom of primary and metastatic bone tumors, and the prolonged painful state will affect patients physically and psychologically to varying degrees. External application of traditional Chinese medicine (EA-TCM) has the characteristics

External Application of Traditional Chinese Medicine or in Combination with Three-Step Analgesic Drugs for Cancer-induced Bone Pain: A Systematic Review and Meta-analysis

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Review question / Objective: Cancer-induced bone pain (CIBP) is one major symptom of primary and metastatic bone tumors, and the prolonged painful state will affect patients physically and psychologically to varying degrees. External application of traditional Chinese medicine (EA-TCM) has the characteristics of simple operation, rapid effect, green and safe, and has been widely used as an adjuvant therapy for CIBP in clinic. this study aimed to summarize the effect of EA-TCM or combined with three-step analgesic drugs for CIBP.

Condition being studied: Cancer-induced Bone Pain.

Information sources: EMBASE, PubMed, Cochrane Library, Web of Science, Scopus, Chinese National Knowledge Infrastructure (CNKI), China Science and Technology Journal Database (VIP), Chinese Biomedical Literature Service System (SinoMed) and WanFang database

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 August 2021 and was last updated on 06 March 2023 (registration number INPLASY202180004).

of simple operation, rapid effect, green and safe, and has been widely used as an adjuvant therapy for CIBP in clinic. this study aimed to summarize the effect of EA-TCM or combined with three-step analgesic drugs for CIBP.

Condition being studied: Cancer-induced Bone Pain.

METHODS

Search Strategy: Two investigators (Fei Wang and Gui-hua Lai) independently searched databases EMBASE, Web of Science, PubMed, Scopus, Cochrane Library, Chinese National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Service System (SinoMed), China Science and Technology Journal Database (VIP) and WanFang from their inception to 31 December, 2022, using the MeSH Terms ("external treatment" OR "external use" OR "external application" OR "powder" OR "paste" OR "cream" OR "patch" OR "traditional Chinese medicine" OR "Chinese medicine" OR "TCM") AND ("bone cancer pain" OR "cancer induced bone pain" OR "bone metastasis cancer pain" OR "bone metastatic pain") AND ("clinical" OR "random").

Participant or population: CIBP patients.

Intervention: The treatment group was treated with EA-TCM or in combination with three-step analgesic drugs.

Comparator: The control group were treated by three-step analgesic drugs alone or in combination with placebo externally.

Study designs to be included: RCT.

Eligibility criteria: Types of Participants. patients with definite primary lesions, and bone metastases confirmed by imaging examination and presenting with symptoms of pain could be enrolled in this review. The study did not place limits on age, gender, or nationality.

Types of interventions. The treatment group was treated with EA-TCM or in combination with three-step analgesic drugs, while patients in the control group were treated by three-step analgesic drugs alone or in combination with placebo externally. There is no limitation on the dosage form of EA-TCM, which can be powder, paste, or patch, etc..

Types of Outcome measures. Included studies had clear efficacy evaluation criteria with at least one of the following clinical indicators, such as pain relief rate,

pain score (NRS score and VAS score), breakthrough pain, analgesic duration, quality of life, or incidence of side effects.

Types of studies. Included in this study were randomized controlled trials (RCTs) of EA-TCM or combination with three-step analgesic drugs for the treatment of CIBP.

Information sources: EMBASE, PubMed, Cochrane Library, Web of Science, Scopus, Chinese National Knowledge Infrastructure (CNKI), China Science and Technology Journal Database (VIP), Chinese Biomedical Literature Service System (SinoMed) and WanFang database.

Main outcome(s): Pain relief rate, pain score, breakthrough pain, analgesic duration, quality of life, adverse effects.

Quality assessment / Risk of bias analysis: Cochrane manual.

Strategy of data synthesis: Review Manager Software 5.4.1(Nordic Cochran Center, Copenhagen, Denmark) is utilized to carry out the data analysis of dichotomous and continuous outcomes. Continuous data uses weighted mean difference (WMD) or standardized mean difference (SMD), while dichotomous data utilizes risk ratio (RR), both with 95% confidence intervals (CIs). Heterogeneity of test is evaluated by the inconsistency index (I²) statistics. When the heterogeneity shown by statistical results is not statistically significant (P >0.1 and I² 50%), using random effect model.

Subgroup analysis: Subgroup analysis analyzed the source of heterogeneity. If the heterogeneity was too high, we performed only a descriptive analysis.

Sensitivity analysis: Sensitivity analysis analyzed the source of heterogeneity. If the heterogeneity was too high, we performed only a descriptive analysis.

Country(ies) involved: China.

Keywords: External application of traditional Chinese medicine, three-step

analgesic drug, cancer-induced bone pain,
systematic review, meta-analysis.

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