INPLASY PROTOCOL

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Review Stage at time of this submission: **Data analysis.**

Conflicts of interest:
None declared.

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

Wang, F[1]; Lai, GH[2]; Zhou, F[3]; Nie, DR[4]; Lei, SJ[5]; Wu, ZJ[6]; Deng, Q[7]; Wang, Y[8]; Cao, JX[9].

Review question / Objective: The purpose of this study was to compare the effect of EA-TCM(external application of traditional Chinese medicine) combined with three-step analgesic drugs versus three-step analgesic drugs in the treatment of patients with CIBP, and the selected research method was a randomized controlled trial.
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 19 September 2022 (registration number INPLASY202180004).

INTRODUCTION

Review question / Objective: The purpose of this study was to compare the effect of EA-TCM(external application of traditional Chinese medicine) combined with three-step analgesic drugs versus three-step analgesic drugs in the treatment of patients with CIBP, and the selected research method was a randomized controlled trial.

Condition being studied: Cancer-induced Bone Pain.

METHODS

Search Strategy: Two researchers (F. Wang and G.H. Lai) independently searched 9 electronic databases (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) from their inception until August 31, 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"). The languages of publication were restricted to English and Chinese.

Participant or population: CIBP patients.

Intervention: External application of traditional Chinese medicine combined with three-step analgesic drug.

Comparator: Three-step analgesic drug alone.

Study designs to be included: RCT.

Eligibility criteria: Types of participants Studies of 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 Patients in the treatment group received EA-TCM combined with three-step analgesic drugs, while patients in the control group should be treated by three-step analgesic drugs alone. There is no restriction 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, frequency of breakthrough pain, duration of analgesia, quality of life, or incidence of adverse effects.
Types of studies The included studies were randomized controlled trials (RCTs).

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, frequency of breakthrough pain, duration of analgesia, quality of life, or incidence of 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: No subgroup analysis was performed in this study.

Sensitivity analysis: In Review Manager Software 5.4.1, sensitivity analysis was performed to reflect the sensitivity of one article by the change of effect size after deletion.

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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