INPLASY PROTOCOL

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None declared.

Comparison of efficacy and safety of complementary and alternative therapies for Scapulohumeral Periarthritis A Bayesian network meta-analysis protocol

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Review question / Objective: **Scapulohumeral periarthritis is a disease with high incidence and great pain. The current western treatments with many side effects, poor efficacy can not fundamentally solve the problem. Complementary and alternative therapies have played a magical effect in the treatment of scapulohumeral periarthritis . However, it is not clear which complementary and alternative therapy is more effective. Therefore, we propose a protocol to compare the efficacy and safety of various complementary and alternative therapies through network meta-analysis (NMA) to provide choice guidance for the therapy.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 April 2021 and was last updated on 08 April 2021 (registration number INPLASY202140044).

INTRODUCTION

Review question / Objective: **Scapulohumeral periarthritis is a disease with high incidence and great pain. The current western treatments with many side effects, poor efficacy can not fundamentally solve the problem. Complementary and alternative therapies have played a magical effect in the treatment of scapulohumeral periarthritis . However, it is not clear which complementary and alternative therapy is more effective. Therefore, we propose a protocol to compare the efficacy and safety of various complementary and alternative**

therapies through network meta-analysis (NMA) to provide choice guidance for the therapy.

Rationale: A comprehensive search will be conducted for randomized controlled trials of complementary and alternative therapy for scapulohumeral periarthritis as well as ongoing trials. The time limit is from the establishment of the database until January 2021. Literature and data extraction were completed independently by two researchers. Through pairwise comparison and Meta analysis of Bayesian NMA, all the evidences are evaluated comprehensively. STATA16.0 and WinBUGS1.4.3 software will be used for data processing and analysis, and recommendation evaluation will be used to develop and evaluate grades to classify the quality of NMA evidence.

Condition being studied: Scapulohumeral periarthritis(SP) is a disease with chronic and specific inflammatory change caused by degeneration and strain of muscle, ligament, tendon, synovial capsule and joint capsule around shoulder joint. The incidence of scapulohumeral periarthritis is 2%-5%, accounting for about 42% in shoulder diseases. It is more common in the middle-aged and elderly and has a younger trend at present. The incidence in women is higher than that in men. It's main manifestations are shoulder pain and limitation of shoulder movement. The initial pain is paroxysmal. With the progress of the disease, it can be transformed into persistent and severe pain, usually aggravated at night, which can seriously affects sleep. It is often accompanied by limitation of movement, even accompanied by different degrees of deltoid muscle atrophy. Scapulohumeral periarthritis is a chronic disease with long course, severe shoulder pain, limited movement and high disability rate, which makes patients suffer extremely pain, prone to insomnia, anxiety and other psychological problems, seriously affecting the quality of life. Therefore, there is an urgent need to find a way to treat the disease. At present, the main methods of western medicine in the treatment of SP are oral drugs, local anesthesia, local blocking therapy, physiotherapy, surgical treatment, and etc. Surgical treatment has limited indications, high cost and more risks. Although there are many other treatments, which can temporarily relieve symptoms, the long-term effect is not good, and oral western medicine has certain side effects. Complementary and alternative therapies for SP consist of many methods, such as Chinese Herbal medicine, acupuncture, moxibustion, massage, exercise, yoga, Baduanjin, Taichi, and cupping therapy. They possess advantages of good and lasting therapeutic effects and few side effects, etc. Nevertheless, reviewing all the current researches, we found that there's a lack of systematic analysis of the efficacy and safety of various complementary and alternative therapies which can rank their efficacy. Based on these findings, we conducted a study of complementary and alternative therapies in the treatment of scapulohumeral periarthritis, and proposed a NMA protocol to explore the efficacy of different complementary and alternative therapies.

METHODS

Search strategy: We will search PubMed, CNKI, Wanfang database, CochraneLibrary, VIP database (VIP), EMBASE, Web of Science, and Cochrane Central Register of Control Trials, Clinical Trials.gov clinical registration system. The language is limited to Chinese or English. The time range of retrieval is from the date of the establishment of the database to January30, 2021. The retrieval skills and attentions will be studied in detail, and the retrieval will be carried out by combination of subject words and free words. The final retrieval strategy is determined after many searches. We will collect all completed or ongoing RCT of complementary and alternative therapies for SP.

Participant or population: According to internationally recognized diagnostic criteria, patients diagnosed as SP will be included, regardless of source, sex, age, etiology, course, severity and race. And

there must be clear criteria for evaluating therapeutic effects.

Intervention: The experimental group was treated with Chinese Herbal Medicine, acupuncture, moxibustion, massage, exercise, yoga, Baduanjin, Taichi, and cupping therapy. All kinds of treatments can be used alone or in combination.

Comparator: The control group was given routine treatments such as western medicine, placebo, non-treatment and so on.

Study designs to be included: We will include (RCT) randomized controlled trials of complementary and alternative therapies related to this study published in China and internationally.The language is limited to Chinese or English. The time range of retrieval is from the date of the establishment of the database to January 30, 2021.

Eligibility criteria: According to internationally recognized diagnostic criteria, patients diagnosed as SP will be included, regardless of source, sex, age, etiology, course, severity and race. And there must be clear criteria for evaluating therapeutic effects.

Information sources: PubMed, CNKI, Wanfang database, Cochrane Library, VIP database (VIP), EMBASE, Web of Science, and Cochrane Central Register of Control Trials, Clinical Trials.gov clinical registration system.

Main outcome(s): VAS score (visual analogue scale), Shoulder motor function score, effective rate.

Quality assessment / Risk of bias analysis: In this study, the deviation risk assessment tool recommended in the Cochrane system reviewer's Handbook 5.3 will be used to evaluate the quality of the included literature. It was carried out independently by two researchers (GMH and LCC). If there is a disagreement, the decision will be made through discussion, and if necessary, the third researcher(QXY or JZY) will make the decision and explain the reason. The evaluation criteria will include the following aspects: correct application of randomization; the application of allocation hiding ;the blindness of participants and researchers; the integrity of results and data; selective reporting of results; and other related biases. According to the above criteria, the bias risk included in the study is divided into three levels: "low bias risk", "high bias risk" and "ambiguous bias risk".

Strategy of data synthesis: We will use Stata16.0 software for paired Meta analysis and WinBUGS software for Bayesian NMA statistical analysis. Odds ratio (OR) will be adopted for counting data, Mean difference (MD) or standardized mean difference (SMD) will be adopted for continuous variable data. Therapeutic effects are evaluated by the effect value and its 95% confidence interval (CI). We will use I2 value and P value to evaluate whether there is statistical heterogeneity. When P value ≥ 0.1 and I2 value ≤ 50%, it means that there is no statistical heterogeneity between studies. We will use the fixed effect model. When P value < 0.1 and I2 value > 50%, it means that there is statistical heterogeneity between studies, and then it is necessary to analyze the causes of heterogeneity, such as country, sex, age, course of disease and other factors. If the heterogeneity is caused by these reasons, we will use subgroup analysis and sensitivity analysis as well as meta regression to further solve the problem. If there is still heterogeneity, we will choose the random effect model. If the above methods still can not solve the problem of heterogeneity, we will abandon meta-analysis and adopt descriptive analysis.

Subgroup analysis: When there is clear statistical heterogeneity between studies, we will use subgroup analysis and sensitivity analysis as well as meta regression to further solve the problem.

Sensitivity analysis: When there is clear statistical heterogeneity between studies, we will use subgroup analysis and

sensitivity analysis as well as meta regression to further solve the problem.

Language: **The language is limited to Chinese or English.**

Country(ies) involved: **China.**

Keywords: **Complementary and alternative therapies, scapulohumeral periarthritis, web meta-analysis, protocol.**

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