INPLASY PROTOCOL

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None.

Safety and efficacy of f acupotomy combined with Massage in the treatment of cervical spondylotic radiculopathy A protocol for a systematic review and meta-analysis

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Review question / Objective: **We will use a systematic review and meta-analysis to evaluate the efficacy and safety of acupotomy combined with Massage in the treatment of cervical spondylotic.**
Condition being studied: **It has been shown that acupotomy therapy is effective and can realive the pain of patients with cervical spondylotic radiculopathy. We will focuse on exploring the effectiveness of acupotomy combined with Massage for patients with cervical spondylotic radiculopathy, and compared and analyzed the results of treatment with manual massage alone. Therefore, the purpose of this meta-analysis is to evaluate the literature regarding the efficacy and safety of using f acupotomy combined with Manipulative Massage in the treatment of cervical radiculopathy.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 January 2021 and was last updated on 01 January 2021 (registration number INPLASY202110002).

INTRODUCTION

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METHODS

Search strategy: With “zhen dao”, “xiao zhen dao”, “tui na”“cervical spondylotic radiculopathy”, “CSR” , “cervical degenerative radiculopathy ”, as Chinese retrieval words, retrieve in Chinese database(CNKI, Wanfang Data Knowledge Service Platform, Chinese Journal Service Platform (VIP), Chinese Biomedical Database); With “acupotomy” , “acupotome”,“needle knife”,“needle scalpel”,“mini scapel-needle” “acupotomology,” “massage” ,“cervical spondylotic radiculopathy”, “cervical degenerative radiculopathy ” “CSR” , as English search terms, retrieve in English databases(PubMed, Embase, Web of Science, the Cochrane Library).

Participant or population: Inclusion criteria were: The diagnosis of patient with cervical spondylotic radiculopathy is clear：①the patient had cervical nerve root compression,with pain of neck and typical root symptoms and signs, consistenting with the lesion of the cervical nerve root innervation area; ②Spurling’s test and Eaton’s test are positive. Exclusion criteria were: (1)studies published repeatedly;(2)the full text was not available;(3)Studies without relevant outcome indicators or with obvious data errors;(4) the study was an experimental in vitro or biomechanical study; or(5)the study was a review article, case report or conference article; (6)the study reported on special populations (e.g., elderly, infants, pregnant women).

Intervention: The treatment group was treated with acupotomy therapy with massage (times of treatment, frequency of treatment, and length of treatment period will not be restricted.).

Comparator: The control group was treated with Massage therapy.

Study designs to be included: Randomized controlled trials(RCTs) will be included.

Eligibility criteria: 2.3 Eligibility criteria 2.3.1 types of studies. We collected all available Randomized controlled trials（RCTs）of acupotomy combined with Massage for cervical spondylotic radiculopathy, regardless of blindness, publication, and region, but in Chinese and English only. 2.3.2 Research subjects. Among patients with definite diagnosis of cervical spondylotic radiculopathy(nationality, race, age, gender and course of disease were unlimited). 2.3.3 Intervention measures. The treatment group was treated with acupotomy therapy with massage (times of treatment, frequency of treatment, and length of treatment period will not be restricted.), while the control group was treated with Massage therapy, and the control group shall be no restrictions on outcome indicatiors. 2.3.4 Outcome indicatiors. Primary outcome: 1 efficacy evaluation method in“Guidelines for Clinical Research of New Drugs in Traditional Chinese Medicine,” score reduction=(pretreatment score-posttreatment score)/pretreatment score×100%; 2 visual analogue score (VAS). Secondary outcomes: 1 Cervical spondylosis Clinical Evaluation Scale（CASCS）; 2 The Neek Disability (NDI) ; 3 Incidence of adverse reactions. 2.4 Inclusion and exclusion criteria Inclusion criteria were: The diagnosis of patient with cervical spondylotic radiculopathy is clear：1 the patient had cervical nerve root compression,with pain of neck and typical root symptoms and signs, consistenting with the lesion of the cervical nerve root innervation area; 2 Spurling’s test and Eaton’s test are positive. Exclusion criteria were: (1)studies published repeatedly; (2)the full text was not available; (3)Studies without relevant outcome indicators or with obvious data errors;(4) the study was an experimental in vitro or biomechanical study; or(5)the study was a review article, case report or conference article; (6)the

study reported on special populations (e.g., elderly, infants, pregnant women).

Information sources: Use computer to retrieve English databases (PubMed, Embase, Web of Science, the Cochrane Library) and Chinese databases (CNKI, Wan Fang, VIP, Chinese biomedical database), from the establishment of database to December 2020, for randomized controlled trials(RCTs) of acupotomy combined with Massage in the treatment of cervical spondylotic radiculopathy

Main outcome(s): Primary outcome: 1 efficacy evaluation method in"Guidelines for Clinical Research of New Drugs in Traditional Chinese Medicine," score reduction=(pretreatment score-posttreatment score)/pretreatment score×100%; 2 visual analogue score (VAS). Secondary outcomes: 1 Cervical spondylosis Clinical Evaluation Scale (CASCS); 2 The Neek Disability (NDI); 3 Incidence of adverse reactions.

Quality assessment / Risk of bias analysis: The Cochrane collaboration's tool for assessing risk of bias will be used to do the risk of bias assessment of included studies. According to the performance of the studies above evaluation items, the 2 researchers will give 3 judgments (low-risk, unclear, high-risk judgments) one by one, and then carry out cross-checking after that. Both of them will have a discussion when there are some disagreement, and If they still can not reach an agreement, opinion will be held with a third party researcher.

Strategy of data synthesis: 2.8 Statistical analysis 2.8.1. Data analysis and processing. The RevMan 5.3 software provided by the Cochrane Collaboration will be used for statistical analysis.For the continuous variables, Weighted Mean Difference (WMD) is selected as the statistic; for the dichotomous variables, relative risk is selected as the statistic; all the above are represented by effect value and 95% confidence interval(CI). Heterogeneity test was performed for all included studies, I2 value is used to quantitatively evaluate the inter-study heterogeneity.If I2≤50%,the heterogeneity is good ,and the fixed-effect model is adopted; If I2 >50%, the heterogeneity is significant, and the causes of heterogeneity need to be further analyzed. If there is no obvious clinical or methodological heterogeneity, it is means that there is statistical heterogeneity, and random-effect model is used for analysis. If there is significant clinical heterogeneity between the two groups and subgroup analysis is not possible, descriptive analysis is used. 2.8.2 Sensitivity analysis.The sensitivity analysis will be carried out in a one-by-one elimination method to test the stability of meta-analysis results of indicators 2.8.3 Assessment of reporting biases. If less than 10 studies were included in an outcome measure, funnel plots were used to assess publication bias. Meanwhile, Begg and Egger test were used to assess the evaluation of potential publication bias. 2.8.4 Evidence quality evaluation. The Grading of Recommendations Assessment, Development, and Evaluation (GRADE)will be used to assess the quality of evidence.And the quality of evidence will be rated as high, moderate, low, and very low.

Subgroup analysis: The treatment group: was treated with acupotomy therapy with massage (times of treatment, frequency of treatment, and length of treatment period will not be restricted.); the control group :was treated with Massage therapy.

Sensibility analysis: The sensitivity analysis will be carried out in a one-by-one elimination method to test the stability of meta-analysis results of indicators.

Language: in Chinese and English only.

Country(ies) involved: China.

Keywords: acupotomy, Massage, cervical spondylotic radiculopathy, meta-analysis, randomized controlled trials.

Contributions of each author:

Author 1 - Haiyan Zhang - The author drafted the manuscript.
Author 2 - Mingshuang Zhu.
Author 3 - Yanlin Yang.
Author 4 - Cao Jihui.