INPLASY PROTOCOL

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None declared.

Efficacy and safety of needle knife for the treatment of upper limb spasticity after stroke: Protocol for a systematic review and meta-analysis

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Review question / Objective: **Population: All patients should be diagnosed with stroke and show symptoms of upper limb muscle spasm, and should be older than 18 years of age. Intervention: The intervention group received needle knife alone or in combination with routine rehabilitation treatment (manual therapy, exercise therapy, and electronic biofeedback, etc.). Comparison: In the control group received only conventional rehabilitation treatment, the methods of rehabilitation training are not limited (including all types of rehabilitation training methods for upper limb spasticity after stroke, such as Bobath Technology, Rood Technology, Brunnstrom Therapy, Excercise Relearning Therapy, and Proprioceptive Neuromuscular Facilitation). Outcome: the Modified Ashworth Scale (MAS), Simplified Fugl-Meyer Assessment scale (SFMA), Modified Barthel Index (MBI), China Stroke Scale (CSS), adverse reactions.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 March 2022 and was last updated on 18 March 2022 (registration number INPLASY202230090).

INTRODUCTION

Review question / Objective: **Population: All patients should be diagnosed with stroke and show symptoms of upper limb muscle spasm, and should be older than 18 years of age. Intervention: The intervention group received needle knife alone or in combination with routine rehabilitation treatment (manual therapy, exercise therapy, and electronic biofeedback, etc.). Comparison: In the control group received only conventional rehabilitation treatment, the methods of**

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Condition being studied: Stroke, also known as "cerebrovascular accident", is an acute cerebrovascular disease caused by a sudden rupture of a blood vessel in the brain or a blockage of a blood vessel caused by atherosclerosis, which prevents blood from flowing to the brain and causes brain tissue damage. It includes hemorrhagic stroke and ischemic stroke. Stroke is characterized by a high rate of disability. The disease has high morbidity, mortality, and disability rates and poses a serious threat to human health. One of the main sequelae of stroke is limb spasm . Studies have shown that 90% of patients develop limb spasms within three weeks after stroke onset, and foreign epidemiological studies have shown the incidence of myospasm after cerebrovascular accidents to be between 4%-27% within 1 month and 17%-46% within 3 months, with upper limb spasms being the main manifestation in more than half of these patients. Limb spasticity is an abnormal movement pattern that is mainly due to the loss of control of lower motor neurons following damage to the upper motor nerve center, resulting in hyperreflexia of the spinal cord stem vomiting. Upper limb spasticity develops from flaccid paralysis, and patients with upper limb spastic paralysis have unfavorable upper limb flexion and extension in mild cases, and severe upper limb flexion and inversion in severe cases, making it difficult to extend, which severely affects patients' daily life and also adversely affects patients' subsequent further recovery, and long-term limb unfavorability more severely affects patients' motivation for rehabilitation, forming a vicious circle that seriously affects patients' life and later rehabilitation . The upper limb is an important carrier of our information and emotional communication, and it is responsible for most of our daily activities. Therefore, the rehabilitation of upper limb spasticity is particularly important,if upper limb spasticity cannot be recovered, it will have a great impact on the quality of life and psychological status of patients after stroke. The most commonly used treatments are acupuncture, massage, physical factor therapy, exercise rehabilitation, oral medications, and botulinum toxin injections. These treatments can improve the symptoms of spasticity and hemiparesis to some extent. However, the recovery effect varies from person to person, but some interventions, have greater side effects. Studies have shown that selective cutting of tendons by small needle knife can release tendons and ligaments, so as to weaken the strength of abnormally excited tendons, reduce muscle tension, correct or partially correct dynamic malformations, and promote the balance between spastic and antagonistic muscles. Small needle knife therapy was first put into clinical practice in the 1980s, and has been recognized by clinicians for its simple operation, little invasion, little damage and good efficacy.

METHODS

Participant or population: All patients should be diagnosed with stroke and show symptoms of upper limb muscle spasm, and should be older than 18 years of age. However, race, gender, and educational status are not limited. The diagnosis of stroke should meet WHO criteria. Participants with unstable vital signs or inability to cooperate with rehabilitation treatment should be excluded, such as patients with impaired hearing, visual and cognitive or severe infection, organ dysfunction, and so on.

Intervention: The intervention group received needle knife alone or in combination with routine rehabilitation

treatment (manual therapy, exercise therapy, and electronic biofeedback, etc.).

Comparator: In the control group received only conventional rehabilitation treatmen, the methods of rehabilitation training are not limited (including all types of rehabilitation training methods for upper limb spasticity after stroke, such as Bobath Technology, Rood Technology, Brunnstrom Therapy, Excercise Relearning Therapy, and Proprioceptive Neuromuscular Facilitation).

Study designs to be included: Only randomized controlled trials (RCTs) will be included in this study.

Eligibility criteria: Inclusion: Randomized controlled clinical trials and quasi-RCTs. We will exclude any other literature including non-randomized clinical controlled trials, retrospective research literature, conference abstracts, case reports, repeated published literature, and literature of information without data.We will include only the literature of randomized controlled trials (RCTs) of aromatherapy massage for KOA. Nonrandomized controlled studies case reports, case series and reviews will not be included in this study.

Information sources: We will collect relevant articles by searching the following databases: PubMed, Web of Science, Medicine, EMBASE, Cochrane Library, China National Knowledge Infrastructure, China Biomedical Literature Database, China Science Journal Database, and Wan-Fang Database.

Main outcome(s): We will include the Modified Ashworth Scale (MAS) and Simplified Fugl-Meyer Assessment scale (SFMA) as the main outcomes. The MAS will be used to evaluate the muscle tone of the patient's upper limbs and divided into five grades according to severity. The SFMA, 100 points in total, can assess movement function of patient's limbs (including upper and lower limbs), yet only the part of SFMA about the upper limbs was used (66 points) in this study.

Additional outcome(s): (1)Modified Barthel Index (MBI) used to evaluate the daily living ability of patients with stroke. (2)China Stroke Scale (CSS) used to assess the neurological deficit of stroke patients. (3)Adverse reactions.

Quality assessment / Risk of bias analysis: Data extraction will be performed independently by two reviewers (LSY and ZJC), and the results will be cross-matched. When the differences and opinions are inconsistent, they should be settled through discussion. If the differences encountered cannot be resolved through discussion, a third researcher will be invited to resolve them. Excel will be used to extract data, including the first author, country, year of publication, patient characteristics, number of participants, interventions, outcomes, results, main conclusions, conflicts of interest, ethical approval, and other information. If necessary, we will contact the corresponding author by e-mail to obtain more accurate data. Two researchers (PTT and LJH) will independently evaluate the bias risk, including studies using the assessment tool of risk bias in the Cochrane Handbook V.5.1.0. The contents included random sequence generation, allocation sequence concealment, blinding of participants and personnel, outcome assessors, incomplete outcome data, selective outcome reporting, and other sources of bias. The assessment results were rated as low-risk, high-risk, or uncertain risk. In the process, if there is disagreement, a third reviewer (WYF) will be invited to make a decision.

Strategy of data synthesis: The meta-analysis of data from included outcomes will be performed using the RevMan V.5.4.1, and we will choose a randomized or fixed effect model for data statistics according to the results of the heterogeneity test. The enumeration data were expressed as relative risk (RR), and the weight mean difference (WMD) was used as the measurement data; each effect amount was expressed in 95% confidence interval (CI). The specific methods were as follows: If the heterogeneity was low ($I^2 < 50\%$, the

fixed-effects model was used for data synthesis. If there is high heterogeneity (I^2 > 50%), the random-effects model will be used for data synthesis after excluding possible heterogeneity sources. The investigation methods included subgroup and sensitivity analyses. If data cannot be synthesized, we provide a descriptive analysis to solve this problem.

Subgroup analysis: If there was high heterogeneity (I2 > 50%) among the included studies, we conducted a subgroup analysis to analyze the sources of heterogeneity according to the following factors: age, sex, race, course, sample size, different methods of electro-acupuncture or rehabilitation, and other possible factors affecting the results.

Sensitivity analysis: To test the stability and reliability of the results of this study, we conducted a sensitivity analysis according to the following points: method quality, sample size, and missing data. After that, we will perform a data analysis again and compare the results. If there was no directional change after the sensitivity analysis, the results were stable.

Language: English and Chinese.

Country(ies) involved: China.

Keywords: MAS=Modified Ashworth scale, SFMA=simplified Fugl-Meyer Assessment, MBI=Modified Barthel Index, CSS=China Stroke Scale, RR=relative risk, WMD=weight mean difference, CI=confidence interval.

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