

INPLASY PROTOCOL

To cite: Li et al. Acupuncture combined with Chinese herbal medicine for post-stroke deglutition disorder: a systematic review and meta-analysis. Inplasy protocol 2021120023. doi: 10.37766/inplasy2021.12.0023

Received: 04 December 2021

Published: 04 December 2021

Corresponding author:
Li Qinglin

liqinglin20121@163.com

Author Affiliation:
Heilongjiang University of
traditional Chinese Medicine

Support: Province Natural
LH2019H051.

**Review Stage at time of this
submission:** Preliminary
searches.

Conflicts of interest:
None declared.

Acupuncture combined with Chinese herbal medicine for post-stroke deglutition disorder: a systematic review and meta-analysis

Li, Q¹; Li, X²; Mei, J³; Ben, Y⁴; Zheng, X⁵.

Review question / Objective: In this systematic review, for patients with deglutition disorders after stroke, the intervention measure is to emphasize the efficacy and safety of acupuncture combined with Chinese herbal medicine. And the control measures could be routine treatment, rehabilitation training or acupuncture only. The outcome variables are VFSS (videofluoroscopic swallowing study) score, SSA (Standardized Swallowing Assessment) score, quality of life scale and effective rate and the incidence of aspiration pneumonia. The research method is randomized controlled trial.

Information sources: Two researchers searched the following databases from their inception: EMBASE, OVID-MEDLINE, the Cochrane Library, PubMed (via website), Scopus databases, China National Knowledge Infrastructure (CNKI) (via website), China Biology Medicine disc (CBMdisc) (via website), China Science and Technology Journal Database (VIP) (via website), and Wanfang Data (via website).

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 04 December 2021 and was last updated on 04 December 2021 (registration number INPLASY2021120023).

INTRODUCTION

Review question / Objective: In this systematic review, for patients with deglutition disorders after stroke, the intervention measure is to emphasize the efficacy and safety of acupuncture

combined with Chinese herbal medicine. And the control measures could be routine treatment, rehabilitation training or acupuncture only. The outcome variables are VFSS (videofluoroscopic swallowing study) score, SSA (Standardized Swallowing Assessment) score, quality of

life scale and effective rate and the incidence of aspiration pneumonia. The research method is randomized controlled trial.

Condition being studied: With the development of aging society, the incidence rate of cerebrovascular diseases is increasing. The rate of related patients complicated with pseudobulbar paralysis is about 36% ~ 78%. Dysphagia is the most common clinical symptom of cerebrovascular disease complicated with pseudobulbar paralysis, which has an adverse effect on the prognosis of patients with cerebrovascular diseases, mainly reflected in related complications such as pneumonia, malnutrition, dehydration and so on. Among them, the occurrence of dysphagia after cerebral infarction will increase the incidence of aspiration pneumonia by 7 times. The mortality of cerebral infarction patients caused by pulmonary infection is about 10%, accounting for 1 / 3 of all elderly pneumonia deaths. It has a great obstacle to the rehabilitation of patients, brings great distress to patients' daily life, Therefore, it is urgent to improve the curative effect of deglutition disorders after stroke. Under the guidance of the overall concept of traditional Chinese medicine and the meridian theory of traditional Chinese medicine, acupuncture uses a needle to pierce the meridian points of the human body according to a certain method, so as to achieve the purpose of treating diseases. With the development of modern medical science and technology, some studies believe that acupuncture points are related to the interaction of regional brain structure and brain functional areas. In recent years, with the increasing reports of acupuncture, combination of acupuncture and medicine and rehabilitation training in the treatment of this disease, its remarkable clinical efficacy has been verified and affirmed. Through the modern pharmacological analysis of single traditional Chinese medicine, it can not only promote cell growth, enhance cell life and function, reduce vascular resistance, increase blood flow, anti platelet

aggregation, anti thrombosis, improve circulation and enhance immunity, but also stimulate smooth muscle. Therefore, combination of acupuncture and Chinese herbal medicine is used widely in treating deglutition disorders after stroke.

METHODS

Search strategy: Two researchers searched the following databases from their inception : EMBASE , OVID-MEDLINE , the Cochrane Library , PubMed (via website), Scopus databases, China National Knowledge Infrastructure (CNKI) (via website), China Biology Medicine disc (CBMdisc) (via website), China Science and Technology Journal Database (VIP) (via website), and Wanfang Data (via website). Firstly, the subject words and free words are retrieved, then the logical relationship is determined, and the retrieval is carried out by connecting with "or" "and" . for example: strokes:ab,ti OR stroke:ab,ti OR 'cerebrovascular accidents':ab,ti OR (cva:ab,ti AND 'cerebrovascular accident':ab,ti) OR (cvas:ab,ti AND 'cerebrovascular accident':ab,ti) OR 'cerebrovascular apoplexy':ab,ti OR 'apoplexy, cerebrovascular':ab,ti OR 'vascular accident, brain':ab,ti OR 'brain vascular accident':ab,ti OR 'brain vascular accidents':ab,ti OR 'vascular accidents, brain':ab,ti OR 'cerebrovascular stroke':ab,ti OR 'cerebrovascular strokes':ab,ti OR 'stroke, cerebrovascular':ab,ti OR 'strokes, cerebrovascular':ab,ti OR apoplexy:ab,ti OR 'cerebral stroke':ab,ti OR 'cerebral strokes':ab,ti OR 'stroke, cerebral':ab,ti OR 'strokes, cerebral':ab,ti OR 'stroke, acute':ab,ti OR 'acute stroke':ab,ti OR 'acute strokes':ab,ti OR 'strokes, acute':ab,ti OR 'cerebrovascular accident, acute':ab,ti OR 'acute cerebrovascular accident':ab,ti OR 'acute cerebrovascular accidents, acute':ab,ti 'deglutition disorders':ab,ti OR 'deglutition disorder':ab,ti OR 'disorders, deglutition':ab,ti OR 'swallowing disorders':ab,ti OR 'swallowing disorder':ab,ti OR dysphagia:ab,ti OR 'oropharyngeal dysphagia':ab,ti OR

'esophageal dysphagia':ab,ti OR 'dysphagia, esophageal':ab,ti 'acupuncture therapy':ab,ti OR 'acupuncture treatment':ab,ti OR 'acupuncture treatments':ab,ti OR 'therapy, acupuncture':ab,ti OR 'pharmacopuncture treatment':ab,ti OR 'treatment, pharmacopuncture':ab,ti OR 'pharmacopuncture therapy':ab,ti OR 'therapy, pharmacopuncture':ab,ti OR acupotomy:ab,ti OR acupotomies:ab,ti OR 'electrical needle':ab,ti OR 'fire needle':ab,ti OR 'cluster acupuncture':ab,ti 'traditional chinese medicine':ab,ti OR decoction:ab,ti OR 'traditional medicine, chinese':ab,ti The above search results are connected with "and".

Participant or population: Patients with stroke disease diagnosed by CT or MRI scan and stroke scale score, with dysphagia confirmed by videofluorescent swallowing study (VFSS) assessment, regardless of ischemic or hemorrhagic stroke. Other causes of dysphagia will be excluded. There is no restriction on the patient's ethnicity, nationality, education level, age, gender, or duration of illness.

Intervention: Patients with post-stroke dysphagia in the experimental group must take acupuncture combined with Chinese herbal medicine as the main program (including ordinary acupuncture, electroacupuncture, fire acupuncture and various characteristic acupuncture methods) can be combined with routine drug treatment for stroke or used alone.

Comparator: The control group was treated with conventional western medicine, simple acupuncture, rehabilitation or simple traditional Chinese medicine.

Study designs to be included: The type of study is a randomized controlled trial of acupuncture combined with medicine in the treatment of dysphagia after stroke, including computer coding, randomized control table and other grouping methods. Blind method can not be mentioned in this paper. Patients with stroke disease diagnosed by CT or MRI scan and stroke

scale score, with dysphagia confirmed by videofluorescent swallowing study (VFSS) assessment.

Eligibility criteria: Exclusion criteria 1) The dosage form of traditional Chinese medicine is external treatment of traditional Chinese medicine, such as traditional Chinese medicine sticking, traditional Chinese medicine popsicle, traditional Chinese medicine atomization, etc. 2) The control group was treated with pure traditional Chinese medicine, but the taste and dose of traditional Chinese medicine were omitted or unclear. 3) the control group used different acupoints during acupuncture treatment. 4) repeated published literature, systematic evaluation, animal experiments, cases and other non randomized controlled trials. 5) Clinical studies without control group 6) there is no clear outcome index or the outcome index is only the effective rate 7) the full text cannot be obtained. The type of study is a randomized controlled trial of acupuncture combined with medicine in the treatment of dysphagia after stroke, including computer coding, randomized control table and other grouping methods. Blind method can not be mentioned in this paper. Patients with stroke disease diagnosed by CT or MRI scan and stroke scale score, with dysphagia confirmed by videofluorescent swallowing study (VFSS) assessment.

Information sources: Two researchers searched the following databases from their inception: EMBASE, OVID-MEDLINE, the Cochrane Library, PubMed (via website), Scopus databases, China National Knowledge Infrastructure (CNKI) (via website), China Biology Medicine disc (CBMdisc) (via website), China Science and Technology Journal Database (VIP) (via website), and Wanfang Data (via website).

Main outcome(s): The primary outcome measure was the water swallow test (WST). This method is a commonly used clinical examination method of bedside swallowing function. The patient is instructed to take a seat, drink 30ml warm boiled water according to the doctor's

advice, and evaluate the patient's swallowing function by observing the patient's drinking time and choking cough. It is mainly used for the patient's drinking water evaluation. The swallowing function was divided into 5 grades according to the clinical manifestations. The secondary outcomes included videofluoroscopic swallowing study (VFSS), which is usually used to evaluate swallowing function. Swallowing radiography was performed with X-ray simulated positioning machine to record the dynamic process of food from mouth to throat and the occurrence of aspiration, leakage, choking and food storage. The total score ranged from 0 to 10. The higher the score, the better the swallowing function of the patient.

Additional outcome(s): The other outcome included SSA (Standardized Swallowing Assessment) score. The scale includes three parts; Part 1 evaluates the patients' head, lip and trunk control, pharyngeal reflex, breathing style, sound intensity, soft palate movement, consciousness level and spontaneous cough. Part 2 instructs the patient to drink 5 ml of water repeating for 3 times, and observe the running water at the mouth when drinking water, laryngeal movement, repeated swallowing and laryngeal function when swallowing. Part 3 shows when swallowing for two or more times is normal. The patient is instructed to drink 60ml of water and observe the drinking and swallowing conditions. ; The total score of the three parts ranges from 18 to 46. The higher the score, the worse the patient's swallowing function. At the same time, the quality of life scale is used to evaluate the improvement of other aspects. After all, diet, as an irreplaceable part of life, will enhance disease resistance and improve the quality of life. Adverse events are also important, The incidence of aspiration pneumonia will be recorded and counted. We should also pay attention to the incidence of aspiration pneumonia, which is the key information to judge the prognosis of patients.

Quality assessment / Risk of bias analysis:

The included RCTs were assessed according to the Cochrane risk of bias assessment tool, and this process was carried out independently by the two review authors (Ben Yuwei and Zhengxue). Quality was assessed as having a low, an unclear, or a high risk of bias according to seven criteria: (1) random allocation method (selection bias); (2) allocation concealment (selection bias); (3) blinding of assessors (performance bias); (4) blinding of outcome assessment (detection bias); (5) integrity of data results (attrition bias); (6) selective reporting (reporting bias); and (7) other sources of bias. Any disagreements that arose at any stage between the two review were resolved through discussion with a third author (Li Qinglin).

Strategy of data synthesis: All statistical analyses were performed using RevMan 5.3 and STATA 15.0. For dichotomous variables, the relative risk (RR) with its 95% confidence interval (CI) was calculated. For continuous variables, the mean difference (MD) and standardized mean difference (SMD) with their 95% CIs were calculated. The heterogeneity between each group was tested by the Cochran's Q statistic and the I^2 test. Studies with an I^2 of 25% to 50% were considered to have low heterogeneity, and I^2 values of 50% to 75% and $> 75%$ were considered indicative of moderate and high levels of heterogeneity, respectively. Fixed-effect models were used to combine studies if the I^2 test was not significant (P for heterogeneity < 0.1). Otherwise, random-effect models were used. $P < 0.05$ was considered statistically significant for the between-group difference.

Subgroup analysis: If substantial heterogeneity was detected, we looked for reasonable explanations, and subgroup analysis or sensitivity analysis could be applied to explore the causes of heterogeneity. If the sources of heterogeneity could not be determined, a descriptive analysis was adopted. To explore the possible factors for the statistical heterogeneity, subgroup analysis will be performed on the basis of the interventions if necessary: Subgroup

analysis can be carried out and divided into control group for acupuncture or control group for routine treatment or control group for rehabilitation treatment. The causes of heterogeneity can be found through this grouping.

Sensitivity analysis: STATA 15.0 software will be used by us to perform sensitivity analysis to explore the reliability and stability of the present results of the study.

Country(ies) involved: China.

Keywords: Acupuncture; Traditional Chinese Medicine; Deglutition; Stroke.

Contributions of each author:

Author 1 - Li Qinglin - Writing and editing.

Email: liqinglin20121@163.com

Author 2 - Li Xiaoning - Identify topics and make overall planning.

Author 3 - Mei Jilin - Review literature.

Author 4 - Ben Yuwei - Literature retrieval.

Email: byw8292@163.com

Author 5 - Zheng Xue - Literature retrieval.

Email: 2016341093@qq.com