

INPLASY PROTOCOL

To cite: Xiaoyu et al. Massage for constipation in patients with stroke: a systematic review and meta-analysis. Inplasy protocol 202040061. doi: 10.37766/inplasy2020.4.0061

Received: 12 April 2020

Published: 12 April 2020

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

Conflicts of interest:
None.

Massage for constipation in patients with stroke: a systematic review and meta-analysis

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Review question / Objective: Is massage effective for the number of bowel movements and the time for bowel movements after treatment for patients with constipation after stroke? How long can this effect be maintained? Has the quality of life of the patients improved?

Condition being studied: This article reviews randomized controlled trials of massage therapy for symptoms related to stroke patients with constipation, drug therapy, sham massage, and non-treatment. All participants were diagnosed with post-stroke constipation and received massage therapy. The main result of our study is the improvement and duration of the patient's overall symptoms. There are no restrictions on language and date..

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 April 2020 and was last updated on 12 April 2020 (registration number INPLASY202040061).

INTRODUCTION

Review question / Objective: Is massage effective for the number of bowel movements and the time for bowel movements after treatment for patients with constipation after stroke? How long can this effect be maintained? Has the quality of life of the patients improved?

Rationale: Massage, as one of the important external therapies in traditional Chinese medicine, has the function of adjusting viscera and promoting meridians and collaterals. It is not only effective in treating constipation after apoplexy, but also can avoid adverse drug reactions and adverse reactions of cross-medication.

However, there are few Meta-analysis kinds of literature published on the treatment of post-stroke constipation by massage.

Condition being studied: This article reviews randomized controlled trials of massage therapy for symptoms related to stroke patients with constipation, drug therapy, sham massage, and non-treatment. All participants were diagnosed with post-stroke constipation and received massage therapy. The main result of our study is the improvement and duration of the patient's overall symptoms. There are no restrictions on language and date.

METHODS

Search strategy: The published literature will be identified by searching PubMed, Embase, Cochrane Central Register of Controlled Trials and four Chinese databases (CNKI, CBM, Wangfang Data and VIP database) to identify any relevant study. The search strategy is developed by a medical librarian(JS) according to key terms from previous literature reviews. The detailed search strategy is attached(see online supplementary appendix 1). We will not apply any language or date restrictions.

Participant or population: Subjects included in the study should be eligible for a variety of cerebrovascular disease diagnostic criteria, or subjects included in the study were diagnosed with stroke by imaging studies as defined by the World Health Organization. At the same time, the subjects involved in the study were diagnosed with stroke and accompanied by symptoms of constipation. The diagnosis was based on the Rome II/III diagnostic criteria or the Chinese herbal medicine clinical research guide. No limitations on age, ethnicity or nationality were set.

Intervention: Patients in the treatment interventions were given massage therapy (such as massage, massage, acupressure, etc.) or massage combined with other therapies. No restrictions are imposed on times of treatment and length of the treatment period.

Comparator: Patients in the control interventions were given comfort therapy (placebo, false acupoint, fake massage, blank control, etc.) and other therapies (Western medicine, Chinese medicine/ Chinese patent medicine, non-drug therapy, etc.) were consistent with the treatment group.

Study designs to be included: All of the RCTs reporting the application of massage for constipation in patients with stroke were included.

Eligibility criteria: Massage as a clinical study of adjuvant treatment; patients with a history of constipation before stroke, or history of gastrointestinal or gastrointestinal disease surgery; diagnostic criteria are not clear or no diagnostic criteria; repeated publications; review literature; clinical cases Observations; cases, case tests, animals; documents that cannot be extracted from data.

Information sources: PubMed、Embase、The Cochrane Library、China national knowledge infrastructure (CNKI) China scientific journal database (VIP) 、China biomedical journal database (CBM) and Wang Fang Data. We will not apply any language or date restrictions.

Main outcome(s): The primary outcome was effectiveness. According to the efficacy judgment standard in the "Diagnostic and Efficacy Standards for TCM Syndrome", the effects of treatment on patients are divided into four levels: cure, marked effect, effective and ineffective. 1) Cure: During the 2 days of treatment, the patient has a bowel movement, the stool is transferred, the bowel movement is smooth, and the accompanying symptoms disappear. 2) Significant effect: During the treatment within 2 days of the patient's bowel movement, the stool is transferred, but the bowel movement is not smooth. The accompanying symptoms are relieved; 3) Effective: The patient has defecation within 3 days of the treatment, the stool is soft and dry, the bowel movement is not

smooth, and the accompanying symptoms are relieved; 4) Invalid: the symptoms of the patient after treatment No improvement. Total effective rate = (number of cases cured + number of effective cases + number of valid cases) / total number of cases × 100%.

Additional outcome(s): Secondary outcome measures include the proportion of patients with defecation time, interval between bowel movements, number of bowel movements, changes in stool characteristics, etc. Using standard defecation integral measurement, stool traits and defecation force were determined by Bristol stool trait classification, defecation labour force and linear visual analogue scale. Or use the “Constipation Symptoms and Efficacy Assessment Questionnaire” prepared by the Anorectal Surgery Group of the Chinese Medical Association Surgery Society in 2005. The questionnaire was divided into 6 aspects: difficulty in defecation; faecal traits; time of defecation; falling, incomplete, sensation; frequency of bowel movements; bloating scores were 0 to 3 points, the higher the score, the more severe the symptoms. We will sum up the number of adverse reactions or adverse events.

Data management: Secondary outcome measures include the proportion of patients with defecation time, interval between bowel movements, number of bowel movements, changes in stool characteristics, etc. Using standard defecation integral measurement, stool traits and defecation force were determined by Bristol stool trait classification, defecation labour force and linear visual analogue scale. Or use the “Constipation Symptoms and Efficacy Assessment Questionnaire” prepared by the Anorectal Surgery Group of the Chinese Medical Association Surgery Society in 2005. The questionnaire was divided into 6 aspects: difficulty in defecation; faecal traits; time of defecation; falling, incomplete, sensation; frequency of bowel movements; bloating scores were 0 to 3 points, the higher the score, the more

severe the symptoms. We will sum up the number of adverse reactions or adverse events.

Quality assessment / Risk of bias analysis: Two reviewers evaluated the bias risk of inclusion in the study according to the Cochrane Handbook for RCT bias risk assessment tools. If there is a disagreement, the discussion is resolved or judged by a third reviewer. The scope of the evaluation includes: 1 the application of the random method; 2 the allocation of hidden applications; 3 the implementation and whether the participants perform double-blind operation; 4 the final evaluation after clinical trials to apply blindness; 5 the integrity of the outcome data after clinical trials; Whether there is selective reporting; 7 there is no other risk of bias. The Cochrane Bias Risk Tool will make a risk judgment on the specific implementation process of the above seven aspects of the RCT included in the literature.

Strategy of data synthesis: RevMan 5.3 software from the Cochrane Collaboration A meta-analysis of the included studies. Continuity variable Weight mean difference (MD) and its 95% confidence interval (CI) representation; Number data selection risk ratio (RR) and its 95% CI representation $P < 0.05$ was statistically significant. Cochrane Q used in each study Test for heterogeneity test and combine I^2 to assess the large heterogeneity small. When $P \geq 0.1$ and $I^2 < 50\%$, it indicates that the studies do not exist. Statistical heterogeneity, using a fixed-effect model; The machine effect model performs a meta-analysis. Obvious clinical heterogeneity Use subgroup analysis or sensitivity analysis to process, or only Descriptive analysis. Use the inverted funnel chart to determine whether there is a publication bias Rely on. The test level for the meta-analysis is set to $\alpha = 0.05$.

Subgroup analysis: We will perform the following subgroup analysis to study heterogeneity when there is sufficient data. We will perform subgroup analysis based on age, gender, type of stroke (hemorrhagic and ischemic stroke), different definitions of constipation, stages

of stroke (acute, subacute or chronic), type of massage (abdomen, limbs, etc.) and controls Type of group (placebo, fake massage, no treatment or other active treatment or medication). A subgroup analysis based on different dietary groups takes into account that eating habits may play a role, and habits are playing an important role in the development of constipation. The intervention effect was analyzed using the χ^2 test, with $p < 0.05$, indicating a statistically significant difference between the subgroups.

Sensibility analysis: We will conduct sensitivity analysis to explore the possible reasons for the increase in heterogeneity, such as (length of time or quality of massage treatment) if the quantitative synthesis is not appropriate, we will conduct qualitative description.

Language: None.

Country(ies) involved: China.

Keywords: Massage, constipation, stroke, meta-analysis, systematic review

Contributions of each author:

Author 1 - Author 1 drafted the manuscript.
Author 2 - Author 2 literature selection and information extraction.
Author 3 - Author 3 literature selection and information extraction
Author 4 - Author 4 review the accuracy of literature information and information extraction.
Author 5 - Author 5 designed the search strategy.
Author 6 - Author 6 provided statistical expertise.
Author 7 - The author read, provided feedback and approved the final manuscript.
Author 8 - The author read, provided feedback and approved the final manuscript
Author 9 - The author read, provided feedback and approved the final manuscript