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Comparison of the efficacy and tolerability of different repetitive transcranial magnetic stimulation modalities for post-stroke dysphagia: a systematic review and Bayesian network meta-analysis protocol

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ABSTRACT

Introduction Up to 78% of patients who had a stroke develop post-stroke dysphagia (PSD), a significant consequence. Life-threatening aspiration pneumonia, starvation, and water and electrolyte abnormalities can result. Several meta-analyses have shown that repeated transcranial magnetic stimulation (rTMS) improves swallowing in patients who had a stroke; however, the optimum model is unknown. This study will be the first Bayesian network meta-analysis (NMA) to determine the best rTMS modalities for swallowing of patients who had a stroke.

Methods and analysis PubMed, Web of Science, Embase, Google Scholar, Cochrane, the Chinese National Knowledge Infrastructure, the Chongqing VIP Database and WanFang Data will be searched from their creation to 2 September 2023. All randomised controlled trials associated with rTMS for PSD will be included. Only Chinese or English results will be studied. Two researchers will independently review the literature and extract data, then use the Cochrane Collaboration's Risk of Bias 2.0 tool to assess the included studies' methodological quality. The primary outcome is swallowing function improvement, whereas secondary outcomes include side effects (eg, paraesthesia, vertigo, seizures) and quality of life. A pairwise meta-analysis and NMA based on a Bayesian framework will be conducted using Stata and R statistical software. The Grading of Recommendations Assessment, Development, and Evaluation system will assess outcome indicator evidence quality.

Ethics and dissemination As all data in this study will be taken from the literature, ethical approval is not needed. We will publish our work in peer-reviewed publications and present it at academic conferences.

PROSPERO registration number CRD42023456386.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study will collect a wide range of evidence to assess the efficacy and tolerability of repetitive transcranial magnetic stimulation for post-stroke dysphagia.
⇒ The study's outcome indicators will be coupled with the subjective assessment scale and objective physiological index.
⇒ The Grading of Recommendations Assessment, Development, and Evaluation system will be implemented to assess the quality of the evidence.
⇒ Language bias may result from searching solely Chinese and English databases for literature.

INTRODUCTION

Stroke is the second leading cause of death and the third leading cause of disability worldwide,[1 2] with more than 17 million new cases reported each year.[3] The Global Burden of Disease Study 2019 showed that about 101 million people have a stroke worldwide, and the number of deaths due to stroke has reached 65.5 million.[4] Sequelae of varying degrees can occur after stroke, such as dyskinesia, cognitive impairment, dysphagia, speech disorder, anxiety, depression, fatigue and other symptoms, which cause a heavy burden on the lives of patients and their families.[5–8] Among them, post-stroke dysphagia (PSD) is a common and serious complication after stroke, and its incidence ranges from 37% to 78%.[6] About 20–43% of patients have persistent dysphagia after 3 months, mainly manifested as choking on drinking, unable to eat and can cause a variety of complications, such as aspiration pneumonia, malnutrition, and water and electrolyte disorders.[9] In severe cases, it may lead to asphyxia, thereby increasing the risk of death.[10] In addition, PSD can further lead to a series of psychological problems in patients, such as fear of

eating, anxiety, depression, among others, which cause serious distress to patients' psychology and daily lives.[11 12] However, these negative psychological states will in turn lead to the aggravation of PSD, which affects the recovery and quality of life of patients, thus forming a vicious circle.[13 14] It is worth noting that early screening, intervention and management of PSD have not received enough attention.[15 16] Consequently, the timely diagnosis and effective treatment of PSD have become urgent problems to be solved in clinical work.

The pathogenesis of PSD is quite complex, which may be related to damage to the swallowing cortical centre, descending cortical fibres, bulbar swallowing centre and extrapyramidal system.[17–20] At present, the clinical treatment methods for PSD are limited. Compensatory interventions based on diet and nutrition interventions combined with recovery interventions based on swallowing function rehabilitation training are widely used.[21 22] However, these therapies have problems such as inflated cost, long cycle and poor compliance, which are not conducive to clinical application.[23–25] Nevertheless, repetitive transcranial magnetic stimulation (rTMS), as a non-invasive treatment technique, can directly regulate the excitability of the swallowing cortex or promote the reorganisation of swallowing cortex function by generating evoked potentials through pulsed magnetic fields. It has the advantages of simple operation, being non-invasive, painless and having high safety, and it does not require the active cooperation of patients, which brings new opportunities for the treatment of PSD.[24 25]

There are various stimulation modalities for treating PSD with rTMS. It is believed that low-frequency rTMS (LF-rTMS) (≤1 Hz) can attenuate cortical excitability, while high-frequency rTMS (HF-rTMS) (>1 Hz) can enhance cortical excitability.[26 27] Consequently, previous studies usually used HF-rTMS (3 Hz, 5 Hz and 10 Hz) to stimulate (excite) the lesion side (the affected side) or LF-rTMS (1 Hz) to stimulate (inhibit) the non-lesion side (the healthy side) to improve the swallowing function of patients with PSD.[28–30] The selection of the above stimulation modality is dependent on the competitive cerebral hemisphere model. rTMS can enhance or inhibit the excitability of the contralateral cerebral hemisphere, reshape the balance between the two hemispheres and thus achieve the goal of restoring swallowing function after stroke.[31 32] In addition, some studies have shown that HF-rTMS of the contralateral cerebral cortex or bilateral cerebral cortex stimulation can also improve or even contribute to the recovery of swallowing function in patients with PSD. Some researchers have also shown that HF-rTMS of the opposite cerebral cortex or stimulation of both cerebral cortices can help patients with PSD swallow better or even get their swallowing back.[24 33–37] This may be related to functional reorganisation and compensation of the swallowing motor cortex function in the contralateral hemisphere.[38 39] As a result, there are significant debates about whether rTMS should be applied to the affected side, the healthy side or both sides, and whether LF-rTMS or HF-rTMS should be applied on this basis.

At present, many scholars have conducted evidence-based medical research on rTMS in the PSD.[40–42] Liao *et al* published a systematic review and meta-analysis in 2017, which confirmed that rTMS has a positive effect on PSD. Moreover, compared with LF-rTMS, HF-rTMS may be more beneficial to patients.[40] Tan *et al* also conducted a systematic review and meta-analysis in 2022 and found that rTMS has a long-term effect on the recovery of swallowing function after stroke.[41] Hsiao *et al* published a meta-analysis in 2023, which confirmed that both HF-rTMS on the affected side and LF-rTMS on the healthy side could improve the swallowing function of patients who had a stroke.[42] However, they are based on traditional meta-analysis methods, which can only achieve a direct comparison between two interventions and lack a comparison of the efficacy of different rTMS modalities. Network meta-analysis (NMA) can be used to compare the efficacy of different rTMS treatment regimens.

Consequently, this study will use the Bayesian NMA method to compare the efficacy of different rTMS modalities, rank their effectiveness and synthesise the results to obtain the best rTMS treatment regimens and provide reliable and comprehensive evidence for clinical treatment decisions in patients with PSD.

METHODS AND ANALYSES

Protocol design and registration

We plan to do a systematic review and NMA based on a Bayesian framework. This protocol was implemented according to the Preferred Reporting Item for Systematic Reviews and Meta-Analyses Protocol[43] and has been registered on PROSPERO (CRD42023456386). Any amendments to this agreement will be made through PROSPERO.

Inclusion criteria

Types of studies

Only randomised controlled trials (RCTs) presented in English or Chinese will be included in the study. Animal trials, meta-analyses, systematic reviews, abstracts, conference presentations, case reports and cohort studies will be excluded.

Types of participants

All participants will meet the following criteria: (1) patients with ischaemic or haemorrhagic stroke (including cerebral hemisphere and brain stem) diagnosed by CT, MRI and other related examinations, not limited to stroke stage; (2) patients with a final diagnosis of swallowing dysfunction on a clinical swallowing-related scale or by objective instrumental examination; and (3) adult patients (≥18 years old) regardless of gender, ethnicity, race and education level.

Types of interventions

The intervention of the experimental group may be rTMS treatment with different stimulation modalities. Based on

our previous literature search, rTMS treatment regimens may have a choice of five stimulation modalities. Among the stimulation modalities will mainly include LF-rTMS on the healthy side,[27 30] HF-rTMS on the affected side,[24 30 32 34 36 37] HF-rTMS on the healthy side,[32 33 35–37] HF-rTMS bilaterally[24 32 34 36 37] and LF-rTMS on the healthy side combined with HF-rTMS on the affected side.[44]

Types of control groups

The control group may be conventional rehabilitation therapy, sham stimulation therapy or another rTMS treatment regimen different from the experimental group.

Outcomes

The primary outcome will be improvement in swallowing function, which will be measured with a swallowing assessment scale and objective physiological measures of swallowing function. Among them, the Standardized Swallowing Assessment (SSA) and the Penetration Aspiration Scale (PAS) will be included in the subjective swallowing assessment. Objective swallowing measurements will include a videofluoroscopic swallowing study (VFSS) and surface electromyography (sEMG). The secondary outcomes will include quality-of-life measures such as the Swallowing Quality-of-Life Questionnaire and adverse events (including dizziness, headache, paraesthesia, seizures). The tolerability of the rTMS intervention will be evaluated by the occurrence of adverse events.

PAS is an indicator of food invasion into the airways. The score is between 1 and 8 points, with a higher score indicating a higher risk of aspiration and a greater degree of dysphagia.[45] The SSA is composed of three parts[46]: (1) the clinical examination mainly includes eight items such as consciousness level, head and trunk control, and lip control, with a total score of 8–23 points; (2) the patient is asked to swallow 5 mL of water three times, and the mouth is observed for running water, laryngeal movement, repeated swallowing, wheezing during swallowing and laryngeal function after swallowing, with a total score of 5–11 points; (3) if no abnormal manifestations are observed in the above examination, the patient is instructed to drink 60 mL of water. Observations are made to check whether the patient can consume all the water, if there is any coughing or wheezing during or after swallowing, if there is any laryngeal function impairment after swallowing and if there is any sign of aspiration. The total score is 5–12 points. The SSA scores range from 18 to 46, with higher scores indicating more severe dysphagia in the patient. sEMG can quantitatively evaluate the functional status of neuromusculars during swallowing, reflect the difficulty and duration of tongue–laryngeal complex elevation and predict the risk of aspiration in patients with dysphagia.[47] VFSS can evaluate the situation throughout the swallowing stage, dynamically observe the delivery of food and diagnose whether there is a hidden aspiration, which is recognised as the gold standard for the diagnosis of dysphagia.[48]

Exclusion criteria

We will refer to the following exclusion criteria: (1) non-RCTs, including cohort studies, case reports, meta-analyses, reviews and conference papers; (2) dysphagia not caused by stroke (eg, trauma, Parkinson's disease); (3) outcome indicators related to swallowing function were not reported; (4) repeated publication; and (5) full text cannot be obtained or data cannot be extracted.

Data sources and search strategy

We will search PubMed, Web of Science, Embase, Google Scholar, Cochrane, China National Knowledge Infrastructure, Chongqing VIP Database and WanFang Data from the database's inception to 2 September 2023. All RCTs related to rTMS for PSD will be included. The studies will be limited to results published in Chinese or English. The search terms will include "repetitive transcranial magnetic stimulation", "rTMS", "post-stroke dysphagia", "PSD" and other related terms. At the same time, we will conduct a secondary manual search of the references in the included literature and relevant systematic reviews to avoid missing important literature. In the case of PubMed, we will present the search strategy in detail in the online supplemental material.

Study selection

First, two researchers (LY and DZ) will use EndNote V.X9 software to eliminate duplicate literature, then they will conduct a preliminary screen of the literature by reading the title and abstract to exclude the articles that do not meet the inclusion criteria, and finally, they will evaluate the potentially qualified studies by reading the full text to determine the final included literature. In case of any disagreement, the third researcher (QX) will help to resolve the problem. We will present the entire literature screening process in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow chart,[43] and the detailed process is shown in figure 1.

Data extraction

After two researchers (LY and DZ) read the final included literature, the following data will be extracted separately: (1) basic information (first author, publication time, country, sample size, intervention measures); (2) patient information (mean age, gender, hemiplegic side of stroke, stroke stage, course of disease); (3) rTMS-specific parameters and treatment protocols (stimulation frequency, stimulation target, stimulation intensity, total number of pulses, coil type, treatment protocol and duration); and (4) outcome measures (data on each outcome and adverse event and follow-up time). In cases of disagreement, the third researcher (QX) will assist in resolution.

Risk-of-bias assessment

Two researchers (LY and DZ) will independently evaluate the literature that meets the inclusion criteria using the Risk of Bias 2.0 provided by Cochrane Collaboration.[49] It consists of the following five aspects: (1) bias in the randomisation process; (2) bias from the intended intervention;

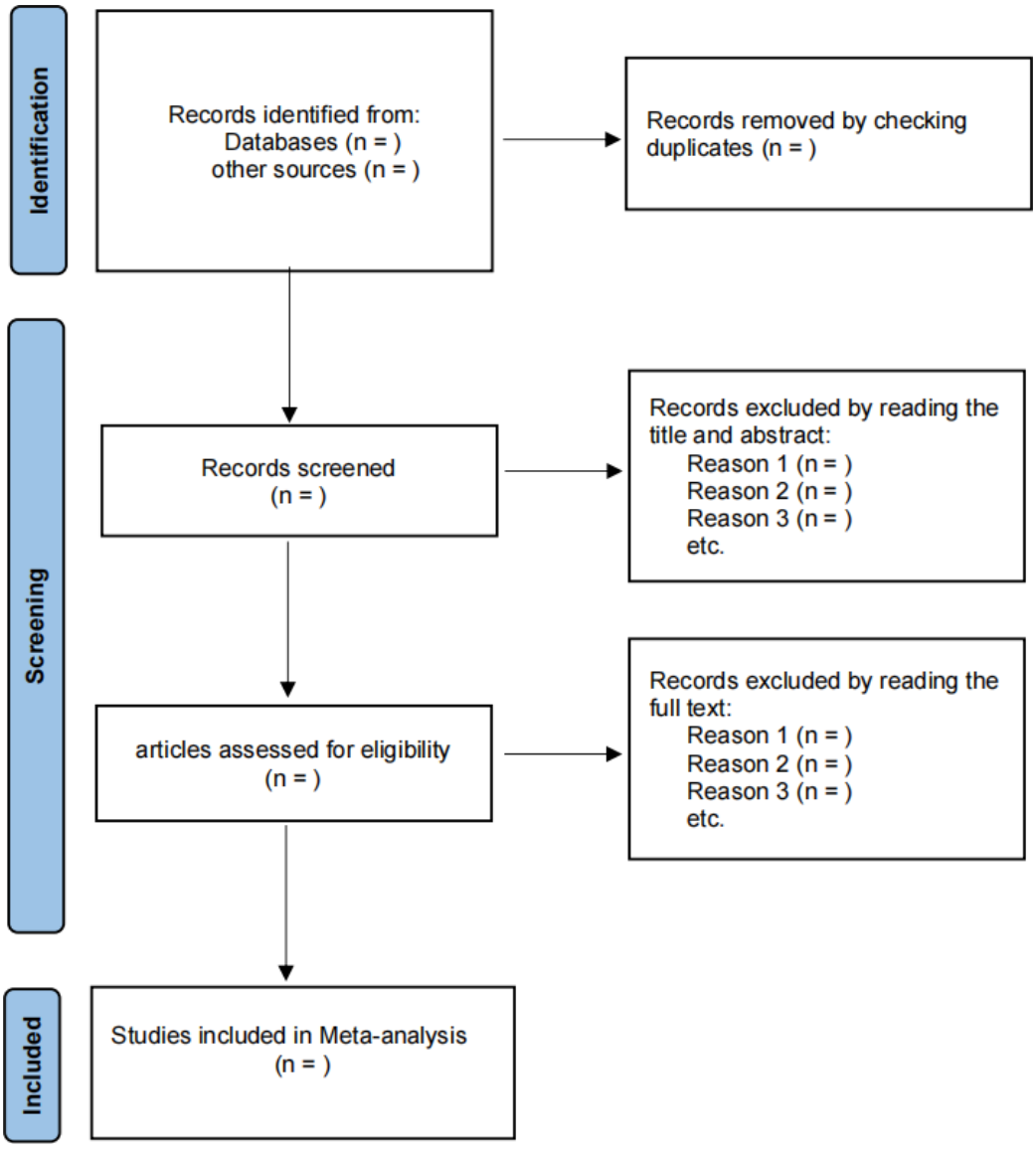

Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow chart of study selection.

(3) bias of missing outcome data; (4) outcome measurement bias and (5) bias of selective reporting. The degree of risk of bias was divided into 'low risk of bias', 'high risk of bias' and 'uncertain risk of bias'. The overall risk of bias in a study was determined by combining the level of bias for each item. In cases of disagreement, the third researcher (QX) will participate and reach a consensus.

Data synthesis and statistical analyses

Pairwise meta-analysis

Before performing the NMA, we will perform a standard pairwise meta-analysis using Stata V.14.2 (StataCorp, College Station, Texas, USA). X^2 test and I^2 statistic will be used to evaluate the heterogeneity of the studies. If $I^2 \leq 50\%$, indicating less heterogeneity, the fixed-effects model will be used for pooling. If $I^2 > 50\%$, indicating large heterogeneity, the random-effects model will be selected for pooling.[50] For continuous variables, the mean difference (MD) and its 95% CI will be used if the measurement instrument is the same. The standard MD and its 95% CI will be used if the measurement instrument is different. For dichotomous data, relative risk and its 95% CI will be used.

Network meta-analysis

We will perform a Bayesian NMA using Stata V.14.2 and R (V.4.1.2) (available at Index of/src/base/R-4 (r-project.org)). Stata V.14.2 will be used to draw a network plot for different stimulation modalities of rTMS. In addition, the efficacy of different rTMS modalities will be ranked according to the surface under the cumulative ranking curve provided by Stata V.14.2. We will use R (V.4.1.2) to perform Bayesian NMA of random-effects models and use the Markov Chain Monte Carlo algorithm for statistical calculation. Each model will use four Markov chains to set the initial values. The number of iterations will be 50 000: the first 20 000 will be used for annealing to eliminate the influence of the initial values and the last 30 000 will be used for sampling calculations.[51 52]

Assessment of similarity and consistency

Based on the selection of the above effect indicators, the principle of framework construction and the selection of statistical methods, R (V.4.1.0) software will be used to construct the consistency model and inconsistency model of Bayesian NMA and calculate their relevant results. R (V.4.1.0) software will be used to build the consistency model and the inconsistency model of Bayesian NMA and figure out their results. This is based on the choice of the above effect indicators, the framework construction principle and the statistical methods.[52] For the Bayesian NMA results of the generated consistency model and inconsistency model, we will use the Deviance Information Criterion (DIC) for global inconsistency detection. Significant global inconsistencies will be considered if the difference in DIC values between the two models is greater than one. For local inconsistency tests, if the outcome forms a closed-loop structure (including any pairwise direct comparisons), we will use node splitting to detect inconsistencies between direct and indirect comparisons. If there are any pairwise direct comparisons in the outcome of a local inconsistency test, we will use node splitting to find problems between direct and indirect comparisons if the structure is closed. Local inconsistency in the results will be considered at $p<0.05$; if the network diagram does not form a closed-loop structure, the inconsistency between the two results above will be determined directly by visual inspection. For the trace and density map and convergence diagnostics map generated by R (V.4.1.0), convergence diagnosis will be carried out through the Brooks-Gelman-Rubin method. If the potential scale reduced factor value is close to 1, it can be considered that the convergence is good, which will indicate that the statistical results are stable and credible.

Sensitivity analysis and subgroup analysis

When heterogeneity is significant, we will carefully read the original literature again to find whether there are significant clinical, methodological and statistical differences between studies.[53] We will further explore sources of heterogeneity by performing sensitivity analyses or subgroup analyses with the use of Stata V.14.2.[54]

Meta-regression analysis

If necessary, we will perform a meta-regression analysis of factors such as patient demographics that may contribute to heterogeneity between studies. If the meta-regression coefficient is $p<0.05$, it will be considered one of the sources of heterogeneity.[55]

Assessment of publication bias

If the number of included studies exceeds 10, we will assess small-study effects or the publication bias by the comparison-adjusted funnel plots generated and the results of Egger's test.[56 57]

Quality of evidence

The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) will be applied to evaluate the quality of evidence for all outcomes in the pairwise and network meta-analyses. Two researchers will import the data into GRADEprofiler software (GRADEpro, V.3.6.1) (available at www.gradeworkinggroup.org), respectively, to evaluate the quality of the evidence. The GRADE system will include five evaluation items: risk of bias, inconsistency, indirectness, precision and publication bias.[58] The level of evidence was graded as very low, low, moderate and high.[59]

Patient and public involvement

There will be no direct patient or public involvement in any aspect of this study.

Ethics and dissemination

As a literature-based systematic review and NMA, the data used in this study will all be extracted from pre-existing literature. Therefore, ethical approval is not required for this study. The findings will be submitted to peer-reviewed journals and disseminated at national/international academic conferences.

DISCUSSION

In recent years, with the development of brain imaging technology and non-invasive nerve stimulation technology, as well as the understanding of the neurophysiological characteristics of swallowing, rTMS has become one of the methods for the treatment of PSD. Many studies have confirmed the effectiveness of rTMS in the treatment of dysphagia and its superiority over other techniques.[42 60 61] The guideline for the diagnosis and treatment of PSD published by the European Stroke Organisation and European Society also recommends rTMS for PSD and suggests that it is more beneficial in combination with conventional swallowing therapy.[62] However, there is no unified standard for the selection of stimulation modalities when rTMS is used to treat PSD. In addition, there is no clear evidence-based medical evidence to support which stimulation modalities has the best effect. To some extent, these will lead to controversy and confusion in clinical application and hinder the process of recovery of patients with dysphagia after stroke.

This study conducted a comprehensive and quantitative analysis of the published literature data by the method of NMA to explore the effectiveness of different rTMS modalities, and to provide a basis for the comprehensive prevention and treatment of stroke dysphagia. Nonetheless, the study has several limitations: First, the severity, stage and lesion location of patients who had a stroke in this study were not uniform, and the effect of heterogeneity cannot be fully excluded. Second, the languages of the included articles were limited to Chinese and English, which may leave out valuable literature. Finally, the ranking of results based on NMA is only a statistical and methodological reference, due to the method itself still having some defects and limitations of application, the

choice of rTMS should still be used in conjunction with the specific conditions of patients in the clinical process.

To the best of our knowledge, the present study will be the first systematic review and Bayesian NMA to compare the efficacy and tolerability of different rTMS modalities for PSD. The results of this study will help physicians and patients choose the optimal rTMS treatment and provide the latest theoretical basis for the rehabilitation application of rTMS in PSD.

Contributors QC conceived the original idea and initiated this protocol. HB was responsible for quality control and review of the articles. LY, DZ and QX participated in literature screening and literature extraction. The manuscript was prepared and written by QC and MK. XJ and LY collaborated on the revision of the paper. HL and MK conducted data analysis. All authors read and agreed to publish the protocol.

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