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Meta Analysis of the Therapeutic Effect of Repetitive Transcranial Magnetic Stimulation on Gait and Limb Balance Ability in Patients with Lower Limb Dysfunction after Cerebral Infarction

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ADMINISTRATIVE INFORMATION

Support - The author(s) received no financial support for the research.

Review Stage at time of this submission - Piloting of the study selection process.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 April 2024 and was last updated on 27 April 2024.

INTRODUCTION

Review question / Objective To systematically evaluate the effects of different stimulation parameters and stimulation sites on the therapeutic effect of rTMS on lower limb motor dysfunction and limb balance ability after stroke, and find reasonable and effective stimulation sites andparameters.

Condition being studied Current research suggests that both low-dose and high-dose rTMS can improve the prognosis of gait and limb balance after stroke. However, different stimulation parameters and sites have an important impact on the prognosis of gait and limb balance ability after rTMS treatment of post-stroke cerebral infarction. It has not been reported so far on how to choose the stimulation site and parameters.

METHODS

Participant or population Participants: diagnosis stroke.

Intervention rTMS and their advanced variants.

Comparator Sham group.

Study designs to be included included published RCTs (individual-designed, cluster-designed, or the first half of crossover).

Eligibility criteria In accordance with the PICOS approach [18],the inclusion criteria were as follows: (a) participants: diagnosis stroke;(b) intervention: rTMS and their advanced variants; (c)comparator: sham group; (d) outcomes: pre- and post-interventional assessments of gait velocity, balance and/or lower limb motor function; (e) study design: included published RCTs (individual-designed, cluster-designed, or the first half of crossover). We excluded studies on the acute effects of a single session on Stroke, and studies that did not clearly describe the targeted stimulation location of rTMS, resting motor threshold, pulses per session. Unavailability of means and standard deviations in

the results or if authors did not reply to our request for data.

Information sources We performed a systematic search in the PubMed, MEDLINE, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), and Web of Sciencedatabases from the date of their inception to June 18, 2024.

Main outcome(s) Pre- and post-interventional assessments of gait velocity, balance and/or lower limb motor function.

Quality assessment / Risk of bias analysis The risk of bias for each individual study was assessed independently by researchers using the using the Cochrane Risk of Bias version 2 tool (RoB2) , including five domains: randomisation process; deviations from intended interventions; missing outcome data; outcome measurement; and selection of reported results.For cluster randomized controlled trials, the RoB 2.0 tool uses an additional domain to assess risk of bias due to the timing of identifying and recruiting participants [20], in addition to the five domains above. Each area was assessed as (1) high risk, (2) low risk and (3) some concern. For each study, if all domains showed low risk, the overall risk of bias was low; if any of the above domains showed high risk, or the assessment results of multiple domains showed some concern, the overall risk of bias was high; otherwise, Overall risk of bias was low. Disagreements were resolved by consensus among reviewers or in consultation with a third reviewer.

Strategy of data synthesis To determine the effectiveness of rTMS on gait velocity, balance and lower limb motor function. Missing standard deviations (SDs): When standard errors (SEs) instead of SDs were presented, the former was converted to SDs: ($SD=SE\sqrt{n}$). If both were missing, we estimated the SD from confidence intervals (CI), t values, or p values as described in Section 7.7.3 of the Cochrane Handbook for Systematic Reviews [21].The amount of baseline and post change between the experimental group and control group were calculated by the following formula: Meanchange= Meanpost– Meanbaseline; $SDchange=\sqrt{(SDbaseline^2+SDpost^2-2*R*SDbaseline*SDpost)}$, where R is a constant (R=0.5)[22].Cohen's criteria were used to interpret the magnitude of SMDbs: 0.8, large[23].We used contour-enhanced funnel plots for gait velocity, balance and lower limb motor function to investigate the presence of a small study effect. Based on the rTMS types, dosage (pulses/session, total session, resting motor threshold (%)), and stimulation site, a random effect meta regression and subgroup analysis was performed to examine whether rTMS-specific variables influence the efficacy of rTMS on gait velocity, balance, and lower limb motor function in stroke patients. Data analysis was achieved based on the R statistical environment (V.4.32, http://www.r-project.org). The measured effects were considered significant at $p<0.05$. Data are reported as standard mean difference (SMD) and 95% credible intervals (CrIs).

Subgroup analysis Subgroup analysis is being conducted that when the stimulation site was the non-motor cortex area (left dorsolateral prefrontal cortex projection area) and the motor cortex of affected.

Sensitivity analysis Sensitivity analysis was achieved based on the R statistical environment (V.4.32, http://www.r-project.org).

Country(ies) involved China/Dali Bai Autonomous Prefecture People's Hospital.

Keywords Stroke; Lower limb motor dysfunction; Repetitive transcranial magnetic stimulation; Meta analysis.

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