

Effectiveness of rehabilitation training combined with acupuncture on aphasia after cerebral hemorrhage

A systematic review protocol of randomized controlled trial

Xin-shu Dong, MM^a, Guang-fu Song, MM^b, Cheng-ji Wu, MM^{c,*}, Chun-yin Zou, MM^c, Guang-tao Sun, MM^c, Zuo-yi Huang, MM^c

Abstract

Background: This study aims to systematically evaluate the effectiveness of rehabilitation training (RT) combined with acupuncture on aphasia after cerebral hemorrhage (CH).

Methods: PUBMED, Cochrane Central Register of Controlled Trials, EMBASE, Web of Science, Ovid, Cumulative Index to Nursing and Allied Health Literature, Allied and Complementary Medicine Database, Chinese Biomedical Literature Database, and China National Knowledge Infrastructure will be searched to identify any potential studies from inception to March 1, 2019, without language restrictions. All randomized controlled trials and case-controlled studies assessing the effectiveness of RT combined with acupuncture for the treatment of aphasia following CH will be included in this study. Cochrane risk of bias tool will be used to determine the methodological quality for included studies. RevMan 5.3 software (Cochrane Community, London, UK) will be utilized to perform statistical analysis.

Results: This study will systematically evaluate the effectiveness of RT and acupuncture for aphasia post CH. Primary outcome includes aphasia, which can be measured by Aachen Aphasia Test or Communicative Activity Log or other related scales. Secondary outcomes consist of speech performance, as assessed by Western Aphasia Battery-Revised; measure of skill in Supported Conversation scales; measure of Participation in Conversation scales; types of strategies used in conversation; occurrence and repair of conversation breakdowns; as well as any adverse events.

Conclusion: The results of this study will provide present evidence on assessing effectiveness of RT and acupuncture after CH.

Dissemination and ethics: The findings of this study are expected to be published in peer-reviewed journals. It does not require ethical approval, because no individual data will be utilized in this study.

Systematic review registration: PROSPERO CRD42019131587.

Abbreviations: CH = cerebral hemorrhage, CIs = confidence intervals, RCTs = randomized controlled trials, RT = rehabilitation training.

Keywords: acupuncture, aphasia, cerebral hemorrhage, effectiveness, rehabilitation training

X-SD and G-FS contributed equally to this study.

This work has been supported by Heilongjiang University Student Innovation Training Project (No. 201810222032), and Heilongjiang Provincial Health and Family Planning Commission Funded Project (No. 2016-316). The financial supporter will not involve any parts of this study.

The authors have no conflicts of interest.

^a Rehabilitation Unit of Fourth Department of Neurology, ^b Brain Surgery Unit of Fourth Department of Neurology, ^c Fourth Department of Neurology, First Affiliated Hospital of Jiamusi University, Jiamusi, China.

* Correspondence: Cheng-ji Wu, Fourth Department of Neurology, First Affiliated Hospital of Jiamusi University, No. 348 Dexiang Street, Jiamusi 154002, China (e-mail: chengji7185@yeah.net).

Copyright © 2019 the Author(s). Published by Wolters Kluwer Health, Inc. This is an open access article distributed under the Creative Commons Attribution License 4.0 (CCBY), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Medicine (2019) 98:24(e16006)

Received: 17 May 2019 / Accepted: 17 May 2019

<http://dx.doi.org/10.1097/MD.00000000000016006>

1. Introduction

Cerebral hemorrhage (CH) is a very common disease in the neurosurgery department.^[1-3] Its incidence ranges from 50.6 to 80.7 per 100,000 people, which accounts for 18.8% to 47.6% of all acute cerebrovascular diseases among Chinese population.^[4] The high rates of mortality and disability, as well as the high financial burden are associated with this disorder.^[5-8] In addition, most survivors suffer from server impairments, such as limbs paralysis or weakness, depression, bladder or bowel disorders, and aphasia.^[9-20] Therefore, timely and effective managements are very important for the CH survivors.

Many managements are reported to treat CH survivors effectively, such as medications, supportive care, surgery, physical therapy, acupuncture, rehabilitation training (RT), and any other therapies,^[21-24] especially for CH survivors with aphasia. Several clinical trials have reported that acupuncture and RT can treat CH survivors with aphasia and have achieved promising effectiveness.^[25-32] However, no study systematically

assesses the effectiveness of acupuncture and RT for aphasia following CH.

2. Methods and analysis

2.1. Study registration

This study has already completed registration on PROSPERO (CRD42019131587). It will comply with the preferred reporting items for systematic reviews and meta-analyses (PRISMA) protocol statement guidelines.

2.2. Eligibility criteria for study selection

2.2.1. Participants/population. Patients with aphasia after CH will be included without any limitations, such as gender, age, and so on. However, we will exclude studies with aphasia before CH, or caused by any other disorders.

2.2.2. Interventions/exposure. Any types of acupuncture combined RT will be used as only treatment for patients in the experimental group.

The control group can receive any treatments except acupuncture or RT alone or combination.

2.2.3. Study types. All randomized controlled trials (RCTs) and case-controlled studies (CCS) assessing the effectiveness of RT combined with acupuncture for aphasia after CH will be considered for inclusion in this study. However, any other studies except the RCTs or CCSs will not be considered in this study.

2.2.4. Outcome measurements. Primary outcome of aphasia will be measured by Aachener Aphasia Test or Communicative Activity Log or other related scales. Secondary outcomes include speech performance, as assessed by Western Aphasia Battery-Revised; measure of skill in Supported Conversation scales; measure of Participation in Conversation scales; types of strategies used in conversation; occurrence and repair of conversation breakdowns, as well as any adverse events.

2.3. Literature search

We will search the following literature sources from their inception to the April 1, 2019, without any language restrictions: PubMed, Cochrane Central Register of Controlled Trials, EMBASE, Web of Science, Ovid, Cumulative Index to Nursing and Allied Health Literature, Allied and Complementary Medicine Database, Chinese Biomedical Literature Database, and China National Knowledge Infrastructure. In addition, we will also search Google scholar, clinical registry, reference lists of all relevant reviews and eligible studies, and conference proceedings. All RCTs and CCS on assessing the effectiveness of RT combined with acupuncture for the treatment of aphasia following CH will be considered. The detailed strategy of PubMed is summarized in Table 1. The equivalent search strategies will be utilized to other electronic databases.

2.4. Study selection

Two authors will independently scrutinize the titles or abstracts initially for all literature records first. Then, full texts will be reviewed carefully based on the predefined eligibility criteria. The

Table 1

Search strategy for PubMed database.

Number	Search terms
1	Cerebral hemorrhage
2	Intracerebral hemorrhage
3	Hemorrhagic stroke
4	Hemorrhagic apoplexy
5	Intracranial hemorrhage
6	Putamen hemorrhage
7	Cerebral bleeding
8	Or 1–7
9	Aphasia
10	Language disorder
11	Or 9–10
12	Acupuncture
13	Electroacupuncture
14	Manual acupuncture
15	Fire needling
16	Warm needling
17	Scalp acupuncture
18	Auricular acupuncture
19	Or 12–18
20	Rehabilitation training
21	Rehabilitation education
22	Physical therapy
23	Or 20–22
24	8 and 11 and 19 and 23

results of the study selection in this study will be reported in the flowchart and will follow PRISMA guidelines with detailed reasons of exclusion for each study. A third author will resolve any disagreements between 2 reviewers.

2.5. Data extraction and management

Two authors will extract following information from each included study and will save all data in a data extraction sheet: general information (first author, published year, region, age, sex, ethnicity, disease types); relevant study methods (sample size, randomization, allocation, and blinding); interventions methods (details of interventions, including dosage, frequency, treatment duration); and outcome measurements (primary and secondary outcomes, adverse events, and any others). Any divergences between 2 authors will be resolved by a consensus or arbitration with a third author.

2.6. Dealing with missing data

The primary authors will be contacted to acquiring the insufficient or missing data if any of them arise. If we are not able to obtain those data, we will just analyze the available data, and also will discuss its potential impact in the Discussion section.

2.7. Risk of bias assessment

Cochrane risk of bias tool will be used to evaluate the risk of bias assessment for all eligible studies. It assesses each study through 7 aspects and is classified into 3 levels of low, unclear, and high risk of bias. Two reviewers will independently assess each study, and a third reviewer will involve solving any divergences between 2 reviewers in this study.

2.8. Reporting bias

Funnel plot and Egger regression test will be carried out to check if there is any reporting bias when more than 10 studies are entered in this study.

2.9. Statistical analysis

RevMan 5.3 software will be applied to conduct statistical analysis. All continuous data will be presented as mean difference or standardized mean difference with 95% confidence intervals. All the dichotomous data will be showed as risk ratio with 95% confidence intervals.

We will use I^2 test to check any heterogeneity among included studies. $I^2 \leq 50\%$ means that acceptable heterogeneity is identified, and a fixed-effect model is used for data pooling. Otherwise, it means that high heterogeneity is found, and a random-effect model is used for data pooling. Under this situation, we will also carry out subgroup analysis based on the different types of treatments, control interventions, and outcome measurements. If there is still very high heterogeneity, data will not be pooled, and meta-analysis will not be carried out for reports of outcome results. Instead, we will report all outcome results as narrative summary. Moreover, we will also carry out sensitivity analysis to check robustness and stability of pooled results by removing low-quality studies.

3. Discussion

This study will systematically assess the effectiveness and safety of acupuncture combined with RT for the treatment of aphasia following CH. Although several clinical trials have reported that acupuncture combined with RT can effectively treat aphasia after CH, no study has systematically explored this issue. Therefore, in this study, we will first evaluate the effectiveness and safety of acupuncture and RT for the treatment of patients with aphasia after CH. The results of this study will provide most current evidence on assessing effectiveness of acupuncture and RT on aphasia following CH.

Author contributions

Conceptualization: Xin-shu Dong, Guang-fu Song, Cheng-jie Wu, Chun-yin Zou, Guang-tao Sun.

Data curation: Xin-shu Dong, Guang-fu Song, Cheng-jie Wu, Chun-yin Zou, Guang-tao Sun, Zuo-yi Huang.

Formal analysis: Xin-shu Dong, Guang-fu Song, Cheng-jie Wu, Chun-yin Zou, Guang-tao Sun.

Funding acquisition: Xin-shu Dong.

Investigation: Cheng-jie Wu, Chun-yin Zou.

Methodology: Xin-shu Dong, Guang-fu Song, Guang-tao Sun, Zuo-yi Huang.

Project administration: Cheng-jie Wu.

Resources: Xin-shu Dong, Chun-yin Zou, Guang-tao Sun, Zuo-yi Huang.

Software: Guang-fu Song, Guang-tao Sun.

Supervision: Cheng-jie Wu.

Validation: Xin-shu Dong, Chun-yin Zou, Zuo-yi Huang.

Visualization: Xin-shu Dong, Chun-yin Zou, Guang-tao Sun, Zuo-yi Huang.

Writing – original draft: Xin-shu Dong, Guang-fu Song, Cheng-jie Wu, Guang-tao Sun, Zuo-yi Huang.

Writing – review & editing: Xin-shu Dong, Guang-fu Song, Cheng-jie Wu, Chun-yin Zou, Guang-tao Sun, Zuo-yi Huang.

References

- [1] Hu W, Xin Y, Chen X, et al. Tranexamic acid in cerebral hemorrhage: a meta-analysis and systematic review. *CNS Drugs* 2019;33:327–36.
- [2] Song GF, Wu CJ, Dong SX, et al. Rehabilitation training combined acupuncture for limb hemiplegia caused by cerebral hemorrhage: a protocol for a systematic review of randomized controlled trial. *Medicine (Baltimore)* 2019;98:e14726.
- [3] Qureshi AI, Ezzeddine MA, Nasar A, et al. Prevalence of elevated blood pressure in 563,704 adult patients with stroke presenting to the ED in the United States. *Am J Emerg Med* 2007;25:32–8.
- [4] Liu M, Wu B, Wang WZ, et al. Stroke in China: epidemiology, prevention, and management strategies. *Lancet Neurol* 2007;6:456–64.
- [5] Brodefiek J, Connolly S, Feldmann E, et al. Guidelines for the management of spontaneous intracerebral hemorrhage in adults. *Stroke* 2007;38:2001–23.
- [6] Krishnamurthi RV, Feigin VL, Forouzanfar MH, et al. Global and regional burden of first-ever ischaemic and haemorrhagic stroke during 1990-2010: findings from the Global Burden of Disease Study 2010. *Lancet Glob Health* 2013;1:259–81.
- [7] Rennert RC, Signorelli JW, Abraham P, et al. Minimally invasive treatment of intracerebral hemorrhage. *Expert Rev Neurother* 2015;15:919–33.
- [8] Adeoye O, Broderick JP. Advances in the management of intracerebral hemorrhage. *Nat Rev Neurol* 2010;6:593–601.
- [9] Seo JS, Yang HS, Jung S, et al. Effect of reducing assistance during robot-assisted gait training on step length asymmetry in patients with hemiplegic stroke: a randomized controlled pilot trial. *Medicine (Baltimore)* 2018;97:e11792.
- [10] Kim BR, Kang TW. The effects of proprioceptive neuromuscular facilitation lower-leg taping and treadmill training on mobility in patients with stroke. *Int J Rehabil Res* 2018;41:343–8.
- [11] Klein CS, Power GA, Brooks D, et al. Neural and muscular determinants of dorsiflexor weakness in chronic stroke survivors. *Motor Control* 2013;17:283–97.
- [12] Kirkevold M, Kildal Bragstad L, Bronken BA, et al. Promoting psychosocial well-being following stroke: study protocol for a randomized, controlled trial. *BMC Psychol* 2018;6:12.
- [13] Chun HY, Whiteley WN, Dennis MS, et al. Anxiety after stroke: the importance of subtyping. *Stroke* 2018;49:556–64.
- [14] Tekeoğlu Y, Adak B, Göksoy T. Effect of transcutaneous electrical nerve stimulation (TENS) on Barthel Activities of Daily Living (ADL) index score following stroke. *Clin Rehabil* 1998;12:277–80.
- [15] Guo GY, Kang YG. Effectiveness of neuromuscular electrical stimulation therapy in patients with urinary incontinence after stroke: a randomized sham controlled trial. *Medicine (Baltimore)* 2018;97:e13702.
- [16] Marinelli L, Balestrino M, Mori L, et al. A randomised controlled cross-over double-blind pilot study protocol on THC:CBD oromucosal spray efficacy as an add-on therapy for post-stroke spasticity. *BMJ Open* 2017;7:e016843.
- [17] Harari D, Norton C, Lockwood L, et al. Treatment of constipation and fecal incontinence in stroke patients: randomized controlled trial. *Stroke* 2004;35:2549–55.
- [18] Palmer R, Witts H, Chater T. What speech and language therapy do community dwelling stroke survivors with aphasia receive in the UK? *PLoS One* 2018;13:e0200096.
- [19] Vuksanović J, Milovanović T, Konstantinović L, et al. Effect of type of language therapy on expressive language skills in patients with post-stroke aphasia. *Int J Lang Commun Disord* 2018;53:825–35.
- [20] Hu XY, Zhang T, Rajah GB, et al. Effects of different frequencies of repetitive transcranial magnetic stimulation in stroke patients with non-fluent aphasia: a randomized, sham-controlled study. *Neurol Res* 2018;40:459–65.
- [21] Cai Gf, Shang L, Liu K, et al. Remodeling of cross electro-nape-acupuncture on cough reflex in patients with tracheotomy after cerebral hemorrhage: a randomized controlled trial. *Zhongguo Zhen Jiu* 2015; 35:3–6.
- [22] Zhang Y, Chen WA. Effect of minimally invasive surgery on the blood-brain barrier in patients with cerebral hemorrhage. *J Neurosurg Sci* 2016;60:18–20.
- [23] Seguin P, Laviolle B, Dahyot-Fizelier C, et al. Effect of oropharyngeal povidone-iodine preventive oral care on ventilator-associated pneumonia in severely brain-injured or cerebral hemorrhage patients: a multicenter, randomized controlled trial. *Crit Care Med* 2014;42:1–8.

- [24] Huhtakangas J, Tetri S, Juvela S, et al. Effect of increased warfarin use on warfarin-related cerebral hemorrhage: a longitudinal population-based study. *Stroke* 2011;42:2431–5.
- [25] Yuan P, Bao CL, Dong GR. Clinical safety research of penetrating acupuncture at the head points for cerebral hemorrhage at the acute stage. *Zhongguo Zhen Jiu* 2012;32:577–81.
- [26] Wei CH. Analysis of nursing effect of rehabilitation nursing intervention on patients with stroke aphasia. *Pract J Clin Nurs* 2018;3:132.
- [27] Kong HT. Observation on the therapeutic effect of acupuncture and moxibustion combined with language rehabilitation training on stroke aphasia. *Pract Chin Med J* 2018;34:359.
- [28] Huang H. Language rehabilitation training and nursing intervention for patients with stroke and aphasia. *China Mod Pharm Appl* 2016;10:256–7.
- [29] Cui LJ. Early rehabilitation nursing experience of patients with acute stroke. *Liaoning J Trad Chin Med* 2015;42:1987–8.
- [30] Wang Ht, Chen F. Therapeutic effect of three-needle therapy combined with language rehabilitation training on stroke aphasia. *J Pract Med* 2015;31:482–4.
- [31] Shi XY, Fang JR. Clinical observation of 58 patients with aphasia after stroke. *Med Inform* 2006;9:1653–4.
- [32] He YL. Treatment of 83 cases of language disorder by acupuncture at tongue point. *Henan Trad Chin Med* 1993;13:143–4.