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Acupuncture for hearing loss after traumatic brain injury
A protocol for systematic review of randomized controlled trial

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Abstract

Background: This study aims to systematically assess the effectiveness and safety of acupuncture on hearing loss (HL) after traumatic brain injury (TBI).

Methods: In this study, the following databases will be retrieved from inception up to the May 1, 2019: PUBMED, EMBASE, Cochrane Library, Cumulative Index to Nursing and Allied Health Literature, Allied and Complementary Medicine Database, and Chinese Biomedical Literature Database. All databases will be retrieved without any language restrictions. Two reviewers will independently carry out article selection, data collection, and risk of bias evaluation. Any disagreements will be solved by a third reviewer through discussion.

Results: This study will systematically investigate the effectiveness and safety of acupuncture for treating HL after TBI through evaluating HL assessment, hearing threshold, quality of life, and adverse events.

Conclusion: The expected findings of this study will provide latest evidence for assessing the effectiveness and safety of acupuncture for HL after TBI.

Ethics and dissemination: This study is supposed to be published in a peer-reviewed journal. No ethical approval is needed because this study will based on the literature analysis, but not the individual patient.

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Abbreviations: CIs = confidence intervals, HL = hearing loss, RCTs = randomized controlled trials, TBI = traumatic brain injury.

Keywords: acupuncture, effectiveness, hearing loss, randomized controlled trial, safety, traumatic brain injury

1. Introduction

Traumatic brain injury (TBI) is a very important factor which can cause death or disability worldwide.[1–3] It has been estimated that >40% of patients were hospitalized as a result of TBI.[4,5] Its

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prevalence rates vary from 3.2 to 5.3 million in the United States.[4,5] Many studies have reported that many factors can cause TBI, including motor vehicle accidents, fall from heights, and blunt trauma.[2,6–10] Such disorder can result in long-term disability of cranial nerve deficit, headache, behavioral changes, hemiparesis, and hearing loss (HL).[11–22]

Previous studies have reported that acupuncture can treat HL effectively, including HL caused by TBI.[23–27] However, presently, no study has systematically assessed its effectiveness and safety for the treatment of TBI patients with HL. Thus, this study aims to explore the effectiveness and safety of acupuncture for the treatment of HL caused by TBI.

2. Methods

2.1. Inclusion criteria for study selection

2.1.1. Type of studies. This study will consider all associated randomized controlled trials (RCTs) of acupuncture for HL after TBI. However, all other studies, except RCTs, will be excluded.

2.1.2. Type of participants. This study will consider all patients who are clinically diagnosed with HL after TBI without any restrictions of age, sex, and race.

2.1.3. Type of interventions. The patients in the experimental group can utilize acupuncture alone. Any combinations of acupuncture with other treatments will not be considered.

The patients in the control group can use any treatments, except any forms of acupuncture.

2.1.4. Type of outcomes. The primary outcome includes HL. It can be measured by any scales or tools, such as Brock grade, acceptable noise level test. The secondary outcomes consist of hearing threshold, as assessed by pure-tone audiometry, speech audiometry, or any other relevant tools; and quality of life, as measured by any associated scales, such as 36-Item Short Form Health Survey or others. In addition, we will also assess recorded adverse events.

2.2. Search strategy

The following electronic databases will be retrieved from inception up to May 1, 2019: PUBMED, EMBASE, Cochrane Library, Cumulative Index to Nursing and Allied Health Literature, Allied and Complementary Medicine Database, and Chinese Biomedical Literature Database without any language restrictions. The detailed strategy of PUBMED is shown in Table 1. Similar strategies will be used to any other electronic databases.

In addition, this study will also retrieve clinical trial registry, dissertations, and reference lists of all included studies.

2.3. Data collection and management
2.3.1. Study selection.
Two reviewers will independently scan the titles and abstracts for all identified literatures.

All irrelevant studies will be excluded at the first stage. After that, all remaining studies will be read by full texts at second stage. The whole process of study selection will abide to the predefined study eligibility criteria. Its results will be presented in the flowchart of Preferred Reporting Items for Systematic Review and Meta-analysis with detailed reason for each excluded study at each stage.

2.3.2. Data collection. After selection, data will be collected from each eligible study based on the previous designed data collection sheet. Two reviewers will independently collect data.

Table 1
Search strategy applied in PUBMED database.

Number	Search terms
1	Traumatic brain injury
2	Brain injury
3	Head injury
4	Or 1–3
5	Hearing loss
6	Hearing loss, sensorineural
7	Hearing loss, sudden
8	Sudden deafness
9	Hearing impairment
10	Sensorineural hearing loss
11	Or 5–10
12	Acupuncture
13	Electro-acupuncture
14	Or 12–13
16	Randomized controlled trial
17	Controlled clinical trial
18	Randomly
19	Randomized
20	Trial
21	Placebo
22	Or 16–21
23	4 and 11 and 14 and 22

Any disagreements will be resolved by a third reviewer through discussion. The collected information comprise of general information, such as title, first author, location, among others; patient characteristics, such as age, sex, and so on; study methods, such as randomization, blinding, and so on; treatment details, such as dosage, frequency, and so on; outcomes, such as primary, secondary outcomes, and so on.

If some essential information is missing or insufficient, we will contact primary authors by email and request those data. If we cannot achieve those data, we will only analyze available data.

2.3.3. Risk of bias assessment. In this study, we will use Cochrane risk of bias tool for the risk of bias assessment. It consists of 7 aspects, and each aspect is divided as high risk of bias, unclear risk of bias, and low risk of bias. Two reviewers independently assess all risk of bias for each eligible study. A third reviewer will judge any divergences regarding the risk of bias assessment between two reviewers.

2.4. Data synthesis and analysis
2.4.1. Measurement of treatment effect.
For continuous outcomes, the collection data will be expressed as mean difference or standardized mean difference with 95% confidence intervals. As for dichotomous outcomes, the collection data will be expressed as risk ratio with 95% confidence intervals.

2.4.2. Assessment of heterogeneity. Heterogeneity will be checked by using I^2 index. The value of $I^2 < 50\%$ ($I^2 \leq 50\%$) means satisfied heterogeneity, and a fixed-effect model will be used. Otherwise, the value of $I^2 > 50\%$ means significant heterogeneity, and a random-effect model will be utilized.

2.4.3. Data synthesis. RevMan 5.3 Software will be used for statistical analysis in this study. If I^2 is $< 50\%$, data among eligible studies will be pooled and meta-analysis will be carried out. Otherwise, data pooling and meta-analysis will be carried according to the results of subgroup analysis. If significant heterogeneity still exists after subgroup analysis, data will not be pooled, and only narrative summary will be reported.

2.4.4. Subgroup analysis. If the value of I^2 is $> 50\%$, subgroup analysis should be performed to detect any possible reasons for the significant heterogeneity according to the different characteristics, treatment schedules, and outcome measurements.

2.4.5. Sensitivity analysis. Sensitivity analysis will also be carried out to check the robustness of pooled results data, missing data, and methodological quality.

2.4.6. Reporting bias. If sufficient studies are included, we will also carry out funnel plot and Egger regression test to identify any possible reporting bias.

3. Discussion

Numerous clinical studies have reported that acupuncture can be utilized for the treatment of patients with HL caused by TBI.[23–27] This study will comprehensively search as more as possible electronic databases to avoid missing more potential studies. Two reviewers will independently carry out all literature identification, data extraction, and methodological quality assessment. Any divergences will be solved by a third reviewer via discussion. The results of this study will summarize the effectiveness and safety of acupuncture for the treatment of HL caused by TBI. It will provide very helpful evidence for clinical practice and patients.

Author contributions

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References

[1] Carbonara M, Fossi F, Zoerle T, et al. Neuroprotection in traumatic brain injury: mesenchymal stromal cells can potentially overcome some limitations of previous clinical trials. Front Neurol 2018;9:885.

[2] Wong VS, Langley B. Epigenetic changes following traumatic brain injury and their implications for outcome, recovery and therapy. Neurosci Lett 2016;625:26–33.

[3] Hutchinson PJ, Kolias AG, Timofeev IS, et al. Trial of decompressive craniectomy for traumatic intracranial hypertension. N Engl J Med 2016;375:1119–30.

[4] Thurman DJ, Alverson C, Dunn KA, et al. Traumatic brain injury in the United States: a public health perspective. J Head Trauma Rehabil 1999;14:602–15.

[5] Zaloshnja E, Miller T, Langlois JA, et al. Prevalence of long-term disability from traumatic brain injury in the civilian population of the United States, 2005. J Head Trauma Rehabil 2008;23:394–400.

[6] Iaccarino C, Carretta A, Nicolosi F, et al. Epidemiology of severe traumatic brain injury. J Neurosurg Sci 2018;62:535–41.

[7] Ahmed S, Venigalla H, Mekala HM, et al. Traumatic brain injury and neuropsychiatric complications. Indian J Psychol Med 2017;39:114–21.

[8] Roberts I, Sydenham E. Barbiturates for acute traumatic brain injury. Cochrane Database Syst Rev 2012;12:CD000033.

[9] Risdall JE, Menon DK. Traumatic brain injury. Philos Trans R Soc Lond B Biol Sci 2011;366:241–50.

[10] Lux WE. A neuropsychiatric perspective on traumatic brain injury. J Rehabil Res Dev 2007;44:951–62.

[11] Sabo T, Supnet C, Purkayastha S. Secondary intracranial hypertension (pseudotumor cerebri) presenting as post-traumatic headache in mild traumatic brain injury: a case series. Childs Nerv Syst 2018;34:681–90.

[12] Jang SH, Seo YS. Headache due to spinothalamic tract injury in patients with mild traumatic brain injury: Two case reports. Medicine (Baltimore) 2019;98:e1430.

[13] Silverberg ND, Martin P, Panenka WJ. Headache Trigger Sensitivity and Avoidance after Mild Traumatic Brain Injury. J Neurotrauma 2019;36:1544–50.

[14] Hong CK, Joo JY, Shim YS, et al. The course of headache in patients with moderate-to-severe headache due to mild traumatic brain injury: a retrospective cross-sectional study. J Headache Pain 2017;18:48.

[15] Pavlovic D, Pekic S, Stojanovic M, et al. Traumatic brain injury: neuropathological, neurocognitive and neurobehavioral sequelae. Pituitary 2019;22:270–82.

[16] Popovitz J, Mysore SP, Adwanikar H. Long-term effects of traumatic brain injury on anxiety-like behaviors in mice: behavioral and neural correlates. Front Behav Neurosci 2019;13:6.

[17] Gracies JM, Brashear A, Jech R, et al. Safety and efficacy of abobotulinumtoxinA for hemiparesis in adults with upper limb spasticity after stroke or traumatic brain injury: a double-blind randomised controlled trial. Lancet Neurol 2015;14:992–1001.

[18] Dadlani R, Agrawal R. Fluctuating hemiparesis as a result of traumatic brain injury-associated hyponatremia. J Neurosci Rural Pract 2018; 9:445–6.

[19] Jang SH, Bae CH, Seo JP. Injury of auditory radiation and sensorineural hearing loss from mild traumatic brain injury. Brain Inj 2019;33:249–52.

[20] Chen JX, Lindeborg M, Herman SD, et al. Systematic review of hearing loss after traumatic brain injury without associated temporal bone fracture. Am J Otolaryngol 2018;39:338–44.

[21] Shangkuan WC, Lin HC, Shih CP, et al. Increased long-term risk of hearing loss in patients with traumatic brain injury: A nationwide population-based study. Laryngoscope 2017;127:2627–35.

[22] Karch SJ, Capó-Aponte JE, McIlwain DS, et al. Hearing loss and tinnitus in military personnel with deployment-related mild traumatic brain injury. US Army Med Dep J 2016;52–63.

[23] Tian B. Observation on the therapeutic effect of acupuncture combined with western medicine on sudden deafness. Hubei Journal of Traditional Chinese Medicine 2017;39:22–4.

[24] Pang XH, Wu XZ, Gao L. Therapeutic effect of intravenous injection of Jiaqianglong combined with acupuncture on sudden deafness. Sichuan Journal of Traditional Chinese Medicine 2017;35:204–6.

[25] Mo WQ, Yan J, Yang H, et al. Therapeutic effect of acupuncture and moxibustion combined therapy on tinnitus in sensorineural deafness. Shanghai Journal of Acupuncture and Moxibustion 2017;36:960–3.

[26] Zhang RR, Cai WW, Huo TT, et al. Therapeutic effect of syndrome differentiation acupuncture combined with ultra-laser on sudden deafness. Sichuan Journal of Traditional Chinese Medicine 2015;33:159–61.

[27] Han X, Jin YJ, Ge GZ. Therapeutic effect of acupuncture combined with ear exercises on 34 patients with hearing impairment caused by brain injury. Chinese Journal of Practical Nervous Diseases 2012;15:94–5.