

Acupuncture treatment for optic atrophy

A protocol for systematic review

Ping-ping Zhou, MB, Peng Sun, MM, Hong-wei Liu, MM*, Yan Meng, MB

Abstract

Background: Optic atrophy (OPA) is a very tricky disorder. Presently, no effective management is available for this condition. Previous studies have reported that acupuncture may be effective for the treatment of OPA. However, its effectiveness is still inconclusive. Thus, this study will aim to assess the effectiveness and safety of acupuncture for OPA.

Methods: A comprehensive literature search for relevant studies will be performed from the databases of PUBMED, EMBASE, CINAHI, Cumulative Index to Nursing and Allied Health Literature, Allied and Complementary Medicine Database, Cochrane Library, Chinese Biomedical Literature Database, China National Knowledge Infrastructure, and other literature sources from inception up to the present. No language limitations will be applied to all literature searches. We will consider all randomized controlled trials (RCTs) and case-controlled trials (CCTs) for assessing the effectiveness and safety of acupuncture for OPA. The primary outcomes include the rates of vision improvement and visual field improvement. The secondary outcomes consist of the increased visual field average sensitivity, pattern visual evoked potential (PVEP) amplitude, and shortened PVEP latency, as well as any expected and unexpected adverse reactions. Risk of bias assessment will be performed by Cochrane risk of bias for RCTs and Newcastle-Ottawa Scale for CCTs.

Results: In this study, we will outline details of the aims and methods on the effectiveness and safety of acupuncture for the treatment of OPA.

Conclusion: The results of this study will summarize the most current evidence of acupuncture for the treatment of patients with OPA.

Dissemination and ethics: The results of this study are expected to be published on peer-reviewed journals. This is a literature-based study; therefore, no ethical approval is necessary.

Systematic review registration: PROSPERO CRD42019135785

Abbreviations: CCTs = case-controlled trials, OPA = optic atrophy, PVEP = pattern visual evoked potential, RCTs = randomized controlled trials.

Keywords: acupuncture, effectiveness, optic atrophy, safety

1. Introduction

Optic atrophy (OPA) is a very tricky disorder, which involves the death of the retinal ganglion cell axons caused by various eye diseases, and results in optic nerve lesions.^[1–3] It often manifests as the degeneration and disappearance of optic nerve fibers,

conduction dysfunction, visual field changes, vision decrease and loss.^[4–6] In China, previous study has reported that OPA ranks as the second factor in children's visual impairment, which seriously threatens quality of life in patients with this disorder.^[7] Unfortunately, there are still no effective managements for treating this condition because of the complicated causes, and its poor prognosis.

Acupuncture has been utilized in clinical practice in China for thousands of years.^[8–11] It has been used to treat a variety of conditions and has achieved a promising effectiveness.^[12–20] Several previous studies have reported that acupuncture may also benefit for patients with OPA.^[21–26] However, its effectiveness for this disorder is still inconclusive. Thus, this study will comprehensively and systematically assess the effectiveness and safety of acupuncture for patients with OPA.

2. Methods and analysis

2.1. Study registration

This study has been registered on PROSPERO (CRD42019135785), and we have reported it in accordance with the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-analysis Protocol.

PS and P-PZ contributed equally to this study.

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The authors report no conflicts of interest.

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2.2. Eligibility criteria for study selection

2.2.1. Types of studies. Any randomized controlled trials (RCTs) and case-controlled trials (CCTs) of acupuncture for the treatment OPA will be considered for inclusion. However, nonclinical trials, and noncontrol trials will be excluded.

2.2.2. Types of patients. We will include any diagnosed criteria of OPA regardless their race, sex, and age.

2.2.3. Types of interventions. We will include studies that have implemented acupuncture monotherapy as an experimental treatment.

Control therapy can be any treatments, except any forms of acupuncture therapies.

2.2.4. Types of outcomes. Eligible studies will be included if more than one of the following outcomes have reported.

2.2.4.1. Primary outcome.

- Rate of vision improvement;
- Rate of visual field improvement.

2.2.4.2. Secondary outcome.

- Increased visual field average sensitivity;
- Pattern visual evoked potential (PVEP) amplitude;
- Shortened PVEP latency;
- Any expected and unexpected adverse reactions.

2.3. Search strategy for study identification

2.3.1. Electronic databases searches. This study will include a comprehensive literature search from PUMBED, EMBASE, CINAHI, Cumulative Index to Nursing and Allied Health Literature, Allied and Complementary Medicine Database, Cochrane Library, Chinese Biomedical Literature Database, and China National Knowledge Infrastructure, and other literature sources from their inception to the present regardless any language restrictions. The search strategy for PubMed is detailed in Table 1. Identical search strategies will also be used for any other electronic databases.

2.3.2. Other literature sources. We will also retrieve any other gray literature sources, such as conference proceedings, dissertations, and reference lists of eligible studies.

2.4. Study selection

Two independent authors will check the titles and summaries for each retrieved record according to the eligibility criteria. After that, all irrelevant records will be excluded. Then, the remaining records will be read by full-texts and will be judged if they meet the finally eligibility criteria. Any disagreements regarding the study selection between 2 authors will be solved by a third author through discussion. The flowchart of all study selection procedure is shown in Figure 1.

2.5. Data extraction and management

Two trained authors will independently extract the required information from all eligible studies according to the pre-designed data extraction form. A third trained author will help to check and to solve any disagreements occurred between 2 authors. Extracted

Table 1
Search strategy for PubMed.

Number	Search terms
1	Optic Atrophy
2	Optic neuropathy
3	Optic nerve damage
4	Vision decrease
5	Vision loss
6	Or 1–5
7	Acupuncture
8	Electroacupuncture
9	Needling
10	Treatment
11	Therapy
12	Intervention
13	Or 7-12
14	Randomized controlled trials
13	Clinical trials
14	Random
15	Randomized
16	Randomly
17	Allocation
18	Placebo
19	Blind
20	RCTs
21	Or 14-20
22	6 and 13 and 21

information consists of publication details, general characteristics of eligible studies (such as name, title, publication year, and so on), patient details (such as sex, age, and so on), details of treatments, as well as the outcome measurements.

2.6. Missing data dealing with

Where applicable, any missing data will be inquired by contacting primary authors by using email. When it is not possible, only available data will be analyzed. Meanwhile, we will discuss its possible effects on the combined outcome results.

2.7. Risk of bias assessment

In this study, we will apply different assessment tools to evaluate different types of studies. We will use Cochrane risk of bias tool to assess the risk of bias for all RCTs, and the risk of bias for all CCTs will be evaluated by using newcastle–ottawa scale. Two trained authors will independently assess the risk of bias for each eligible study. If there are disagreements between 2 authors, a third trained author will be asked for help to solve those disagreements by discussion.

2.8. Rating quality of evidence

In this study, the overall strength of the evidence will also be assessed by Grading of Recommendations Assessment, Development, and Evaluation tool.^[27] We will summarize the results in the tables of Summary of Findings.

2.9. Statistical analysis

RevMan 5.3 software will be utilized for statistical analysis in this study.

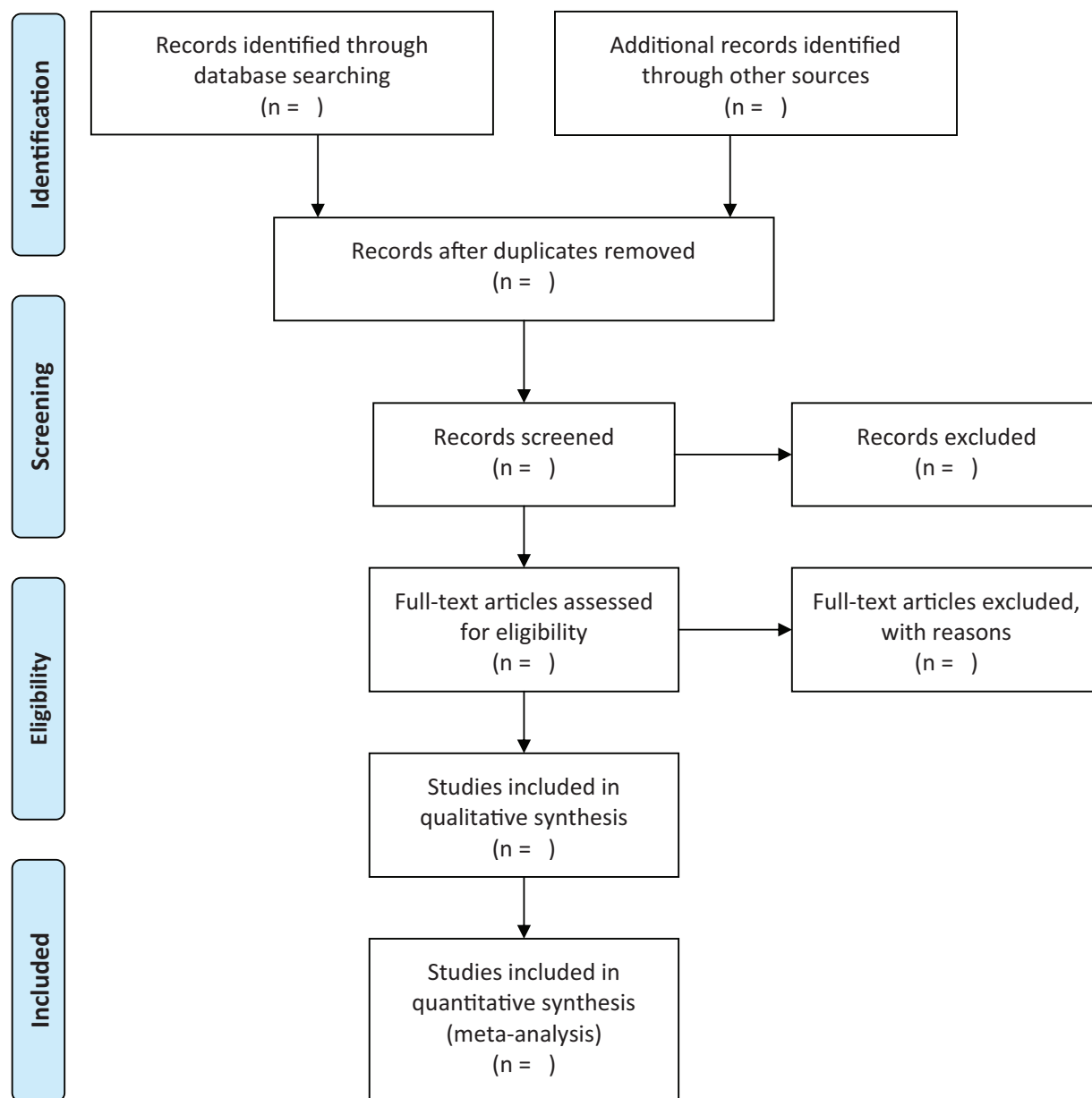


Figure 1. Flow diagram of study selection process.

2.9.1. Treatment effects measurements. Continuous data will be expressed as mean difference or standardized mean difference with 95% confidence intervals.

Dichotomous data will be employed by using as risk ratio with 95% confidence intervals.

2.9.2. Assessment of heterogeneity. We will assess heterogeneity by using I^2 test. If $I^2 \leq 50\%$, minor heterogeneity will be regarded. Otherwise, if $I^2 > 50\%$, substantial heterogeneity will be observed in this study. Then, subgroup analysis will be conducted to identify any possible reasons that can result in substantial heterogeneity.

2.9.3. Data synthesis. If minor heterogeneity is found ($I^2 \leq 50\%$), a fixed-effects model will be employed for data pooling,

and meta-analysis will be carried out. If significant heterogeneity is found ($I^2 > 50\%$), a random-effects model will be employed for data pooling. At the same time, subgroup analysis will also be conducted. If there is still substantial heterogeneity after subgroup analysis, data will not be pooled, and meta-analysis will not be carried out. Instead, we will report narrative summary for outcome results.

2.9.4. Subgroup analysis. Subgroup analysis will be applied in accordance with different characteristics, treatment types, and outcome tools.

2.9.5. Sensitivity analysis. Sensitivity analysis will be conducted to identify the robustness and stability of pooled outcome results by removing low quality of studies.

2.9.6. Reporting bias analysis. If >10 qualified studies are included, Funnel plot and Egger regression analysis will be carried out to check the publication bias.

3. Discussion

OPA is a very common and tricky disorder, and can result in vision decrease or even loss, which significantly affect their quality of life. Several previous studies have reported that acupuncture can treat OPA effectively and safely.^[12–20] However, its effectiveness for treating this disorder is still inconclusive. Therefore, this study will systematically assess the effectiveness and safety of acupuncture for the treatment of patients with OPA. The findings of this study will summarize most recent evidence of acupuncture for treating OPA.

Author contributions

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Data curation: Ping-ping Zhou, Peng Sun, Hong-wei Liu, Yan Meng.

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Supervision: Hong-wei Liu.

Validation: Ping-ping Zhou, Peng Sun, Hong-wei Liu, Yan Meng.

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Writing – original draft: Ping-ping Zhou, Peng Sun, Hong-wei Liu, Yan Meng.

Writing – review & editing: Ping-ping Zhou, Peng Sun, Hong-wei Liu, Yan Meng.

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