

INPLASY PROTOCOL

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Acupuncture for diabetic ophthalmoplegia: a systematic review

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Conflicts of interest:
The authors have no conflicts of interest in this work.

Review question / Objective: The aim of this review is to assess the efficacy and safety of acupuncture for diabetic ophthalmoplegia.

Condition being studied: Diabetic ophthalmoplegia(DO) presents with ocular movement disorders including paralytic strabismus, diplopia, enlarged pupils, narrow eyelids, nystagmus etc. Diabetes, one of the various primary diseases, is growing rapidly in modern society and draws the attention of worldwide public health care. Treatment for DO mainly targets on controlling the diabetes and releasing ocular symptoms. An ocular surgery could correct the position of eye but it's hard to prevent a recurrence. Also diplopia could not be removed to some people. In conclusion, a surgery will be taken only when a half-year conservative treatment is invalid. However, for diabetic ophthalmoplegia, or any type of ophthalmoplegia, people have no international consensus or instructions of conservative treatments. And the efficacy and the safety of conservative treatments for DO still need to be verified. What's more, the meaning of the studies on diabetic ophthalmoplegia is not limited. As some researches point out that other type of ophthalmoplegia, such as chronic progressive external ophthalmoplegia(CEPO), also have an obstacle of the regulation of blood glucose.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 August 2020 and was last updated on 14 August 2020 (registration number INPLASY202080060).

INTRODUCTION

Review question / Objective: The aim of this review is to assess the efficacy and

safety of acupuncture for diabetic ophthalmoplegia.

Rationale: Diabetic ophthalmoplegia(DO) presents with ocular movement disorders including paralytic strabismus and diplopia. With diabetes growing rapidly in modern society, DO draws the attention of worldwide public health care. However people have no international consensus or instructions of conservative treatments. Acupuncture is one of the conservative treatments with needle inserting into the skin and stimulating the acupoints for clinical purposes. But the evidence of its efficacy and safety is warranted.

Condition being studied: Diabetic ophthalmoplegia(DO) presents with ocular movement disorders including paralytic strabismus, diplopia, enlarged pupils, narrow eyelids, nystagmus etc. Diabetes, one of the various primary diseases, is growing rapidly in modern society and draws the attention of worldwide public health care. Treatment for DO mainly targets on controlling the diabetes and releasing ocular symptoms. An ocular surgery could correct the position of eye but it's hard to prevent a recurrence. Also diplopia could not be removed to some people. In conclusion, a surgery will be taken only when a half-year conservative treatment is invalid. However, for diabetic ophthalmoplegia, or any type of ophthalmoplegia, people have no international consensus or instructions of conservative treatments. And the efficacy and the safety of conservative treatments for DO still need to be verified. What's more, the meaning of the studies on diabetic ophthalmoplegia is not limited. As some researches point out that other type of ophthalmoplegia, such as chronic progressive external ophthalmoplegia (CEPO), also have an obstacle of the regulation of blood glucose.

METHODS

Search strategy: We will search for all published randomized controlled trials (RCTs) of acupuncture treatments for diabetic ophthalmoplegia published in English or Chinese in eight databases including PubMed, EMBASE, the Cochrane Library, Web of Science, the Chinese

Science and Technology Journal Full-text Database (CNKI), Wanfang Database, the Chinese Biomedical Literature Database (VIP) and SinoMed up to June 2020. The keywords include but are not limited to acupuncture, ophthalmoplegia, paralysis of oculomotor/trochlear/abducens nerve, paralytic strabismus, acupuncture, randomized controlled trials. The above terms in Chinese will be adapted and searched in Chinese databases.

Participant or population: Patients of any gender and at any age who were diagnosed with diabetic ophthalmoplegia.

Intervention: Interventions to be studied include: manual acupuncture, electroacupuncture, scalp acupuncture, dermal acupuncture, auricular acupuncture, warm needling, plum-blossom needling, or intradermal needling. Acupoint injections, acupoint catgut embedding, laser acupuncture, moxibustion and cupping, and herbal medicine were excluded.

Comparator: Comparators include placebo control, sham acupuncture, no treatment, medicine, eyewear, prism and other complementary treatments.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: Randomized controlled trials meet the aforementioned criteria about participants, interventions, and comparators.

Information sources: We will include the studies from eight databases including PubMed, EMBASE, the Cochrane Library, Web of Science, the Chinese Science and Technology Journal Full-text Database (CNKI), Wanfang Database, the Chinese Biomedical Literature Database (VIP) and SinoMed up to June 2020. Also, sources from reference will also be included.

Main outcome(s): 1. percentage/numbers of patients with improved symptoms 2. distance of eyeball movement 3. angle of

diplopia 4.angle of strabismus 5.size of palpebrae.

Additional outcome(s): 6.size of pupil 7. main symptom scores 8.any adverse Events 9. control of diabetic mellitus.

Data management: Noteexpress software will be used to store and screen all retrieved articles. Relevant data and information, such as authors, year of publication, population, sample size, intervention, comparator, outcome measurements, time of follow up, will be extracted from original articles and recorded in excel tables for further analysis. Data analysis will be conducted by RevMan5.3. Two researchers will conducted the screen process independently. A third searcher will be invited to solve disagreement during the process if any.

Quality assessment / Risk of bias analysis: Two reviewers will independently use The Cochrane Collaboration's Risk of bias tool to assess the methodological quality of the included studies. We will classify each study as 'low', 'unclear' and 'high' risk of bias in six aspects as follows: 1. Sequence generation; 2. Allocation concealment; 3. Blinding (or masks); 4. Incomplete data assessment 5. Selective outcome reporting; 6. Other sources of bias.

Strategy of data synthesis: Included studies will be categorized by types of intervention. Data of the same outcome measurement from different studies will be synthesized.

Subgroup analysis: Included studies will be categorized by types of interventions and/ or comparisons. Data of the same outcome measurement under same category will be synthesized and compared.

Sensibility analysis: From the group of synthesized studies, we will remove studies with obvious deviation from other studies, such as studies with very small sample size, to observe whether the result will be changed or not.

Language: English.

Country(ies) involved: China.

Keywords: diabetic ophthalmoplegia, acupuncture, diabetes, paralytic strabismus, systematic review.

Contributions of each author:

Author 1 - Tianheng Sun - The author managed searched studies and drafted the manuscript.

Author 2 - Huan Chen - The author provide expertise in manuscripts.

Author 3 - Zhishun Liu - The author contributed to correspondence and provided guidance.