

## Short Review

### A Short Review Based on the Article Entitled “Evaluation of Literature Quality of Traditional Chinese Medicine Treatment on Ischemic Optic Neuropathy”

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Our study [1] “Evaluation of Literature Quality of Traditional Chinese Medicine Treatment on Ischemic Optic Neuropathy” evaluated the quality of the 50 included works of literature. The findings revealed that anterior ischemic optic neuropathy accounted for the majority of study subjects (46.15%), while acupuncture treatment was scarcely documented (5.77%). Randomized controlled trials (RCTs) constituted 65.38% of all trial types, but their credibility was found to be low. None of the articles employed concealed sequences, blinding methods, or sample size estimation. Only one article reported drop-out cases, but it lacked a reason-and-intention-to-treat analysis. Safety assessments were not reported in the majority of the literature (80.77%). These research results indicate that the quality of relevant literature on Traditional Chinese Medicine (TCM) treatment of ION is generally subpar. Future research should focus on studies where the intervention is acupuncture treatment and standardized and rigorous multi-center large-sample clinical trials.

#### Overview of Research Background and Purpose

Ischemic Optic Neuropathy (ION) is caused by an acute circulatory disturbance in the nutrient blood vessels of the optic nerve [2]. Depending on the affected optic nerve segment, ION is divided into anterior ischemic optic neuropathy (AION) and posterior ischemic

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optic neuropathy (PION). The former is caused by insufficient blood supply to the optic disc due to circulatory disorder of the short posterior ciliary arteries, resulting in acute hypoxic edema of the optic disc, accounting for 90% of ION cases [2]. The latter is caused by the acute circulation of the optic nerve blood vessels from the lamina cribrosa to the optic chiasm disorder, a disease in which optic nerve function is damaged due to ischemia. AION has traditionally been divided into cases associated with vasculitis (usually giant cell arteritis or temporal arteritis), and cases unrelated to vasculitis [3]. Non-arteritic anterior ischemic optic neuropathy (NAION) is the most common cause of acute optic nerve damage in persons older than 50 years of age, with an annual incidence of 2.3 cases per 100,000 to 10.2 cases per 100,000 [3,4]. Arteritic anterior ischemic optic neuropathy (AAION) only accounts for 10% to 15% of AION cases [5]. Giant cell arteritis (GCA) is a serious ophthalmic emergency that requires prompt identification based on medical history, inflammatory indicators, and morphological evidence [5].

At present, the clinical treatment of ION is mainly glucocorticoids, circulation improvement, nerve nutrition, and other drugs. Traditional Chinese medicine (TCM) is a treasure of China. Ancient sages continuously summarized clinical data, and as a result, a comprehensive theoretical framework and novel diagnostic and therapeutic approaches were developed. ION can belong to the category of “blurred vision” or “sudden blindness” (《The standard rope of diagnosis and treatment》) in TCM. The patient is aged and has insufficient yin in the liver and kidneys, and the yin does not check and balance yang, the liver yang is hyperactive and the qi and blood rush upward; or the patient has a long-term illness with deficiency of both qi and blood, and the eyes and orifices are not nourished; or a long-term illness enters the collaterals, and the qi and blood flow is sluggish; or internal injuries to emotions and emotions lead to stagnation of liver qi, which turns into the fire due to long-term stagnation; or stagnation of heat in the blood damages the meridians, causing heat evil and blood stasis to block the meridians, causing the “Xuan Fu” in the eyes to be blocked and visual function to be impaired. Abnormality of qi and blood in the eye is the key to the pathogenesis.

The treatments are mostly based on replenishing qi and nourishing blood, activating blood circulation, clearing the orifices, and tonifying the liver and kidneys. Traditional Chinese medicine compounds such as Xuefu Zhuyu Decoction, Buyang Huanwu Decoction, etc. promote blood circulation and remove blood stasis [6]. In addition, acupuncture is another commonly used TCM therapy favored by clinicians and patients due to its convenience, safety, and effectiveness. The treatment is mainly based on the stimulation of acupoints around the eyes, such as BI-1 (Jingming), BI-2 (Cuanzhu), and Ex-hn7 (Qiuhou). TCM believes that the eyes and internal organs are connected to each other through special pathways called “meridian and collateral”, so acupoints distributed over the distal end of four limbs are also usually selected. Acupuncture can improve blood circulation and blood perfusion in the optic disc arteries by increasing the blood flow velocity of the carotid artery, ophthalmic artery, and short posterior ciliary artery and reducing vascular resistance [7,8]. It can also increase nerve

excitability and promote nerve cell conduction, inhibit the apoptosis of retinal ganglion cells, thereby improving tissue blood supply and metabolism [7].

Research on ION in TCM has gradually increased in recent years, and its efficacy has been confirmed. Currently, there are no specific TCM therapeutic interventions in the relevant treatment guidelines for ION. Therefore, this study conducted a status analysis and quality evaluation of relevant literature to explore whether TCM therapy has a reliable evidence-based basis for treating this disease, intending to provide a reference for clinical treatment.

## Research Summary and Outlook

Use "ischemic optic neuropathy", "Traditional Chinese Medicine", "acupuncture" "Chinese traditional patent medicine" etc. as subject headings, and treatment-related drug names as keywords. Searched PubMed, Embase, Cochrane Library, SinoMed, China National Knowledge Infrastructure (CNKI), Chongqing VIP (CQVIP), and Wanfang Data from January 2009 to August 2019. After a rigorous screening process, 50 articles were identified which included 52 studies.

In this study, the results showed that the research objects were mainly AION (24 studies, 46.15%), the others were ION (19 studies, 36.54%) and NAION (9 studies, 17.31%). The intervention measures were mainly traditional Chinese medicine compounds (36 studies, 69.23%), and others included Chinese traditional patent medicine (13 studies, 25%) and acupuncture (3 studies, 5.77%). Among the included literature on the treatment of ION with traditional Chinese medicine compounds, the main syndrome differentiation types include qi stagnation and blood stasis syndrome, qi deficiency and blood stasis syndrome, phlegm and blood stasis syndrome, etc. Xuefu Zhuyu Decoction, Buyang Huanwu Decoction, and self-made prescriptions are used respectively. The treatment is mainly based on promoting blood circulation and removing blood stasis, which corresponds to the pathogenesis of blood stasis. However, during ION disease, early tissue ischemic edema and ischemic changes caused by different pathogenic factors cannot be summarized as blood stasis. The principles of syndrome differentiation should be adhered to and combined with disease differentiation. In studies on the use of Chinese traditional patent medicine for treatment, the main efficacy of medicines is to promote blood circulation and remove blood stasis, and there are no indications for ION. The pathological mechanism of ION is mainly hypoperfusion injury, which is somewhat different from vascular obstructive diseases such as cerebral infarction. Therefore, the clinical use of such drugs to treat ION requires more in-depth mechanisms or clinical research confirmation.

There is little literature focusing on acupuncture treatment. A high-quality before-and-after controlled trial showed that after 8 weeks of electroacupuncture treatment alone, the visual acuity improvement rate was 81.71%. Among them, the visual acuity of 27 eyes (27.96%) improved by 4 lines or returned to the pre-disease level. The average visual field defect and average light sensitivity were both improved. It is speculated that acupuncture can promote blood circulation in the brain, eyes, and arteries around the optic disc, and increase the excitability of optic nerve cells. It can be seen that acupuncture therapy is of great significance to the visual prognosis of patients with ION, but there are not many relevant studies at present.

RCTs accounted for the most (34 studies, 65.38%), followed by case series (7 studies), case reports (6 studies), and cohort studies (3 studies). Systematic reviews and non-randomized controlled trials (NRCTs) were the least, with 1 each. RCT is the "gold standard" for evaluating the effect of intervention. The quality of the RCT studies included in this study is generally subpar, especially in the generation of randomization plans, blinding, allocation concealment, analysis of reasons for subject dropout and loss to follow-up, sample size estimation, etc. The overall risk of bias in NRCT studies is high, especially in 4 aspects: baseline comparison between groups, loss to follow-up rate, blinding method, and calculation of sample size. The loss to follow-up, intention-to-treat analysis, and sensitivity analysis of the study subjects were not explained. Dropouts and group changes during the trial cannot be ruled out, which may lead to loss-to-follow-up bias. Cohort studies often need to pay attention to the representativeness of the sample. The patients are all from hospitalized cases. However, hospitalized cases are generally more seriously ill, resulting in differences in group representativeness. In multi-center trials, relevant confounding factors need to be controlled, especially demographic characteristics and disease severity. When determining exposure factors, in addition to reporting clear investigation methods, the time and continuity of medication should also be considered. Case reports are mostly used to report rare diseases, causes, clinical characteristics, etc. The case reports included in this study rarely involve the above content, none of them involve safety assessment, and most observation indicators are greatly affected by subjective factors.

38 studies (73.08%) used "effectiveness" as a composite outcome indicator to evaluate the efficacy of interventions, of which 27 studies referred to works or expert consensus, and 11 studies were based on existing literature, but the standards were different. 35 studies (67.31%) reported detailed diagnostic criteria, 19 studies of the intervention measures involved TCM syndrome differentiation, and 7 studies explained the TCM syndrome diagnosis criteria. In addition, only 10 studies (19.23%) reported the occurrence of adverse reactions, of which 1 study reported the type and incidence of adverse reactions in detail, 1 study reported the type of adverse reactions, and other studies reported no adverse reactions.

On the whole, although relevant research on TCM in the field of ION has made certain progress, there are still the following shortcomings in clinical research design: (1) The diagnostic and treatment standards of traditional Chinese and Western medicine for ION have not yet been unified. (2) Most studies focus on AION and traditional Chinese medicine compounds are the mainstay, and there are few studies on PION and acupuncture. It's worth noting that the main prescription for NAION treatment is Chinese materia medica which has the effect of promoting blood circulation and removing blood stasis. The effective components of Chinese materia medica have the characteristics of multi-target, which can be verified by additional experiments in the future. (3) Most studies use TCM combined with unconventional treatments as intervention measures in the treatment group, such as acupuncture combined with medicine, Chinese patent medicine combined with compound Chinese medicine, etc., which is not conducive to specific evaluation. The efficacy of intervention measures, especially when the efficacy of another combined intervention measure is not yet clear, was not included in this study. (4) The included studies all used visual acuity and visual field as outcome indicators but lacked of detailed description of the blind method. Factors influence and researchers selectively report risks. (5) Some studies report adverse reactions, but only a few studies fully report the number or

proportion, group, and treatment measures of adverse reactions. (6) Most studies report composite outcome indicators without describing other intuitive independent indicators, which may easily lead to differential misclassification bias and make it inconvenient to understand the characteristics of TCM. (7) Many studies have inadequate descriptions of baseline information between groups such as the severity of the disease, increasing the risk of study selection bias; some trials did not state the name of the drug, but only reported part of the drug name or treatment principles; only the number of samples was reported, but the number of eyes included was not reported. Incomplete reporting of data is one of the main reasons for reducing the trustworthiness of research and is not conducive to judging the authenticity and validity of the trial.

In summary, more large-scale and high-quality clinical randomized controlled trials on traditional Chinese medicine compounds and acupuncture are needed in the future to provide more reliable evidence-based evidence for TCM treatment of ION and clarify its efficacy advantages in the overall treatment.

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