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国际中医临床实践指南 视神经萎缩

International Clinical Practice Guideline of Chinese Medicine Optic Atrophy

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前言

请注意本文件的某些内容可能涉及专利。本文件的发布机构不承担识别专利的责任。

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本文件起草程序遵守了世界中医药学会联合会发布的《世界中联国际组织标准管理办法》和 SCM 0001-2009《标准制定和发布工作规范》。

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引言

本文件规范了视神经萎缩的中医临床诊断与治疗,为国际中医师临床实践提供了视神经萎缩的中医药治疗策略与方法。本文件简明实用,操作性强,可作为临床实践、诊疗规范和质量评价的重要参考依据。

中国已发布的《中医眼科常见病诊疗指南 视神经萎缩》(2012 版)、《中医临床诊疗指南释义 视神经萎缩》(2015 版)、《视神经萎缩中医临床诊疗专家共识》(2019 版)对视神经萎缩的中医药诊疗发挥了较好的指导作用,但既往中医临床指南限于研究条件,多以专家共识作为推荐标准,国际认可度较低。随着循证医学研究在中医药领域的快速发展和应用,证据级别较高的研究成果不断涌现,本文件在既往指南基础上,在证据级别较高的中医药治疗视神经萎缩高质量研究中筛选出临床疗效可靠、安全、便于推广的治疗方法,以提高中医药治疗的临床疗效。

本文件是依据现有研究证据和科学评价方法制定出的声明性文件。在临床实践中,医师可参考本文件并结合患者具体情况进行个体化治疗。

国际中医临床实践指南 视神经萎缩

1 范围

本文件规定了视神经萎缩的中医术语和定义、诊断、辨证和治疗等。

本文件适用于中医眼科临床从业医师对视神经萎缩的诊断和治疗依据,中西医结合、 西医眼科从业医师和其他学科中医师也可参照本文件相关内容。

2 规范性引用文件

下列文件对于本文件的应用是必不可少的。凡是注日期的引用文件,仅所注日期的版本适用于本文件;凡是不注日期的引用文件,其最新版本(包括所有的修改版)适用于本文件。

GB/T 16751.1 中医临床诊疗术语 疾病部分

GB/T 16751.2 中医临床诊疗术语 证候部分

GB/T 16751.3 中医临床诊疗术语 治法部分

2012 中医眼科常见病诊疗指南 视神经萎缩

2015 中医临床诊疗指南释义 视神经萎缩

2019 视神经萎缩中医临床诊疗专家共识

SCM 2-2007 中医基本名词术语中英对照国际标准

2009 WHO 西太平洋地区传统医学名词术语国际标准

3 术语和定义

下列术语和定义适用于本文件。

3. 1

视神经萎缩

不是一种单独的疾病,是视网膜至外侧膝状体之间的视网膜神经节细胞及其轴索因各种病变引起的损害,致使神经纤维丧失、神经胶质细胞增生的最终结局。

注 1: 临床上主要分为原发性和继发性视神经萎缩两大类,患者多有视功能减退和视野缩小,视神经萎缩因视盘局部毛细血管减少或消失,胶质细胞增生,色泽呈苍白色。

注 2: 引起视神经萎缩的病因可包括: 血管性、感染性、代谢性、创伤性、中毒性、肿瘤/副肿瘤综合征、自身免疫性/炎症性、压迫性和遗传性病因等; 从发病机制上又可分为三大类: 上行性、下行性和先天遗传性病变。上行性神神经萎缩指原发病变位于视盘和视网膜,萎缩过程由眼内向球后视神经、颅内发展; 下行性视神经萎缩指原发病变位于颅内或眶内段视神经, 其萎缩过程逐渐向眼球侧发展。

注 3: 视神经萎缩属于中医学"青盲"范畴。

3. 2

青盲

患眼外观正常,瞳神气色无异,唯眼神呆钝,远近视物昏矇不清,又不能矫正,最终 不睹三光,故名青盲,俗称青盲瞎。

注:《证治准绳》曰: "夫青盲者,瞳神不大不小,无缺无损,仔细视之,瞳神内并无些少别样气色,俨然与好人一般,只是自看不见,方为此证。"

4 诊断

4.1 病史

多数患者有头眼部外伤史、肿瘤、恶性贫血、使用视神经毒性药物、青光眼、缺血性病变、遗传性疾病等病史。

4.2 临床表现

视力减退,甚者可降至无光感。多伴有不同程度的色觉异常,常见为红绿色盲。单眼 发病者可出现患侧的相对性传入性瞳孔阻滞。视盘灰白色或苍白色,因病因不同边界清楚 或者模糊,视网膜血管变细。

4.3 辅助检查

4.3.1 视野

检查可见向心性视野缩小、中心暗点、旁中心暗点、扇形缺损、双颞侧偏盲及同侧偏盲。

4.3.2 视觉电生理

可见 P-100 波峰潜时延迟、振幅降低,重者无法引出波形。

4.3.3 光学相干断层成像术(OCT)

可见视网膜神经纤维层厚度薄变。

5 辨证

5.1 肝郁气滞证

眼外观正常,视物昏朦;视盘色淡白或苍白,或视盘生理凹陷扩大加深如杯状,血管向鼻侧移位,动、静脉变细;兼见情志不舒或易怒,胸胁胀痛,食少太息,口干口苦;舌红,苔薄白或薄黄,脉弦或细弦。

5.2 肝肾不足证

视力渐降,视物昏矇,甚至失明;眼底见视盘色淡白或苍白;全身症见头晕耳鸣,腰膝酸软;舌淡,苔薄白,脉沉细无力。

5.3 气血两虚证

视力渐降,日久失明;视盘色淡或苍白;面色无华,唇甲色淡,失眠健忘,神疲乏力,懒言少语,心悸气短;舌淡苔薄白,脉沉细。

5.4 气滞血瘀证

视力下降日久,或因头目外伤,视力渐丧;眼底见视盘色苍白,边界清,血管变细; 兼见头目疼痛,健忘失眠,多梦;舌质暗红,或有瘀斑,苔薄白,脉涩。

6 治疗

6.1 治疗原则

中医治疗原则根据其病因病机有所不同,分别采用疏肝解郁、补益肝肾、益气养血、行气活血、开窍明目等疗法。本病当从肝脾肾着手,辨明虚实,对症治疗。

6.2 方药

6.2.1 肝郁气滞证

治法: 疏肝解郁, 开窍明目。

方药: 逍遥散(《太平惠民和剂局方》): 柴胡、当归、白芍、白术、茯苓、薄荷、煨姜、炙甘草。(证据级别 D,强推荐)

加减: 视物模糊甚者加菊花、枸杞子、石菖蒲以补肾开窍明目; 郁热日久者加枳壳、郁金以助疏肝理气解郁; 气滞血瘀者加丹参、红花、川芎以加强行血活血; 肝郁血虚者加党参、制首乌以益气养血; 耳鸣失聪神烦者加蝉蜕、远志以开窍明目, 宁心定神。

6.2.2 肝肾不足证

治法: 补益肝肾, 开窍明目。

方药: 左归饮(《景岳全书》): 熟地黄、山茱萸、山药、枸杞子、茯苓、炙甘草。 (证据级别 D, 强推荐)

加减:气虚血瘀者加太子参、当归、枳壳以益气活血;肾气虚者加楮实子、菟丝子以助补肾开窍;肾阴虚加女贞子、五味子以滋肾阴;腰膝酸软者加狗脊、杜仲以滋补肝肾; 五心烦热重者加知母、黄柏、竹叶以滋<mark>阴</mark>除烦。

6.2.3 气血两虚证

治法: 益气养血, 宁神开窍。

方药:人参养荣汤(《太平惠民和剂局方》):白芍、当归、陈皮、人参、肉桂、黄芪、白术、茯苓、五味子、远志、熟地黄、生姜、大枣、炙甘草。(专家共识,强推荐)

加减:血虚偏重加制何首乌、龙眼肉以养血安神;可适加枳壳、柴胡等理气之品,或加川芎入血分而理气。

6.2.4 气滞血瘀证

治法: 行气活血, 化瘀通络。

方药:血府逐瘀汤(《医林改错》): 桃仁、红花、当归、生地黄、川芎、赤芍、牛膝、桔梗、柴胡、枳壳、甘草。(专家共识,强推荐)

加减: 瘀血日久入络, 加丹参、郁金、地龙以化瘀通络。

6.3 中成药

6.3.1 口服剂

气滞血瘀证: 复方血栓通胶囊(证据级别 C,强推荐)、复方丹参片(证据级别 D,弱推荐)

肝肾不足证: 明目地黄丸(证据级别 C,强推荐)、补肾明目丸(证据级别 D,强推荐)、杞菊地黄丸(证据级别 D,弱推荐)、石斛夜光丸(证据级别 D,弱推荐)

肝郁气滞证: 疏肝明目丸(证据级别 D,强推荐)、明目逍遥颗粒(证据级别 D,强推荐)

气血两虚证:人参养荣丸(证据级别 D,弱推荐)请根据临床情况,选择适宜的服用方法和疗程。

6.3.2 中药注射剂

银杏叶提取物注射液(证据级别 D,强推荐) 复方丹参注射液(证据级别 D,弱推荐) 生脉注射液(证据级别 D,弱推荐) 葛根素注射液(证据级别 D,弱推荐) 灯盏细辛注射液(证据级别 D,弱推荐) 川芎嗪注射液(证据级别 D,弱推荐)

6.4 其他疗法

6.4.1 穴位注射

复方樟柳碱(主要成分:氢溴酸樟柳碱、普鲁卡因)太阳穴注射(证据级别 C,强推荐)

6.4.2 药物离子导入

丹参注射液(主要成分丹参)(证据级别 D, 弱推荐) 中药配方川芎、当归、赤芍、丹参、柴胡、葛根、黄芪、熟地黄(证据级别 D, 弱推 荐)

6.4.3 穴位贴敷

配方丹参、人参、麝香、冰片等(证据级别 D, 弱推荐)

6.4.4 耳穴贴压

取穴眼、目1、目2、肝、肾、心(专家共识,强推荐)

6.4.5 针刺治疗

根据针灸辨证论治于预视神经萎缩的临床文献和相关教材,结合专家共识整理而得。(专家共识,强推荐)

主穴: 睛明、承泣、上明、丝竹空、太阳、阳白、鱼腰、四白;

配穴: 肝郁气滞证: 肝俞、太冲、行间、合谷、光明;

肝肾不足证: 肝俞、肾俞、三阴交、关元、太溪; 气血两虚证: 合谷、百会、足三里、胃俞、脾俞; 气滞血瘀证: 血海、气海、风池、合谷、足三里。

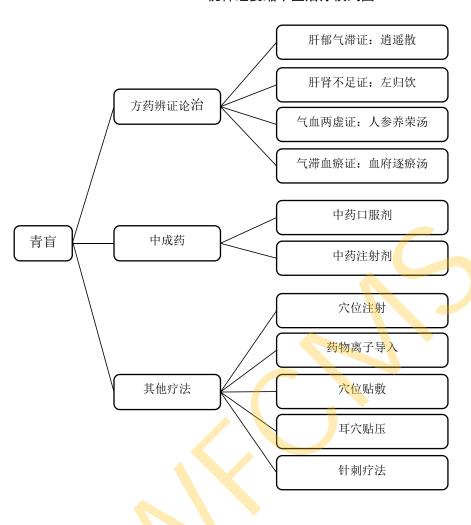
附录 A (资料性) 视神经萎缩的诊断

A.1 视神经萎缩的诊断标准

(ZYXH/T287-305-2012 中医眼科常见病诊疗指南 Guidelines for Diagnosis and Treatment of Common Internal Diseases in Chinese Medicine—Diseases of Chinese Medicine,ISBN978-7-117-08476-5/R·8477 视神经疾病中西医结合诊治 Optic Neuropathies Diagnosis and treatment of Integrated Traditional Chinese And Western Medicine)

- (1)视力逐渐下降
- (2)色觉障碍
- (3)视野逐渐向心性缩小,也可见其他类型视野缺损
- (4) 患眼或病情严重眼有 RAPD
- (5)视盘色泽变淡或苍白
- (6)视觉电生理检查或颅眶影像学检查有助于诊断

附录 B (规范性) 视神经萎缩中医治疗模式图



附录 C

(资料性)

证据评价及推荐原则

C.1 证据评价和分级

参照 GRADE(Grading of Recommendations Assessment, Development and Evaluation)分级方法,随机对照试验最初被定为高质量证据,其质量可因 5 个因素下降;观察性研究被定为低质量证据,其质量可因 3 个因素上升;最终证据质量被分为高、中、低、极低 4 级。

文献筛选和评价过程由两名评价员独立进行,如双方意见不一致,通过协商解决或由第三方裁决。具体内容见表 C.1:

研究设计 最初证据级别 降级/升级因素 证据级别 描述 随机对照试验 高 偏倚风险 -1 严重 非常确信真实值接近效应估计值 高(A) -2 非常严重 -1 严重 不一致性 -2 非常严重 间接性 -1 严重 中 (B) 对效应估计值有中等程度信心: 真实 值可能接近估计疗效,但也可能有很 -2 非常严重 -1 严重 不精确性 大差别 -2 非常严重 发表偏倚 -1 可能 低 (C) 对效应估计值信心有限: 真实值与估计 -2 非常可能 值可能有很大差别 低 效应量大 +1 大 观察性研究 +2 非常大 剂量-效应关系 +1 明显关联 极低(D) 对效应估计值几乎没有信心: 真实值与 混杂因素 +1 效应增加 估计值可能有很大差别 +1 效应显著降低

表 C.1 证据评价和分级

C.2 推荐原则

由于中医药治疗视神经萎缩的文献研究多数存在报告内容不全面、设计欠规范、辨证选 方多样、疗效标准不统一等问题,使研究结果可信性偏低,因此本文件的推荐原则为结合传 统中医理论、文献研究和专家经验等综合因素考虑后制定,所有证据均需取得专家共识后方可列入推荐。

推荐强度确定原则:凡是对某项治疗措施强推荐人数超过总人数 75%,则强推荐使用 该治疗措施;如果不推荐使用人数比例≥50%,则为不推荐;其他情况为弱推荐。

附录 D

(资料性)

利益冲突的宣言

《国际中医临床实践指南 视神经萎缩》指南制定小组所有成员均声明,完全独立进行本指南的编制工作,未与任何利益团体发生联系。



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Foreword

Patent issues may be existed in this guideline, and World Federation of Chinese Medicine Societies declared that they are not to blame.

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Introduction

This document aims to further standardize the international TCM clinical diagnosis and treatment of optic atrophy (OA), and to provide international the TCM therapeutic strategies and methods of OA for international TCM practioners. The document is concise and practical with strong operability. It could be regarded as a valuable reference for clinical practice, diagnosis and treatment regulations and quality evaluation.

In China, the published *Guidelines for Diagnosis and Treatment of Common Diseases of Ophthalmology in Traditional Chinese Medicine -- Optic Atrophy, Clinical Practice Guideline of Traditional Chinese Medicine -- Optic Atrophy and Clinical Practice Guideline of Expert Consensus -- Optic Atrophy have played a guiding role in the treatment of optic atrophy with Chinese medicine. However, research methods still need to improve with the increasing emergence of evidence-based medical researches and limitation of previous guidelines. The context of this document focuses on diagnosis and treatment of optic atrophy with Chinese medicine based on previous guidelines, strict quality assessments are conducted in the treatment of optic atrophy to screen therapeutic methods of high level evidences, reliable clinical efficacy, safety and convenient to popularize, which aims to improve the clinical efficacy of TCM treatment on optic atrophy.*

The document is a declaration file based on available research evidences and specific methods. Clinical practitioners could regard the document as reference and make the individualized treatment according to the combination of concrete clinical situations and the document.

International Clinical Practice Guideline of Chinese

Medicine Optic Atrophy

1 Scope

This document provides the basic requirements of the terms and definitions, diagnosis, syndrome differentiation and treatment of Chinese medinice for optic atrophy.

As a diagnosis and treatment basis for optic atrophy, this document applies to TCM ophthalmologists at various levels. This document can also be a reference for integrated Traditional and Western medicine ophthalmologists and Western medicine ophthalmologists or doctors of other TCM departments.

2 Normative References

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 16751.1 Clinic terminology of traditional Chinese medical diagnosis and treatment—Diseases

GB/T 16751.2 Clinic terminology of traditional Chinese medical diagnosis and treatment—Syndromes

GB/T 16751.3 Clinic terminology of traditional Chinese medical diagnosis and treatment—Therapeutic methods

《 Guidelines for Diagnosis and Treatment of Common Diseases of Ophthalmology in Traditional Chinese Medicine-- optic atrophy》 (2012)

《 Clinical Practice Guideline of Traditional Chinese Medicine-- optic atrophy》 (2015)

《Clinical Practice Guideline of Expert Consensus-- optic atrophy》 (2019) International Standard Chinese-English Basic Nomenclature of Chinese Medicine (SCM 2-2007)

 $\langle\!\langle WHO \mbox{ International Standard Terminologies on Traditional Medicine in the Western Pacific Region <math display="inline">\rangle\!\rangle$

3 Terms and Definitions

The following terms and definitions apply for this document.

3.1

Optic Atrophy

It is not a single disease, but damage caused by various lesions of retinal ganglion cells and their axons between the retina and the lateral geniculate body, resulting in the loss of nerve fibers and the final outcome of gliosis.

Note 1: In clinical pathology, optic atrophy can be classified into Primary optic atrophy and Secondary optic atrophy. Patients have decreased visual function and reduced visual field, optic atrophy due to optic disc local capillaries reduced or disappeared, gliosis, color is pale.

Note 2: The etiology of optic atrophy may include vascular, infectious, metabolic, traumatic, toxic, neoplastic/paraneoplastic syndrome, autoimmune/inflammatory, compressive and hereditary causes. In terms of pathogenesis, it can be divided into three categories: ascending, descending and congenital hereditary lesions. Ascending neuroatrophy refers to the primary lesions located in the optic disc and retina, and the atrophy process develops from the posterior optic nerve and intracranial area of the eye. Descending optic atrophy refers to the primary lesion located in the intracranial or medial orbital segment of the optic nerve, and the atrophy process gradually develops to the eyeball side.

Note 3: Optic atrophy belongs to traditional Chinese medicine "green blindness" category.

3.2

Blue Blindness

The appearances of the eyes are normal, but the eyes are lack of the gloss. Patients' main symptoms are blurred vision and the diminished capacity to differentiate objects in various distances. There is no method to restore their eyesight. The status will lead to blindness eventually. It is named "blue blindness" in Chinese medicine. *Zheng Zhi Zhun Sheng* records : "fu qing mang zhe, tong shen bu da bu xiao, wu que wu sun, zi xi shi zhi, tong shen nei bing wu xie shao bie yang qi se, yan ran yu hao ren yi ban, zhi shi zi kan bu jian, fang wei ci zheng."

4 Diagnosis

4.1 History

Most patients have a history of head and eye trauma, tumors, pernicious anemia, use of optic neurotoxic drugs, glaucoma, Ischemic lesions, and hereditary diseases.

4.2 Clinical Manifestations

It includes severe vision loss, in some cases it could be no light perception. Besides color vision can be affected at different levels, especially red and green. A relative afferent pupillary defect(RAPD) may be found in unilaterally affected cases. The disc is discolored or may be pale. The disc boundary could be sharply or blurred depending on its possible causes, the retinal blood vessel is thin.

4.3 Clinical Examination

4.3.1 Visual Field

The visual field defects include concentric contraction of visual field, central scotoma, paracentral scotoma, fan-shaped defect, bitemporal hemianopia or homonymous hemianopia.

4.3.2 Visual Electrophysiology

The latency period of pattern visual electrophysiology or light visual electrophysiology will increase, and the amplitude will decrease obviously, or the wave may totally disappear.

4.3.3 Optical coherence tomography (OCT)

The retinal nerve fiber laver thickness becomes thinner.

5 Syndrome Differentiation

5.1 Liver Depression and Qi Stagnation Syndrome

Eye appearance is normal, but vision is dim. Pale optic disk, or enlarged and deepened like a cup, displacement of blood vessels to the nasal side, thinning of arteries and veins, bad mood and irritable, chest pain, poor appetite and like to sigh, dry and bitter mouth, red tongue, thin white or yellow tongue coating, thin or string pulse.

5.2 Liver and Kidney Deficiency Syndrome

Decrease vision, dim vision, and even blindness. Pale optic disk, dry mouth and eye, dizziness and tinnitus, weakness of waist and knees, upset hot and night sweats. Pale tongue, thin white tongue coating, thin pulse.

5.3 Qi and Blood Deficiency Syndrome

Decrease vision, and even blindness. pale optic disk, pale Looking, pale lips and nails, insomnia and forgetfulness, Spirit fatigue and faintness, Lazy to talk,

flustered and short breath, pale tongue, thin white tongue coating, deep and thin pulse.

5.4 Qi Stagnation and Blood Stasis Syndrome

Long time decrease vision, head and eye trauma, pale and Clear border with optic disk, thinning of blood vessel, head and eye pain, insomnia and forgetfulness, dreamy, dark red or ecchymosis tongue, thin white tongue coating, unsmooth pulse.

6 Treatment

6.1 Therapeutic Principles and Methods

The principles of TCM treatment are different according to the etiology and pathogenesis, respectively adopting therapies such as soothing the liver and relieving stagnation, nourishing the liver and kidney, nourishing qi and nourishing blood, activating qi and promoting blood circulation, and opening orifices and improving eyesight. The disease should start from the liver, spleen and kidney, identify deficiency and stasis, and treat symptomatically.

6.2 Prescription

6.2.1 Liver Depression and Qi Stagnation Syndrome

Therapeutic methods: Soothing the liver and relieving depression, enlightening eyesight.

Formula and herbs: Xiaoyao Powder (Xiaoyao San, tài píng huì mín hé jì jú fāng). Chaihu(Chinese Thorowax Root),Danggui(Chinese Angelica), Baishao(White Peony Root),Baizhu(White Atractylodes Rhizome), Fuling(Indian Bread),Bohe(Mint Leaves), Weishengjiang(Simmer Ginger),Zhigancao(Honeyfried Licorice Root). (quality of envidence: D, strong recommendation)

Modification:For the cases with blurred vision, Juhua(Chrysanthemum Flos), Gouqizi(Barbary Wolfberry Fruit), Shichangpu(Acorus Tatarinowii Schott) can tonify the kidney and enlighten the eyes. For the cases with long periods of depression, Zhiqiao(Citrus Aurantium) and Yujin(Turmeric Root) can be added to relieve liver qi and resolve depression. For the cases with blood stasis, add Danshen(Salvia Root), Honghua(Safflower) and Chuanxiong(Sichuan Lovage Rhizome) to strengthen blood circulation. For cases with liver stagnation and blood deficiency, add Dangshen(Codonopsis Pilosula) and Zhiheshouwu(Radix Polygoni Multiflorito) to nourish qi and blood. For cases with tinnitus and deafness, add Chantui(Periostracum Cicada), Yuanzhi(Milkwort Root) to improve

hearing and vision and calm down.

6.2.2 Liver and Kidney Deficiency Syndrome

Therapeutic methods: Nourishing liver and kidney, enlightening eyesight.

Formula and herbs:Zuogui Drink(Zuogui Yin, jǐng yuè quán shū). Shudihuang(Prepared Rehmannia Root), Shanzhuyu(Asiatic Cornelian Cherry Fruit), Shanyao(Common Yam Rhizome), Gouqizi(Barbary Wolfberry Fruit), Fuling(Indian Bread), Zhigancao(Honey-fried Licorice Root), Taizishen(Radix Ginseng), Danggui(Chinese Angelica), Zhiqiao(Citrus aurantium). (quality of envidence: D, strong recommendation)

Modification: with deficiency and blood For qi stasis, Shichangpu (Acorus Tatarinowii Schott), Niuxi (Achyranthes Root) and Danshen(Salvia Root) can be added to strengthen the collaterals, opening the eyesight.Chushizi(Papermulberry orifices and improving Tusizi(Dodder Seed) can be added to tonify the kidney and improve eyesight. Nyzhenzi (Fruit of Glossy Privet) and Wuweizi(Chinese Magnoliavine Fruit) can be added to nourish the yin of kidney. For cases with the waist and knees are sore and weak, add Gouji (Cibotium Barometz Root) and Duzhong(Eucommia Ulmoides). For the case with feverish sensation in chest, palms and soles, add Zhimu(Common Anemarrhena Rhizom). Huangbai(Amur Cork-Tree). Zhuye(Bamboo Leaf).

6.2.3 Qi and Blood Deficiency Syndrome

Therapeutic methods: Tonifying qi and nourishing blood, calming the mind and enlightening the senses.

Formula and herbs: Renshen Yangrong Decoction (Renshen Yangrong Tang, tàipíng huì mín hé jì jú fāng).Baishao(White Peony Root), Danggui(Chinese Angelica), Chenpi (Dried **Tangerine** Peel), Renshen(Ginseng), Rougui(Cinnamon), Huangqi(Milkvetch Root), Baizhu(White Atractylodes Rhizome), Fuling(Indian Bread), Zhigancao(Honey-fried Licorice Root), Wuweizi(Chinese Magnoliavine Fruit). Yuanzhi(Milkwort Root). Shudihuang(Prepared Rehmannia Root), Shengjiang(Fresh Ginger) , Dazao(Fructus Jujubae). (expert consensus, strong recommendation)

Modification: For the case with serious blood deficiency, add Zhiheshouwu(Fleece Flower Root) and Longyanrou(Longan Meat) to nourish blood and soothe the nerves. Add Zhiqiao (Citrus Aurantium), Chaihu(Chinese Thorowax Root) to regulate qi, or add Chuanxiong(Sichuan Lovage Rhizome) to regulate qi from blood.

6.2.4 Qi Stagnation and Blood Stasis Syndrome

Therapeutic methods: Activating qi and promoting blood circulation, removing blood stasis and dredging collaterals.

Formula and herbs: Xuefu Zhuyu Decoction (Xuefu Zhuyu Tang, yī lín gǎi cuò): Taoren(Peach Seed), Honghua(Safflower), Danggui(Chinese Angelica), Shengdihuang(Unprocessed Rehmannia Root), Chuanxiong(Sichuan Lovage Rhizome), Chishao(Red Peony Root), Niuxi(Achyranthes Root), Jiegeng(Campanulaceae Root), Chaihu(Chinese Thorowax Root), Zhiqiao(Citrus Aurantium), Gancao(Liquorice Root). (expert consensus, strong recommendation)

Modification: For the case with serious blood stasis, add Danshen(Salvia Root), Yujin(Turmeric Root) and Dilong(Earthworm) to help remove blood stasis and dredge collaterals.

6.3 Traditional Chinese Patent Medicine

6.3.1 Chinese herb oral

Qi stagnation and blood stasis syndrome: Fufang Xueshuantong Capsules(quality of envidence: C, strong recommendation), Fufang Danshen Tablets(quality of envidence: D, weak recommendation)

Liver and kidney deficiency syndrome: Mingmu Dihuang Pills(quality of envidence: C, strong recommendation), Bushen Mingmu Pills(quality of envidence: D, strong recommendation), Qiju Dihuang Pills(quality of envidence: D, weak recommendation), Shihu Yeguang Pills(quality of envidence: D, weak recommendation)

Liver depression and qi stagnation syndrome: Shugan Mingmu Pills(quality of envidence: D, strong recommendation), Mingmu Xiaoyao Granules(quality of envidence: D, strong recommendation)

Qi and blood deficiency syndrome: Buzhong Yiqi Pills(quality of envidence: D, weak recommendation)

Please choose the appropriate dosage and duration of treatment according to the clinical situation.

6.3.2 Chinese herb injection

Yinxingye Injection:(main ingredient: Ginkgo biloba extract).(quality of envidence: D, strong recommendation)

Shuxuetong Injection: (Main Ingredients: Leeches, Geosaurus). (quality of envidence: D, weak recommendation)

Compound Salvia miltiorrhiza Bge injection(main ingredients: Salvia miltiorrhiza Bge, Dalbergia odorifera).(quality of envidence: D, weak

recommendation)

Shengmai Injection: (Main Ingredients: Red Ginseng, Ophiopogon, Schisandra). (quality of envidence: D, weak recommendation)

Gegensu injection:(main ingredient: Puerarin).(quality of envidence: D, weak recommendation)

Dengzhan Xixin Injection: (Main Ingredient: Extraction of phenolic acids from Erigeron Breviscapus). (quality of envidence: D, weak recommendation)

Chuanxiongqin Injection:(main ingredient: Ligustrazine Hydrochloride). (quality of envidence: D, weak recommendation)

6.4 Other therapy

6.4.1 Acupoint injection

Fufang Zhangliujian: (Main Ingredients: Anisodine Hydrobromide, Procaine)
Intravenous Injection. (quality of envidence: C, strong recommendation)

6.4.2 Drug iontophoresis

Danshen injection: (Main Ingredients: Salvia Root). (quality of envidence: D, weak recommendation)

Chinese herb formula 1:(Sichuan Lovage Rhizome, Chinese Angelica, Red Peony Root, Salvia Root, Chinese Thorowax Root, Kudzu root, Milkvetch Root, Prepared Rehmannia Root).(quality of envidence: D, weak recommendation)

6.4.3 Acupoint application

Formulation 1:(Salvia, Ginseng, Musk, Borneol, etc).(quality of envidence: D, weak recommendation)

6.4.4 Ear acupressure

Ear Acupoint 1:(Eye, Eye-1, Eye-2, Liver, Kidney, Heart).(expert consensus, strong recommendation)

6.4.5 Acupuncture

According to the clinical studies and related textbooks on optic atrophy treated with acupuncture, combined with expert consensus.(expert consensus, strong recommendation)

Main points: Jingming(BL1), Chengqi(ST1), Shangming, Sizhukong(SJ23), Taiyang(EX-HN5), Yangbai(GB14), Yuyao(EX-HN4), Sibai(ST2).

Matching points:

Liver Depression and Qi Stagnation Syndrome: Ganshu(BL18),

Taichong(LR3), Xingjian(LR2), Hegu(LI4), Guangming(GB37).

Liver and Kidney Deficiency Syndrome: Ganshu(BL18), Shenshu(BL23), Sanyinjiao(SP6), Guanyuan(CV4), Taixi(KI3).

Qi and Blood Deficiency Syndrome: Hegu(LI4), Baihui(GV20), Zusanli(ST36), Weishu(BL21), Pishu(BL20).

Qi Stagnation and Blood Stasis Syndrome: Xuehai(SP10), Qihai(CV6), Fengchi(GB20), Hegu(LI4), Zusanli(ST36).



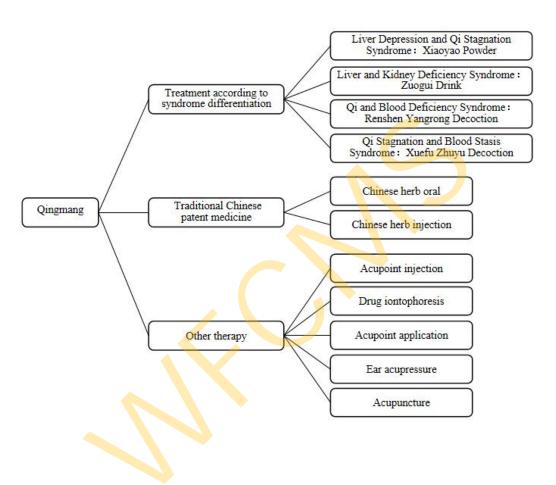
APPENDIX A

(Informative Appendix) Diagnostic criteria for optic atrophy

(ZYXH/T287-305-2012 Guidelines for Diagnosis and Treatment of Common Internal Diseases in Chinese Medicine—Diseases of Chinese Medicine, ISBN978-7-117-08476-5/R·8477 Optic Neuropathies Diagnosis and treatment of Integrated Traditional Chinese And Western Medicine)

- (1) Progressive decline in vision
- (2) Color Disorder
- (3) Progressive concentric reduction of visual field and other types of visual field defects
 - (4) RAPD in an eye or in a serious condition
 - (5) Lightening or paleness of the optic disc
- (6) Visual electrophysiological examination or cranial/orbital imaging examination is helpful for diagnosis

APPENDIX B (Normative Appendix) Treatment Pattern Diagram of Chinese Medicine on Optic Atrophy



APPENDIX C

(Informative Appendix)

Evidence Evaluation and Recommendation Principle

C.1 Evaluation and Grade

The evidence classification principle of this docement is based on the GRADE(Grading of Recommendations Assessment, Development and Evaluation), randomized controlled trials were initially designated as high-quality evidence, the quality of which could be reduced by five factors, while observational studies were rated as low-quality evidence, but its quality could be increased by three factors. Finally, the quality of evidence is sorted into high, moderate, low, and very low.

The process of screening and evaluation of the literatures are carried out independently by two evaluators. If the views of the two parties are inconsistent, they would resolve through negotiation or adjudication by a third one. See the table C.1 below for details:

Table C1: Evaluation and Grade

	* 1.1 1 1. C				
	Initial quality of a				
Study design	body of evidence	Lower/High <mark>e</mark> r		Quality level	Definition
Randomized controlled trials	High s	Risk of Bias Inconsistency	-1 Serious -2 Very serious -1 Serious -2 Very serious		We are very confident that the true effect lies close to that of the estimate of the effect trials
		Indirectness	-1 Serious -2 Very seriou		We are moderately confident in the effect estimate: The true effect is
		Imprecision	-1 Serious -2 Very seriou	IS	likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
		Publication bia	as -1 Likely -2 Very likely	Low(C)	Our confidence in the effect estimate is limited:The true effect may be substantially different from the estimate of the effect
Observational studies	Low	Large effect	+1 Large +2 Very large	Very low(D)	We have very little confidence in the effect estimate: The true effect
		Dose response All plausible residual confounding	+1 Evidence of +1 Would red demonstrat +1 Would sugg spurious eff no effect wa	uce a te effect gest a fect if	is likely to be substantially different from the estimate of effect

C.2 Recommended principle

The fact that most of studies on the treatment of optic atrophy in TCM are not comprehensive, the design of studies is often less standardized, the selection of formula is diverse, and the efficacy standard is not uniform, which attribute to the outcome bias. Therefore, all the evidences are required to obtain expert consensus before being included into the recommendation.

The general principle of the expert consensus is that if the total number of experts who strongly recommend one treatment exceeds 75%, then it is strong recommendation. If the number of experts who recommend it is below or equal to 50%, then it is not recommended; other situations are sorted into the weak recommendation.



APPENDIXE D

(Informative Appendix)

Announcement of Interest Conflicts

The opinion or interest of funding institution would not have any impact on this guideline, and all of the members declared that there was not any interest conflicts.



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