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Clinical Study on the Treatment of Alzheimer's Disease of Spleen Deficiency and Phlegm Obstruction Type by Wenpi Tongluo Kaiqiao Formula Combined with Acupuncture

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Abstract: *Objective:* To observe the clinical efficacy of Wenpi Tongluo Kaiqiao Formula combined with acupuncture in the treatment of Alzheimer's disease (AD) of spleen deficiency and phlegm obstruction type. *Methods:* 90 cases with AD of spleen deficiency and phlegm obstruction type who were admitted to the Department of Encephalopathy of the First Affiliated Hospital of Guangxi University of Chinese Medicine from December 2023 to October 2024 were selected and randomly divided into the control group, the decoction group, and the acupuncture-medication group, with 30 cases in each group. The control group was given donepezil hydrochloride tablets orally; the decoction group was given Wenpi Tongluo Kaiqiao Formula in addition to the treatment in the control group; the acupuncture-medication group was given acupuncture method of invigorating the spleen, resolving phlegm, and opening the orifices in addition to the treatment in the decoction group. The treatment course for each group was 4 weeks. After treatment, the clinical total effective rate of the three groups was compared, and their safety was evaluated. *Results:* 81 cases completed the trial (27 cases in the control group, 26 cases in the decoction group, and 28 cases in the acupuncture-medication group). There was a statistically significant difference in the total effective rate among the three groups ($P < 0.05$), with the acupuncture-medication group having the best efficacy, followed by the decoction group, and the control group having the poorest efficacy. There were no adverse reactions reported in any group during the treatment course. *Conclusion:* Wenpi Tongluo Kaiqiao Formula combined with acupuncture is more effective than either taking donepezil hydrochloride tablets alone or taking donepezil hydrochloride tablets combined with Wenpi Tongluo Kaiqiao Formula for this type of AD, and it is worthy of clinical promotion.

Keywords: Wenpi Tongluo Kaiqiao Formula; Acupuncture; Alzheimer's disease; Spleen Deficiency and Phlegm Obstruction Type; Clinical Observation

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1. Introduction

Alzheimer's disease (AD) is a common neurodegenerative disorder in the elderly, characterized by cognitive decline, memory impairment, and behavioral abnormalities. Its pathogenesis involves cholinergic dysfunction, amyloid beta (Aβ) deposition, tau protein phosphorylation. Existing medications (e.g., acetylcholinesterase inhibitors) can alleviate symptoms, but have high costs and toxic side effects. In traditional Chinese medicine (TCM), AD is categorized as dementia.

Professor Zihui Wu, a renowned TCM expert from Guangxi, proposed that spleen deficiency and phlegm obstruction is the key pathogenesis, and used Wenpi Tongluo Kaiqiao Formula to warm the spleen, resolve phlegm, unblock collaterals, and open orifices. Clinically, this formula has been shown to improve TCM symptoms. Additionally, acupuncture can intervene in the pathogenesis of AD and improve neurological function. This study investigates the therapeutic efficacy of combining these two approaches, as reported below.

2. Background and methods

2.1. General information

90 cases with Alzheimer's disease (AD) of the spleen deficiency and phlegm obstruction type were enrolled and randomly divided into 3 groups (30 cases in each group). During the study, 3 cases dropped out of the control group (1 due to medication-related pain, 1 lost to follow-up, and 1 due to dizziness), 4 cases dropped out of the decoction group (2 lost to follow-up and 2 unexpectedly withdrew), and 2 cases dropped out of the acupuncture-medication group (both due to voluntary withdrawal). The baseline characteristics (age, gender, education level, disease duration) showed no statistically significant differences ($P > 0.05$) among the three groups, indicating comparability. This study was approved by the hospital ethics committee (Approval No.: 2023-015-01), and informed consent was obtained from all patients and their families.

2.2. Diagnostic criteria

2.2.1. Western medicine diagnosis

Refer to the diagnostic criteria for AD in the International Classification of Diseases, Tenth Revision (ICD-10) [1].

2.2.2. Chinese medicine diagnosis

Refer to the syndrome differentiation of spleen deficiency and phlegm obstruction type in the Internal Medicine of Traditional Chinese Medicine (2017 Edition) [2] (main symptoms include cognitive decline, combined with secondary symptoms, tongue and pulse signs).

2.3. Inclusion and exclusion criteria

2.3.1. Inclusion criteria

(1) Meet the diagnostic criteria for both Western medicine and Traditional Chinese Medicine (TCM);
(2) Aged 65–85 years old;
(3) Mini-Mental State Examination (MMSE) score of 10–24 and Clinical Dementia Rating (CDR) score of 1.0–2.0;
(4) Provide informed consent.

2.3.2. Exclusion criteria

(1) CDR score of 3.0, illiteracy, or severe sensory impairment;
(2) Other comorbidities (e.g., sequelae of cerebral infarction, Parkinson's disease);
(3) Use of antidepressants, antipsychotics, or nootropic drugs not specified in this study within the past month, which cannot be discontinued;
(4) History of allergies, major organ dysfunction, or suicidal tendencies.

2.4. Treatment methods

2.4.1. Control group

Onepezil hydrochloride tablets (5 mg/tablet; National Medicine Approval Number H20050978) , 10 mg per time, once daily before bedtime, for 4 weeks.

2.4.2. Decoction group

In addition to the treatment in the control group, Wenpi Tongluo Kaiqiao Formula was added [Huangqi (Radix Astragali seu Hedysari) 30 g, Yizhiren (Fructus Alpiniae Oxyphyllae) 10 g, Sanqi (Radix et Rhizoma Notoginseng) 10 g, Chichangpu (Rhizoma Acori Tatarinowii) 10 g, Heshouwu (Radix Polygoni Multiflori) 10 g, Jiaogulan (Herba GynoStemmae Pentaphilli) 10 g], decocted in water, 200 mL per pack, twice daily, take it warm after breakfast and dinner, for 4 weeks.

2.4.3. Acupuncture-medication group

In addition to the treatment in the decoction group, the acupuncture method of invigorating the spleen, resolving phlegm, and opening the orifices was added. The selected acupoints included Baihui (GV20), Sishencong (EX-HN1), Fengfu (GV16), Taixi (KI3), Xuanzhong (GB39), Zusanli (ST36), Fenglong (ST40), Zhongwan (CV12). Neutral reinforcement and reduction, retaining needle for 30 min, once daily, 5 times per week, for 4 weeks.

2.5. Efficacy evaluation criteria

Refer to efficacy index assessment based on the Mini-Mental State Examination (MMSE) [3]: Efficacy index = (Post-treatment Score – Pre-treatment Score) / Pre-treatment Score × 100%. Clinical recovery: efficacy index ≥ 85%; Markedly effective: 50% ≤ efficacy index < 85%; Effective: 20% ≤ efficacy index < 50%; Ineffective: efficacy index < 20%. Total effective rate = (Number of Cases with Clinical Recovery + Markedly Effective + Effective) / Total Cases × 100%.

2.6. Statistical methods

SPSS 21.0 was used for analysis. The Kruskal-Wallis H test was employed to compare the overall differences in efficacy among the three groups. A P-value < 0.05 was considered statistically significant.

3. Results

3.1. Comparison of clinical efficacy among the three groups

The Kruskal-Wallis H test revealed statistically significant differences in overall efficacy among the three groups (P < 0.05). The total effective rates were as follows: control group (59.26%, 16/27), decoction group (78.57%, 22/28), and acupuncture-medication group (92.59%, 25/27). The acupuncture-medication group demonstrated the highest efficacy, followed by the decoction group, while the control group showed the lowest efficacy. See **Table 1** for details.

Table 1. Comparison of clinical efficacy among the three groups [n (%)]

Group	Cases	Ineffective	Effective	Markedly effective	Clinical recovery	Total effective
Control	27	11 (40.74)	16 (59.26)	0 (0.00)	0 (0.00)	16 (59.26)
Decoction	28	6 (21.43)	18 (64.29)	4 (14.28)	0 (0.00)	22 (78.57)
Acupuncture-Medication	27	2 (7.40)	11 (40.74)	13 (48.15)	1 (3.70)	25(92.59)

4. Discussion

The pathogenesis of AD is complex, involving Aβ deposition [4], Tau protein phosphorylation [5], and cholinergic dysfunction [6]. The commonly used drugs like donepezil hydrochloride can alleviate symptoms, but may cause adverse reactions such as gastrointestinal discomfort, insomnia, dreaminess, and muscle spasms [7]. In Traditional Chinese Medicine, the pathogenesis of spleen deficiency with phlegm obstruction type is characterized by dysfunction

of the spleen in transportation, leading to malnourishment of the brain marrow and phlegm turbidity blocking the brain collaterals. Therefore, Wenpi Tongluo Kaiqiao Formula is used for intervention (with Huangqi and Yizhiren as sovereign medicinal to invigorate the spleen and benefit intelligence, Shichangpu and Sanqi as minister medicinal to resolve phlegm and unblock collaterals, Heshouwu and Jiaogulan as assistant medicinal to tonify the liver and kidney and resolve phlegm accumulation). Modern pharmacological studies have shown that astragaloside can reduce Aβ generation [8]. Yizhiren extract can improve cognitive impairment and neuroinflammatory reactions induced by Aβ [9]. Shichangpu extract can inhibit Aβ misfolding [10]. Notoginsenoside can downregulate Tau phosphorylation [11]. Acupuncture at the Governor Vessel points (GV20, EX-HN1, GV16) and spleen-kidney strengthening points (ST36, ST40, KI3, etc.) can regulate neurotransmitters and inhibit neuroinflammation [12,13], which works together with herbal medicine to regulate zang-fu organs and unblock meridians, offering a multi-target approach to improve AD pathology.

5. Conslusion

In conclusion, the combination of Wenpi Tongluo Kaiqiao Formula and acupuncture demonstrates definite efficacy and good safety in treating AD of spleen deficiency and phlegm obstruction type, providing a novel integrative Chinese and Western medicine approach for AD management.

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Disclosure statement

The author declares no conflict of interest.

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