Journal of Clinical and Nursing Research, 2025, Volume 9, Issue 4
http://ojs.bbwpublisher.com/index.php/JCNR
Online ISSN: 2208-3693
Print ISSN: 2208-3685

Clinical Observation on the Treatment of Brain Atrophy and Senile Dementia with Yizhi Xingnao Decoction Combined with Yizhi Pill

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Abstract: *Objective*: To analyze the therapeutic effect of Yizhi Xingnao Decoction + Yizhi Pill on cerebral atrophy and Alzheimer's disease (AD). *Methods*: Ninety-two patients with cerebral atrophy and AD who were admitted to the hospital from September 2022 to September 2024 were selected and randomly divided into two groups using a random number table. The traditional Chinese medicine (TCM) group was treated with Yizhi Xingnao Decoction + Yizhi Pill, while the western medicine group was treated with Donepezil Hydrochloride. Indicators such as total effective rate, TCM syndrome score, dementia degree score, and cognitive function score were compared between the two groups. *Results*: The total effective rate of the TCM group was higher than that of the Western medicine group ($P < 0.05$). After treatment, the TCM syndrome score, dementia degree score, and cognitive function score of the TCM group were all lower than those of the Western medicine group ($P < 0.05$). *Conclusion*: Yizhi Xingnao Decoction + Yizhi Pill can improve the clinical efficacy of patients with cerebral atrophy and AD, reduce disease symptoms and dementia severity, and improve patients' cognitive function.

Keywords: Yizhi Xingnao Decoction; Yizhi Pill; Cerebral atrophy; Alzheimer's disease

Online publication: April 30, 2025

1. Introduction

Both cerebral atrophy and AD are neurodegenerative diseases that commonly occur in the elderly. The former manifests as a reduction in brain cell content and a decrease in brain tissue volume, with symptoms including decreased intelligence, changes in thinking patterns, and language barriers. The latter is accompanied by symptoms such as memory loss and personality changes. Both diseases have similar symptoms and can chronically affect the mental health of elderly patients, requiring early treatment. Donepezil hydrochloride is a commonly used drug for these diseases, which can improve symptoms and repair brain neurons. However,

it cannot essentially address the cause of the disease, so the long-term efficacy is poor. Traditional Chinese medicine has a long history of treating these two diseases and can provide dialectical treatment based on the etiology and pathogenesis of the diseases, resulting in higher treatment effectiveness [1]. Yizhi Xingnao Decoction is a commonly used traditional Chinese medicine decoction for AD, which has the effects of clearing the mind, removing blood stasis, promoting blood circulation, nourishing the liver, and benefiting the kidneys. Combining it with Yizhi Pill can enhance the effects of dispelling blood stasis and promoting blood circulation, exerting therapeutic mechanisms such as benefiting the kidneys and nourishing the heart. Therefore, in this study, a total of 92 patients with cerebral atrophy and AD were selected to evaluate the therapeutic effect of Yizhi Xingnao Decoction + Yizhi Pill.

2. Materials and methods

2.1. General information

Ninety-two patients with cerebral atrophy and AD who were admitted to the hospital from September 2022 to September 2024 were included in the study. They were randomly divided into two groups using a random number table: the traditional Chinese medicine (TCM) group with 46 patients (25 males and 21 females) and the western medicine group with 46 patients (26 males and 20 females). The age range of the TCM group was 62–87 years, with a mean age of (69.53 ± 2.74) years, and a disease duration of 0.6–5 years, with a mean duration of (2.61 ± 0.75) years. The age range of the Western medicine group was 61–89 years, with a mean age of (69.85 ± 2.68) years, and a disease duration of 0.5–5 years, with a mean duration of (2.66 ± 0.79) years. There were no significant differences in baseline characteristics between the two groups ($P > 0.05$).

Inclusion criteria: Patients with cerebral atrophy confirmed by cranial magnetic resonance imaging; comprehensive diagnosis of AD based on laboratory tests and clinical symptoms; age over 60 years; Mini-Mental State Examination (MMSE) score not exceeding 20; and complete basic information.

Exclusion criteria: allergy to drug ingredients; presence of mental illnesses such as depression; cognitive impairment induced by factors such as alcoholism; hematopoietic system diseases or abnormal organ function; and withdrawal from the study.

2.2. Methods

The Western medicine group was treated with Donepezil hydrochloride: the drug was administered orally at a dose of 5 mg once daily for 3 months.

The TCM group was treated with Yizhi Xingnao Decoction combined with Yizhi Pill. The composition of Yizhi Xingnao Decoction was as follows: Yizhi Ren (10g), He Shou Wu (18g), Gu Sui Bu (10g), Gou Qi Zi (30g), Bu Gu Zhi (10g), Guang Yu Jin (10g), Dan Shen (30g), Tian Zhu Huang (10g), Shi Chang Pu (10g), and Chuan Xiong (10g). Additional herbs were added based on specific symptoms: Bai Zhu, Dang Shen, and Ren Shen for Qi deficiency; Rou Gui, Fu Zi, and Rou Cong Rong for Yang deficiency; Ji Xue Teng for blood deficiency; Bai Zhu for oral drooling; Shui Zhi and Yi Mu Cao for blood stasis; Quan Xie and Fu Zi for mouth and eye deviation; Gui Zhi for upper limb weakness; Gou Teng and Wu Gong for unstable gait; Sang Zhi for lower limb weakness; and Long Chi, Fu Shen, and Zao Ren for insomnia and dreaminess. The herbs were boiled in water to produce 300 ml of decoction daily, which was divided into two portions and administered as one dose. The treatment course consisted of one month of treatment followed by a one-week break, for a total of three courses.

Yizhi Pill was administered orally at a dose of 2 pills (8g) twice daily for 3 months.

2.3. Observation indicators

(1) TCM syndrome score: A 4-point scoring system was used to evaluate symptoms such as intellectual decline, soreness and weakness of the waist and knees, fatigue and desire to lie down, and insomnia and dreaminess. Scores ranged from 0 to 3, with higher scores indicating greater symptom severity.

(2) Dementia severity score: The Clinical Dementia Rating (CDR) scale was used, which includes six items such as memory, judgment, and problem-solving ability. Scores for each item ranged from 0 to 3, with higher scores indicating greater dementia severity.

(3) Cognitive function: The Neuropsychiatric Inventory (NPI) was used, which includes 12 items such as delusions and hallucinations. Each item was scored on a 12-point scale, with a total possible score of 144. Lower scores indicated better cognitive function.

2.4. Efficacy evaluation criteria

(1) Significant efficacy: Complete resolution of symptoms, normal orientation and consciousness function, normal social function and self-care ability, and a reduction in TCM syndrome score by more than 75%.

(2) Initial efficacy: Partial improvement in symptoms, orientation, and consciousness function, improvement in social function and self-care ability, and a reduction in TCM syndrome score by 30%–75%.

(3) No efficacy: No improvement in symptoms, orientation, consciousness function, or TCM syndrome score, with a reduction in syndrome score by less than 30%.

2.5. Statistical analysis

Data were analyzed using SPSS 28.0 software. Measurement data were expressed as mean ± standard deviation ([±s]) and compared using t-tests. Count data were expressed as frequencies and percentages ([n/%]) and compared using chi-square tests. Statistical significance was set at $P < 0.05$.

3. Results

3.1. Comparison of total effective rates between the two groups

The total effective rate of the traditional Chinese medicine (TCM) group was higher than that of the western medicine group ($P < 0.05$).

Table 1. Comparison of total effective rates between the two groups [n/%]

Group	Number of Cases	Significant Effect	Initial Effect	No Effect	Total Effective Rate
TCM group	46	31(67.39)	13(28.26)	2(4.35)	95.65(44/46)
Western medicine group	46	26(56.52)	10(21.74)	10(21.74)	78.26(36/46)
x^2	-	-	-	-	6.133
P	-	-	-	-	0.013

3.2. Comparison of TCM syndrome scores between the two groups

Before treatment, there was no difference in TCM syndrome scores between the two groups ($P > 0.05$). After treatment, the TCM syndrome score of the TCM group was lower than that of the Western medicine group ($P < 0.05$).

Table 2. Comparison of TCM syndrome scores between the two groups [$\bar{x}$ false±s, scores]

Group	Number of cases	Mental decline		Soreness and weakness of waist and knees	
		Before treatment	After treatment	Before treatment	After treatment
TCM group	46	2.01 ± 0.32	0.51 ± 0.28	1.86 ± 0.41	0.56 ± 0.10
Western medicine group	46	2.03 ± 0.34	0.77 ± 0.31	1.88 ± 0.43	0.72 ± 0.16
t		0.291	4.221	0.228	5.751
P	-	0.772	＜ 0.001	0.820	＜ 0.001
Group	**Number of Cases**	**Fatigue and desire to lie down**		**Insomnia and dreaminess**	
		Before treatment	**After treatment**	**Before treatment**	**After treatment**
TCM group	46	1.77 ± 0.48	0.49 ± 0.11	2.12 ± 0.43	0.61 ± 0.15
Western medicine group	46	1.79 ± 0.45	0.73 ± 0.14	2.14 ± 0.40	0.99 ± 0.18
t	-	0.206	9.142	0.231	11.000
P	-	0.837	＜ 0.001	0.818	＜ 0.001

3.3. Comparison of dementia severity scores between the two groups

Before treatment, there was no difference in dementia severity scores between the two groups ($P > 0.05$). After treatment, the dementia severity score of the traditional Chinese medicine (TCM) group was lower than that of the Western medicine group ($P < 0.05$).

Table 3. Comparison of dementia severity scores between the two groups [$\bar{x}$ false±s, points]

Group	Number of cases	Memory		Judgment and problem solving skills		Orientation	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
TCM group	46	2.15 ± 0.33	0.81 ± 0.19	2.08 ± 0.37	0.74 ± 0.14	2.10 ± 0.43	0.80 ± 0.18
Western medicine group	46	2.12 ± 0.36	1.07 ± 0.21	2.10 ± 0.39	0.98 ± 0.15	2.12 ± 0.45	1.16 ± 0.22
t	-	0.417	6.227	0.252	7.933	0.218	8.590
P	-	0.678	＜ 0.001	0.801	＜ 0.001	0.828	＜ 0.001
Group	**Number of cases**	**Social affairs**		**Personal care**		**Family and hobbies**	
		Before treatment	**After treatment**	**Before treatment**	**After treatment**	**Before treatment**	**After treatment**
TCM group	46	1.95 ± 0.42	0.67 ± 0.15	1.91 ± 0.50	0.64 ± 0.13	1.87 ± 0.38	0.71 ± 0.14
Western medicine group	46	1.97 ± 0.44	0.92 ± 0.22	1.93 ± 0.48	0.94 ± 0.17	1.89 ± 0.35	1.05 ± 0.19
t	-	0.223	6.368	0.196	9.508	0.263	9.771
P	-	0.824	＜ 0.001	0.845	＜ 0.001	0.793	＜ 0.001

3.4. Comparison of cognitive function scores between the two groups

Before treatment, there was no significant difference in cognitive function scores between the two groups ($P > 0.05$). However, after treatment, the cognitive function score of the traditional Chinese medicine (TCM) group was lower than that of the Western medicine group ($P < 0.05$).

Table 4. Comparison of cognitive function scores between the two groups [$\bar{x}$ false±s, points]

Group	Number of cases	Before treatment	After treatment
TCM group	46	27.68 ± 2.94	15.02 ± 2.03
Western medicine group	46	27.15 ± 2.81	18.92 ± 2.44
t	-	0.884	8.334
P	-	0.379	＜ 0.001

4. Discussion

Western medicine believes that the pathogenesis of cerebral atrophy and AD is related to the reduction of neurotransmitter content, and cholinergic activity has a strong involvement in the occurrence and progression of these diseases [2]. Based on this, Western medicine often chooses Donepezil hydrochloride for the treatment of cerebral atrophy and AD. This drug is a commonly used cholinesterase inhibitor that can reduce the activity of central neurons, modulate the physiological effects of acetylcholinesterase, and thus increase the accumulation of acetylcholine in the synaptic cleft, improving various symptoms such as intellectual decline [3]. However, this drug has a single therapeutic target, and its full efficacy depends on the function of cholinergic neurons, resulting in significant differences in treatment response and thus limiting its therapeutic potential.

Traditional Chinese medicine (TCM) considers cerebral atrophy as a neurological disease induced by physical weakness and aging, with etiological factors including depletion of essence and blood, Qi and blood deficiency, and kidney Qi deficiency. Patients often present with emptiness of the brain and memory decline. AD is categorized as a “dementia” disease, with etiological factors such as turbid phlegm, blood stasis, and impeded Qi and blood circulation. The pathogenesis is primarily kidney deficiency and marrow depletion. Both diseases affect the brain and are related to the functions of the heart, spleen, liver, and other organs [4]. Therefore, treatments aiming to awaken the brain, enhance intelligence, nourish the kidneys, and promote blood circulation and remove blood stasis are necessary.

Yizhi Xingnao Decoction is a classic formula for cerebral atrophy and AD. The formula includes Yizhi Ren, which has effects such as improving intelligence, solidifying essence, warming the kidneys, and reducing urination; He Shou Wu, which nourishes the kidneys and essence, promotes bowel movements and detoxifies, and augments essence and blood [5]; Gu Sui Bu, which promotes blood circulation, strengthens bones, and nourishes the kidneys; Gou Qi Zi, which benefits essence and tonifies the liver and kidneys; Bu Gu Zhi, which aids yang and warms the kidneys; Guang Yu Jin, which promotes Qi circulation to relieve depression, clears the mind and heart, and relieves pain and promotes blood circulation; Dan Shen, which relieves pain, regulates menstruation by promoting blood circulation, and eliminates blood stasis; Tian Zhu Huang, which clears the mind, calms fright, resolves phlegm, and clears heat; Shi Chang Pu, which improves intelligence, opens the orifices, and awakens the brain; and Chuan Xiong, which relieves pain, promotes Qi and blood circulation, and dispels wind. The combined use of these herbs can open the orifices, awaken the brain, nourish the liver

and kidneys, and more [6]. Based on the patient's symptoms, additional herbs can be added or subtracted to correct manifestations such as Qi deficiency, blood stasis, and limb weakness, thereby promoting symptom improvement.

The medicinal herbs in Yizhi Pill include Shu Di Huang, which nourishes essence and marrow and tonifies blood and yin; Yuan Zhi, which awakens the mind, improves intelligence, and opens the orifices; Shui Zhi, which opens the orifices, dredges channels, and breaks blood stasis; Hong Hua, which eliminates blood stasis, relieves pain, and promotes menstrual blood circulation; Bing Pian, which clears heat and detoxifies, and awakens the mind and opens the orifices; Chuan Lian Zi, which detoxifies, clears heat, and regulates qi and soothes the liver; and She Xiang, which relieves pain, reduces swelling, and awakens the mind and opens the orifices. The combined use of these herbs can reduce turbidity, eliminate phlegm, open the orifices, nourish the kidneys, nourish the heart, promote blood circulation, and more [7].

The results showed that the total effective rate of the TCM group was higher than that of the Western medicine group, and the TCM syndrome score, dementia severity score, and cognitive function score of the TCM group were lower than those of the Western medicine group after treatment ($P < 0.05$). The reasons for these findings are multifaceted: Yizhi Ren contains terpenoids, which can enhance memory, and its formaldehyde extract can significantly improve atrial contraction ability, thereby regulating blood circulation [8]. He Shou Wu can enhance the activity of superoxide dismutase in brain tissue, reduce the specific content of peroxidized lipids, effectively resist cellular aging, enhance brain cell activity, prevent neuronal damage, reduce the degree of cerebral atrophy, and improve patients' cognitive function. Medicinal herbs such as Dan Shen and Chuan Xiong can scavenge free radicals in the body, regulate lipid levels and blood microcirculation, enhance Qi and blood nourishment, and tonify the kidneys. Shi Chang Pu contains volatile oils and other components that can resist convulsions and restore patients' memory function [9]. The medicinal herbs in Yizhi Pill, such as He Shou Wu, Shui Zhi, and Hong Hua, can reduce blood viscosity, restore coronary blood flow, and have strong anti-aging effects. Bing Pian can increase the blood-brain barrier penetrability of medicinal components, reduce existing cerebrovascular resistance, and thereby regulate microcirculation. She Xiang can improve central nervous system function, prevent memory impairment caused by components such as sodium nitrite or scopolamine, and correct the degree of cerebral tissue hypoxia. The combined use of these two medications can broaden therapeutic targets and achieve multi-channel treatment, thereby improving patients' dementia severity [10].

5. Conclusion

In summary, the combination of Yizhi Xingnao Decoction and Yizhi Pill demonstrates promising therapeutic effects for patients with cerebral atrophy and AD. It can improve their dementia severity, other symptoms, and restore cognitive function, with high feasibility for treatment.

Disclosure statement

The author declares no conflict of interest.

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